SECURITIES AND EXCHANGE COMMISSION

# FORM F-1/A

Registration statement for securities of certain foreign private issuers [amend]

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## FILER

**Iroko Pharmaceuticals Inc.**
CIK:**1566717**| IRS No.: **000000000** | State of Incorp.:**D8** | Fiscal Year End: **1231**
Type: **F-1/A** | Act: **33** | File No.: **333-189428** | Film No.: **13938311**
SIC: **2834** Pharmaceutical preparations

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*ONE KEW PLACE*
*150 ROUSE BOULEVARD*
*PHILADELPHIA PA 19112*

Business Address
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*PHILADELPHIA PA 19112*
*267-546-3003*

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**Registration No. 333-189428**

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

## Amendment No. 2
**To**
## FORM F-1
**REGISTRATION STATEMENT**
**UNDER THE SECURITIES ACT OF 1933**

# Iroko Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

| **British Virgin Islands** | **2834** | **Not Applicable** |
|---|---|---|
| (State or other jurisdiction of incorporation or organization) | (Primary Standard Industrial Classification Code Number) | (I.R.S. Employer Identification No.) |

**Iroko Pharmaceuticals Inc.**
One Kew Place, 150 Rouse Boulevard, Philadelphia, PA 19112
(267) 546-3003
(Address, including zip code, and telephone number, including area code, of registrant` s principal executive offices)

**Moji James**
**General Counsel**
**Iroko Pharmaceuticals Inc.**
One Kew Place, 150 Rouse Boulevard, Philadelphia, PA 19112
(267) 546-3003
(Name, address, including zip code, and telephone number, including area code, of agent for service)

*Copies to:*

**Carmelo M. Gordian**
**Ted A. Gilman**
**Andrews Kurth LLP**
**111 Congress, Suite 1700**
**Austin, TX 78701**
**(512) 320-9200**

**Richard D. Truesdell, Jr.**
**Davis Polk & Wardwell LLP**
**450 Lexington Avenue**
**New York, NY 10017**
**(212) 450-4000**

**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

## CALCULATION OF REGISTRATION FEE

| TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED | PROPOSED MAXIMUM AGGREGATE OFFERING PRICE [1] | AMOUNT OF REGISTRATION FEE |
|---|---|---|
| Ordinary shares, par value $0.01 | $145,000,000 | $19,778 |

(1) Estimated solely for the purpose of computing the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended. Includes the offering price of shares that the underwriters have the option to purchase to cover over-allotments, if any.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

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## PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

### Item 6. Indemnification of Directors and Officers

Our Amended and Restated Memorandum and Articles of Association provides that we shall indemnify any of our directors, officers or anyone serving at our request as a director of another entity against all expenses, including legal fees, and against all judgments, fines and amounts paid in settlement and reasonably incurred in connection with legal, administrative or investigative proceedings or suits. If such person provides an undertaking to repay expense advances under certain circumstances, we shall pay any expenses, including legal fees, incurred by any such person in defending any legal, administrative or investigative proceedings in advance of the final disposition of the proceedings. If a person to be indemnified has been successful in defense of any proceedings referred to above, such person is entitled to be indemnified against all expenses, including legal fees, and against all judgments and fines reasonably incurred by such person in connection with the proceedings. We are required to indemnify a director or officer only if he or she acted honestly and in good faith with a view to what he or she believed to be our best interests and, in the case of criminal proceedings, the director or officer had no reasonable cause to believe that his or her conduct was unlawful. The decision of our board of directors as to whether the director or officer acted honestly and in good faith with a view to what he or she believed to be our best interests, and as to whether the director or officer had no reasonable cause to believe that his or her conduct was unlawful, is in the absence of fraud sufficient for the purposes of indemnification, unless a question of law is involved. The termination of any proceedings by any judgment, order, settlement, conviction or the entry of nolle prosequi does not, by itself, create a presumption that a director or officer did not act honestly and in good faith and with a view to our best interests or that the director or officer had reasonable cause to believe that his or her conduct was unlawful.

We have entered into indemnification agreements with our directors and officers pursuant to which we agree to indemnify them against a number of liabilities and expenses which could be incurred by such persons in connection with claims made by reason of their being such a director or officer.

We may purchase and maintain insurance in relation to any of our directors or officers against any such liability asserted against, and/or expense incurred by, the directors or officers in that capacity.

The form of underwriting agreement to be filed as Exhibit 1.1 to this registration statement will also provide for indemnification of us and our directors and officers upon the terms and subject to the conditions specified therein.

### Item 7. Recent Sales of Unregistered Securities

Since January 1, 2010, Iroko Intermediate made sales of the following unregistered securities which were exchanged for our securities pursuant to the Reorganization Transactions described in ‘‘Corporate Formation and Reorganization’’ above:

- Between August 2010 and September 2011, Iroko Intermediate issued and sold an aggregate of 93,962,188 shares of its common stock to Iroko Holdings S.A. (the precursor to Cordial Investments Inc., or Cordial) at a per share price of $1.00.
- In February, 2012, Iroko Intermediate issued 98,393,500 shares of its Series A preferred stock and 9,000,000 shares of its common stock to Iroko Holdings S.A. (the precursor to Cordial) in exchange for 93,962,188 shares of its common stock pursuant to an Agreement and Plan of Reorganization.
- In March 2012, Iroko Intermediate issued 14,000,000 shares of Series A preferred stock to Iroko Holdings S.A. (the precursor to Cordial) in exchange for $14,000,000.
- From March 2012 to March 2013, Iroko Intermediate granted stock options (852,500 of which were issued pursuant to an exchange of options previously issued by Iroko Holdings S.A.) under its 2012 Stock Option/Stock Issuance Plan to purchase an aggregate of 981,300 shares of its common stock at an exercise of $1.52 per share to a total of 56 employees, directors and consultants. Of these, 18,375 have been exercised and 962,925 remain outstanding as of March 31, 2013.

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- Since January 1, 2010, Iroko Intermediate issued and sold an aggregate of 18,375 shares of its common stock to employees, directors and consultants at an exercise price of $1.52 per share upon the exercise of stock options granted under its 2012 Stock Option/Stock Issuance Plan. All 18,375 shares remain outstanding.

In addition, (1) in April 2013, we issued 60,000,000 convertible preference shares to Cordial in connection with the capitalization of outstanding indebtedness owed by Iroko Pharmaceuticals Inc. pursuant to the Reorganization Transactions described in "Corporate Formation and Reorganization" above, (2) in May 2013, we issued 5,000,000 convertible preference shares to Cordial at a per share price of $1.00, and (3) in June 2013, we issued 5,000,000 convertible preference shares to Cordial at a per share price of $1.00.

Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were placed upon the stock certificates issued in these transactions.

**Item 8. Exhibits and Financial Statement Schedules**

(a) Exhibits

| EXHIBIT NUMBER | EXHIBIT TABLE |
|---|---|
| 1.1* | Form of Underwriting Agreement |
| 3.1* | Form of Amended and Restated Memorandum and Articles of Association of the Registrant, to be effective upon completion of the offering |
| 4.1* | Specimen Ordinary Share Certificate of the Registrant |
| 5.1* | Opinion of Walkers as to the validity of the securities being offered |
| 10.1† | Form of Indemnification Agreement for directors and officers of the Registrant, as currently in effect |
| 10.2† | Amended and Restated 2012 Share Option Plan |
| 10.3† | Form of Notice of Grant – Standard Exercise Option for Amended and Restated 2012 Share Option Plan |
| 10.4* | Employment Agreement, dated , by and between Iroko Pharmaceuticals Inc. and Osagie Imasogie |
| 10.5† | Employment Agreement, dated July 21, 2011, by and between Iroko Holdings LLC and John Vavricka |
| 10.6† | Employment Agreement, effective as of April 6, 2012, by and between Iroko Holdings LLC and Clarence L. Young, M.D. |
| 10.7† | Employment Agreement, dated February 21, 2012, by and between Iroko Holdings LLC and Moji James |
| 10.8† | Form of Employment, Confidential Information, and Invention Assignment Agreement |
| 10.9** | Exclusive Sub-license Agreement dated December 6, 2007, by and between Iroko Pharmaceuticals S.a.r.l and Aspen Pharmacare Holdings, Limited |
| 10.10* | Amended and Restated Nano-Reformulated Compound License and Option Agreement dated as of December 28, 2012, by and between the Registrant, Iroko Pharmaceuticals, LLC, iCeutica Pty Ltd and iCeutica Inc. |

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| | |
|---|---|
| 10.11* | Nano-Reformulated Compound License and Option Agreement, dated as of December 28, 2012, by and between the Registrant, iCeutica Pty Ltd and iCeutica Inc. |



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| EXHIBIT NUMBER | EXHIBIT TABLE |
|---|---|
| 10.12* | Promissory Note, dated as of December 28, 2012, by and between the Registrant and iCeutica Inc. |
| 10.13†** | Confidential Service Agreement, dated as of November 30, 2012, by and between the Registrant and Ventiv Commercial Services, LLC |
| 10.14* | Management Services Agreement, dated as of _____, by and between the Registrant and Phoenix IP Ventures-III, LLC |
| 10.15** | Manufacturing and Supply Agreement between Iroko Pharmaceuticals (Luxembourg) S.a.r.l and Aspen Global Incorporated dated April 1, 2008 and First Addendum dated August 17, 2011. |
| 10.16†** | Master Services Agreement between Iroko Pharmaceuticals, LLC and Aptuit Inc. (n/k/a Catalent CTS, Inc.) dated September 10, 2010. |
| 10.17** | Capital Project Agreement between Iroko Pharmaceuticals, LLC and Catalent CTS, Inc. dated May 10, 2012 and Binding Term Sheet for Submicron-formulated Pharmaceutical Products Exclusive Commercial Manufacturing Agreement between Iroko Pharmaceuticals, LLC and Catalent CTS, Inc. dated September 14, 2012. |
| 10.18* | Purchase Agreement among Drawbridge Iroko Holdings LLC, Phoenix IP Ventures LLC, Phoenix IP Ventures-I, LP, Iroko Holdings LLC and Brox Acquisition Co. dated August 10, 2010. |
| 10.19† | Revolving Credit Facility between Cordial Investments Inc. and Iroko Pharmaceuticals Inc. dated May 23, 2013. |
| 16† | Letter re: Change in Certifying Accountant |
| 21.1* | List of Subsidiaries of the Registrant |
| 23.1† | Consent of KMPG LLP. |
| 23.2* | Consent of Walkers (included in Exhibit 5.1) |
| 23.3† | Consent of Impact Rx |
| 24.1† | Power of Attorney (included on the signature page) |

* To be filed by amendment.

** Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from the Registration Statement and submitted separately to the Securities and Exchange Commission.

† Previously filed.

(b) Financial Statement Schedules

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or the notes thereto.

**Item 9. Undertakings**

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the Underwriting Agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in

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the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.



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The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.



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## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, Iroko Pharmaceuticals Inc. has duly caused this registration statement on Form F-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Philadelphia, State of Pennsylvania, on the 27th day of June, 2013.

**Iroko Pharmaceuticals Inc.**

By: /s/ Moji James
Moji James
Senior Vice President, General Counsel and Secretary

## SIGNATURES AND POWER OF ATTORNEY

Pursuant to the requirements of the Securities Act of 1933, as amended this registration statement has been signed by the following persons in the capacities indicated on the 27th day of June, 2013.

| SIGNATURE | TITLE |
|---|---|
| * | President, Chief Executive Officer |
| John F. Vavricka | (Principal Executive Officer) |
| * | Chief Financial Officer |
| Fred C. Krieger | (Principal Financial and Accounting Officer) |
| * | Chairman of the Board |
| Osagie Imasogie | |
| * | Director |
| Nathan Burkey | |
| * | Director |
| Jeremy Fletcher | |
| | Director |
| David U' Prichard | |

*By: /s/ Moji James
Moji James
Attorney-in-Fact



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| | |
|---|---|
| 10.18* | Purchase Agreement among Drawbridge Iroko Holdings LLC, Phoenix IP Ventures LLC, Phoenix IP Ventures-I, LP, Iroko Holdings LLC and Brox Acquisition Co. dated August 10, 2010. |

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| 21.1* | List of Subsidiaries of the Registrant. |
| 23.1† | Consent of KMPG LLP |
| 23.2* | Consent of Walkers (included in Exhibit 5.1) |
| 23.3† | Consent of Impact Rx |
| 24.1† | Power of Attorney (included on the signature page) |

* To be filed by amendment.

** Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from the Registration Statement and submitted separately to the Securities and Exchange Commission.

† Previously filed.

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**Exhibit 10.9**

[***] indicates material that has been omitted pursuant to a Request for Confidential Treatment filed with the Securities and Exchange Commission. A complete copy of this agreement, including redacted portions so indicated, has been filed separately with the Securities and Exchange Commission.

**IROKO PHARMACEUTICALS (LUXEMBOURG) SARL**

**and**

**ASPEN PHARMACARE HOLDINGS LIMITED**

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# EXCLUSIVE SUB-LICENSE AGREEMENT

**6 DECEMBER, 2007**

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**APPENDICES**



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**EXCLUSIVE SUB-LICENSE AGREEMENT**

**1. PARTIES**

1.1. ASPEN PHARMACARE HOLDINGS LIMITED
Registration No. 1985/002935/06; and

1.2. IROKO PHARMACEUTICALS (LUXEMBOURG) SARL

**2. INTERPRETATION**

In this Agreement –

2.1. clause headings are for convenience and shall not be used in its interpretation;

2.2. unless the context clearly indicates a contrary intention –

2.2.1. an expression which denotes –

2.2.1.1. any gender includes the other genders;

2.2.1.2. a natural person includes an artificial person and vice versa;

2.2.1.3. the singular includes the plural and vice versa;

2.2.2. the following expressions shall bear the meanings assigned to them below and cognate expressions bear corresponding meanings –

2.2.2.1. "**ADVERSE EVENT**" means any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of the PRODUCT, whether or not considered related to the PRODUCT. An ADVERSE EVENT for the purposes of this AGREEMENT can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of the PRODUCT. It also includes failure to produce expected benefits (i.e. lack of efficacy), abuse or misuse;

2.2.2.2. "**AFFILIATE/S**" means, in relation to one person, any other person which is controlled by, under common control with, or controls the other. Without limiting the generality of the foregoing, a company shall be deemed to have control of another if (directly or indirectly) it owns a majority of the voting shares of or is entitled (directly or indirectly) to appoint a majority of the directors of the other company. "Control" means the ability to determine the policies and/or management of a person, whether through the ownership of securities, by contract or otherwise;

2.2.2.3. "**AGENCY**" or "**AGENCIES**" means any governmental regulatory authority involved in granting approvals for the MANUFACTURING or COMMERCIALISATION of the PRODUCTS in the TERRITORY and any other equivalent authority (or any successor organization of any such entity) elsewhere;



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2.2.2.4. "**AGREEMENT**" means the agreement set out in this document, incorporating the Appendices hereto;

2.2.2.5. "**APPLICABLE LAWS**" means all or any:

statutes, subordinate legislation and common law,

regulations,

ordinances and bylaws, and

directives, codes of practice, circulars, guidance notes, judgments and decisions of any competent authority,

compliance with which is mandatory in relation to the subject matter of this AGREEMENT;

2.2.2.6. "**ASPEN**" means ASPEN PHARMACARE HOLDINGS LIMITED, Registration Number 1985/002935/06, a company duly registered and incorporated in accordance with the company laws of the Republic of South Africa and having its registered office at Building 8, Healthcare Park, Woodlands Drive, Woodmead, Johannesburg, Republic of South Africa;

2.2.2.7. "**BOARD**" means the Board of Managers set up by the parties to oversee the COMMERCIALISATION of the PRODUCTS in the TERRITORY.

2.2.2.8. "**BUDGET**" means the budget developed and approved by the BOARD for the upcoming calendar year, including reasonably detailed projections of revenues, expenses, cash flow and profit or loss, and all assumptions underlying same;

2.2.2.9. "**BULK SUPPLY TERM**" means (on a PRODUCT by PRODUCT, country by country basis) the period between (i) the termination of the MERCK DISTRIBUTION TERM; and (ii) the date of the commencement of the MANUFACTURING TERM;

2.2.2.10. "**BUSINESS DAY/S**" means any day other than a Saturday, Sunday or official public holiday in the Republic of South Africa and/or the Grand Duchy of Luxembourg, as the case may be;

2.2.2.11. "**CONTROL**" means either the ownership of more than 50% (FIFTY PERCENT) of the ordinary share capital of IROKO carrying the rights to vote at general meetings or the power to nominate a majority of the board of directors of IROKO;

2.2.2.12. "**COMMERCIALISE**" **or** "**COMMERCIALISATION**" means all of the operations required for the promotion, distribution, marketing and/or sale of the PRODUCTS in the TERRITORY;

2.2.2.13. "**CONDITIONS**" means the suspensive conditions to this AGREEMENT as set out in clause 4;

2.2.2.14. "**CONFIDENTIAL INFORMATION**" means any information including, but not limited to, information regarding a PARTY' S past, current and future



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services and products, research and development plans and results, customers, sales and operating information, marketing plans and strategies, cost and pricing information, data, media, know-how, designs, drawings, specifications, source codes, technical information, concepts, reports, methods, processes, techniques, operations, devices and like, future projections, business plans, software, listings, holdings, alliances, investments, financials, transactions and general business operations, label claims, patents, copyrights, trade secrets, information relating to or underlying such intellectual property rights and other proprietary information, sketches, models, inventions, apparatus, equipment, algorithms, information technology systems and programs, software source documents, formulae, research and development, clinical data, experimental work, design details and specifications and other technical information relating to past, current, future and proposed products and services, engineering data, financial information, procurement requirements, purchasing and manufacturing information, customers and customer lists and profiles, business forecasts and sales, marketing and merchandising plans and data, future projections, fee schedules, stock ownership and all materials prepared on the basis of any of the foregoing, whether or not the foregoing information is patented, tested, reduced to practice, or subject to copyright;

2.2.2.15. "**DISTRIBUTION TRANSFER DATE**" shall have the meaning ascribed thereto in clause 7.1;

2.2.2.16. "**EFFECTIVE DATE**" means the 1st (FIRST) BUSINESS DAY after the fulfilment of the CONDITIONS;

2.2.2.17. "**HEAD LICENSE**" has the meaning ascribed thereto in Clause 3.3.

2.2.2.18. "**IFRS**" means International Financial Reporting Standards as promulgated by the International Accounting Standards Board and as adopted by ASPEN as its accounting standard;

2.2.2.19. "**IROKO**" means IROKO PHARMACEUTICALS (LUXEMBOURG) SARL, a société à responsabilité limitée formed under the laws of the Grand Duchy of Luxembourg and having its registered office at 65, Boulevard Grande Duchesse Charlotte, L-1331, Luxembourg, LUXEMBOURG;

2.2.2.20. "**IROKO DATA**" means all knowledge, know-how or other proprietary information and material in relation to the PRODUCTS (whether or not patentable) including, but not limited to, substance, formulations, techniques, methodology, manufacturing process, equipment, data, reports, source of supply, patent position, business plans, research and test results relating to the PRODUCTS owned, developed or used by, or licensed to, IROKO, and those which may belong to third parties for use of which IROKO has made sufficient arrangements;

2.2.2.21. "**IROKO LLC**" means Iroko Pharmaceuticals, LLC, a limited liability company formed under the laws of the State of Delaware, USA, and a shareholder of IROKO.

2.2.2.22. "**LICENSE FEE PERIOD**" means (on a PRODUCT by PRODUCT, country by country basis) the calendar quarter calculated from the commencement date of the BULK SUPPLY TERM and each consecutive calendar quarter thereafter;



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2.2.2.23. "**MANUFACTURE" or "MANUFACTURING" or "MANUFACTURED" or "MANUFACTURES**" means, as applicable, all the production, the procurement of all or any raw materials, excipients, API' s and other inputs of whatever nature, warehousing, quality control testing (including in-process and release) and release of the PRODUCTS;

2.2.2.24. "**MANUFACTURING TERM**" means (on a PRODUCT by PRODUCT, country by country basis) the period between (i) the termination of the BULK SUPPLY TERM; and (ii) the 6th (SIXTH) anniversary from the signature date *plus* the earlier of (x) two years or (y) the time necessary to complete the technical transfer of the MANUFACTURING process to new third party manufacturers;

2.2.2.25. "**MARKETING AUTHORISATIONS**" means any license or approval of any AGENCY necessary for the MANUFACTURE, PACKAGING, export and/or COMMERCIALISATION of the PRODUCTS in the TERRITORY;

2.2.2.26. "**MERCK**" means, collectively, Merck & Co., Inc., a corporation organized under the laws of the State of New Jersey and Merck and Company, Incorporated, a corporation organized under the laws of the State of Delaware;

2.2.2.27. "**MERCK FEE**" shall have the meaning ascribed thereto in clause 3.7.1;

2.2.2.28. "**MERCK DISTRIBUTION TERM**" means (on a PRODUCT by PRODUCT, country by country basis) the period between (i) the EFFECTIVE DATE; and (ii) the commencement of the DISTRIBUTION TRANSFER DATE;

2.2.2.29. "**NET SALES**" means, for each PRODUCT in each country in the TERRITORY, the applicable gross invoice amounts for the sale of the PRODUCT, during the relevant period, less reasonable and customary deductions for the following with respect to the PRODUCT, all determined in accordance with IFRS consistently applied: (i) all trade, cash and quantity credits, discounts, refunds and rebates other than early pay cash discounts; (ii) credits or allowances for returns, recalls, rejections, damages to or destruction of the PRODUCT, retroactive price reductions, and charge backs; (iii) sales or excise taxes, including such amounts which are to be paid on the basis of the sales price; and (iv) bad debts written off;

2.2.2.30. "**PACK", "PACKED", "PACKING" or "PACKAGING**" means the filling, primary and secondary packaging and labelling of the PRODUCTS into sales packs and the procurement of all or any raw materials, packaging materials and other inputs of whatever nature relevant thereto;

2.2.2.31 "**PARTIES**" mean the parties to this AGREEMENT and "**PARTY**" shall mean any one of them;

2.2.2.32. "**PRIORITY COUNTRIES**" means those countries set out in **Appendix I** in respect of which ASPEN shall be obliged to use its best endeavours to COMMERCIALISE, or procure the COMMERCIALISATION of (as the case may be) the PRODUCTS;



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2.2.2.33. "**PRODUCTS**" means the products described in **Appendix A**;

2.2.2.34. "**QUARTERLY LICENSE FEE**" means that amount calculated in accordance with the provisions of **Appendix E**;

2.2.2.35. "**REGULATORY COSTS**" means reasonable direct costs and indirect costs, including but not limited to, license fees associated with change applications and retention/renewal, regulatory agency fees; courier fees; photocopy fees; translations; notarisations; CPP' s, samples of product and/or printed for submission, manpower/resource costs, consulting fees, bio-studies, new methods and their validation, stability data and other work done directly with the PRODUCTS pursuant to procuring transfer of applicant, manufacturer, packer and laboratory;

2.2.2.36. "**SIGNATURE DATE**" means the date of signature of this AGREEMENT by the PARTY signing last in time;

2.2.2.37. "**SPECIFICATIONS**" means the specifications and testing methods for the PRODUCTS, their active pharmaceutical ingredients and excipients as set out in the MARKETING AUTHORISATIONS, including, for the avoidance of doubt, packaging and labelling specifications;

2.2.2.38. "**SRC PRODUCT**" means lndocin® (Indomethacin) Sustained Release Capsules 75mg as is set out in **Appendix B**;

2.2.2.39. "**SUPPOSITORIES**" means those PRODUCTS set out in **Appendix B**;

2.2.2.40. "**TERM**" means the period commencing on the EFFECTIVE DATE and terminating on the 50 (FIFTIETH) anniversary of the EFFECTIVE DATE;

2.2.2.41. "**TERRITORY**" means the entire African continent, the entire South and Central American continents, including the islands of the Caribbean (excluding Puerto Rico as it is considered part of North America), Ireland, the United Kingdom, Australia and New Zealand, and the entire Asian continent (excluding China (other than Hong Kong), Japan, Pakistan, Korea, any US territories (i.e. Guam) and Sri Lanka (the latter only insofar as it relates to Aldomet®);

2.2.2.42. **THIRD PARTY SUB-LICENSEE/S**" means those third party sub-licensee/s appointed to COMMERCIALISE the PRODUCTS in accordance with the provisions of this AGREEMENT;

2.2.2.43. "**TRADEMARKS**" means those trademarks which are applied for, owned and/or registered in the name of IROKO and/or its AFFILIATES in the TERRITORY which are or which may, from time to time, be used in the COMMERCIALISATION of the PRODUCTS and all related industrial or intellectual property, trade dress, designs, labels, labeling, house marks, logos and other indices of ownership;

2.2.2.44. "**WORLDWIDE MANUFACTURING AND SUPPLY AGREEMENT**" means the Manufacturing and Supply Agreement which Pharmacare Limited and IROKO will enter into contemporaneously with this AGREEMENT pursuant to which Pharmacare Limited will MANUFACTURE and supply the PRODUCTS to IROKO in the territory thereunder and the PRODUCTS for their COMMERCIALISATION in the TERRITORY pursuant to the terms of this AGREEMENT.



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2.3. should any provision in a definition be a substantive provision conferring rights or imposing obligations on any PARTY, effect shall be given to that provision as if it were a substantive provision in the body of this AGREEMENT;

2.4. any reference to an enactment, regulation, rule or by-law is to that enactment, regulation, rule or by-law as at the SIGNATURE DATE, and as amended from time to time;

2.5. when any number of days is prescribed, such number shall exclude the first and include the last day, unless the last day falls on a day other than a business day, in which case the last day shall be the next succeeding business day;

2.6. any schedule to this AGREEMENT shall form part of, and be deemed to be incorporated in, this AGREEMENT;

2.7. where any term is defined within a particular clause, other than the interpretation clause, that term shall bear the meaning assigned to it in that clause wherever it is used in this AGREEMENT;

2.8. the use of the word "including" or "includes" followed by a specific example/s shall not be construed as limiting the meaning of the general wording preceding it and the *eiusdem generis* rule shall not be applied in the interpretation of such general wording or such specific example/s;

2.9. the expiration or termination of this AGREEMENT shall not affect those provisions of this AGREEMENT which expressly provide that they will operate after any such expiration or termination or which of necessity must continue to have effect after such expiration or termination, notwithstanding the fact that the clauses themselves do not expressly provide for this;

2.10. in its interpretation, the *contra proferentem* rule of construction shall not apply (this AGREEMENT being the product of negotiations between the PARTIES), nor shall this AGREEMENT be construed in favour of or against any PARTY by reason of the extent to which any PARTY or its professional advisors participated in the preparation of this AGREEMENT;

2.11. any reference to days (other than a reference to business days), months or years shall be a reference to calendar days, months or years, as the case may be; and

2.12. recordals shall be binding on the PARTIES and are not merely for information purposes.

## 3. RECORDAL AND INTRODUCTION

3.1. IROKO LLC has acquired the IROKO DATA and the exclusive rights to COMMERCIALISE the PRODUCTS on a worldwide basis from MERCK, provided, however, that MERCK shall continue to COMMERCIALISE the PRODUCTS on a PRODUCT by PRODUCT, country by country basis during the MERCK DISTRIBUTION TERM. In connection with such acquisition, IROKO LLC and MERCK entered into a supply agreement whereby MERCK is obligated to supply and provide a safety stock of the PRODUCTS to IROKO LLC, on a PRODUCT by PRODUCT, country by country basis, in finished PACK until the MARKET AUTHORIZATION is transferred, and in bulk PACK until at least March 20, 2009, with such PRODUCTS having a minimum remaining shelf life which will enable the viable COMMERCIALISATION thereof in the TERRITORY.



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3.2. The IROKO DATA is of a form and nature sufficient to procure the transfer of the MARKETING AUTHORISATIONS from MERCK to IROKO LLC for the COMMERCIALISATION of the PRODUCTS in the TERRITORY.

3.3. IROKO has entered into an "Exclusive Head License Agreement" (the "HEAD LICENSE") with IROKO LLC pursuant to which IROKO LLC has granted to IROKO (1) the right to use the IROKO DATA and MARKETING AUTHORIZATIONS in, inter alia, the TERRITORY for the purpose of procuring (either through its own or its AFFILIATES' endeavours or through the endeavours of THIRD PARTY SUB-LICENSEES) the COMMERCIALIZATION of the PRODUCTS and (ii) the right (either through its own or its AFFILIATES' endeavours or through the endeavours of THIRD PARTY SUB-LICENSEES) to receive PRODUCTS in bulk from MERCK for the purpose of causing them to be PACKED and COMMERCIALIZED in, inter alia, the TERRITORY and (iii) the right (either through its own or its AFFILIATES' endeavours or through the endeavours of THIRD PARTY SUB-LICENSEES) to MANUFACTURE and PACK the PRODUCTS for the purposes of their COMMERCIALIZATION in, inter alia, the TERRITORY.

3.4. Pursuant to the HEAD LICENSE, IROKO now wishes to sublicense such rights to ASPEN, in the TERRITORY.

3.5. ASPEN undertakes to use its best endeavours, in cooperation with IROKO, to procure the transfer of the MARKETING AUTHORISATIONS, in accordance with the timelines as set out in **Appendix C** in the PRIORITY COUNTRIES, from MERCK to ASPEN, its AFFILIATES and/or the THIRD PARTY LICENSEE/S and thereafter to COMMERCIALISE the PRODUCTS or procure the COMMERCIALISATION thereof (as the case may be) exclusively in the TERRITORY. For countries other than the PRIORITY COUNTRIES, at its first meeting the filing strategy will be agreed by the BOARD on a country by country basis or such later date as agreed by the PARTIES in writing, and for such countries where the PARTIES determine a submission is required, the PARTIES shall use their best endeavours to submit the filings therefor by 15 March 2008.

3.6. IROKO shall be responsible for procuring the transfer of the MARKETING AUTHORISATIONS outside of the TERRITORY from MERCK and for the COMMERCIALISATION of the PRODUCTS in those countries (excluding the Territory) where it holds rights to COMMERCIALIZE the PRODUCTS.

3.7. Subject to the terms and on the conditions set out in this AGREEMENT and in consideration for ASPEN' s payments pursuant to Clause 13.1, IROKO is prepared to grant to ASPEN-

3.7.1. during the MERCK DISTRIBUTION TERM, and after, and in consideration of, the payment of the license fee pursuant to clauses 13.1.1. and 13.1.2 hereunder, the right to receive an amount equal to 50% (FIFTY PERCENT) of the net profits generated by MERCK on account of the COMMERCIALISATION by MERCK of the PRODUCTS in the TERRITORY *plus* an amount equal to 50% (FIFTY PERCENT) of all or any damages paid by MERCK consequent upon a breach by MERCK of its obligations arising from or related to the PRODUCTS in the TERRITORY, relevant to the subject matter of this AGREEMENT (collectively the "MERCK FEE");

3.7.2. during the BULK SUPPLY TERM, the rights to receive the PRODUCTS in bulk from MERCK for the purposes of causing them to be PACKED and COMMERCIALISED in the TERRITORY;



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3.7.3. during the MANUFACTURING TERM, the rights to MANUFACTURE and PACK the PRODUCTS exclusively for the purposes of their COMMERCIALISATION in the TERRITORY; and

3.7.4. during the TERM, an exclusive license to use the IROKO DATA and the MARKETING AUTHORISATIONS in the TERRITORY for the purpose of procuring (either through its own or its AFFILIATES' endeavours or through the endeavours of the THIRD PARTY SUB-LICENSEES) the COMMERCIALISATION of the PRODUCTS in the TERRITORY;

provided, however that no conveyance of ownership is granted to ASPEN and all right, title and interest in and to the IROKO DATA, TRADEMARKS and the MARKETING AUTHORISATIONS, and any other proprietary rights contained therein, shall be retained by the owner thereof.

**4. SUSPENSIVE CONDITIONS**

4.1. This AGREEMENT is subject to the fulfilment of the CONDITIONS by no later than 20 February 2008.

4.1.1. that ASPEN obtains the written approval, to the extent necessary, of the Exchange Control Department of the RSA Reserve Bank pursuant to the Currencies and Exchanges Act, 9 of 1933 to the contents of this AGREEMENT;

4.1.2. that ASPEN obtains the written approval, to the extent necessary, of the South African Department of Trade and Industry to the contents of this AGREEMENT.

4.2. ASPEN shall use its best commercial endeavours to procure the fulfilment of the CONDITIONS and shall keep IROKO regularly informed of its progress in fulfilling the CONDITIONS.

4.3. ASPEN shall be entitled to extend the time period for the fulfilment of the CONDITIONS for a maximum period of 30 (THIRTY) days on written notice to IROKO given at any time prior to the expiry for the time period for the fulfilment thereof.

4.4. If the CONDITIONS are not timely fulfilled (but subject to clauses 4.2 and 4.3)-

4.4.1. the whole of this AGREEMENT shall have no force or effect; and

4.4.2. no PARTY shall have any claim against the other PARTY in terms of this AGREEMENT.

**5. GRANT OF RIGHTS**

5.1. During the MERCK DISTRIBUTION TERM, and after the payment of the license fee pursuant to clauses 13.1.1. and 13.1.2 hereunder, IROKO shall pay to ASPEN the MERCK FEE, which shall be paid no later than 10 Business Days after the end of each calendar quarter.

5.2. During the BULK SUPPLY TERM, IROKO shall cause MERCK, pursuant to its supply agreement with IROKO LLC, to deliver to ASPEN the PRODUCTS in bulk for the purposes of causing them to be PACKED and COMMERCIALISED in the TERRITORY. Notwithstanding the aforesaid, the SUPPOSITORIES and the SRC PRODUCT will be MANUFACTURED and PACKED pursuant to the provisions of clause 15.1.



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5.3. During the MANUFACTURING TERM, IROKO grants to ASPEN and ASPEN hereby accepts the rights to MANUFACTURE and PACK the PRODUCTS exclusively for the purposes of their COMMERCIALISATION in the TERRITORY. Notwithstanding the aforesaid, the SUPPOSITORIES and the SRC PRODUCT will be MANUFACTURED and PACKED pursuant to the provisions of clause 15.1.

5.4. During the TERM, IROKO hereby grants to ASPEN, and ASPEN hereby accepts, subject to the terms and on the conditions set out in this AGREEMENT, an exclusive sub-license to use the IROKO DATA and MARKETING AUTHORISATIONS in the TERRITORY for the purpose of procuring (either through its own or its AFFILIATES' endeavours or through the endeavours of THIRD PARTY SUB-LICENSEES) the COMMERCIALISATION of the PRODUCTS in the TERRITORY.

5.5. After the MERCK DISTRIBUTION TERM -

5.5.1. ASPEN shall COMMERCIALISE or procure the COMMERCIALISATION of the PRODUCTS in the PRIORITY COUNTRIES, and in those parts of the TERRITORY as determined by the BOARD; and

5.5.2. the BOARD will determine which of ASPEN, its AFFILIATES or THIRD PARTY SUB-LICENSEES will COMMERCIALISE the PRODUCTS in which part/s of the TERRITORY and the terms and conditions pertaining to such COMMERCIALISATION.

5.6. ASPEN shall not use or apply the IROKO DATA and/or MARKETING AUTHORISATIONS for any purpose whatsoever, other than in connection with the PRODUCTS and as provided in this AGREEMENT.

5.7. ASPEN undertakes that it will not, without the prior written consent of IROKO-

5.7.1. COMMERCIALISE the PRODUCTS outside of the TERRITORY;

5.7.2. supply the PRODUCTS to any third party which it and/or its AFFILIATES have reason to believe may COMMERCIALISE the PRODUCTS outside of the TERRITORY.

5.8. IROKO shall have the exclusive rights to use the IROKO DATA for the purposes of COMMERCIALISING the PRODUCTS in those countries (excluding the TERRITORY) where it holds rights to COMMERICIALIZE the PRODUCTS and reserves all rights not explicitly granted herein.

5.9. Except as otherwise provided herein, IROKO hereby irrevocably undertakes that it will not, during the TERM, without the prior written consent of ASPEN –

5.9.1. use the IROKO DATA for the purposes of COMMERCIALISING the PRODUCTS in the TERRITORY or allow its AFFILIATES and/or any third party to use the IROKO DATA for such purposes;

5.9.2. supply the PRODUCTS to any third party which it and/or its AFFILIATES have reason to believe may COMMERCIALISE the PRODUCTS in the TERRITORY;

5.10. no conveyance of ownership is granted to ASPEN herein and all right, title and interest in and to the IROKO DATA, TRADEMARKS and the MARKETING AUTHORISATIONS, and other proprietary rights contained therein is retained by the owner thereof.



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## 6. DURATION

Notwithstanding the SIGNATURE DATE, this AGREEMENT shall endure for the TERM, unless terminated earlier in accordance with the provisions hereof.

## 7. MERCK DISTRIBUTION TERM

7.1. After the EFFECTIVE DATE, MERCK shall continue to COMMERCIALISE the PRODUCTS on a PRODUCT by PRODUCT, country by country basis, on IROKO LLC' s behalf until such date as (i) the MARKETING AUTHORISATIONS (on a PRODUCT by PRODUCT, country by country basis) are transferred from MERCK to IROKO LLC (or its designee); and (ii) MERCK and IROKO LLC mutually agree, such date to be no later than 30 (THIRTY) days after the applicable transfer date on a PRODUCT by PRODUCT, country by country basis (each, the "DISTRIBUTION TRANSFER DATE"). On a PRODUCT by PRODUCT, country by country basis in the TERRITORY, from and after and in consideration of the payment by ASPEN of the license fee pursuant to clauses 13.1.1. and 13.1.2. until the DISTRIBUTION TRANSFER DATE on a PRODUCT by PRODUCT, country by country basis, IROKO shall pay to ASPEN the MERCK FEE. The MERCK FEE shall be paid quarterly, in United States Dollars, within 10 (TEN) BUSINESS DAYS after the expiration of each calendar quarter, together with a report reconciling the amounts so paid. For each country in the TERRITORY, ASPEN and/or the THIRD PARTY SUB-LICENSEE/S shall undertake the COMMERCIALISATION of the PRODUCTS for such country upon the respective DISTRIBUTION TRANSFER DATE.

7.2. ASPEN shall be entitled, at all reasonable times, either directly or through its duly authorised agents, to undertake an inspection and/or audit of all or any of IROKO' S reports, books of account and the like in an endeavour to verify the MERCK FEE or any component thereof and IROKO shall give ASPEN and/or its duly authorized agents, its full co-operation in this regard and shall procure that IROKO LLC provide such information as ASPEN may reasonably require to verify the computation of the MERCK FEE. The authorised agents or representatives of ASPEN shall, however, prior to conducting any such inspection and/or audit, enter into a "confidentiality and lock-out agreement" in a form reasonably acceptable to IROKO that would require the agent or representative to maintain confidentiality of the information obtained and desist from trading in the securities of IROKO for a period specified therein.

7.3. Should ASPEN dispute the MERCK FEE or any component thereof, then the PARTIES shall enter into negotiations in good faith with regard to agreeing the MERCK FEE or, failing such agreement within 10 (TEN) days after the commencement of such negotiation, either PARTY shall be entitled to refer the dispute/disagreement for determination by an independent auditor appointed by agreement between the PARTIES, in writing, or failing such agreement within 5 (FIVE) days after either PARTY has required such referral, appointed by the President for the time being of the South African Institute of Chartered Accountants (or his successor-in-title) if IROKO requests such an appointment, or appointed by the then President of the Luxembourg lnstitut des Reviseurs d' Entrepises (or his successor-in-title), if ASPEN requests such an appointment. Such auditor shall act as an expert and not as an arbitrator and his decision shall, save for any manifest error, be final and binding on the PARTIES.

## 8. BULK SUPPLY TERM

8.1. With effect from each DISTRIBUTION TRANSFER DATE, IROKO shall use its best commercial endeavours to procure that MERCK delivers to ASPEN, its AFFILIATES or any third party packer appointed by the BOARD the PRODUCTS in bulk, in that quality and according to that quantity as are necessary to procure their COMMERCIALISATION



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in the TERRITORY in accordance with the provisions of this AGREEMENT. ASPEN shall advise IROKO of its requirements of the PRODUCTS in bulk and IROKO shall timely cause orders to be placed with MERCK for such PRODUCTS to the extent reasonably consistent with past orders.

8.2. ASPEN, its AFFILIATES or the third party packer (as the case may be) shall PACK the PRODUCTS received from MERCK in bulk in accordance with the SPECIFICATIONS (insofar as they relate to PACKAGING), APPLICABLE LAWS and Good Manufacturing Practice for their COMMERCIALISATION in the TERRITORY.

8.3. In the event of ASPEN and/or its AFFILIATES attending to PACK the PRODUCTS so supplied by MERCK in bulk, it/they shall be entitled to a PACKAGING fee calculated on a [***] basis, determined in accordance with IFRS, and payable in accordance with **Appendix D**. The BOARD shall determine whether a third party packer shall PACK the PRODUCTS so supplied by MERCK in bulk and the terms and the conditions applicable thereto.

8.4. ASPEN shall pay MERCK, in full, for the PRODUCTS supplied, in bulk, to ASPEN and ASPEN shall be solely liable for all costs and expenses associated with the delivery thereof to an address in the Republic of South Africa as is nominated, from time to time, by ASPEN.

8.5. In respect of the PRODUCTS to be supplied by MERCK in bulk, IROKO shall provide MERCK, or shall cause MERCK to be provided, with a written rolling 24 (TWENTY FOUR) month forecast of its requirements, the first 6 (SIX) months of which shall constitute a firm order. MERCK shall deliver such firm order (provided it is consistent with the most recent forecasts) to IROKO LLC or its designee, Ex Works (INCOTERMS 2000), MERCK' S manufacturing plant, at which time title shall pass to IROKO or its AFFILIATES, and IROKO is to notify MERCK (or shall cause MERCK to be notified) of any defects within 45 (FORTY FIVE) days thereof. Payment for the PRODUCTS in bulk is to be made to MERCK within 60 (SIXTY) days of delivery.

## 9. TRANSITIONAL UNDERTAKINGS

9.1. Within 30 (THIRTY) days of the EFFECTIVE DATE, IROKO shall be obliged to deliver or cause to be delivered to ASPEN copies of the registration files for all of the MARKETING AUTHORISATIONS for the PRODUCTS and all other documentation as may be reasonably required by ASPEN.

9.2. IROKO shall use its best commercial endeavours to undertake or procure the undertaking of all necessary actions, with the utmost dispatch and good faith, to –

9.2.1. facilitate the transfer of the MARKETING AUTHORISATIONS from MERCK to ASPEN, its AFFILIATES and/or the THIRD PARTY LICENSEE/S;

9.2.2. facilitate the PACKING of the bulk PRODUCTS by ASPEN, its AFFILIATES and/or third party packers; and

9.2.3. facilitate the MANUFACTURE and PACKING of the PRODUCTS by ASPEN,

including without limiting the generality of the foregoing, procuring that MERCK provides ASPEN with all reasonable co-operation in this regard. Each PARTY undertakes to sign or procure the signing of all and any documents necessary to give effect to the registration and maintenance of the MARKETING AUTHORISATIONS, to procure the PACKING of the PRODUCTS supplied in bulk by MERCK and/or the MANUFACTURE and PACKING of the

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PRODUCTS by ASPEN, upon the request therefor. The provisions of this clause 9.2 shall, where applicable, apply *mutatis mutandis* to the SUPPOSITORIES, ALDOMET® (METHYLDOPA) TABLETS 125MG and/or SRC PRODUCT.

9.3. Both PARTIES hereby undertake to use their respective best endeavours to procure the transfer, on a PRODUCT by PRODUCT, country by country basis, of (i) the MARKETING AUTHORISATIONS from MERCK to ASPEN, its AFFILIATES and/or the THIRD PARTY SUB-LICENSEES; (ii) the approval in accordance with the APPLICABLE LAWS pertaining to ASPEN as the packer of the PRODUCTS; (iii) the approval in accordance with the APPLICABLE LAWS pertaining to ASPEN as the manufacturer and packer of the PRODUCTS; and (iv) the approval in accordance with the APPLICABLE LAWS of new printed PACKAGING for the PRODUCTS. The provisions of this clause 9.3 shall, where applicable, apply *mutatis mutandis* to the SUPPOSITORIES, ALDOMET® (METHYLDOPA) TABLETS 125MG and/or SRC PRODUCT.

## 10. BEST EFFORTS TO COMMERCIALISE

For the duration of the BULK SUPPLY TERM and the MANUFACTURING TERM, ASPEN shall use its best efforts to COMMERCIALISE or procure the COMMERCIALISATION of the PRODUCTS in the PRIORITY COUNTRIES.

## 11 . MARKETING AUTHORISATIONS

11.1. As soon as is practically possible after the EFFECTIVE DATE, ASPEN and IROKO shall do all things reasonably necessary, with the utmost dispatch and good faith, to procure (i) the transfer of the MARKETING AUTHORISATIONS in the TERRITORY from MERCK to ASPEN, its AFFILIATES and/or the THIRD PARTY SUB-LICENSEES; (ii) the approval in accordance with the APPLICABLE LAWS pertaining to ASPEN as the manufacturer and packer of the PRODUCTS; and (iii) the approval in accordance with the APPLICABLE LAWS of new PACKAGING for the PRODUCTS, all in accordance with the procedures and time lines set out in **Appendix C .**

11.2. Notwithstanding the provisions of clause 11.1, in the event of the existing MARKETING AUTHORISATIONS requiring further work to be undertaken thereon in order to procure their transfer to ASPEN, its AFFILIATES and/or the THIRD PARTY SUB-LICENSEE/S, the PARTIES shall take all necessary steps to cause the necessary further work to be undertaken and shall cooperate in the utmost good faith to that end. IROKO will use its best commercial endeavours to procure the consent of MERCK for any technical work requiring MERCK' s consent.

11.3. All or any reasonable fees, costs and expenses incurred by ASPEN and/or IROKO and mutually agreed to by the PARTIES in procuring (i) the transfer of the MARKETING AUTHORISATIONS to ASPEN, its AFFILIATES and/or the THIRD PARTY SUB-LICENSEE/S and/or associated with any further work which requires to be undertaken in order to procure such transfer; (ii) the approval in accordance with the APPLICABLE LAWS pertaining to ASPEN as the manufacturer and packer of the PRODUCTS; and (iii) the approval in accordance with the APPLICABLE LAWS of new PACKAGING for the PRODUCTS, shall be deemed to be REGULATORY COSTS. The provisions of this clause 11.3 shall, where applicable, apply *mutatis mutandis* to the SUPPOSITORIES, ALDOMET® (METHYLDOPA) TABLETS 125MG and/or SRC PRODUCT.

11.4. After the transfer of the MARKETING AUTHORISATIONS to ASPEN, its AFFILIATES and/or the THIRD PARTY SUB-LICENSEES, ASPEN will be solely responsible for maintaining all MARKETING AUTHORISATIONS in the TERRITORY. All or any fees, costs or expenses incurred and paid by ASPEN in so maintaining the MARKETING AUTHORISATIONS shall be deemed to be a REGULATORY COST.



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11.5. Should additional data be required for the purposes of obtaining and/or maintaining the MARKETING AUTHORISATIONS, then the PARTIES shall meet and undertake negotiations in good faith to determine an appropriate method to obtain such additional data. The costs and expenses incurred in obtaining the said additional data shall be deemed to be a REGULATORY COST.

11.6. Upon the expiration or earlier termination of this AGREEMENT, ASPEN shall, at IROKO' S cost, promptly take all necessary actions, with the utmost dispatch and good faith, to facilitate the transfer of the MARKETING AUTHORISATIONS from ASPEN to IROKO or its designee(s). ASPEN undertakes to sign all or any documents necessary to give effect to such re-registration of the MARKETING AUTHORISATIONS upon IROKO' S request therefor.

**12. PRODUCTS LABELLING, PROPRIETARY RIGHTS AND TRADEMARKS**

12.1. After the MERCK DISTRIBUTION TERM, the PRODUCTS, including the PACKAGING, sold in the TERRITORY shall bear the TRADEMARKS. The format and quality of the PRODUCTS packaging and the quality and content of the PRODUCTS packaging inserts, labels and promotional material relating to the PRODUCTS shall be the responsibility of ASPEN upon IROKO' S approval (which shall be within 21 (twenty-one) working days of receipt of such request from ASPEN) and shall meet the requirements of the MARKETING AUTHORISATIONS . Notwithstanding the aforesaid, where IROKO is, pursuant to the APPLICABLE LAWS, obliged to affix its marks/names to any PRODUCTS packaging, then the same shall be affixed in the manner as is required by the APPLICABLE LAWS.

12.2. ASPEN agrees not to claim or to assert any rights of property in or to the TRADEMARKS or the goodwill associated therewith in the TERRITORY and will take no action which may destroy, damage or impair in any way the ownership or rights of the owner thereof in and to such TRADEMARKS in the TERRITORY. ASPEN shall not register in its own name, or on behalf of any other person, any trademark, trade name, brands, labelling, designs or other indicia of ownership imitating or conflicting with or resembling the TRADEMARKS in the TERRITORY, and shall not associate the TRADEMARKS with any article, other than the PRODUCTS to be COMMERCIALISED by ASPEN pursuant to this AGREEMENT, and shall at the request, cost and expense of IROKO do all such acts and things and execute all such documents as IROKO shall, acting reasonably, consider necessary or proper for the protection and maintenance of the TRADEMARKS in the TERRITORY.

12.3. ASPEN shall give immediate notice to IROKO of any known or presumed counterfeits, copies, imitations, simulations of, or infringements upon, the TRADEMARKS in the TERRITORY or any other infringement or other act or unfair competition against the TRADEMARKS in the TERRITORY and shall, at IROKO' s cost and expense, give IROKO its full co-operation in the protection of the TRADEMARKS in the TERRITORY.

12.4. IROKO undertakes, at its cost and expense, to maintain or cause to be maintained the TRADEMARKS in the TERRITORY throughout the TERM.

12.5. Where IROKO requires the PACKAGING to reflect a language other than the English language ("**other language**"), IROKO shall supply ASPEN with the relevant translation for such packaging, prior to ASPEN PACKING the PRODUCTS with PACKAGING that reflects the other language.



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12.6. ASPEN acknowledges that all intellectual property in the packaging design, TRADEMARKS, labelling, package insert and artwork supplied by IROKO to ASPEN pursuant to this clause 12 is owned or licensed by IROKO and shall remain IROKO' S property following any termination of this AGREEMENT for any reason, and that nothing in this AGREEMENT grants to ASPEN any right, title or interest in the ownership of such intellectual property. ASPEN will take all reasonable precautions to ensure the protection of IROKO' S rights in such intellectual property and further acknowledges that any improvements thereto shall also be the sole and exclusive property of IROKO. For the avoidance of doubt the provisions of this clause 12.6 apply only to the packaging design, TRADEMARKS, labelling, package insert and artwork supplied by IROKO to ASPEN pursuant to this clause 12 and not to packaging designs, trademarks, labelling, packaging inserts and/or artwork developed, devised or owned by ASPEN and/or its AFFILIATES.

**13. LICENSE FEE/TAX**

13.1. For the grant of the exclusive license rights in respect of the IROKO DATA and the rights to COMMERCIALISE the PRODUCTS in the TERRITORY, ASPEN shall pay to IROKO –

13.1.1. a once-off license fee for the exclusive rights to COMMERCIALISE the PRODUCTS in the TERRITORY for the amount of US$10,274,400.00 (TEN MILLION TWO HUNDRED SEVENTY FOUR THOUSAND AND FOUR HUNDRED UNITED STATES DOLLARS);

13.1.2. a once-off payment for the knowledge and know-how in relation to the IROKO DATA for the amount of US$2,568,600.00 (TWO MILLION FIVE HUNDRED SIXTY EIGHT THOUSAND AND SIX HUNDRED UNITED STATES DOLLARS); and

13.1.3. the QUARTERLY LICENSE FEE for the ongoing maintenance and use of the IROKO DATA and the COMMERCIALISATION of the PRODUCTS in the TERRITORY.

13.2. For purposes of calculating the QUARTERLY LICENSE FEE set forth in clause 13.1.3, from the EFFECTIVE DATE all sales of products containing indomethacin and/or methyldopa sold by ASPEN in the TERRITORY (other than those such products sold by ASPEN in South Africa by public tender) shall be included in the NET SALES computation.

13.3. Those amounts set out in clauses 13.1.1 and 13.1.2 shall be due and payable within 7 (SEVEN) days of the date of the fulfilment of the CONDITIONS and will be paid –

13.3.1. without deduction or set-off unless ASPEN is required to withhold any amount by law;

13.3.2. by electronic transfer in immediately available funds; and

13.3.3. into a bank account nominated by IROKO, in writing, from time to time.

13.4. The QUARTERLY LICENSE FEE shall be due and payable by ASPEN within 30 (THIRTY) days of the end of each LICENSE FEE PERIOD together with a report to IROKO (in the form of **Appendix F**) reconciling the amounts so paid .

13.5. The QUARTERLY LICENSE FEE will be paid -



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13.5.1. in United States Dollars (the actual rate of currency conversion shall apply in all circumstances where it is necessary for ASPEN to convert currency for the purpose of paying the QUARTERLY LICENSE FEE);

13.5.2. without deduction or set-off unless ASPEN is required to withhold any amount by law;

13.5.3. by electronic transfer in immediately available funds; and

13.5.4. into a bank account nominated by IROKO, in writing, from time to time.

13.6. After the MERCK DISTRIBUTION TERM, ASPEN shall, within 15 (FIFTEEN) calendar days after each month, provide to IROKO a territory report on sales activity (in the form of **Appendix G** hereto) for each PRODUCT in each country in the TERRITORY.

13.7. After the MERCK DISTRIBUTION TERM, ASPEN shall, within 30 (THIRTY) calendar days after each month, provide to IROKO a territory pro-forma income statement of the business activity undertaken throughout the TERRITORY (in the form of **Appendix F** hereto) that includes the determination of the QUARTERLY LICENSE FEE and such other financial information as is requested by IROKO, from time to time, acting reasonably. Such pro-forma income statements shall show information in United States Dollars and shall include the activity of the relevant month and the year-to-date results on a calendar-year basis.

13.8. IROKO shall be entitled, at all reasonable times, either directly or through its duly authorised agents, to undertake an inspection and/or audit of all or any of ASPEN' S reports, books of account, manufacturing facilities and the like in an endeavour to verify the QUARTERLY LICENSE FEE or any component thereof and ASPEN shall give IROKO and/or its duly agents, its full co-operation in this regard. The authorised agents or representatives of IROKO shall, however, prior to conducting any such inspection and/or audit, enter into a "confidentiality and lock-out agreement" in a form reasonably acceptable to ASPEN that would require the agent or representative to maintain confidentiality of the information obtained and desist from trading in the securities of ASPEN for a period specified therein.

13.9. Should IROKO dispute the QUARTERLY LICENSE FEE or any component thereof, then the PARTIES shall enter into negotiations in good faith with regard to agreeing the QUARTERLY LICENSE FEE or, failing such agreement within 10 (TEN) days after the commencement of such negotiation, either PARTY shall be entitled to refer the dispute/disagreement for determination by an independent auditor appointed by agreement between the PARTIES, in writing, or failing such agreement within five (5) days after either PARTY has required such referral, appointed by the President for the time being of the South African Institute of Chartered Accountants (or his successor-in-title) if IROKO requests such an appointment, or appointed by the then President of the Luxembourg lnstitut des Reviseurs d' Entreprises (or his successor-in-title), if ASPEN requests such an appointment. Such auditor shall act as an expert and not as an arbitrator and his decision shall, save for any manifest error, be final and binding on the PARTIES.

13.10. Where any withholding tax may be reduced as a consequence of the application of the Luxembourg/South African Double Tax Agreement ("DTA"), IROKO may qualify for relief under the DTA. To so obtain relief under the DTA, ASPEN will be required to approach the South African Revenue Services on behalf of IROKO to obtain the necessary withholding certificate to reduce any withholding tax payable.



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13.11. IROKO hereby warrants that it qualifies for tax relief under the DTA and that it can supply the documentation, if any, necessary for obtaining such withholding certificate.

**14. SUPPLY AND MANUFACTURE OF THE PRODUCTS**

14.1. For the MANUFACTURING TERM, Pharmacare Limited, an Affiliate of ASPEN, shall MANUFACTURE and PACKAGE the PRODUCTS (other than, initially, the SUPPOSITORIES, ALDOMET® (METHYLDOPA) TABLETS 125MG and/or SRC PRODUCT) for COMMERCIALIZATION (1) by IROKO in those countries (other than the Territory), where it holds rights to COMMERCIALIZE the PRODUCTS and (2) by ASPEN in the TERRITORY, all in accordance with the WORLDWIDE MANUFACTURING AND SUPPLY AGREEMENT and the provisions of **Appendix J**.

14.2. The PARTIES undertake, in the utmost good faith, to do all things necessary to ensure that after the expiry of the MANUFACTURING TERM, there is a continuous supply of the PRODUCTS for the purposes of their COMMERCIALISATION in the TERRITORY and, to this end, they shall be obliged to appoint a third party manufacturer to MANUFACTURE and PACKAGE and supply the requisite quantity and quality of the PRODUCTS.

14.3. IROKO will use its best endeavours to procure that all documents, data or information which ASPEN, acting reasonably, requires to MANUFACTURE and PACK the PRODUCTS is provided to it as soon as is practically possible and no more than 30 (thirty) days after the SIGNATURE DATE.

14.4. Notwithstanding any other provision of this Agreement, the PARTIES may, by written agreement, procure the MANUFACTURE of the PRODUCTS by ASPEN and/or its AFFILIATES and the PACKING of the PRODUCTS by a third party in circumstances where it will be to the PARTIES' mutual best interests to do so.

**15. SUPPLY AND MANUFACTURE OF THE SUPPOSITORIES, ALDOMET® (METHYLDOPA) 125MG TABLETS AND SRC PRODUCT**

15.1. Subject to clause 15.2, until such time as the BOARD elects for ASPEN to MANUFACTURE and PACK (or procure that one or more of ASPEN' S AFFILIATES MANUFACTURES and PACKS) the SUPPOSITORIES and/or SRC PRODUCT, and ASPEN accepts such appointment, the SUPPOSITORIES, ALDOMET® (METHYLDOPA) TABLETS 125MG and/or SRC PRODUCT shall be MANUFACTURED and PACKED by a third party ("the third party manufacturer") appointed by IROKO. The PARTIES shall procure that the said third party manufacturer supplies the SUPPOSITORIES, ALDOMET® (METHYLDOPA) TABLETS 125MG and/or SRC PRODUCT directly to ASPEN, its AFFILIATES and/or the THIRD PARTY SUB-LICENSEE/S on terms and conditions acceptable to ASPEN, acting reasonably. ASPEN shall pay the third party manufacturer directly for the SUPPOSITORIES, ALDOMET® (METHYLDOPA) TABLETS 125MG and/or SRC PRODUCT.

15.2. In the event of ASPEN being in a position to procure an alternative supply of the SUPPOSITORIES, ALDOMET® (METHYLDOPA) TABLETS 125MG and/or SRC PRODUCT, which comply with the APPLICABLE LAWS, more cost effectively than those being supplied by the third party manufacturer, from time to time, then ASPEN shall have the right to source the SUPPOSITORIES, ALDOMET® (METHYLDOPA) TABLETS 125MG and/or SRC PRODUCT from the alternative supplier and IROKO shall render to ASPEN all necessary and reasonable support and assistance in this regard.



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**16. ASPEN WARRANTIES**

16.1. ASPEN hereby warrants that –

16.1.1. during the BULK SUPPLY TERM, where it PACKS the PRODUCTS, it will do so strictly in accordance with –

16.1.1.1. the SPECIFICATIONS (insofar as they relate to PACKAGING);

16.1.1.2. APPLICABLE LAWS;

16.1.1.3. the requirements of the MARKETING AUTHORISATIONS; and

16.1.1.4. Good Manufacturing Practice;

16.1.2. subject to the provisions of clause 14.4, during the MANUFACTURING TERM, it will MANUFACTURE and PACK the PRODUCTS (other than the SUPPOSITORIES, ALDOMET® (METHYLDOPA) TABLETS 125MG and/or the SRC PRODUCT) strictly in accordance with –

16.1.2.1. their SPECIFICATIONS;

16.1.2.2. APPLICABLE LAWS;

16.1.2.3. the requirements of the MARKETING AUTHORISATIONS; and

16.1.2.4. Good Manufacturing Practice;

16.1.3. the execution, delivery and performance by ASPEN of this AGREEMENT and the consummation of the transactions contemplated herein are within ASPEN' S corporate powers. Subject to the fulfilment of the CONDITIONS, this AGREEMENT is a legal, valid and binding obligation of ASPEN, enforceable against ASPEN in accordance with its terms; and

16.1.4. it owns 100% (ONE HUNDRED PERCENT) of the capital stock/share capital of Pharmacare Limited.

16.2. Notwithstanding the aforesaid, ASPEN makes no representations or warranties (whether express or implied), other than those set out in clause 16.1, and WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, ASPEN MAKES NO REPRESENTATION OR WARRANTIES, WHETHER EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OF THE PRODUCTS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, OR REGARDING THE SCOPE, VALIDITY OR ENFORCEABILITY OF THE MARKETING AUTHORISATIONS, IROKO DATA, TRADEMARKS OR ANY OTHER INTELLECTUAL PROPERTY RELATING TO THE PRODUCTS WHICH ARE TO BE USED TO MANUFACTURE AND/OR COMMERCIALISE THE PRODUCTS IN THE TERRITORY.

**17. IROKO WARRANTIES AND UNDERTAKINGS**

17.1. IROKO warrants to ASPEN that:

17.1.1. the execution, delivery and performance by IROKO of this AGREEMENT and the consummation of the transactions contemplated herein are within IROKO' S corporate powers and have been authorised by all necessary corporate action on the part of IROKO. This AGREEMENT is a legal, valid and binding obligation of IROKO, enforceable against IROKO in accordance with its terms;



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17.1.2. to its knowledge, the IROKO DATA will be sufficient, without the necessity of ASPEN undertaking further work thereon, to transfer all MANUFACTURING, PACKING and MARKETING AUTHORISATIONS in the TERRITORY from MERCK to ASPEN, its AFFILIATES and/or the THIRD PARTY SUB-LICENSEE/S;

17.1.3. the grant of the rights to ASPEN pursuant to this AGREEMENT will not infringe the rights of any third party;

17.1.4. IROKO has the right, free and clear of any liens, encumbrances or claims by third parties to use the IROKO DATA and to sub-license the same to ASPEN on the terms and subject to the conditions set out in this AGREEMENT; and

17.1.5. neither ASPEN or its AFFILIATES shall incur any liability, loss, damages or other claim of whatever nature or description flowing from and arising out of the MANUFACTURE, PACKING and/or COMMERCIALISATION of the PRODUCTS in the TERRITORY, insofar as such MANUFACTURE, PACKING and/or COMMERCIALISATION took place prior to the EFFECTIVE DATE, and without limiting the generality of the aforegoing, any liability, loss, damages or other claims, of whatever nature, in relation to product liability claims, product recalls, product returns and/or customer complaints.

17.2. IROKO undertakes to ASPEN that –

17.2.1. it will procure timely and full compliance with all of the obligations arising out of or flowing from all or any agreements concluded between IROKO LLC and MERCK ("the IROKO/MERCK Agreement") relevant to the subject matter of this AGREEMENT;

17.2.2. it shall, at its cost and expense, use its best commercial endeavours to do all things necessary to procure that MERCK fully complies with all of MERCK' s obligations arising out of or flowing from the IROKO/MERCK Agreement and that, against request, it shall appraise (or procure that ASPEN be so approved), ASPEN, in writing (or procure that ASPEN be so appraised), of MERCK' s said compliance or lack thereof (as the case may be).

17.3. IROKO hereby represents to ASPEN (which representation ASPEN hereby relies upon) that during the MERCK DISTRIBUTION TERM, MERCK has an obligation to supply the PRODUCTS in bulk to IROKO LLC.

**18. INDEMNITIES**

18.1. IROKO shall indemnify and hold ASPEN harmless from and against all liability, damages, losses and/or expenses (including, without any limitation, reasonable attorney' s fees and expenses) of any nature whatsoever and howsoever arising suffered, incurred and/or paid by ASPEN arising out of any negligent acts or omission by IROKO or a breach by IROKO of the provisions of this AGREEMENT, including without limiting the generality of the aforegoing, a breach by IROKO of its warranties given under this AGREEMENT.

18.2. ASPEN shall indemnify and hold IROKO harmless from and against all liability, damages, losses and/or expenses (including, without any limitation, attorney and own client costs) of any nature whatsoever and howsoever arising suffered, incurred and/or paid by IROKO arising out of any negligent acts or omission by ASPEN or a breach by ASPEN of the provisions of this AGREEMENT, including without limiting the generality of the foregoing, a breach by ASPEN of its warranties given under this AGREEMENT.



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18.3. ASPEN agrees to give notice to IROKO of the assertion of any claim, or commencement of any suit, action or proceeding in respect of which indemnity may be sought under 18.1 promptly after receipt of notice from a third party of the assertion of such claim or the commencement of such suit, action or proceeding. In the event indemnification is sought by ASPEN, notice shall be given as soon as reasonably possible but within five business days after it becomes aware of any legal action being instituted indicating in such notice at least the nature of the event, action or state of facts for which indemnification is sought. IROKO shall be entitled at its own cost to participate in or, to the extent that it shall wish to do so, to assume and control the defence with its own counsel of any such claim, suit, action or proceeding . If ASPEN elects to participate in such defence, it shall be liable for its own legal costs and other expenses subsequently and reasonably incurred by ASPEN in connection with such defence in the event that ASPEN determines that representation of both parties by the same counsel would be inappropriate due to an actual or potential conflict of interest between them. Whether or not IROKO elects to assume the defence of any claim, suit, action or proceeding, it shall not be liable for any compromises or settlement of any such claim, suit, action or proceeding effected without its consent, which consent shall not unreasonably be withheld. The parties agree to co-operate to the fullest extent possible in connection with any third party claim, suit, action or proceeding for which indemnification is or may be sought under this agreement.

IROKO agrees to give notice to ASPEN of the assertion of any claim, or commencement of any suit, action or proceeding in respect of which indemnity may be sought under 18.2 promptly after receipt of notice from a third party of the assertion of such claim or the commencement of such suit, action or proceeding. In the event indemnification is sought by IROKO, notice shall be given as soon as reasonably possible but within five business days after it becomes aware of any legal action being instituted indicating in such notice at least the nature of the event, action or state of facts for which indemnification is sought. ASPEN shall be entitled at its own cost to participate in or, to the extent that it shall wish to do so, to assume and control the defence with its own counsel of any such claim, suit, action or proceeding. If IROKO elects to participate in such defence, it shall be liable for its own legal costs and other expenses subsequently and reasonably incurred by IROKO in connection with such defence in the event that IROKO determines that representation of both parties by the same counsel would be inappropriate due to an actual or potential conflict of interest between them. Whether or not ASPEN elects to assume the defence of any claim, suit, action or proceeding, it shall not be liable for any compromises or settlement of any such claim, suit, action or proceeding effected without its consent, which consent shall not unreasonably be withheld or delayed. The parties agree to co-operate to the fullest extent possible in connection with any third party claim, suit, action or proceeding for which indemnification is or may be sought under this Agreement.

18.4. ASPEN agrees to indemnify and hold harmless IROKO against all product liability claims arising out of a breach by ASPEN of its warranties in clause 16 or a breach of the provisions of this Agreement by ASPEN, and IROKO agrees to indemnify and hold harmless ASPEN against all product liability claims arising out of a breach by IROKO of its warranties in clause 17 or a breach of the provisions of this Agreement by IROKO. Both the indemnity by ASPEN and the counter indemnity by IROKO given under this clause 18.4 are given, *mutatis mutandis,* on the same basis as set out in clause 18.3. Without limiting the ordinary meaning of the words “product liability” such words include the liability imposed on the seller, manufacturer or supplier of a product for physical damage, injury or harm (whether consequential or otherwise) caused to a consumer, user or any other person affected by a defect in the product.



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18.5. In the event that IROKO makes any payment pursuant to its indemnification obligations under this agreement, all rights of ASPEN to pursue any claim to receive payment or other consideration from any other third party which may be liable with respect to such claim, suit, action or proceeding for which indemnification was provided, shall be deemed to have been unconditionally and irrevocably ceded to IROKO. ASPEN shall execute and deliver such instruments and agreements and take such other action as may be required to effect such cession to IROKO. This clause 18.5 shall apply *mutatis mutandis* with regard to the indemnity by ASPEN pursuant to clause 18.4.

18.6. Neither party ("**offending party**") shall under any circumstances whatsoever (even if advised of a possibility of such damages) be liable for any indirect, special or consequential loss or damage sustained by the other party howsoever caused, including whether or not caused by the negligence of the offending party, its agents or employees or arising out of contract, delict, negligence, strict liability or otherwise, but excluding, however, any loss or damage arising out of fraud or wilful misconduct of the offending party.

**19. SAFETY AGREEMENT AND BUSINESS CONTINUITY PLAN**

19.1. The PARTIES have negotiated and agreed a Safety Agreement which is annexed hereto, marked **Appendix J**. The Safety Agreement includes, *inter alia*, procedures for the receipt, investigation, recordal, communication and exchange between the PARTIES of ADVERSE EVENTS reports, pregnancy reports and any other information concerning the safety of the PRODUCTS. The Safety Agreement is in accordance with and allows the PARTIES to fulfil their obligations pursuant to the APPLICABLE LAWS. The Safety Agreement is a part of this AGREEMENT and shall be signed by the PARTIES contemporaneously with the signature of this AGREEMENT.

19.2. ASPEN shall, within 30 (THIRTY) days of the EFFECTIVE DATE, provide IROKO with its business continuity plan, which plan shall be reasonably satisfactory to IROKO. If not so satisfactory, ASPEN and IROKO shall, with the utmost dispatch and good faith, negotiate a plan that shall substantially meet IROKO' S reasonable objections.

**20. ETHICAL STANDARDS AND HUMAN RIGHTS OF IROKO**

20.1. Unless otherwise required or prohibited by the APPLICABLE LAWS, IROKO warrants to ASPEN that, to the best of its knowledge, in relation to the performance of its obligations in terms of this AGREEMENT –

20.1.1. it does not employ engage or otherwise use any child labour in circumstances such that the tasks performed by any such child labour could reasonably be foreseen to cause either physical or emotional impairment to the development of such child;

20.1.2. it does not use forced labour in any form (prison, indentured, bonded or otherwise) and its employees are not required to lodge papers or deposits on starting work;

20.1.3. it provides a safe and healthy workplace, presenting no immediate hazards to its employees. Any housing provided by IROKO to its employees is safe for habitation. IROKO provides access to clean water, food, and emergency healthcare to its employees in the event of accidents or incidents at the IROKO' S workplace;

20.1.4. it does not discriminate against any employees on any ground (including race, religion, disability or gender);



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20.1.5. it does not engage in or support the use of corporal punishment, mental, physical, sexual or verbal abuse and does not use cruel or abusive disciplinary practices in the workplace;

20.1.6. it pays each employee at least the minimum wage, or a fair representation of the prevailing industry wage, (whichever is the higher) and provides each employee with all legally mandated benefits;

20.1.7. it complies with the laws on working hours and employment rights in the countries in which it operates;

20.1.8. it is respectful of its employees right to join and form independent trade unions and freedom of association.

20.2. IROKO shall ensure that it has ethical and human rights policies and an appropriate complaints procedure to deal with any breaches of such policies. In the case of any complaints, IROKO shall report the alleged complaint and proposed remedy to ASPEN.

**21. ETHICAL STANDARDS AND HUMAN RIGHTS OF ASPEN**

21.1. Unless otherwise required or prohibited by the APPLICABLE LAWS, ASPEN warrants to IROKO that, to the best of its knowledge, in relation to the performance of its obligations in terms of this AGREEMENT –

21.1.1. it does not employ engage or otherwise use any child labour in circumstances such that the tasks performed by any such child labour could reasonably be foreseen to cause either physical or emotional impairment to the development of such child;

21.1.2. it does not use forced labour in any form (prison, indentured, bonded or otherwise) and its employees are not required to lodge papers or deposits on starting work;

21.1.3. it provides a safe and healthy workplace, presenting no immediate hazards to its employees. Any housing provided by ASPEN to its employees is safe for habitation. ASPEN provides access to clean water, food, and emergency healthcare to its employees in the event of accidents or incidents at the ASPEN' S workplace;

21.1.4. it does not discriminate against any employees on any ground (including race, religion, disability or gender);

21.1.5. it does not engage in or support the use of corporal punishment, mental, physical, sexual or verbal abuse and does not use cruel or abusive disciplinary practices in the workplace;

21.1.6. it pays each employee at least the minimum wage, or a fair representation of the prevailing industry wage, (whichever is the higher) and provides each employee with all legally mandated benefits;

21.1.7. it complies with the laws on working hours and employment rights in the countries in which it operates;

21.1.8. it is respectful of its employees right to join and form independent trade unions and freedom of association.



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21.2. ASPEN shall ensure that it has ethical and human rights policies and an appropriate complaints procedure to deal with any breaches of such policies. In the case of any complaints, ASPEN shall report the alleged complaint and proposed remedy to IROKO.

**22. CONFIDENTIALITY**

22.1. For the purposes of this clause 22, each PARTY is sometimes referred to as a "**Disclosing Party**" in its capacity as the party providing information to the other PARTY hereunder, and as a "**Receiving Party**" in its capacity as the PARTY receiving information from the other PARTY hereunder.

22.2. Subject to clauses 22.5 and 22.6 and save as required by any law or by any regulatory body to which a Receiving Party is subject, during the period of this AGREEMENT and for five years after termination of this AGREEMENT, the Receiving Party shall: -

22.2.1. keep the CONFIDENTIAL INFORMATION confidential and ensure that proper and secure storage is provided for all the CONFIDENTIAL INFORMATION;

22.2.2. not expressly or impliedly, directly or indirectly disclose or allow to be disclosed any of the CONFIDENTIAL INFORMATION to any other person other than with the prior written consent of the Disclosing Party or in accordance with clauses 22.3 and 22.4; and

22.2.3. not expressly or impliedly, directly or indirectly (and whether for its own benefit or the benefit of any other person) use and/or exploit or allow to be used and/or exploited any of the CONFIDENTIAL INFORMATION for any purpose other than the proper performance of its obligations under this AGREEMENT or any other written agreement in connection with the business between the PARTIES.

22.3. During the term of this AGREEMENT, the Receiving Party may disclose the CONFIDENTIAL INFORMATION to its or its AFFILIATES' employees and/or professional advisers to the extent that it is necessary for the purpose of this AGREEMENT or any other AGREEMENT current from time to time in connection with the business between the PARTIES **("the Recipient")**.

22.4. The Receiving Party shall procure that each Recipient is made aware of and complies with all the Receiving Party' s obligations of confidentiality under this AGREEMENT as if the Recipient was a party to this AGREEMENT. The Receiving Party shall be responsible for the compliance or non compliance of the Recipient with the obligations of confidentiality under this AGREEMENT.

22.5. The obligations contained in clauses 22.2 to 22.4 shall not apply to any CONFIDENTIAL INFORMATION which:-

22.5.1. as at the EFFECTIVE DATE is, or at any time after the EFFECTIVE DATE, comes into the public domain other than through any unlawful act or omission or any breach of this AGREEMENT or any other confidence by the Receiving Party or any Recipient;

22.5.2. can be proved by the Receiving Party to have been known (other than through any unlawful act or omission or any breach of this AGREEMENT or any other confidence by the Receiving Party or any Recipient) to the Receiving Party prior to it being disclosed by the Disclosing Party to the Receiving Party;



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22.5.3. subsequently comes lawfully into possession of the Receiving Party from a third party; or

22.5.4. can be proved by the Receiving Party to have been developed independently by the Receiving Party other than from information disclosed by the Disclosing Party or disclosed in breach of any of the obligations contained in clauses 22.2 to 22.4 or of any other confidence or pursuant to any unlawful act or omission .

22.6. Upon termination of this AGREEMENT, each party shall, at the other PARTY' S direction, either return or destroy all of the other PARTY' S CONFIDENTIAL INFORMATION which it has in its possession or under its control.

22.7. In addition to that information set out in clauses 22.5.1, 22.5.2, 22.5.3 and 22.5.4, ASPEN shall have the right (subject only to the limitations of the APPLICABLE LAWS) to disclose CONFIDENTIAL INFORMATION relevant to the PRODUCTS and/or the COMMERCIALISATION thereof to medical insurers, medical practitioners and/or other distributors of the PRODUCTS in the TERRITORY, on a need to know basis and to the extent required, provided, however, that the recipient of such CONFIDENTIAL INFORMATION shall agree, in writing, to be subject to confidentiality obligations no less stringent than those set forth herein.

**23. BOARD OF MANAGERS**

23.1. Composition:

In order to oversee the COMMERCIALISATION of the PRODUCTS in the TERRITORY, the PARTIES shall, promptly following the EFFECTIVE DATE (but no later than 10 (TEN) days thereafter), set up the BOARD. Each of IROKO and ASPEN shall appoint the Co-chairs of the BOARD (each, a "CO-CHAIR"). In the case of IROKO, the CO-CHAIR shall be the [Vice President of Commercial Affairs] (or his/her successor-in-title) or an officer senior to that individual and, in the case of ASPEN, the CO-CHAIR shall be the Commercial Executive: International Operations (or his/her successor-in-title) or an officer senior to that individual. Thereafter, following consultations between the two CO-CHAIRS regarding the proposed composition of the BOARD, including the number of individuals who shall sit on the BOARD and the areas of expertise to be represented on the BOARD, each CO-CHAIR shall appoint an equal number of BOARD members. Each PARTY shall have the right, from time to time, after consultation with the other PARTY, to remove any individual appointed by it to the BOARD, including a CO-CHAIR, and to appoint new BOARD member(s) to replace those who shall have been removed by it or who shall have resigned. The number of members of the BOARD may be enlarged or reduced from time to time by mutual decision of the CO-CHAIRS, so long as each PARTY shall retain the same number of members on the BOARD. The BOARD may appoint committees from among its members, which committees may be assisted by persons from outside the BOARD. The committees shall report to the BOARD.

23.2. Role of Board:

The BOARD shall be responsible for overseeing the COMMERCIALISATION of the PRODUCTS in the TERRITORY. To that effect, it shall adopt, annually, no less than 60 days prior to the beginning of each calendar year, a strategic plan ("PLAN") intended to optimize sales of PRODUCTS in the TERRITORY. ASPEN shall have sole responsibility for carrying out such PLAN and for regularly reporting on its execution to the BOARD, not less often than at each meeting of the BOARD.



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The PLAN shall cover the following areas (each, an "AREA"): regulatory matters, supply chain, quality assurance, sales and marketing (including without limiting the generality of the aforegoing which of ASPEN, its AFFILIATES or the THIRD PARTY SUB-LICENSEES will COMMERCIALISE the PRODUCTS in which part/s of the TERRITORY), product development and finances and shall include the BUDGET for the upcoming calendar year.

The BOARD shall meet at least 3 (THREE) times per year: once to review and adopt the PLAN; and twice to assess ASPEN' S performance against the PLAN and take such corrective measures as may be necessary in the event such performance deviates materially from the PLAN. ASPEN shall deliver, not less than 15 (FIFTEEN) days prior to each meeting, a comparison, in each AREA, of its year-to-date performance against the PLAN, including its performance against the BUDGET. The meetings shall take place at such time and place as the CO-CHAIRS shall agree from time to time, provided that if the PARTIES are unable to agree on the place for a meeting, such meeting shall take place in London and if they are unable to agree upon the times of the meetings, such meetings shall take place on January 31 (or the subsequent business day if January 31 is not a BUSINESS DAY) and July 31 (or the subsequent business day if July 31 is not a BUSINESS DAY) and, in the case of the meeting devoted to the adoption of the PLAN, October 31 (or the subsequent business day if October 31 is not a BUSINESS DAY). A draft of the PLAN for the upcoming calendar year, including therein the BUDGET, shall be submitted by ASPEN to the BOARD no later than 30 (THIRTY) days prior to the date of the meeting devoted to the adoption of the PLAN.

23.3. Decision-Making:

The PARTIES shall endeavor to reach agreement by consensus on matters presented to the BOARD. Each CO-CHAIR may introduce matters for review and decision-making by the BOARD. Each PARTY, regardless of the number of its representatives who attend a meeting, shall have one vote, which shall be cast by its CO-CHAIR. If the Parties are unable to reach agreement within 10 (TEN) days following a meeting of the BOARD, the matter shall promptly (but not later than 10 (ten) days following the aforementioned 10 (ten) day period) be presented by the CO-CHAIRS to the Chief Executive Officer of IROKO ("CEO"), with a summary of the PARTIES' respective positions, and the CEO shall then promptly and finally decide the matter (the "TIE-BREAKING VOTE"); provided, however, that the following matters shall not be presented to the CEO but shall instead require the unanimous consent of the BOARD: (i) other than the BUDGET for each of the first three (3) years of this AGREEMENT, approval of the BUDGET and (ii) any new, incremental spend in excess of US$200,000.00 (TWO HUNDRED THOUSAND UNITED STATES DOLLARS) above the previous year' s approved BUDGET.

For the avoidance of doubt, (i) in the event the PARTIES are unable to reach agreement on the BUDGET for the first three (3) years of this AGREEMENT, the matter shall be presented to the CEO to cast the TIE-BREAKING VOTE; (ii) the TIE-BREAKING VOTE shall not apply to the MANUFACTURE, PACKING and/or supply of the PRODUCTS (all of which being the subject matter of the WORLDWIDE MANUFACTURING AND SUPPLY AGREEMENT); (iii) the TIE-BREAKING VOTE shall not apply to any regulatory (including without limiting the generality of the aforegoing, technical transfer), issues or matters relevant to this AGREEMENT to the extent that the implementation or giving effect thereto may (a) result in a breach of the APPLICABLE LAWS; and/or (b) adversely impact upon ASPEN and/or its AFFILIATES' reputation and/or relationship with any AGENCY. (In the given circumstances IROKO shall, in its own name, be entitled to implement or give effect to its decision and/or determination and the costs associated therewith shall be deemed to be REGULATORY COSTS); (iv) the TIE-BREAKING VOTE shall not apply to any decision or determination taken by IROKO which is influenced by any factor extraneous to the terms and conditions of this AGREEMENT in circumstances where the implementation or giving effect to such a decision or determination may materially prejudice ASPEN and/or



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its AFFILIATES under this AGREEMENT. (By way of example, where IROKO takes a decision or makes a determination influenced by factors relevant to the MANUFACTURE, PACKAGING and/or COMMERCIALISATION of the PRODUCTS outside of the TERRITORY, in circumstances where such a decision and/or determination may prejudice ASPEN and/or its AFFILIATES); (v) the TIE-BREAKING VOTE shall not apply to or extend over any issues or matters relevant to new formulations (as defined in clause 23.4); and/or (vi) the TIE-BREAKING VOTE shall not apply to or extend over the COMMERCIALISATION of the PRODUCTS in that part of the TERRITORY which does not constitute the PRIORITY COUNTRIES.

Notwithstanding the foregoing, if there shall have occurred a change of CONTROL of IROKO, the CEO shall no longer have a TIE-BREAKING VOTE. In that case, either PARTY shall be entitled to refer the matter for determination by an independent expert appointed by agreement of the PARTIES, or failing such agreement within 5 (FIVE) days after either PARTY has requested such referral, appointed by the then President (or his successor-in-title) or his designee of the American Arbitration Association (if Aspen requests the appointment) or by the then President (or his successor-in-title) or his designee of the South African Institute of Chartered Accountants (if Iroko requests the appointment). The expert shall have significant expertise as a businessperson in the international pharmaceutical industry, including in the AREA or AREAS that are the subject of the dispute/deadlock between the PARTIES. The expert shall act in his or her capacity as a business expert and not as on arbitrator and his or her decision shall be final and binding on the PARTIES. He or she shall render his/her decision, in writing, including the rationale thereof, within 45 (FORTY FIVE) days following his/her appointment. The fees and expenses of the expert and of the appointing authority shall be borne equally by the PARTIES.

23.4. New Product Formulations:

From time to time, the BOARD shall approve the development of new product formulations, such as eye drops, topical formulations and combination products containing steroids or muscle relaxants (the "NEW FORMULATIONS"). ASPEN shall be entitled, but not obliged, to submit a quote for undertaking the development of the NEW FORMULATIONS and IROKO shall be entitled, but not obliged, to accept any such quote as submitted by ASPEN. In the event of ASPEN not submitting such a quote and/or IROKO not accepting any quote so submitted, then the parties shall, by mutual agreement, appoint a third party to undertake the development and they shall equally bear and be liable for the costs thereof. All intellectual property (including the TRADEMARKS) relating to the NEW FORMULATIONS shall belong exclusively to IROKO, provided, however, that IROKO shall license the NEW FORMULATIONS to ASPEN pursuant to this Agreement on the terms set forth in clause 5 and such license shall be coterminous with this Agreement and coextensive with the TERRITORY, unless otherwise agreed to by the PARTIES.

**24. GOVERNING LAWS AND JURISDICTION**

24.1. Subject to clause 23, all matters arising from or in connection with this AGREEMENT, its validity, existence or termination shall be determined in accordance with the laws, as in effect from time to time, of England and Wales (without reference to rules of conflicts of law), save to the extent provided for in clause 24.2.

24.2. Other than for those disputes and/or differences which have been expressly provided with specific relief and remedies pursuant to this AGREEMENT, in the event of any dispute or difference arising between the PARTIES relating to or arising out of this Agreement, including the implementation, execution, interpretation, rectification, termination or cancellation of this agreement, the Chief Executive Officers or Executive Chairperson (as



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the case may be) of the PARTIES shall forthwith meet to attempt to settle such dispute or difference, and failing such settlement within a period of 21 (TWENTY ONE) business days, the said dispute or difference shall, on written demand by any PARTY to the dispute, be submitted to arbitration before 3 (THREE) arbitrators in London in accordance with the United Nations Commission on International Trade Law (UNCITRAL) Arbitration Rules as are in force at the date of the aforementioned written demand.

24.3. Notwithstanding anything to the contrary contained in this AGREEMENT, nothing in this clause 24 shall preclude any party to the arbitration from seeking interlocutory relief in any court having jurisdiction, pending the institution of appropriate proceedings for the enforcement of any rights under this AGREEMENT.

24.4. The PARTIES to the arbitration undertake to keep the arbitration, including the subject matter of the arbitration and the evidence heard during the arbitration, confidential and not to disclose it to anyone except for the purposes of an order to be made in terms of clause 24.5, subject, however, to any disclosure obligations under APPLICABLE LAWS, including securities laws.

24.5. The majority decision of the arbitrators shall, in the absence of manifest error, be final and binding on the PARTIES to the arbitration and may be made an order of court at the instance of any party to the arbitration.

24.6. The provisions of this clause 24 are separate and severable from the rest of this AGREEMENT and shall remain in effect despite the termination or invalidity for any reason of this AGREEMENT.

**25. TERMINATION**

25.1. In the event that

25.1.1. either PARTY is placed under judicial management or is wound up, whether compulsorily or voluntarily; or

25.1.2. either PARTY compromises with its creditors or attempts to do so; or

25.1.3. either PARTY fails to observe any of the provisions or perform any of the other terms and conditions of this AGREEMENT, all of which shall be deemed to be material, and in the event such PARTY fails to remedy such breach or persists with such failure within a period of 14 (FOURTEEN) days of notice to it to remedy such breach or failure,

then in any of the aforesaid events, the other PARTY shall have the right, without prejudice to any other rights might thereupon be available to it -

25.2. to enforce the provisions of this AGREEMENT, and to proceed against the defaulting PARTY for the recovery of damages, if any, due to it; or

25.3. to terminate this AGREEMENT immediately upon notice and to declare the whole balance of all amounts owing pursuant to this AGREEMENT, inclusive of interest to date, forthwith to be due, owing and payable and to proceed against the defaulting PARTY for the recovery of damages, if any, due to it.

25.4. In the event that the cumulative NET SALES for any 3 (THREE) consecutive calendar quarters miss BUDGET by greater than 20% in any part of the TERRITORY, on a country-by-country basis, where ASPEN or its AFFILIATES are COMMERCIALISING the



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PRODUCTS, IROKO shall have the sole and exclusive right to terminate ASPEN as the COMMERCIALISATION partner in such part of the TERRITORY and to appoint a THIRD PARTY SUB-LICENSEE to then COMMERCIALISE the PRODUCTS in that part of the TERRITORY. In the event that a THIRD PARTY SUB-LICENSEE is COMMERCIALISING the PRODUCTS, the BOARD shall review and determine whether or not to replace the THIRD PARTY SUB-LICENSEE. Other than in those circumstances and for those reasons set out in clause 25.1, this AGREEMENT shall not terminate prior to the expiry of its term without the prior written consent of both PARTIES.

25.5. In the event that IROKO launches any new product formulations and/or any products containing nano-size particles in the PRIORITY COUNTRIES ("new variants") containing indomethacin and/or methyldopa as active pharmaceutical ingredients, either alone or in combination with each other or in combination with any other active pharmaceutical ingredient/s, then this AGREEMENT may be terminated by ASPEN in accordance with the provisions of Appendix K.

25.6. If at any time during the term of this AGREEMENT there shall be any change in the legal or beneficial ownership or CONTROL of IROKO, it shall immediately so notify ASPEN in writing.

25.7. Notwithstanding anything to the contrary herein contained, the provisions of clauses 18 to 22, 24, 26 and 28 to 31 shall survive any termination of this AGREEMENT.

**26. EFFECT OF TERMINATION**

Upon discharge or termination of this AGREEMENT –

26.1. ownership of the IROKO DATA, the TRADEMARKS and the MARKETING AUTHORISATIONS shall remain fully vested in IROKO LLC and except as provided below, ASPEN shall cease use of the foregoing;

26.2. any and all improvements to IROKO' S intellectual property, including the PRODUCTS, by whomever made, shall belong exclusively to IROKO LLC and shall be promptly conveyed/transferred to IROKO or its designee;

26.3. ASPEN shall have the right, for a period no longer than six (6) months, to continue to convert its inventories of raw materials, excipients and active pharmaceutical ingredients into the PRODUCTS and thereafter to COMMERCIALISE or procure the COMMERCIALISATION of (as the case may be) such PRODUCTS in the TERRITORY, whereafter it will cease to do so;

26.4. ASPEN shall, at IROKO' S cost and expense (unless termination shall have occurred because of IROKO' S right to terminate pursuant to clause 25.1, in which case it shall be at ASPEN' S expense), do all things necessary to transfer the MARKETING AUTHORISATIONS from ASPEN, its AFFILIATES and/or the THIRD PARTY SUB-LICENSEE/S to IROKO or its nominee.

**27. ADVERSE EVENTS AND FORCE MAJEURE**

27.1. In the event of either of the PARTIES suffering a material prejudice as a consequence of the tax laws or regulations applicable to either of the PARTIES at any time, the PARTIES will enter into good faith negotiations to re-structure the arrangements (as recorded in this AGREEMENT) between the PARTIES in such a way as to diminish the effect of such prejudice to the greatest extent possible.



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27.2. Delay or failure to comply with or breach of any of the terms and conditions of this AGREEMENT if occasioned by or resulting from an act of God or public enemy, fire, explosion, earthquake, perils of the sea, flood, storm or other adverse weather conditions, war declared or undeclared, civil war, revolution, civil commotion or other civil strife, terrorism, riot, strikes, blockade, embargo, sanctions, epidemics, act of an government or other authority, compliance with government orders, demands or regulations, or any circumstances of like or different nature beyond the reasonable control of the PARTY so failing ("**force majeure**"), shall not be deemed to be a breach of this AGREEMENT nor shall it subject either PARTY to any liability to the other.

27.3. If any force majeure occurs in relation to either PARTY which affects or may affect the performance of any of its obligations under this AGREEMENT, it shall notify the other PARTY forthwith as to the nature and extent of the circumstances in question.

27.4. Neither PARTY shall be deemed to be in breach of this AGREEMENT, or shall be otherwise liable to the other PARTY, by reason only of any delay in performance, or the non-performance of any of its obligations hereunder, to the extent that the delay or non-performance is due to any force majeure of which it has duly notified the other PARTY, and the time for performance of that obligation shall be extended accordingly.

27.5. If the performance by either PARTY of any of its obligations under this AGREEMENT is prevented or delayed by force majeure for a continuous period in excess of five (5) working days, the PARTIES shall enter into bona fide discussions with a view to alleviating its effects, or to agreeing upon such alternative arrangements as may be fair and reasonable in the circumstances.

27.6. Should either PARTY be prevented from carrying out its contractual obligations by force majeure lasting continuously for a period of six (6) months, and no mutually acceptable arrangement is arrived at within such period, either PARTY shall be entitled to terminate the AGREEMENT forthwith on written notice.

## 28. NATURE OF RELATIONSHIP

28.1. The relationship of the PARTIES pursuant to this AGREEMENT with regard to the PRODUCTS shall be that of licensor and licensee, neither PARTY being the agent or partner of the other. Neither PARTY shall be entitled to bind the credit of the other.

28.2. Each of the PARTIES undertakes in regard to the carrying out of the provisions of this AGREEMENT that it will act in the utmost good faith in its relationship with the other PARTY.

## 29. NOTICES

29.1. The PARTIES hereto select as their respective domicilia citandi et executandi the following physical addresses:

| Name | Physical Address | Telefax Number |
|---|---|---|
| ASPEN | 1st Floor Aspen House<br>Aspen Park<br>96 Armstrong Avenue<br>La Lucia Ridge<br>Durban, 4019<br>Republic of South Africa<br>Attn: **Group Chief Executive** | +27 31 5808640 |



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| Name | Physical Address |
|---|---|
| IROKO | 65, boulevard Grande-Duchesse Charlotte, L-1331 Luxembourg, LUXEMBOURG<br>Attn: **Gerant** |

provided that a party may change its *domicilium* to any other physical address and its address for the purposes of notices to any other postal address by written notice to the other party to that effect. Such change of address will be effective 7 (seven) days after receipt of notice of the change of *domicilium*.

29.2. All notices to be given pursuant to this AGREEMENT will be in writing and shall be deemed properly served if:-

29.2.1. delivered by hand to a responsible person during normal business hours, be rebuttably presumed to have been received on the date of delivery; or

29.2.2. sent by Federal Express or other like international courier service, be rebuttably presumed to have been received within five (5) business days of posting, or

29.2.3. if sent by facsimile, on the date of receipt of successful facsimile transmission.

**30. AFFILIATES AND ASSIGNMENT**

30.1. Save as is expressly otherwise provided for in this AGREEMENT, ASPEN shall be entitled, but not obliged, to cede and assign its rights and obligations under this AGREEMENT, either in whole or in part, to one or more of its AFFILIATES, provided that any such assignment or delegation shall be subject to prior written notice to and consent of IROKO, which consent shall not be unreasonably withheld or delayed.

30.2. Save as is expressly otherwise provided for in this AGREEMENT, neither PARTY shall be entitled to directly or indirectly sell, assign, transfer, pledge or otherwise encumber its rights and obligations under this AGREEMENT; provided, however, that IROKO shall have the right to assign its rights and obligations under this AGREEMENT in connection with a merger, a consolidation, a sale or license of substantially all of its assets or other equivalent transaction .

**31. GENERAL**

31.1. This AGREEMENT constitutes the whole of the AGREEMENT between the PARTIES hereto relating to the subject matter hereof and save as otherwise provided herein no amendment, alteration, addition, variation or consensual cancellation shall be of any force or effect unless reduced to writing and signed by the PARTIES hereto or their duly authorized representatives.

31.2. The PARTIES agree that no other conditions, warranties or representations whether oral or written, and whether express or implied whether by statute or otherwise, shall apply hereto.

31.3. No addition to, variation, novation or agreed cancellation of this AGREEMENT shall be of any force or effect unless in writing and signed by or on behalf of the PARTIES ..

31.4. The failure of a PARTY in any instance to insist on the strict performance of the terms of this AGREEMENT shall not be construed to be a waiver or relinquishment of any of the terms of this AGREEMENT, either at the time of the PARTY' S failure to insist upon strict performance, or at any subsequent time.



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31.5. All costs, charges and expenses of any nature whatever which may be incurred by a PARTY in enforcing its rights pursuant to this AGREEMENT, including legal costs on the scale of attorney and own client and collection commission, irrespective of whether any action has been instituted, shall be recoverable from the PARTY against which such rights are successfully enforced.

31.6. All provisions in this AGREEMENT are, notwithstanding the manner in which they have been put together or linked grammatically, severable from each other. Any provision of this AGREEMENT which is or becomes unenforceable in any jurisdiction, whether due to voidness, invalidity, illegality, unlawfulness or for any other reason whatsoever, shall, in such jurisdiction only and only to the extent that it is so unenforceable, be treated as *pro non scripto* and the remaining provisions of this AGREEMENT shall be of full force and effect. The PARTIES declare that it is their intention that this AGREEMENT would be executed without such unenforceable provisions if they were aware of such unenforceability at the time of its execution.

31.7. This AGREEMENT may be signed in separate counterparts, each of which shall be deemed to be an original and all of which taken together shall constitute one and the same instrument. A counterpart of this AGREEMENT in fax form shall be conclusive evidence of the original signature and shall be as effective in law as the counterparts in original form showing the original signatures.

31.8. Termination of this AGREEMENT shall not release either PARTY hereto from any liability or right of action which at the time of termination has already accrued to either PARTY hereto or which may thereafter accrue in respect of any act or omission prior to such termination. Such rights shall include but not be limited to the recovery of any monies due hereunder.

**32. COSTS**

Each PARTY shall bear and pay for its own costs of and incidental to the negotiation, drafting, preparation and execution of this AGREEMENT.

**33. NOMINEE AND CONSEQUENT GUARANTEE**

33.1. ASPEN shall be entitled, but not obliged, to designate by delivering written notice to that effect to IROKO on or before the Effective Date any company that is a subsidiary of ASPEN ("the nominee") to be ASPEN' S nominee under this AGREEMENT, whereupon –

33.1.1. the nominee/s shall be deemed to be entitled to all of the rights and to have assumed all of the obligations of ASPEN under this AGREEMENT;

33.1.2. all reference in this AGREEMENT to ASPEN shall be deemed to be references to the nominee, unless the context otherwise requires.

33.2. ASPEN irrevocably and unconditionally guarantees to IROKO the due and punctual observance and performance of all of the terms, conditions and covenants by the nominee contained in this AGREEMENT, including to pay to IROKO, from time to time, on demand any and every sum or sums of money which the nominee is at any time liable to pay to IROKO under or pursuant to this AGREEMENT and which has become due and payable but has not been paid at the time such demand is made.



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33.3. ASPEN irrevocably and unconditionally agrees as a primary obligation to indemnify IROKO from time to time on demand from and against any loss incurred by IROKO as a result of any of the obligations of the nominee under or pursuant to this AGREEMENT.

33.4. The obligations of ASPEN herein contained shall be in addition to and independent of every other security which IROKO may at any time hold in respect of any of the nominee' s obligations under the AGREEMENT.

33 .5. The obligations of ASPEN under this clause 33 shall constitute and be continuing obligations notwithstanding any settlement of account or other matter or thing whatsoever and shall not be considered satisfied by any intermediate payment or satisfaction of all or any of the obligations of the nominee and shall continue in full force and effect until final payment in full of all amounts owing by the nominee hereunder and the total satisfaction of all of the nominee' s actual and contingent obligations hereunder.

33.6. Neither the obligations of ASPEN under this clause 33 nor the rights, powers and remedies conferred in respect of ASPEN upon IROKO by this guarantee or by law shall be discharged, impaired or otherwise affected by:

33.6.1. the winding-up, dissolution, administration or re-organisation of the nominee or any other person or any change in its status, function, control or ownership;

33.6.2. any of the obligations of the nominee or any other person under this AGREEMENT or under any other security taken in respect of any of its obligations there under being or becoming illegal, invalid, unenforceable or ineffective in any respect;

33.6.3. time or other indulgence being granted or agreed to be granted to the nominee in respect of its obligations under this AGREEMENT or under any such other security;

33.6.4. any amendment to, or any variation, waiver or release of, any obligation of the nominee under this AGREEMENT or under any such other security;

33.6.5. any failure to take, or fully to take, any security contemplated by this AGREEMENT or otherwise agreed to be taken in respect of the nominee' s obligations hereunder;

33.6.6. any failure to realise or fully to realise the value of, or any release, discharge, exchange or substitution of, any security taken in respect of the obligations of the nominee under this AGREEMENT; or

33.6 .7. any other act, event or omission which, but for this clause 33, might operate to discharge, impair or otherwise affect any of the obligations of ASPEN herein contained or any of the rights, powers or remedies conferred upon IROKO by this guarantee or by law.



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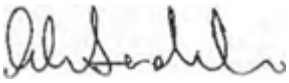
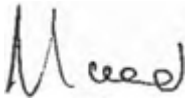
SIGNED by ASPEN at DURBAN, REPUBLIC OF SOUTH AFRICA on this 6TH day of DECEMBER 2007

AS WITNESSES:

For: **ASPEN PHARMACARE HOLDINGS LIMITED**

1. 

2. 

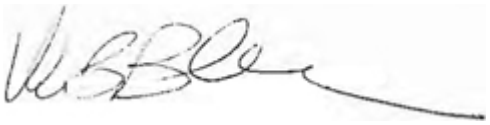


**STEPHEN BRADLEY SAAD,** Chief Executive Officer, warranted by his signature that he is duly authorised hereto

SIGNED by IROKO at Philadelphia, PA on this 6th day of December 2007

**AS WITNESSES:**

For: **IROKO PHARMACEUTICALS** (LUXEMBOURG) SARL

1. 

2. 

OSAGIE IMASOGIE, warranted by his signature that he is duly authorised hereto



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**APPENDIX A**

**PRODUCTS**

PRODUCTS

ALDOMET® (methyldopa) Tablets 125 mg
ALDOMET® (methyldopa) Tablets 250 mg
ALDOMET® (methyldopa) Tablets 500 mg
INDOCIN® (indomethacin) Capsules 25 mg
INDOCIN® (indomethacin) Capsules 50 mg
INDOCIN® (indomethacin) Sustained Release Capsules 75mg
INDOCIN® (indomethacin) Suppositories 25mg
INDOCIN® (indomethacin) Suppositories 50mg
INDOCIN® (indomethacin) Suppositories 100mg

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**APPENDIX B**

**LIST OF SUPPOSITORIES, ALDOMET® 125 MG AND SRC PRODUCT**

INDOCIN® (indomethacin) Suppositories 25mg

INDOCIN® (indomethacin) Suppositories 50mg

INDOCIN® (indomethacin) Suppositories 100mg

INDOCIN® (indomethacin) Sustained Release Capsules 75mg

ALDOMET® (methyldopa) Tablets 125mg

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## APPENDIX C

**PRIORITY COUNTRIES REGULATORY TIMELINES**

| COUNTRY | DATA TRANSFER DATE | COMPILATION PERIOD | SUBMIT TO IROKO | RECEIPT OF REVIEW FROM MERCK | SUBMISSION RETURNED TO ASPEN | DESPATCH OF FILING TO MOH BY ASPEN |
|---|---|---|---|---|---|---|
| PRIORITY | 30 DAYS FROM SIGNATURE | | 31/01/2008 | 01/03/2008 | 08/03/2008 | 15/03/2008 |

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## APPENDIX D

## PACKAGING FEE

The Packaging fee shall be paid to Aspen simultaneously with the Merck Fee.

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## APPENDIX E

## FORMULA FOR THE DETERMINATON OF THE QUARTERLY LICENSE FEE

**[***]**

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Should IROKO dispute the QUARTERLY LICENSE FEE, then the PARTIES shall enter into negotiations in good faith with regard to agreeing the QUARTERLY LICENSE FEE or, failing such agreement within 10 (TEN) days after the commencement of such negotiation, either PARTY shall be entitled to refer the dispute/disagreement for determination by an independent auditor appointed by agreement between the PARTIES, in writing, or failing such agreement within 5 (FIVE) days after either PARTY has required such referral, appointed by the President for the time being of the South African Institute of Chartered Accountants (or his successor-in-title) if IROKO requests such an appointment, or appointed by the then President of the Luxembourg lnstitut des Reviseurs d' Entreprises (or his successor-in-title), if ASPEN requests such an appointment. Such auditor shall act as an expert and not as an arbitrator and his decision shall, save for any manifest error, be final and binding on the PARTIES.

IROKO shall be entitled, at all reasonable times, either directly or through its duly authorised agents, to undertake an inspection and/or audit of all or any of ASPEN' S reports, books of account, manufacturing facilities and the like in an endeavour to verify that the QUARTERLY LICENSE FEE has been correctly calculated and ASPEN shall give IROKO and/or its duly agents, its full co-operation in this regard. The authorised agents or representatives of IROKO shall, however, prior to conducting any such inspection and/or audit, enter into a "confidentiality and lock-out agreement" in a form reasonably acceptable to ASPEN that would require the agent or representative to maintain confidentiality of the information obtained and desist from trading in the securities of ASPEN for a period specified therein.



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## APPENDIX F

## TEMPLATE TERRITORY PRO-FORMA INCOME STATEMENT OF THE BUSINESS ACTIVITY

**[***]**

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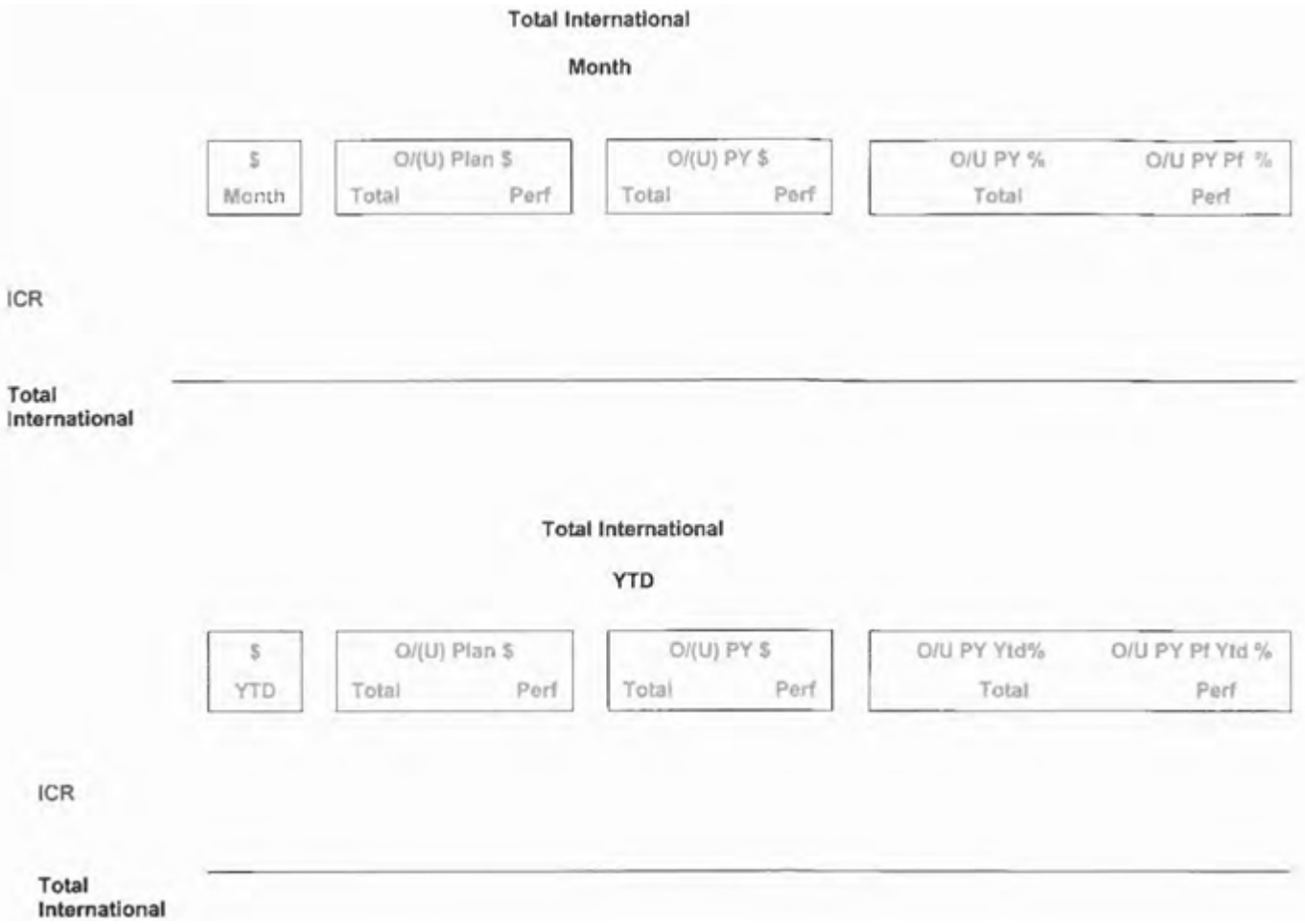
**APPENDIX G**

**TEMPLATE TERRITORY REPORT ON SALES ACTIVITY**




Standard Monthly Reporting Format as above:
Run at following levels:

Total sales for territory (ICR ie all aspen/iroko territories)
Total sales by region ie LATAM,CARICAM,UK/Ire,Africa,Australasia
Total sales by country

Total aldomet sales ICR
Total aldomet sales by region ie LATAM,CARICAM,UK/Ire,Africa,Australasia
Total aldomet sales by country

Total indocid sales ICR
Total indocid sales by region ie LATAM,CARICAM,UK/Ire,Africa,Australasia
Total indocid sales by country

Drill down available to pack level/country on request

Note: performance = sales at planned exchange (instead of the spot exchange at time of sale)

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**APPENDIX H**

**MANUFACTURING PROVISIONS**

1. The price for the PRODUCTS supplied by ASPEN shall be [***], determined in accordance with IFRS.

2. IROKO shall be entitled, at all reasonable times, and during regular business hours, either directly or through its AFFILIATES, to undertake an inspection and/or audit of all or any of ASPEN' S reports, books of account, manufacturing facilities and the like in an endeavour to verify that the PRICE has been calculated on a [***] basis and ASPEN shall give IROKO and/or its duly authorized agents, its full co-operation in this regard. The authorised agents or representatives of IROKO shall, however, prior to conducting any such inspection and/or audit, enter into a "confidentiality and lock-out agreement" in a form reasonably acceptable to ASPEN that would require the agent or representative to maintain confidentiality of the information obtained and desist from trading in the securities of ASPEN for a period specified therein.

3. Delivery and the remaining supply terms relevant to the PRODUCTS shall be in accordance with the terms of the distribution agreements, from time to time, between ASPEN (on the one hand) and its AFFILIATES or the THIRD PARTY SUB-LICENSEES (on the other hand).

4. ASPEN warrants that the PRODUCTS will be MANUFACTURED and PACKED in accordance with good manufacturing practice, APPLICABLE LAWS and the SPECIFICATIONS.

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**APPENDIX I**

**[***]**

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**APPENDIX J**

**SAFETY AGREEMENT**

**Between**

**IROKO PHARMACEUTICALS (LUXEMBOURG) SARL**

**and**

**ASPEN PHARMACARE HOLDINGS LIMITED**

**for the Safety Management of**

**ALDOMET® (METHYLDOPA) AND INDOCIN (INDOMETHACIN)®**

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**Safety Agreement**

This Safety Agreement dated (the "Effective Date") is made by and between Iroko Pharmaceuticals (Luxembourg) Sari, a Societe Anonyme a Responsabilite Limitee formed under the laws of Luxembourg ("Iroko"), whose principal office is at 65, boulevard Grande-Duchesse Charlotte,L-1331, LUXEMBOURG and Aspen Pharmacare Holdings Limited, a South African Company ("Aspen"), whose principal office is at Building 8 Healthcare Park, Woodlands Drive, Woodmead, Sandton 2052, Gauteng, Republic of South Africa . In this Agreement Iroko and Aspen will each be known as a "Party" and collectively, as the "Parties". This Agreement will govern safety data exchange for ALDOMET® (METHYLDOPA) and INDOCIN® (known collectively as the "Medicinal Products") by them or their Affiliates in connection with the Exclusive Sub-License Agreement dated , 2007 between the Parties ("the Exclusive License Agreement").

NOW THEREFORE the Parties hereby agree as follows:

**Glossary of Abbreviations and Definition of Terms**

Capitalised terms used but not otherwise defined herein will have the meanings given such terms in the Exclusive License Agreement to the extent defined therein.

For other terms throughout this Agreement, the following definitions will apply:

**Abuse:** Persistent or sporadic intentional excessive use of a Medicinal Product by a patient or Clinical Trial subject accompanied by harmful physical and/or psychological effects.

**Adverse Event ("AE"):** Any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a Medicinal Product, whether or not considered related to the Medicinal Product. An Adverse Event, for the purposes of this Agreement, can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease (new or exacerbated) temporally associated with the use of the Medicinal Product. It includes failure to produce expected benefits (i.e. lack of efficacy), abuse or misuse.

**Adverse Drug Reaction (" ADR"):** Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product where a causal relationship cannot be excluded.

**Affiliate:** In relation to one person, any other person which is controlled by, under common control with, or controls the other. Without limiting the generality of the foregoing, a company shall be deemed to have control of another if (directly or indirectly) it owns a majority of the voting shares of or is entitled (directly or indirectly) to appoint a majority of the directors of the other company. "Control" means the ability to determine the policies and/or management of a person, whether through the ownership of securities, by contract or otherwise;

**Agreement:** This agreement including any schedules attached to it and any written agreement, document or instrument entered into, made or delivered pursuant to its terms, as any of them may, from time to time, be supplemented.

**Allocated Territories:** Those countries, territories or other jurisdictions for which each Party has responsibilities as defined in this Agreement or the Exclusive License Agreement and which have been allocated to a Party pursuant to the schedule attached here as Appendix One.

**Applicable Law:** All or any statutes, subordinate legislation and common law, regulations, ordinances and bylaws, and directives, codes of practice, circulars, guidance notes, judgment and decisions of any competent authority.

**Business Day:** Any day other than a Saturday, Sunday or official public holiday in the Republic of South Africa and/or the Grand Duchy of Luxembourg, as the case may be.



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**Calendar Day:** Any 24 hour day of the seven day week.

**CIOMS-1:** A standardised international reporting form for individual case safety reports.

**CIOMS-11:** An international reporting standard for periodic reporting tables.

**Clinical Study or Clinical Trial:** Any interventional investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product, and/or identify any adverse reactions to a Medicinal Product, and/or to study absorption, distribution, metabolism, and excretion of a Medicinal Product with the object of ascertaining its safety and/or efficacy. The terms "Clinical Trial" and "Clinical Study" are synonymous.

**Company Core Safety Information ("CCSI"):** Safety information prepared by any MAH that the MAH requires to be included in all Product Labelling in all countries to which the MA held by such MAH applies, except where a local Regulatory Authority specifically requires a modification. CCSI is the reference information by which Listed Adverse Drug Reactions and Unlisted Adverse Drug Reactions are determined for the purpose of periodic reporting for marketed products.

**Compassionate Use:** The use of an Investigational Medicinal Product for an unapproved indication, in circumstances where a Party has supplied it for that use in response to a bona fide unsolicited request from a healthcare professional assuming responsibility for that use by their patient.

**Counterfeit Medicinal Product:** One that is deliberately and fraudulently mislabeled with respect to identity and source.

**Data Lock Point ("DLP"):** The data lock point is defined as the cut-off date for data to be included in a PSUR. It may be set according to the International Birth Date (lBO) of the Medicinal Product. The MAH should in any case submit the PSUR no later than 60 days after the DLP or as required by Applicable Law, if earlier.

**Documentation:** All records in any form (including, but not limited to, written, electronic, magnetic and optical records and scans, radiographs and electrocardiograms) that describe or record safety data and safety related activities covered by this Agreement.

**European Economic Area ("EEA"):** All countries that are member states of the European Union, as constituted from time to time, including upon accession, new member states of the European Union, plus Norway, Iceland and Liechtenstein.

**European Union ("EU"):** All countries that are member states of the European Union, as constituted from time to time, including upon accession, new member states of the European Union.

**Expected Adverse Drug Reaction:** An Adverse Drug Reaction where the nature and/or severity of the reaction is consistent with the term or description used in the 18, CCSI or Local SmPC.

**International Birth Date:** The date that the Medicinal Product is first licensed anywhere in the world.

**Investigator Brochure ("IB"):** A compilation of the clinical and non-clinical data on the Investigational Medicinal Product(s) which is relevant to the study of such Investigational Medicinal Product(s) in human subjects.

**Investigational Medicinal Product ("IMP")** A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a Clinical Study, including a product with a Marketing Authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.



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**Lack of Efficacy Report:** a report of a situation where there is apparent failure of the Medicinal Product or medical technology to bring about the intended beneficial effect on individuals in a defined population with a given medical problem, under ideal conditions of use.

**Line Listing:** Listings of safety data according to defined requirements to meet regulatory reporting obligations e.g. every six (6) months safety line listing required to meet the EU Clinical Trial Directive (2001/20/EC) requirements (as amended from time to time).

**Listed Adverse Drug Reaction:** An ADR, the nature, severity, specificity and outcome of which are consistent with the information in the applicable CCSI or equivalent reference label.

**Marketing Authorisation ("MA"):** Authorisation to market a Medicinal Product.

**Marketing Authorisation Holder (" MAH"):** The entity to which an MA has been issued by a Regulatory Authority that allows the holder to place the Medicinal Product on the market, in compliance with the terms of the MA.

**Medically Important:** AEs requiring medical and scientific judgment to determine if expedited reporting is appropriate. Such events may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes constituting SAEs. Medical and scientific judgement should be exercised in deciding whether an event is a Medically Important Event. Examples of Medically Important Events include intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalisation; or development of drug dependency or drug abuse. For the avoidance of doubt, infections resulting from contaminated medicinal product will be considered a Medically Important Event and subject to expedited reporting requirements.

**Misuse:** Use of a Medicinal Product in a way that is not in accordance with its Marketing Authorisation accompanied by harmful physical and/or psychological effects.

**Non-Serious Adverse Event:** An Adverse Event that does not meet the criteria for a Serious Adverse Event.

**Overdose:** A dose taken (accidentally or intentionally) exceeding the dose as prescribed by the protocol or the maximal recommended daily dose as stated in the Product Labelling, (as it applies to the daily dose for the subject/patient in question). The Parties agree that in the course of conducting a Clinical Study, the terms of the Clinical Study Protocol (as fully approved by all applicable bodies) override the local Product Labelling.

**Periodic Report:** A report of Adverse Events prepared and submitted on a periodic basis to Regulatory Authorities that contains collated data on single case reports and addresses the risk-benefit profile of the Medicinal Product. Periodicity of reporting varies according to local rules and the nature of the report e.g. submitted pursuant to Applicable Laws and regulatory requirements for trial or post-authorisation requirements.

**Periodic Safety Update Report ("PSUR"):** A report of Adverse Events prepared and submitted on a periodic basis to Regulatory Authorities. PSUR includes updates on urgent Safety Issues, major signal detection/evaluation, and changes in efficacy.

**Pharmacovigilance:** The science and activities relating to the detection, collection, recording assessment, understanding, reporting, prevention and/or management of AEs or other Safety Issues related to Medicinal Products and their use.

**Post-Authorisation Safety Study ("PASS" ):** Any study carried out in accordance with the terms of the MA, conducted with the aim of identifying or quantifying a safety hazard relating to the authorised Medicinal Product.



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**Pregnancy Reports:** Reports of pregnancy following maternal or paternal exposure to the product.

**Product Complaints:** Complaints arising from potential deviations in the manufacture, packaging or distribution of the Medicinal Product.

**Product Labelling:** Description of the Medicinal Product and summary of use, safety, and effectiveness that is used internally (e.g. IB and CCSI) or which must be approved by Regulatory Authorities (e.g., Summary of Product Characteristics in the EU).

**Qualified Person for Pharmacovigilance ("QPPV"):** A person from within the EEA Territory appointed by the MAH as responsible for the establishment and maintenance of the Pharmacovigilance system as it pertains to the EEA.

**Regulatory Authority:** Any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities, including the U.S. Food and Drug Administration, the European Medicines Agency, the European Commission, or any other entity exercising regulatory authority with respect to the development, registration, manufacturing, marketing, distribution, transportation, or sale of a Medicinal Product.

**Risk Management Plan:** A document which describes a set of Pharmacovigilance activities and interventions designed to proactively identify, characterise and prevent or minimise risks related to Medicinal Products, including risk communication and the assessment of effectiveness of risk minimisation interventions.

**Safety Database:** A validated database that stores data, compiles, integrates, and produces reports of AEs/SAEs from all reporting sources. Reporting capabilities include individual safety reports, Periodic Reports, and customised reports from queries.

**Safety Issue:** Any information suggesting an emerging safety concern or possible change in the risk-benefit balance for the Medicinal Product, including information on a possible causal relationship between an Adverse Event and the Medicinal Product, the relationship being unknown or incompletely documented previously.

**Serious Adverse Event ("SAE")/Serious Adverse Reaction ("SADR"):** is an event or any untoward medical occurrence that at any dose either:

a) Results in death; or

b) Is life-threatening

*NOTE:* The term "life-threatening" in the definition of "serious" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe; or

c) Requires in-patient hospitalisation or prolongation of existing hospitalisation; or

d) Results in persistent or significant disability/incapacity, or

e) Results in a congenital anomaly/birth defect; or

f) Results in a medically important event or reaction.

**Spontaneous Report:** An unsolicited communication in any form from any source to a company, Regulatory Authority or other organisation that describes an Adverse Event or reaction in a patient given one or more Medicinal Products and which does not derive from a Clinical Study or other organised data collection scheme.



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**Suspected Unexpected Serious Adverse Reaction (SUSAR)**

**Third Party:** Any person other than the Parties and their Affiliates.

**Unexpected Adverse Drug Reaction:** An Adverse Drug Reaction where the nature and/or severity of the reaction is not consistent with the term or description used in the IB.

**Unlisted Adverse Drug Reaction:** An ADR, the nature, severity, specificity or outcome of which is not consistent with the information included in the applicable CCSI or local equivalent reference label.

**Valid Case:** A case that includes each of the following minimum criteria:

An identifiable patient;

The name of the suspect Medicinal Product(s) or Clinical Study if considered related to a Clinical Study procedure/design;

An identifiable reporting source;

An event or outcome.



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## 1 SAFETY DATA EXCHANGE

### 1.1 General Terms

1.1.1 This Agreement will govern the exchange of all safety related information and data from all sources for the Medicinal Products between the Parties and their Affiliates pursuant to the Exclusive License Agreement. Each Party may delegate its responsibilities hereunder in whole or in part to its respective Affiliates.

1.1.2 On matters related to safety, this Agreement will take precedence over any other agreement between the Parties.

1.1.3 Each Party shall cause its respective Affiliates and any such Third Parties performing activities on behalf of such Party that perform responsibilities pursuant to this Agreement or the Exclusive License Agreement to comply with the terms and provisions of this Agreement.

1.1.4 The Allocated Territories for which Aspen has certain responsibilities with respect to The Medicinal Products as set forth herein as of the Effective Date are detailed in Appendix One of this Agreement. Such Allocated Territories (and the Parties assigned thereto) may be modified solely by written amendment of this Agreement as executed by both Parties.

1.1.5 Each Party will agree to follow and comply with all Applicable Laws when performing activities covered by this Agreement. Aspen agrees to advise Iroko of the Applicable Laws in its Allocated Territories relating to Pharmacovigilance. Further, nothing herein shall preclude the Qualified Person for Pharmacovigilance (QPPV) for the Medicinal Products from performing his or her obligations as QPPV under Applicable Law and no such performance, to the extent reasonably required by Applicable Law, shall constitute a violation by any Party of this Agreement.

1.1.6 Iroko will have a nominated Qualified Person for Pharmacovigilance (QPPV) and an appropriate deputy in accordance with requirements in the EU. Contact details for the QPPV(s) for the Medicinal Products are provided in Appendix Two.

1.1.7 Where national regulations in any Allocated Territory require a nominated or responsible individual in that jurisdiction who has specific legal obligations in respect of Pharmacovigilance at a national or local level, the Party responsible for that Allocated Territory shall designate an appropriately qualified individual to fulfill this role for the Medicinal Products. The Parties agree to provide reasonable assistance to such individuals in complying with their legal and regulatory obligations and responsibilities.

1.1.8 Any Party with responsibility with respect to an Allocated Territory shall use reasonable efforts to notify the other Party of any material changes to Applicable Law in such Allocated Territory, of which it becomes aware, provided that this is published and generally available, that could have an impact on the terms of, or performance of, obligations under this Agreement; *provided, however,* that a failure to do so shall not constitute a breach of this Agreement.

1.1.9 Each Party agrees to have and maintain adequate Pharmacovigilance systems (such as standard operating procedures, work instructions, electronic databases and business continuity plans) and resources (this includes staff training) to ensure compliance with all Applicable Law in its Allocated Territories. Each Party agrees to ensure all relevant staff are informed and trained on the process for safety data exchange as described in this Agreement.



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1.1.10 For the avoidance of doubt, compliance with clause 1.1.9 above will include compliance with all applicable privacy and data protection laws, rules and regulations.

1.1.11 Each Party agrees to implement all reasonable physical, technical and administrative safeguards to protect adverse event information from loss, misuse and unauthorised access, disclosure, alteration or destruction.

1.1.12 Each Party agrees to notify the other promptly of any loss, misuse, unauthorised access, disclosures, alteration or destruction of such information of which they become aware.

1.1.13 Contacts for the respective responsibilities within this Agreement are defined in Appendix Two. Each Party agrees to notify the other Party within five (5) Business Days of any changes to the identity or contact information for such contacts set forth in Appendix Two.

1.2 **Rules of Exchange**

1.2.1 Iroko will hold and maintain the global Safety Database of AE reports received by any Party or their Affiliates/Third Parties worldwide for the Medicinal Products.

1.2.2 Direct access to the global Safety Database for the Medicinal Products will not be granted to Aspen (or its Affiliates) but Iroko shall be obliged to provide all reasonable assistance upon receipt of a reasonable request from Aspen for the purposes of compliance with Applicable Law.

1.2.3 Exchange of all safety data pursuant to this agreement will be undertaken by the Parties in English and to the format and timelines specified herein as applicable. Aspen will provide minimum information within these timelines for non English cases and will follow up with translation thereof within 5 (five) calendar days. Source documents will therefore not be appropriate for non English cases.

1.2.4 Each Party will make reasonable checks to ensure that the safety data that it has sent to the other Party in accordance with the terms of this Agreement have been received by the intended recipient at the other Party. The Parties will confirm receipt of SAE reports from each other by sending a confirmation e-mail with the case ID.

In addition, the Parties will each provide each other with listings of all data received monthly. The Parties agree to take the necessary action and send any such safety data that has not been received within one (1) Business Day for all serious cases, and ten (10) Business Days for all other information of discovering the discrepancy and take immediate action to avoid repetition.

1.2.5 The responsibilities for the regulatory reporting of individual case safety reports, Periodic Reports and other safety-related communications with respect to the Medicinal Products commercialized by Aspen, to Regulatory Authorities rests with Aspen for its Allocated Territories, according to Applicable Law unless otherwise provided in this Agreement.

**2 CLINICAL STUDY SAFETY DATA**

2.1 **General**

2.1.1 This Section 2 relates to the receipt and management of individual case safety reports and Periodic Reports that arise from all Clinical Studies and other interventional sources including Compassionate Use of the Medicinal Products



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sponsored by Aspen. For the avoidance of doubt, Aspen will not conduct any sponsored Clinical Study with the Medicinal Products unless the Parties otherwise agree in writing. Aspen will not be responsible for the receipt and management of individual case safety reports in respect of Clinical Studies and Compassionate Use of the Medicinal Products sponsored by Iroko.

2.1.2 Should the Parties agree to conduct any Clinical Trials or otherwise generate additional clinical data or perform additional analyses of additional clinical data, the terms of this Agreement and specifically this Section, will be renegotiated.

## 3 POST MARKETING SAFETY DATA

This Section 3 applies solely to Spontaneous Reports for the Medicinal Products from all sources received by each Party and reports for the Medicinal Products from all other sources except Clinical Studies.

### 3.1 Individual Case Safety Reports

3.1.1 Aspen will provide to Iroko case reports for the Medicinal Products that meet the Valid Case criteria as defined in this Agreement.

3.1.2 Safety case reports for the Medicinal Products that do not meet the Valid Case criteria should be retained by Aspen and actively followed up by them until Valid Case criteria are met and then forwarded by them to Iroko in the timeframes specified in this Agreement. Aspen should make commercially reasonable efforts to obtain such Valid Case criteria.

3.1.3 In the event of receipt by a Party of a Medicinal Products case report with missing Valid Case criteria containing data in relation to a potential Safety Issue, the Parties may agree to exchange such case reports following discussion and mutual agreement at the time of receipt on a case by case basis.

### 3.2 Receipt Date

3.2.1 For the purposes of this Agreement, the “receipt date” is the date when any employee of any Party, its Affiliate or its Third Party first becomes aware of safety-related information.

3.2.2 The time clock (in calendar days) for a case for regulatory reporting purposes starts on the date on which the applicable Party has received information with respect to such a case sufficient to demonstrate that all criteria for a Valid Case are met.

3.2.3 The time clock (in calendar days) for regulatory reporting purposes starts at day 0 for all new information pertaining to a Valid Case, such as follow-up information. However, this should not affect the regulatory reporting schedule for information already received (such as initial case or previous follow-up), and only starts again for that information which is new and received during a separate correspondence to the initial or previous follow-up.

3.2.4 Date of Initial Notification: The date of initial notification is the date when any representative of Aspen is made aware of the minimum information which constitutes a valid report ( an identifiable patient, an identifiable reporter, a suspected reaction, and a suspect drug). This includes both verbal and written communication, and is classes as day zero (0) of the regulatory reporting process. The date of initial notification for faxed documents and post will be taken as the day the messages were printed by the fax machine or delivered to the premises respectively. The date of initial notification for e-mail messages and voice mail



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messages will be the dates those messages were registered as received by their systems. The date of initial notification for all other scenarios will be the date the communication took place. The date of initial notification of any initial and follow- up information must be clearly marked on all documents.

**3.3 Follow Up**

3.3.1 Aspen will be responsible for undertaking appropriate and timely follow-up on reports it has received or of which it has become aware and for forwarding to Iroko for processing in accordance with Section 3.4 below.

3.3.2 Iroko will forward requests for follow-up where required to the relevant Safety Contact at Aspen as defined in Appendix Two.

3.3.3 Aspen agrees to perform follow-up activities as per internal procedures and to action any reasonable requests for follow up received from Iroko and to forward responses in the timelines defined in Section 3.4 below.

3.3.4 Where reports are received from members of the general public, Aspen will attempt follow up with the applicable health care provider, but will still forward valid reports to Iroko in the timelines specified in Section 3.4 below.

**3.4 Exchange of Individual AE/ADR Reports**

3.4.1 Each Party will send reports of individual AEs/ADRs and SAEs/SADRs covered by Section 4 [section reference incorrect?] to the other Party using the method of exchange, format and within the timelines set out in Table 1 and 2 below.

3.4.2 Each of the Parties will acknowledge receipt of the reports sent as per Table 1, to the Safety Contact (as set out in Appendix Two) at the other Party within two (2) Business Days of receipt. The Party sending the report agrees to follow up with relevant Safety Contacts of the other Party if acknowledgments are not received from the receiving Party and the sending Party will resend reports to the Safety Contact of the receiving Party where required.

3.4.3 Iroko will enter the single case report safety data received into the global Safety Database as provided from Aspen. In the event that Iroko identifies an event of concern in the case report that has not been identified by Aspen, Iroko will raise a query to Aspen which Aspen will answer within two (2) Business Days. Where agreement cannot be reached Iroko may enter the new term into its Safety Database for the Medicinal Products.

3.4.4 Aspen shall forward any supplementary supporting data such as laboratory results, discharge letters or autopsy reports to Iroko upon IROKO' S request using the method of exchange, format and within the timelines set out in Table 1 and 2 below. Aspen will ensure any data that would reveal personal details of the patient in discharge summaries and laboratory data or other such documents are scored through in permanent black ink prior to sending such data to Iroko.

3.4.5 In the event of any doubt regarding whether an Adverse Event is a Non-Serious Adverse Event or a Serious Adverse Event, the Parties shall treat that Adverse Event as a Serious Adverse Event. Likewise, in the event of any doubt regarding whether an Adverse Event is fatal, life threatening or serious, or whether an Adverse Event is related or unrelated, the Parties shall classify the Adverse Event in a manner that ensures the shortest relevant reporting timeline.



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**Table 1: Timelines for Exchange: From Aspen to Iroko**

| Type of Report | Timeline Aspen to Iroko | Format | Means of Exchange |
|---|---|---|---|
| Fatal/Life threatening ADRs/AEs | Day 1 | Source Documents | E-mail or Fax |
| All other SADRs/SAEs | Day 3 | Source Documents | E-mail or Fax |
| Pregnancies (regardless of associated AEs) | Day 3 | Source Documents | E-mail or Fax |
| Non-serious AEs | Day 10 | Source Documents | E-mail or Fax |

Timelines for Exchange are presented in calendar days and are subject to the provisions of 1.2.3 above in respect of non English cases.

**Table 2: Timelines for Exchange: From Iroko to Aspen**

| Type of Report | Timeline Iroko to Aspen | Format | Means of Exchange |
|---|---|---|---|
| All SADRs (including fatal & life threatening) originating in the Aspen Allocated Territories | Day 12 | CIOMS I | E-mail or fax |
| Non serious Unexpected ADRs originating in the Aspen Allocated Territories | Day 12 | CIOMS I | E-mail or fax |

Timelines for exchange are presented m calendar days.

### 3.5 Regulatory Authority Notifications

3.5.1 Iroko will provide reports to Aspen on an appropriate form (CIOMS-I) for submission to the appropriate Regulatory Authority in the Allocated Territories by Aspen and in an appropriate timeframe to allow for compliance with Applicable Law. Iroko will have assessed the report as potentially fulfilling the criteria for expedited reporting. Where a shorter timeframe is required by Applicable Law Aspen will submit to the Regulatory Authority source documentation for an AE/SAE arising in the Allocated Territory until the CIOMS-I is available. The CIOMS-I should be submitted as a follow up to the original submission.

3.5.2 Aspen will be responsible for preparing and sending all relevant individual reports and applicable safety data covered by this Section 3 in accordance with Applicable Law to Regulatory Authorities in their Allocated Territories where required.

3.5.3 Aspen will confirm to Iroko the actual date of submission to the Regulatory Authorities in its Allocated territories as soon as possible but no later than two (2) weeks after the submission date. Where Aspen fails to meet the timeline for submission under Applicable Laws, it will provide Iroko with the documented reason for late submission and a binding action plan detailing how it will perform such submission in the shortest time possible after such missed deadline. For the avoidance of doubt Aspen will bear all liability for any penalty (if any) imposed by the Regulatory Authority in respect to such late submission.



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**3.6 Post Marketing Periodic Reports**

3.6.1 Iroko will be responsible for the preparation or provision to Aspen of Periodic Reports (including PSURs, PSUR addenda or PSUR bridging reports) for the Medicinal Products in accordance with ICH E2C (R) Safety Data Management: Periodic Safety Update Reports and Applicable Law.

3.6.2 Iroko will forward electronic copies of any final PSUR, addendum or bridging report to Aspen within fifty-seven (57) days of the Data Lock Point for the PSUR. Where day 57 falls on a day other than a Business Day, Iroko will adjust the timelines accordingly to enable compliance with reporting requirements.

3.6.3 Aspen will be responsible for the submission of any Periodic Report, PSUR, addendum or bridging report in its Allocated Territories if required.

3.6.4 Aspen will confirm to Iroko the actual date of submission in its Allocated Territories as soon as possible but no later than two (2) weeks after the submission date where submission is required.

3.6.5 Aspen will not use, reference or share any information from periodic reports in any marketing presentation, publication or with any external bodies.

3.6.6 Where the Periodic Report, PSUR, addendum or bridging report does not meet local requirements for periodic safety reporting as specified in the Applicable Law of any of the Allocated Territories, Aspen will notify Iroko and Iroko will perform commercially reasonable endeavours to assist Aspen to meet such requirements in collaboration with Regulatory Authorities.

**4 Literature**

4.1 Iroko or its agent will search bio-medical databases for global English language literature reports and Aspen will perform searches for local language reports in its Allocated Territories on a regular basis to identify literature articles containing references to suspected Adverse Drug Reactions or other safety information of relevance in association with the Medicinal Products and forward them to Aspen in the timelines specified in this Agreement.

4.2 If local literature articles, including any articles from local media/press releases, require translation, the minimum Valid Case criteria must be translated into English and forwarded to Iroko as per the timelines in Section 5.4. The full translation and the full reference of each non-English language article should be forwarded as follow-up in the timelines described in Section 5.4 upon receipt of the translation.

**5 PRODUCT COMPLAINTS ASSOCIATED WITH AE REPORTS**

5.1 Aspen will collect and report all Product Complaints associated with the Medicinal Products in its Allocated Territories where there is an associated AE or ADR in accordance with the format, timelines and method defined in Section 3.4.

5.2 Follow-up of Product Complaints involving AE reports must be carried out according to the same procedures for any other AE report and exchanged in the timelines defined in Section 3.4 above.

5.3 Aspen will be responsible for carrying out the investigation of such Product Complaints involving the Medicinal Products that Aspen manufactures (e.g. through manufacturing QA) and will forward the results on any manufacturing investigation to Iroko as follow up in the timelines defined in Section 3.4.



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5.4 Aspen will notify Iroko of any counterfeit activity in its Allocated Territories of which it becomes aware.

5.5 A monthly summary of all product complaints will be sent to Iroko Pharmacovigilance for reconciliation.

## 6 LACK OF EFFECT REPORTS

6.1 Aspen will collect and report all Lack of Effect Reports associated with the Medicinal Products in accordance with the format, timelines and method defined within this Agreement.

6.2 Follow-up of Lack of Effect Reports must be carried out by Aspen according to the same procedures for any other AE report and exchanged with Iroko in the timelines defined within this Agreement.

## 7 Special Situations

### 7.1 Pregnancy Reports

7.1.1 Aspen will collect and report all reports of pregnancy from female patients or partners of male patients exposed to the Medicinal Products of which it becomes aware. Reports should be forwarded as per the timelines in Section 3.4.

7.1.2 Complications of pregnancy or elective termination of pregnancy will be reported by Aspen to Iroko and forwarded as per the timelines in Section 3.4.

7.1.3 Pregnancy outcome data will be sent by Aspen as follow-up in accordance with the timelines in Section 3.4 as applicable.

### 7.2 Post-Authorisation Clinical Trials and Safety Studies

Should the Parties agree to conduct any post-authorisation Clinical Trials or Safety Studies that may be of relevance to the safety of the Medicinal Products the terms of this Agreement and specifically this Section, will be renegotiated.

## 8 Risk management

### 8.1 Ongoing Pharmacovigilance

8.1.1 Iroko will be responsible for the identification, investigation, monitoring and management of any Safety Issues specific to the Medicinal Products.

8.1.2 Aspen agrees to alert Iroko if they become aware of a Safety Issue that has the possibility to affect the benefit-risk ratio with the Medicinal Products within one (1) Business Day of it becoming aware of such a Safety Issue. Such events include but are not limited to:

A Safety Issue arising from a Clinical Study or from post-marketing safety data;

A clinically important increase in the rate of occurrence of an expected Serious Adverse Event;

A significant new hazard to the patient population e.g. lack of efficacy with a Medicinal Product used in treating a life-threatening disease(s); or

A new safety finding from a newly completed animal study with clinical implications e.g., results indicating a carcinogenic potential.



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8.1.3 If Iroko determines that there may be the need for urgent action in relation to a Safety Issue with the Medicinal Products it shall alert Aspen within one (1) Business Day of that determination.

Actions may include, but are not limited to:

A 'Dear Doctor' or 'Dear Healthcare Professional' letter;

A Medicinal Product disposal or recall;

Alteration, suspension or discontinuation of a Clinical Study due to a Safety Issue;

Alteration, suspension or discontinuation of Medicinal Product marketing;

Suspension, modification or discontinuation of Medicinal Product manufacturing; or

A significant change in the Product Labelling.

8.1.4 Aspen is responsible for undertaking communications on pharmacovigilance matters with the relevant Regulatory Authorities in its Allocated Territories in liaison with Iroko.

8.1.5 Aspen will not involve any external expert or an opinion on any safety matter relating to the Medicinal Products, other than where this is required in the normal course of business, without prior written approval by Iroko and, where such an interaction is approved, Iroko will be fully involved in all discussions. The provisions of this clause shall not apply to consultations with external experts to address medical information related enquiries from doctors or pharmacists.

**8.2 Company Core Safety Information (CCSI)**

8.2.1 The CCSI for the Medicinal Products will be prepared and maintained by Iroko as is reasonable from time to time. The CCSI shall reflect the current safety profile of the Medicinal Products.

8.2.2 An electronic copy of the final approved CCSI and associated documentation to support the reason for any change to the previous version of the CCSI seen by Aspen will be forwarded to Aspen by Iroko no later than five (5) Business Days following internal approval and sign off within Iroko for such version.

8.2.3 Where amendment to the CCSI is deemed urgent by Iroko, the timelines and process will be altered accordingly and will be managed by Iroko (refer to Section 8.1).

**8.3 Product Labelling**

8.3.1 Aspen will implement the CCSI, and its updates, into the Product Labelling for Aspen Allocated Territories until such time, if any, the Parties agree in writing that Iroko will have these responsibilities.

8.3.2 Where a Regulatory Authority requires Aspen to deviate from the CCSI in its Product Labelling, Aspen shall notify Iroko in writing no later than five (5) Business Days of receipt of the request and the request will be managed as defined in



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Section 8.1 of this Agreement. Aspen and Iroko shall discuss and agree the revised labeling. For the avoidance of doubt, Aspen will not accept any changes without the prior written consent of Iroko. It is recorded that where the changes are mandated by the Regulatory Authority, Aspen and Iroko are bound to abide by such mandated changes.

8.3.3 Each Party agrees to implement the Medicinal Product labelling into the Patient Information Leaflet such that the content is consistent with the Product Labelling.

8.4 **Patient Risk Management Plans**

8.4.1 Iroko is responsible for preparation and update of any applicable global Risk Management Plan for the Medicinal Products if required.

8.4.2 Iroko will forward electronic copies of any such final Risk Management Plan to Aspen to enable the submission of the Risk Management Plan to Regulatory Authorities in its Allocated Territories if required.

9 **Regulatory Enquiries/Regulatory Action**

9.1 **Regulatory Safety Enquiries**

9.1.1 Aspen will inform Iroko of any safety-related regulatory enquiries relating to the Medicinal Products received from a Regulatory Authority within one (1) Business Day of receipt.

9.1.2 Iroko agrees to provide the response required to Aspen for submission by them to the Regulatory Authorities in the Allocated Territories in the required timeframes set by the respective Regulatory Authority.

9.2 **Regulatory Action**

9.2.1 Aspen agrees to inform Iroko within one (1) Business Day of receipt if it becomes aware of any intention by a Regulatory Authority to take safety-related regulatory action in respect to activities covered by this Agreement in relation to the Medicinal Products.

9.2.2 To the extent that such regulatory action relates to the Medicinal Products, each Party agrees to provide support to the other Party in respect to any regulatory action, and will supply all necessary information as is reasonable to deal with the action.

9.2.3 No less than five (5) Business Days (unless Applicable law dictates shorter timeframes), prior to the response to the action as specified by the Regulatory Authority in respect of the Medicinal Products, Aspen with respect to such regulatory action will provide details of its proposed plans to Iroko for approval. Iroko will have the right to review and amend the proposed Aspen response prior to its submission to the Regulatory Authority, provided that Aspen is in agreement with changes Iroko may request.

9.2.4 Aspen agrees to provide Iroko with copies of the final communications with and responses to the Regulatory Authority in respect of the Medicinal Products as approved by Iroko in advance of the submission.

10 **NON REGULATORY AUTHORITY ENQUIRIES**

Aspen may respond to enquiries that it receives from healthcare professionals regarding the Medicinal Products that relate to matters of safety in the Allocated Territories where it



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holds Market Authorisations, provided that the content of the responses is consistent with the local Product Labelling. If such enquiry involves an identifiable patient and a potential adverse reaction, the enquiry will be sent to Iroko pharmacovigilance within one (1) Business Day for potentially serious ADRs and five (5) Business Days for non-serious cases. Aspen will send to Iroko on a monthly basis a summary of all medical information queries for reconciliation.

## 11 EXTERNAL COMMUNICATIONS

Any public statement by Aspen on the safety of the Medicinal Products which goes beyond the scope of the CCSI must be approved by Iroko before publication by Aspen.

## 12 CONTRACTUAL RELATIONSHIPS

### 12.1 Intra-Company Contractual Relationships

12.1.1 Aspen will ensure that it enters into sufficiently detailed and clear contractual arrangements or have detailed and clear written internal procedures with all of its relevant Affiliates in order to meet its pharmacovigilance obligations under this Agreement.

12.1.2 Iroko or its authorised representatives will have the right to request copies of or to audit or inspect any such contractual arrangements to the extent that they are relevant to the performance of Aspen' s obligations under this Agreement.

### 12.2 Commercial or Third Party Contractual Relationships

12.2.1 Aspen will ensure that it enters into sufficiently detailed and clear contractual arrangements with (a) any commercial or collaboration partners and (b) any Third Parties (including, for the avoidance of doubt, Aspen' s Affiliates as defined in Section 2.2.2.2. of the Exclusive License Agreement) to which pharmacovigilance responsibilities of a Party are delegated hereunder, in each case as necessary in order to meet its obligations under this Agreement. Aspen shall be responsible for ensuring that its contractors and subs comply with the terms of this Agreement. Nothing in this clause shall prejudice the performance of ASPEN' S obligations owed to Iroko pursuant to this Agreement.

12.2.2 Aspen shall ensure that it informs Iroko of any changes to the contractual arrangements described in Section 12.2.1 to the extent that they are relevant to the performance of ASPEN' S obligations pursuant to this Agreement.

12.2.3 Iroko or its authorised representatives shall have the right to request copies of, or to audit or inspect, the provisions of any such contractual arrangements of another Party hereunder to the extent that they are relevant to the performance of such other Party' s obligations pursuant to this Agreement.

## 13 DOCUMENTATION

### 13.1 Record Keeping

Aspen will collect, prepare and maintain complete, current, accurate, organised and legible Documentation in a manner acceptable for the collection of data for submission to, or review by, Regulatory Authorities and in full compliance with this Agreement. For the avoidance of doubt all applicable data protection laws and standards of Good Clinical Practice will be followed by Aspen.



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13.2 **Record Retention**

13.2.1 Each Party will retain Documentation for as long as a Marketing Authorisation is held for the Medicinal Products in any country worldwide.

13.2.2 All Documentation will be retained in a secure area reasonably protected from fire, theft and destruction.

13.2.3 Each Party will make all Documentation available upon request to the other Party for review, copying and audit/ inspection at all times on the provision of reasonable advance notice.

## 14 COMPLIANCE/AUDIT/INSPECTION

14.1 **Compliance/Audit**

14.1.1 Iroko may monitor the conduct of ASPEN' S activities under this Agreement and regularly review compliance with the terms of this Agreement.

14.1.2 Iroko or its authorised representatives shall have the right, exercisable at any time during the term of this Agreement, but no more than twice in any twelve (12) month period, upon reasonable advance notice and at its cost, during regular business hours, to audit the facilities, processes and documentation used by Aspen in its performance of its obligations pursuant to this Agreement. Such activities will include but are not limited to reviews of documentation and staff interviews.

Aspen agrees to take remedial action in a timely manner to correct any omission shown by such audit and avoid repetition.

14.2 **Regulatory Inspections**

14.2.1 Each Party agrees to notify the other Party within two (2) Business Days if any Regulatory Authority contacts it with respect to its intention to conduct or give notice to conduct an inspection in respect to Pharmacovigilance activities including those performed under this Agreement in relation to the Medicinal Products.

14.2.2 Each Party agrees to provide support to the other Party in respect of any Regulatory Authority inspection, and will supply to the other Party all necessary information as is reasonable to enable that Party to deal with the inspectors requests such that neither Party adversely affects the other Party' s ability to comply with requests.

14.2.3 Each Party agrees to co-operate with the other and provide details of actions required in relation to the Medicinal Products and activities covered by this Agreement at the end of the inspection.

14.2.4 Each Party agrees to take remedial action in a timely manner to correct any act or omission identified by the Regulatory Authority inspection to the inspected Party.

## 15 CONFIDENTIALITY

15.1 The terms of this Agreement and any and all information and data disclosed under this Agreement to any Party or its Affiliates shall be deemed "CONFIDENTIAL INFORMATION" of the disclosing Party (or its applicable Affiliate) under any Exclusive License Agreement to which the disclosing Party (or such Affiliate) and the receiving Party (or any of its Affiliates) are parties and, as such, shall be subject to the confidentiality



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provisions contained in such Exclusive License Agreement(s) and the receiving Party (and its Affiliates) shall have the right to use and disclose such CONFIDENTIAL INFORMATION solely as permitted thereunder; provided, however, that such Party shall have the right to use such information to the extent necessary to perform its obligations, or to exercise its rights, hereunder. Notwithstanding the foregoing or anything set forth in any Exclusive License Agreement, a breach of this Section 15.1 (or such confidentiality provisions) by any Party or its Affiliates with respect to any CONFIDENTIAL INFORMATION disclosed to such Party or its Affiliates hereunder shall constitute a breach of this Agreement by such Party and not a breach of such Underlying Agreement.

## 16 DISPUTE MANAGEMENT

Any dispute arising out of or relating to this Agreement will be settled by discussions between the responsible persons outlined in Appendix Two. If the dispute remains unresolved it will be escalated to the Head of Drug Safety Iroko and ASPEN' S Executive of Strategic Business Development and Pharmaceutical Affairs (presently, Mrs. Lorraine Hill). In the event of continued conflict the provisions in Section of the Exclusive License Agreement shall apply.

## 17 MISCELLANEOUS

17.1 Sections 4, 20, 21, 23, 24 and 27 to 32 of the Exclusive License Agreement shall apply to this Agreement.

17.2 Failure to comply with the terms of the SDEA will be managed according to the procedure defined in Section 24 of the Exclusive License Agreement ("Term and Termination").

17.3 Except where the context otherwise requires, wherever used the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders. The words "hereof and "hereunder", and words of similar import, shall be construed to refer to this Agreement (including the Annexes hereto) as an entirety and not to any particular provision. The word "including" as used herein shall mean, including, without limiting the generality of any description preceding such term. The word "or" is used in the inclusive sense (and/or). Any reference in this Agreement to a matter or action being subject to the "mutual agreement" or "mutual consultation" of two (2) or more of the Parties, or words of similar import, shall not be construed as an agreement that such Parties shall agree to such matter or action. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against any Party.

17.4 This Agreement (including the Appendices hereto) constitutes, on and as of the Effective Date, the entire agreement of the Parties with respect to the subject matter of this Agreement, and all prior or contemporaneous understandings or agreements, whether written or oral, between the Parties with respect to such subject matter are superseded.

17.5 The agreements, covenants and representations contained herein are for the benefit of the Parties only and are not for the benefit of any Third Parties.

## 18 REVIEW OF AGREEMENT

This SDE Agreement may be amended from time to time as required taking into account changes to Applicable Laws or regulatory guidance to improve compliance with pharmacovigilance activities covered by this Agreement between the parties. Each Party may recommend a change to the Agreement. The amended Agreement will not take effect until reviewed and signed by authorised representatives of each Party.



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19 **TERMINATION OF THE AGREEMENT**

19.1 This Agreement will be co-terminous with the expiration or termination of the Exclusive License Agreement and managed according to the procedures detailed therein.

19.2 This Agreement supersedes any previous version(s), and is effective upon signatures by authorised representatives of each Party.

19.3 Each Party is bound by its requirements, and it is in effect until each Party agrees to terminate the Agreement or the Exclusive License Agreement is terminated.

‘19.4 Should the Exclusive License Agreement be terminated in its entirety, Iroko and Aspen agree to implement the necessary procedures and practices to ensure that Pharmacovigilance obligations are fulfilled, including safety reporting obligations for any Medicinal Products that may remain in the marketplace.

This Agreement represents the entire and integrated agreement between the Parties in respect of Pharmacovigilance/Safety Issues and supersedes all prior negotiations, representations or agreements either written or oral, regarding its subject matter.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorised representatives, to be effective as of the Effective Date.

SIGNED for and on behalf of
**Iroko Pharmaceuticals (Luxembourg) Sari**

Name of Signatory

Date

SIGNED for and on behalf of
**Aspen Pharmacare Holdings Limited**

Name of Signatory

Date



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## APPENDIX ONE: IROKO SAFETY CONTACTS

**Single Case Management**

For individual case safety reports

Rachael Becker
Drug Safety Specialist

Tel: 44(0) 1985 273433
Fax: 44(0) 1895 231847
E-mail: drugsafety@parexel.com

Parexel PPV
101-105 Oxford Rd.
Uxbridge, Middlesex
UB8 1LZ
UK

**QPPV**

Jonathan West
Associate Director, PAREXEL
PharmacoVigilance
101-105 Oxford Road
Uxbridge, Middlesex
UB8 1LZ
UK

Mobile (for urgent safety and regulatory issues only): 44(0) 7764 143537

Tel: 44(0) 1895 273434
Fax:
E-mail:

**Chief Medical Officer**

Susan Langer, M.D.

Tel:
Fax:
E-mail:

Tel: 267/546-3011
Fax: 267/546-3004
E-mail: slanger@iroko.com



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**APPENDIX ONE: ASPEN SAFETY CONTACTS**

| | | |
|---|---|---|
| For individual case safety reports & medical queries | Carol Sendall<br>Medical Affairs Manager<br>Tel: (0027) 11-2396524<br>Email: sendallc@aspenpharma.com | Aspen Pharmacare,<br>Building 12, Healthcare Park<br>Woodlands Drive,<br>Woodmead<br>Johannesburg<br>South Africa |
| Regulatory | Lorraine Hill<br>Executive : Regulatory Affairs and Responsible Pharmacist<br>Tel : (0027) 31 5808605<br>E-mail : LHill@aspenpharma.com | Aspen Pharmacare,<br>1st Floor Aspen House<br>Aspen Park<br>98 Armstrong Avenue<br>La Lucia Ridge<br>Durban<br>4019<br>South Africa |



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**APPENDIX K**

**TERMINATION IN THE EVENT OF IROKO LAUNCHING A NEW VARIANT (*vide* clause 25.5)**

1. In the event of IROKO launching a new variant within the PRIORITY COUNTRIES during the term of this AGREEMENT, then IROKO shall give to ASPEN no less than 6 (SIX) months written notice ("the Variant Notice") of its intention to do so, which Variant Notice shall –

1.1 give full details of the new variant, including its indications and active pharmaceutical ingredients;

1.2 specify that part/s of the TERRITORY ("the Applicable Territory") in which the new variant is to be launched; and

1.3 specify when the new variant is to be so launched ("the Launch Date").

2. Within 10 (TEN) days of receipt by ASPEN of the Variant Notice, the PARTIES undertake to enter into negotiations in good faith in an endeavour to reach agreement on the terms and conditions of the COMMERCIALISATION of the new variant by ASPEN and/or its AFFILIATES in the Applicable Territory and, if the PARTIES fail to reach such agreement ("a Deadlock") within 40 (FORTY) days of the receipt by ASPEN of the Variant Notice, then IROKO shall, subject to the provisions of clause 3 below, be entitled to COMMERCIALISE or procure the COMMERCIALISATION of (as the case may be) the new variant in the Applicable Territory on such terms and subject to such conditions as it may elect.

3. In the event of –

3.1 a Deadlock;

3.2 IROKO launching a new variant in the Applicable Territory; and

3.3 the sales volumes of any PRODUCT (the "Affected Product") in the country ("the Affected Country") in the Applicable Territory declining by 20% (TWENTY PERCENT) or more in any 12 (TWELVE) months consecutive rolling period within 18 (EIGHTEEN) months from the Launch Date, and such decline is not as a consequence of general market conditions (as defined below) relevant to the PRODUCTS:

then –

3.4 Within 24 (TWENTY FOUR) months of the Launch Date, ASPEN shall have a one-time option, on written notice to IROKO, to terminate the AGREEMENT in respect of the Affected Product in the Affected Country and IROKO shall pay to ASPEN compensation determined in accordance with the following formula, namely –

**[***]**

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For the avoidance of doubt, ASPEN' S right to terminate the AGREEMENT pursuant to the provisions of this Appendix K shall be on a PRODUCT-by-PRODUCT and country-by-country basis and the AGREEMENT shall persist and remain of full force and effect in respect of those PRODUCTS and/or countries which are not the subject matter of the termination.

For the purposes of this Appendix K –

"general market conditions" shall mean conditions affecting the COMMERCIALISATION of the PRODUCTS caused by factors which do not directly or indirectly relate to the launch of a new variant.



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**FIRST ADDENDUM AGREEMENT TO THE EXCLUSIVE SUBLICENSE AGREEMENT**

**between**

**IROKO PHARMACEUTICALS (LUXEMBOURG) SARL**

**and**

**ASPEN PHARMACARE HOLDINGS LIMITED**

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**FIRST ADDENDUM AGREEMENT TO THE EXCLUSIVE SUBLICENSE AGREEMENT**

## 1. DEFINITIONS

Unless otherwise expressly stated, or the context otherwise requires, the words and expressions defined in the AGREEMENT shall bear the same meaning in this ADDENDUM as those ascribed to them in the AGREEMENT. Unless otherwise expressly stated, or the context otherwise requires, the words and expressions listed below shall when used in this ADDENDUM, including this introduction, bear the meaning ascribed to them:

1.1 "ADDENDUM" means this Addendum to the Agreement;

1.2 "AGREEMENT" means the Exclusive Sublicense Agreement between IROKO and ASPEN, dated 6 December 2007.

## 2. INTRODUCTION

2.1 The PARTIES entered into the AGREEMENT.

2.2 The PARTIES wish to amend the AGREEMENT in accordance with the terms and subject to the conditions set out in this ADDENDUM.

## 3. AMENDMENT OF AGREEMENT

The AGREEMENT is hereby amended in the following respects:

3.1 **Clause 2.2.2.2**

By amending clause 2.2.2.2 to read –

"2.2.2.2 "**AFFILIATE/S**" means, in relation to one person, any other person which is CONTROLLED by, under common CONTROL with, or CONTROLS the other;"

3.2 **Clause 2.2.2.6**

By amending clause 2.2.2.6 to read –

"2.2.2.6 "**ASPEN**" means ASPEN PHARMACARE HOLDINGS LIMITED, Registration Number 1985/002935/06, a company duly registered and incorporated in accordance with the company laws of the Republic of South Africa and having its registered office at Building 8, Healthcare Park, Woodlands Drive, Woodmead, ‚Johannesburg, Republic of South Africa, or in the event of ASPEN exercising its rights of nomination in terms of clause 33, MAURITIUS HOLDCO or any assignees or nominees under this AGREEMENT, and any AFFILIATES of the aforegoing persons;"



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3.3 **Clause 2.2.2.11**

By amending clause 2.2.2.11 to read –

"2.2.2.11 "**CONTROL", "CONTROLLED" or "CONTROLS**" means either (I) (x) the ownership of more than 50% (FIFTY PERCENT) of the voting shares or interests of a person carrying the rights to vote at general meetings or (y) the power to nominate a majority of the board of directors of a person; or (II) the ability to determine the policies and/or management of a person, whether through the ownership of securities, by contract or otherwise."

3.4 **Clause 2.2.2.13**

By amending clause 2.2.2.13 to read –

"2.2.2.13 "**CONDITION**" means the suspensive condition to this AGREEMENT as set out in clause 4."

3.5 **Clause 2.2.2.16**

By amending clause 2.2.2.16 to read –

"2.2.2.16 "**EFFECTIVE DATE"** means the first day of the month following the month in which the CONDITION is fulfilled, but in no circumstances later than 1 April 2008;"

3.6 **Clause 2.2.2.22 et seq.**

By amending clause 2.2.2.22 by the deletion of the term "LICENSE FEE PERIOD" and substituting it by "ROYALTY FEE PERIOD" and by deleting all references to "LICENSE FEE PERIOD" throughout the AGREEMENT, including for the avoidance of doubt, throughout the Appendices to the AGREEMENT, and substituting it by "ROYALTY FEE PERIOD".

3.7 **New Clause 2.2.2.24A**

By inserting a new clause 2.2.2.24A after clause 2.2.2.24 to read –

"2.2.2.24A "MAURITIUS HOLDCO" means Aspen Global Incorporated, Company Number 078138, a company Incorporated in Mauritius, having its registered address at care of Kross Border Trust Services Limited, Manor House, 1st Floor, Cnr St George / Chazal Streets, Port Louis, Mauritius;"

3.8 **Clause 2.2.2.34 et seq.**

By amending clause 2.2.2.34 by the deletion of the term "QUARTERLY LICENSE FEE" and substituting it by "QUARTERLY ROYALTY FEE" and by deleting all references to "QUARTERLY LICENSE FEE" throughout the AGREEMENT, including for the avoidance of doubt, throughout the Appendices to the AGREEMENT, and substituting it by "QUARTERLY ROYALTY FEE".



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3.9 **Clause 3.5**

By amending clause 3.5 by the deletion of "15 March 2008" where it appears at the end thereof and substituting it by "15 April 2008".

3.10 **Clause 4.1**

By amending clause 4.1 to read –

"4.1 This AGREEMENT is subject to the fulfilment of the CONDITION that by no later than 15 March 2008, ASPEN obtains the written approval, to the extent necessary, of the Exchange Control Department of the RSA Reserve Bank pursuant to the Currencies and Exchanges Act, 9 of 1933 to the contents of this AGREEMENT. ASPEN hereby represents that no other approvals are required from the South African or Mauritius authorities, including the South African Department of Trade and Industry."

3.11 **Clause 4.3**

By deleting clause 4.3.

3.12 **Clause 4.4**

By amending clause 4.4 by the deletion of the words "(but subject to clauses 4.2 and 4.3)" and substituting same with "(but subject to clause 4.2)" and by renumbering clauses 4.4, 4.4.1 and 4.4.2 as clauses 4.3, 4.3.1 and 4.3.2.

3.13 **Clause 5.1**

By amending clause 5.1 by the deletion of the words "after the end of each calendar quarter" and substituting same with "after the receipt by IROKO of the amounts payable from time to time by MERCK to IROKO during the MERCK DISTRIBUTION TERM. For the avoidance of doubt, IROKO' s obligation shall be solely to pay 50% (FIFTY PERCENT) of the amount so received."

3.14 **Clause 7.1**

By amending clause 7.1 by amending and restating the penultimate sentence thereof as follows –

"The MERCK FEE shall be paid quarterly, in United States Dollars, within 10 (TEN) BUSINESS DAYS after the receipt by IROKO of the amounts payable from time to time by MERCK to IROKO during the MERCK DISTRIBUTION TERM, together with a report reconciling the amounts so paid, and, for the avoidance of doubt, IROKO' s obligation shall be solely to pay 50% (FIFTY PERCENT) of the amount so received."

3.15 **Clause 13**

By amending the heading to clause 13 to read "ROYAL/TAX" and by amending the Index to the AGREEMENT accordingly.



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3.16 **Clause 13.1.1**

By amending clause 13.1.1 by the deletion of the words "a once-off license fee" where they appear in the first line thereof and substituting them by the words "a once-off payment".

3.17 **Clause 13.3**

By amending clause 13.3 by the deletion of the words "within 7 (SEVEN) days of the date of fulfilment of the CONDITIONS" where they appear in the first and second lines thereof and by substituting them with the words "on 2 April 2008".

3.18 **Clause 13.10**

By amending clause 13.10 to read –

"13.10 Where any withholding tax may be reduced as a consequence of the Luxembourg/Mauritius Double Tax Agreement ("DTA"), IROKO may qualify for relief under the DTA. To so apply for relief under the DTA, ASPEN undertakes to approach the Mauritian Revenue Authority on behalf of IROKO and to submit such documentation supplied by IROKO to support the application for the withholding exemption certificate which may reduce any withholding tax payable".

3.19 **Clause 13.11**

By deleting clause 13.11.

3.20 **Clause 14.1**

By amending clause 14.1 to read -

"14.1 For the MANUFACTURING TERM, ASPEN shall MANUFACTURE and PACKAGE the PRODUCTS (other than; Initially, the SUPPOSITORIES, ALDOMET® (METHYLDOPA) TABLETS 125MG and/or SRC PRODUCT) *for* COMMERCIALIZATION (1) by IROKO in those countries (other than the Territory), where it holds rights to COMMERCIALIZE the PRODUCTS and (2) by ASPEN in the TERRITORY, all in accordance with the WORLDWIDE MANUFACTURING AND SUPPLY AGREEMENT and the provisions of Appendix J. It being expressly agreed that ASPEN shall have the right to sub-contract its obligations to MANUFACTURE and PACKAGE the PRODUCTS to Pharmacare Limited, also an Affiliate of ASPEN, in terms of a Toll Manufacturing Agreement to be entered into between ASPEN and Pharmacare Limited."

3.21 **Clause 16.1.4**

By amending clause 16.1.4 to read -

"16.1.4 It owns 100% (ONE HUNDRED PERCENT) of the capital stock/share capital of MAURITIUS HOLDCO and throughout the term of this AGREEMENT, will CONTROL MAURITIUS HOLDCO."



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3.22 **Clause 23.1**

By amending clause 23.1 by the deletion of the square brackets where they appear before the word "Vice" and after the word "Affairs" in the fifth line thereof."

3.23 **Clause 33**

By amending the first three lines of clause 33 to read –

"Subject to IROKO' S prior written consent, which consent shall not be unreasonably withheld or delayed, ASPEN shall be entitled, but not obliged, to designate by delivering written notice to that effect to IROKO on or before the EFFECTIVE DATE, MAURITIUS HOLDCO ("nominee") to be ASPEN' S nominee under this AGREEMENT, whereupon -"

3.24 **Clause 33.1.2**

By amending clause 33.1.2 to read –

"all references in this AGREEMENT to ASPEN shall be deemed to be references to the nominee, except as the context otherwise requires. For the avoidance of doubt and without in any way limiting the scope of the foregoing exception, all references to ASPEN in this clause 33 shall be to "Aspen Pharmacare Holdings Limited" and the reference to ASPEN In clause 16.1.4 shall be to "Aspen Pharmacare Holdings Limited".

3.25 **Clause 33.2**

By amending and restating clause 33.2 to read-

"ASPEN Irrevocably and unconditionally guarantees to IROKO the due and punctual observance and performance of all of the terms, conditions and covenants by the nominee contained in this AGREEMENT, including (I) to pay to IROKO, from time to time, on demand any and every sum or sums of money which the nominee is at any time liable to pay to IROKO under or pursuant to this AGREEMENT and which has become due and payable but has not been paid at the time such demand is made; and (ii) to cause the nominee to perform, and failing such performance by the nominee, perform Itself all obligations required to be performed by the nominee under this AGREEMENT.

The obilgations set forth in this clause 33 (hereafter, the " Guarantee") shall be a guarantee of payment or performance, as the case may be with respect to the underlying obligations under this AGREEMENT, and not a guarantee of collection. ASPEN shall perform Its obligations under this Guarantee regardless of whether any claim is made against the nominee In respect of any of its obligations."

3.26 **Appendix E**

By the deletion of Appendix E and substituting It by the Appendix E as is annexed hereto.



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3.27 **Appendix F**

By the deletion of Appendix F and substituting It by the Appendix F as is annexed hereto.

3.28 **Appendix H**

By the deletion of Appendix H and substituting It by the Appendix H annexed hereto.

3.29 **Appendix J**

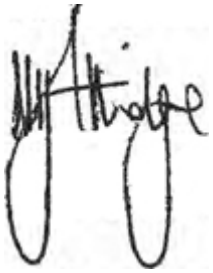
By the deletion of Appendix J and substituting it by the Appendix J annexed hereto.

**4. REMAINDER OF THE AGREEMENT**

Save as is expressly set out above or as necessarily implied by the context hereof, all other terms of the AGREEMENT shall remain of full force and effect.

SIGNED at DURBAN, RSA on this 1ST day of April, 2008.

**For: ASPEN PHARMACARE HOLDINGS LIMITED**



**MICHAEL GUY ATTRIDGE**, he warranting by his signature that he is duly authorized hereto

SIGNED at PHILADELPHIA, PA on this 1ST day of April, 2008.

**For: IROKO PHARMACEUTICALS (LUXEMBOURG) SARL**

**OSAGIE IMASOGIE**, he warranting by his signature that he is duly authorised hereto



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## APPENDIX E

## FORMULA FOR THE DETERMINATON OF THE QUARTERLY LICENSE FEE

**[***]**

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**[***]**

**[***]**

**[***]**

**[***]**

Should IROKO dispute the QUARTERLY LICENSE FEE, then the PARTIES shall enter into negotiations in good faith with regard -to agreeing the QUARTERLY LICENSE FEE or, failing such agreement within 10 (TEN) days after the commencement of such negotiation, either PARTY shall be entitled to refer the dispute/disagreement for determination by an Independent auditor appointed by agreement between the PARTIES, in writing, or falling such agreement within 5 (FIVE) days after either PARTY has required such referral, appointed by the President for the' time being of the South African Institute of Chartered Accountants (or his successor-in-title) if IROKO requests such an appointment, or appointed by the then President of the Luxembourg lnstitut des Reviseurs d' Entreprises (or his successor-in-title), if ASPEN requests such an appointment Such auditor shall act as an expert and not as an arbitrator and his decision shall, save for any manifest error, be final and binding on the PARTIES.

IROKO shall be entitled, at all reasonable times, either directly or through its duly authorised agents, to undertake an inspection and/or audit of all or any of ASPEN' S reports, books of account, manufacturing facilities and the like in an endeavour to verify that the QUARTERLY LICENSE FEE has been correctly calculated and ASPEN shall give IROKO and/or its duly agents, its full co-operation in this regard. The authorised agent or representatives of IROKO shall, however, prior to conducting any such inspection and/or audit, enter into a "confidentiality and lock-out agreement" in a form reasonably acceptable to ASPEN that would require the agent or representative to maintain confidentiality of the information obtained and desist from trading in the securities of ASPEN for a period specified therein.

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## APPENDIX F

## TEMPLATE TERRITORY PRO-FORMA INCOME STATEMENT OF THE BUSINESS ACTIVITY

**[***]**

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**APPENDIX H**

**MANUFACTURING PROVISIONS**

1. The price for the PRODUCTS supplied by ASPEN shall be ASPEN' S costs of MANUFACTURING and PACKING the PRODUCTS (including but not limited to the cost of procuring any manufacturing material, packaging material, packaging Inserts, active and other ingredients, excipients, raw materials and other components of the PRODUCTS used to MANUFACTURE and/or PACK the PRODUCTS, but excluding any profits earned or retained by ASPEN and/or its AFFILIATES pursuant to the MANUFACTURING and/or PACKING of the PRODUCTS), calculated [***], determined in accordance with IFRS.

2. IROKO shall be entitled, at all reasonable times, and during regular business hours, either directly or through its AFFILIATES, to undertake an inspection and/or audit of all or any of ASPEN' S reports, books of account, manufacturing facilities and the like in an endeavour to verify that the PRICE has been calculated [***] and ASPEN shall give IROKO and/or its duly authorized agents, its full co-operation in this regard. The authorised agents or representatives of IROKO shall, however, prior to conducting any such inspection and/or audit, enter into a "confidentiality and lock-out agreement" in a form reasonably acceptable to ASPEN that would require the agent or representative to maintain confidentiality of the information obtained and desist from trading in the securities of ASPEN for a period specified therein.

3. Delivery and the remaining supply terms relevant to the PRODUCTS shall be in accordance with the terms of the distribution agreements, from time to time, between ASPEN (on the one hand) and its AFFILIATES or the THIRD PARTY SUB-LICENSEES (on the other hand).

4. ASPEN warrants that the PRODUCTS will be MANUFACTURED and PACKED in accordance with good manufacturing practice, APPLICABLE LAWS and the SPECIFICATIONS.

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**APPENDIX J**

# SAFETY AGREEMENT

**Between**

**IROKO PHARMACEUTICALS (LUXEMBOURG) SARL**

**and**

**ASPEN PHARMACARE HOLDINGS LIMITED OR ITS NOMINEE APPOINTED IN ACCORDANCE WITH THE PROVISIONS OF CLAUSE 33 OF THE EXCLUSIVE SUB-LICENSE AGREEMENT (AS DEFINED ON PAGE 2 HEREOF)**

**for the Safety Management of**

**ALDOMET® (METHYLDOPA) AND INDOCIN (INDOMETHACIN)®**

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**Safety Agreement**

This Safety Agreement dated April 1, 2008 (the "Effective Date") is made by and between Iroko Pharmaceuticals (Luxembourg) Sarl, a Société Anonyme a Responsabilité Limitée formed under the laws of Luxembourg ("Iroko"), whose principal office is at 65, boulevard Grande-Duchesse Charlotte, L-1331, LUXEMBOURG, and Aspen Pharmacare Holdings Limited, a South African Company ("Aspen"), whose principal office is at Building 8 Healthcare Park, Woodlands Drive, Woodmead, Sandton 2052, Gauteng, Republic of South Africa or its nominee appointed in terms of clause 33 of the Exclusive Sub-License Agreement, dated April 1, 2008 between Aspen Pharmacare Holdings Limited and Iroko ("the Exclusive License Agreement"). In this Agreement Iroko and Aspen will each be known as a "Party' ' and collectively, as the "Parties". This Agreement will govern safety data exchange for ALDOMET® (METHYLDOPA) and INDOCIN® (known collectively as the "Medicinal Products") by them or their Affiliates in connection with the Exclusive License Agreement.

NOW THEREFORE the Parties hereby agree as follows:

**Glossary of Abbreviations and Definition of Terms**

Capitalised terms used but not otherwise defined herein will have the meanings given such terms in the Exclusive License Agreement to the extent defined therein.

For other terms throughout this Agreement, the following definitions will apply:

**Abuse:** Persistent or sporadic intentional excessive use of a Medicinal Product by a patient or Clinical Trial subject accompanied by harmful physical and/or psychological effects.

**Adverse Event ("AE"):** Any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a Medicinal Product, whether or not considered related to the Medicinal Product. An Adverse Event,- for the purposes of this Agreement, can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease (new or exacerbated) temporally associated with the use of the Medicinal Product. It includes failure to produce expected benefits (i.e. lack of efficacy), abuse or misuse.

**Adverse Drug Reaction ("ADR"):** Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product where a causal relationship cannot be excluded.

**Affiliate:** In relation to one person, any other person which is CONTROLLED by, under common CONTROL with, or CONTROLS the other. Without limiting the generality of the foregoing, a company shall be deemed to have CONTROL of another if (directly or indirectly) it owns a majority of the voting shares of or is entitled (directly or indirectly) to appoint a majority of the directors of the other company. "CONTROL" means the ability to determine the policies and/or management of a person, whether through the ownership of securities, by contract or otherwise;

**Agreement:** This agreement including any schedules attached to it and any written agreement, document or instrument entered into, made or delivered pursuant to its terms, as any of them may, from time to time, be supplemented.

**Allocated Territories:** Those countries, territories or other jurisdictions for which each Party has responsibilities as defined in this Agreement or the Exclusive License Agreement and which have been allocated to a Party pursuant to the schedule attached here as Appendix One.



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**Applicable Law:** All or any statutes, subordinate legislation and common law, regulations, ordinances and bylaws, and directives, codes of practice, circulars, guidance notes, judgment and decisions of any competent authority.

**Business Day:** Any day other than a Saturday, Sunday or official public holiday in the Republic of South Africa and/or the Grand Duchy of Luxembourg, as the case may be.

**Calendar Day:** Any 24 hour day of the seven day week.

**CIOMS-i:** A standardised international reporting form for individual case safety reports.

**CIOMS-ii:** An international reporting standard for periodic reporting tables.

**Clinical Study or Clinical Trial:** Any interventional investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product, and/or identify any adverse reactions to a Medicinal Product, and/or to study absorption, distribution, metabolism, and excretion of a Medicinal Product with the object of ascertaining its safety and/or efficacy. The terms “Clinical Trial” and “Clinical Study” are synonymous.

**Company Core Safety Information (“CCSI”):** Safety information prepared by any MAH that the MAH requires to be included in all Product Labelling in all countries to which the MA held by such MAH applies, except where a local Regulatory Authority specifically requires a modification. CCSI is the reference information by which Listed Adverse Drug Reactions and Unlisted Adverse Drug Reactions are determined for the purpose of periodic reporting for marketed products.

**Compassionate Use:** The use of an investigational Medicinal Product for an unapproved indication, in circumstances where a Party has supplied it for that use in response to a bona fide unsolicited request from a healthcare professional assuming responsibility for that use by their patient.

**Counterfeit Medicinal Product:** One that is deliberately and fraudulently mislabeled with respect to identity and source.

**Data Lock Point (“DLP”):** The data lock point is defined as the cut-off data for data to be included in a PSUR. It may be set according to the international Birth Date (IBD) of the Medicinal Product. The MAH should in any case submit the PSUR no later than 60 days after the DLP or as required by Applicable Law, if earlier.

**Documentation:** All records in any form (including, but not limited to, written, electronic, magnetic and optical records and scans, radiographs and electrocardiograms) that describe or record safety data and safety related activities covered by this Agreement.

**European Economic Area (“EEA”):** All countries that are member states of the European Union, as constituted from time to time, including upon accession, new member states of the European Union, plus Norway, Iceland and Liechtenstein.

**European Union (“EU”):** All countries that are member states of the European Union, as constituted from time to time, including upon accession, new member states of the European Union.

**Expected Adverse Drug Reaction:** An Adverse Drug Reaction where the nature and/or severity of the reaction is consistent with the term or description used in the IB, CCSI or Local SmPC.



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**International Birth Date:** The date that the Medicinal Product is first licensed anywhere in the world.

**Investigator Brochure ("IB"):** A compilation of the clinical and non-clinical data on the Investigational Medicinal Product(s) which is relevant to the study of such Investigational Medicinal Product(s) in human subjects.

**Investigational Medicinal Product ("IMP.")** A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a Clinical Study, including a product with a Marketing Authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

**Lack of Efficacy Report:** a report of a situation where there is apparent failure of the Medicinal Product or medical technology to bring about the intended beneficial effect on individuals in a defined population with a given medical problem, under ideal conditions of use.

**Line Listing:** Listings of safety data according to defined requirements to meet regulatory reporting obligations e.g. every six (6) months safety line listing required to meet the EU Clinical Trial Directive (2001/20/EC) requirements (as amended from time to time).

**Listed Adverse Drug Reaction:** An ADR, the nature, severity, specificity and outcome of which are consistent with the information in the applicable CCSI or equivalent reference label.

**Marketing Authorisation ("MA"):** Authorisation to market a Medicinal Product.

**Marketing Authorisation Holder ("MAH' ' ):** The entity to which an MA has been issued by a Regulatory Authority that allows the holder to place the Medicinal Product on the market, in compliance with the terms of the MA.

**Medically Important:** AEs requiring medical and scientific judgment to determine if expedited reporting is appropriate. Such events may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes constituting SAEs. Medical and scientific judgement should be exercised in deciding whether an event is a Medically Important Event. Examples of Medically Important Events include intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalisation; or development of drug dependency or drug abuse. For the avoidance of doubt, infections resulting from contaminated medicinal product will be considered a Medically lmportant Event and subject to expedited reporting requirements.

**Misuse:** Use of a Medicinal Product in a way that is not in accordance with its Marketing Authorisation accompanied by harmful physical and/or psychological effects.

**Non-Serious Adverse Event:** An Adverse Event that does not meet the criteria for a Serious Adverse Event.

**Overdose:** A dose taken (accidentally or intentionally) exceeding the dose as prescribed by the protocol or the maximal recommended daily dose as stated in the Product Labelling, (as it applies to the daily dose for the subject/patient in question). The Parties agree that in the course of conducting a Clinical Study, the terms of the Clinical Study Protocol (as fully approved by all applicable bodies) override the local Product Labelling.



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**Periodic Report:** A report of Adverse Events prepared and submitted on a periodic basis to Regulatory Authorities that contains collated data on single case reports and addresses the risk-benefit profile of the Medicinal Product. Periodicity of reporting varies according to local rules and the nature of the report e.g. submitted pursuant to Applicable Laws and regulatory requirements for trial or post-authorisation requirements.

**Periodic Safety Update Report ("PSUR"):** A report of Adverse Events prepared and submitted on a periodic basis to Regulatory Authorities PSUR includes updates on urgent Safety Issues, major signal detection/evaluation, and changes in efficacy.

**Pharmacovigilance:** The science and activities relating to the detection, collection, recording assessment, understanding, reporting, prevention and/or management of AEs or other Safety Issues related to Medicinal Products and their use.

**Post-Authorisation Safety Study ("PASS"):** Any study carried out in accordance with the terms of the MA, conducted with the aim of identifying or quantifying a safety hazard relating to the authorised Medicinal Product.

**Pregnancy Reports:** Reports of pregnancy following maternal or paternal exposure to the product.

**Product Complaints:** Complaints arising from potential deviations in the manufacture, packaging or distribution of the Medicinal Product.

**Product Labelling:** Description of the Medicinal Product and summary of use, safety, and effectiveness that is used internally (e.g. IB and CCSI) or which must be approved by Regulatory Authorities (e.g., Summary of Product Characteristics in the EU).

**Qualified Person for Pharmacovigilance ("QPPV"):** A person from within the EEA Territory appointed by the MAH as responsible for the establishment and maintenance of the Pharmacovigilance system as It pertains to the EEA.

**Regulatory Authority:** Any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities, including the U.S. Food and Drug Administration, the European Medicines Agency, the European Commission, or any other entity exercising regulatory authority with respect to the development, registration, manufacturing, marketing, distribution, transportation, or sale of a Medicinal Product.

**Risk Management Plan:** A document which describes a set of Pharmacovigilance activities and interventions designed to proactively identify, characterise and prevent or minimise risks related to Medicinal Products, Including risk communication and the assessment of effectiveness of risk minimisation interventions.

**Safety Database:** A validated database that stores data, compiles, integrates, and produces reports of AEs/SAEs from all reporting sources. Reporting capabilities Include Individual safety reports, Periodic Reports, and customised reports from queries.

**Safety Issue:** Any information suggesting an emerging safety concern or possible change in the risk-benefit balance for the Medicinal Product, including information on a possible causal relationship between an Adverse Event and the Medicinal Product, the relationship being unknown or incompletely documented previously.



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**Serious Adverse Event ("SAE")/Serious Adverse Reaction ("SADR"):** is an event or any untoward medical occurrence that at any dose either:

a) Results In death; or

b) Is life-threatening

***NOTE:*** The term "life-threatening" in the definition of "serious" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe; or

c) Requires in-patient hospitalisation or prolongation of existing hospitalisation; or

d) Results in persistent or significant disability/incapacity, or

e) Results in a congenital anomaly/birth defect; or

f) Results in a medically important event or reaction.

**Spontaneous Report:** An unsolicited communication in any form from any source to a company, Regulatory Authority or other organisation that describes an Adverse Event or reaction in a patient given one or more Medicinal Products and which does not derive from a Clinical Study or other organised data collection scheme.

**Suspected Unexpected Serious Adverse Reaction (SUSAR)**

**Third Party:** Any person other than the Parties and their Affiliates.

**Unexpected Adverse Drug Reaction:** An Adverse Drug Reaction where the nature and/or severity of the reaction is not consistent with the term or description used in the IB .

**Unlisted Adverse Drug Reaction:** An ADR, the nature, severity, specificity or outcome of which is not consistent with the information included In the applicable CCSI or local equivalent reference label. ·

**Valid Case:** A case that includes each of the following minimum criteria:

An identifiable patient;

The name of the suspect Medicinal Product(s) or Clinical Study if considered related to a Clinical Study procedure/design;

An identifiable reporting source;

An event or outcome.



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## 1 SAFETY DATA EXCHANGE

### 1.1 General Terms

1.1.1 This Agreement will govern the exchange of all safety related information and data from all sources for the Medicinal Products between the Parties and their Affiliates pursuant to the Exclusive License Agreement. Each Party may delegate its responsibilities hereunder In whole or in part to its respective Affiliates.

1.1.2 On matters related to safety, this Agreement will take precedence over any other agreement between the Parties.

1.1.3 Each Party shall cause its respective Affiliates and any such Third Parties performing activities on behalf of such party that perform responsibilities pursuant to this Agreement or the Exclusive License Agreement to comply with the terms and provisions of this Agreement.

1.1.4 The Allocated Territories for which Aspen has certain responsibilities with respect to The Medicinal Products as set forth herein as of the Effective Date are detailed in Appendix One of this Agreement. Such Allocated Territories (and the Parties assigned thereto) may be modified solely by written amendment of this Agreement as executed by both Parties.

1.1.5 Each Party will agree to follow and comply with all Applicable Laws when performing activities covered by this Agreement. Aspen agrees to advise Iroko of the Applicable Laws in its Allocated Territories relating to Pharmacovigilance. Further, nothing herein shall preclude the Qualified Person for Pharmacovigilance (QPPV) for the Medicinal Products from performing his or her obligations as QPPV under Applicable Law and no such performance, to the extent reasonably required by Applicable Law, shall constitute a violation by any Party of this Agreement.

1.1.6 Iroko will have a nominated Qualified Person for Pharmacovigilance (QPPV) and an·appropriate deputy in accordance with requirements in the EU. Contact details for the QPPV(s) for the Medicinal Products are provided in Appendix Two.

1.1.7 Where national regulations in any Allocated Territory require a nominated or responsible individual in that jurisdiction who has specific legal obligations in respect of Pharmacovigilance at a national or local level, the Party responsible for that Allocated Territory shall designate an appropriately qualified individual to fulfill this role for the Medicinal Products. The Parties agree to provide reasonable assistance to such individuals in complying with their legal and regulatory obligations and responsibilities.

1.1.8 Any Party with responsibility with respect to an Allocated Territory shall use reasonable efforts to notify the other Party of any material changes to Applicable Law in such Allocated Territory, of which it becomes aware, provided that this is published and generally available, that could have an impact on the terms of, or performance of, obligations under this Agreement; *provided, however,* that a failure to do so shall not constitute a breach of this Agreement.

1.1.9 Each Party agrees to have and maintain adequate Pharmacovigilance systems (such as standard operating procedures, work instructions, electronic databases and business continuity plans) and resources (this Includes staff training) to



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ensure compliance with all Applicable Law in its Allocated Territories. Each Party agrees to ensure all relevant staff are informed and trained on the process for safety data exchange as described in this Agreement.

1.1.10 For the avoidance of doubt, compliance with clause 1.1.9 above will include compliance with all applicable privacy and data protection laws, rules and regulations.

1.1.11 Each Party agrees to implement all reasonable physical, technical and administrative safeguards to protect adverse event information from loss, misuse and unauthorised access, disclosure, alteration or destruction.

1.1.12 Each Party agrees to notify the other promptly of any loss, misuse, unauthorised access, disclosures, alteration or destruction of such information of which they become aware.

1.1.13 Contacts for the respective responsibilities within this Agreement are defined in Appendix Two. Each Party agrees to notify the other Party within five (5) Business Days of any changes to the identity or contact information for such contacts set forth in Appendix Two.

1.2 **Rules of Exchange**

1.2.1 Iroko will hold and maintain the global Safety Database of AE reports received by any Party or their Affiliates/Third Parties worldwide for the Medicinal Products.

1.2.2 Direct access to the global Safety Database for the Medicinal Products will not be granted to Aspen (or its Affiliates) but Iroko shall be obliged to provide all reasonable assistance upon receipt of a reasonable request from Aspen for the purposes of compliance with Applicable Law.

1.2.3 Exchange of all safety data pursuant to this agreement will be undertaken by the Parties in English and to the format and timelines specified herein as applicable. Aspen will provide minimum information within these timelines for non English cases and will follow up with translation thereof within 5 (five) calendar days. Source documents will therefore not be appropriate for non English cases.

1.2.4 Each Party will make reasonable checks to ensure that the safety data that it has sent to the other Party in accordance with the terms of this Agreement have been received by the intended recipient at the other Party. The Parties will confirm receipt of SAE reports from each other by sending a confirmation e-mail with the case ID.

In addition, the Parties will each provide each other with listings of all data received monthly. The Parties agree to take the necessary action and send any such safety data that has not been received within one (1) Business Day for all serious cases, and ten (10) Business Days for all other Information of discovering the discrepancy and take immediate action to avoid repetition.

1.2.5 The responsibilities for the regulatory reporting of individual case safety reports, Periodic Reports and other safety-related communications with respect to the Medicinal Products commercialized by Aspen, to Regulatory Authorities rests with Aspen for its Allocated Territories, according to Applicable Law unless otherwise provided in this Agreement.



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## 2 CLINICAL STUDY SAFETY DATA

### 2.1 General

2.1.1 This Section 2 relates to the receipt and management of individual case safety reports and Periodic Reports that arise from all Clinical Studies and other interventional sources including Compassionate Use of the Medicinal Products sponsored by Aspen. For the avoidance of doubt, Aspen will not conduct any sponsored Clinical Study with the Medicinal Products unless the Parties otherwise agree in writing. Aspen will not be responsible for the receipt and management of individual case safety reports in respect of Clinical Studies and Compassionate Use of the Medicinal Products sponsored by Iroko.

2.1.2 Should the Parties agree to conduct any Clinical Trials or otherwise generate additional clinical data or perform additional analyses of additional clinical data, the terms of this Agreement and specifically this Section, will be renegotiated.

## 3 POST MARKETING SAFETY DATA

This Section 3 applies solely to Spontaneous Reports for the Medicinal Products from all sources received by each Party and reports for the Medicinal Products from all other sources except Clinical Studies.

### 3.1 Individual Case Safety Reports

3.1.1 Aspen will provide to Iroko case reports for the Medicinal Products that meet the Valid Case criteria as defined in this Agreement.

3.1.2 Safety case reports for the Medicinal Products that do not meet the Valid Case criteria should be retained by Aspen and actively followed up by them until Valid Case criteria are met and then forwarded by them to Iroko in the timeframes specified in this Agreement. Aspen should make commercially reasonable efforts to obtain such Valid Case criteria.

3.1.3 In the event of receipt by a Party of a Medicinal Products case report with missing Valid Case criteria containing data in relation to a potential Safety Issue, the Parties may agree to exchange such case reports following discussion and mutual agreement at the time of receipt on a case by case basis.

### 3.2 Receipt Date

3.2.1 For the purposes of this Agreement, the “receipt date” Is the date when any employee of any Party, its Affiliate or its Third Party first becomes aware of safety-related information.

3.2.2 The time clock (in calendar days) for a case for regulatory reporting purposes starts on the date on which the applicable Party has received information with respect to such a case sufficient to demonstrate that all criteria for a Valid Case are met.

3.2.3 The time clock (in calendar days) for regulatory reporting purposes starts at day 0 for all new information pertaining to a Valid Case, such as follow-up information. However, this should not affect the regulatory reporting schedule for information already received ( such as initial case or previous follow-up), and only starts again for that information which is new and received during a separate correspondence to the initial or previous follow-up.



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3.2.4 Date of Initial Notification: The date of initial notification is the date when any representative of Aspen is made aware of the minimum information which constitutes a valid report (an identifiable patient, an Identifiable reporter, a suspected reaction, and a suspect drug). This Includes both verbal and written communication, and is classes as day zero (0) of the regulatory reporting process. The date of initial notification for faxed documents and post will be taken as the day the messages were printed by the fax machine or delivered to the premises respectively. The date of Initial notification for e-mail messages and voice mail messages will be the dates those messages were registered as received by their systems. The date of initial notification for all other scenarios will be the date the communication took place. The date of initial notification of any initial and follow-up Information must be clearly marked on all documents.

3.3 **Follow Up**

3.3.1 Aspen will be responsible for undertaking appropriate and timely follow-up on reports it has received or of which it has become aware and for forwarding to Iroko for processing in accordance with Section 3.4 below.

·3.3.2 Iroko will forward requests for follow-up where required to the relevant Safety Contact at Aspen as defined in Appendix Two.

3.3.3 Aspen agrees to perform follow-up activities as per internal procedures and to action any reasonable requests for follow up received from Iroko and to forward responses in the timelines defined in Section 3.4 below.

3.3.4 Where reports are received from members of the general public, Aspen will attempt follow up with the applicable health care provider, but will still forward valid reports to Iroko in the timelines specified in Section 3.4 below.

3.4 **Exchange of Individual AE/ADR Reports**

3.4.1 Each Party will send reports of individual AEs/ADRs and SAEs/SADRs covered by Section 4 [section reference Incorrect?] to the other Party using the method of exchange, format and within the timelines set out in Table 1 and 2 below.

3.4.2 Each of the Parties will acknowledge receipt of the reports sent as per Table 1, to· the Safety Contact (as set out in Appendix Two) at the other Party within two (2) Business Days of receipt. The Party sending the report agrees to follow up with relevant Safety Contacts of the other Party if acknowledgments are not received from the receiving Party and the sending Party will resend reports to the Safety Contact of the receiving Party where required.

3.4.3 Iroko will enter the single case report safety data received into the global Safety Database as provided from Aspen. In the event that Iroko identifies an event of concern in the case report that has not been identified by Aspen, Iroko will raise a query to Aspen which Aspen will answer within two (2) Business Days. Where agreement cannot be reached Iroko may enter the new term into its Safety Database for the Medicinal Products.



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3.4.4 Aspen shall forward any supplementary supporting data such as laboratory results, discharge letters or autopsy reports to Iroko upon IROKO' S request using the method of exchange, format and within the timelines set out in Table 1 and 2 below. Aspen will ensure any data that would reveal personal details of the patient in discharge summaries and laboratory data or other such documents are scored through in permanent black ink prior to sending such data to Iroko.

3.4.5 In the event of any doubt regarding whether an Adverse Event is a Non-Serious Adverse Event or a Serious Adverse Event, the Parties shall treat that Adverse Event as a Serious Adverse Event. Likewise, in the event of any doubt regarding whether an Adverse Event is fatal, life threatening or serious, or whether an Adverse Event is related or unrelated, the Parties shall classify the Adverse Event in a manner that ensures the shortest relevant reporting timeline.

**Table 1: Timelines for Exchange: From Aspen to Iroko**

| Type of Report | Timeline Aspen to Iroko | Format | Means of Exchange |
|---|---|---|---|
| Fatal/Life threatening ADRs/AEs | Day 1 | Source Documents | E-mail or Fax |
| All other SADRs/SAEs | Day 3 | Source Documents | E-mail or Fax |
| Pregnancies (regardless of associated AEs) | Day 3 | Source Documents | E-mail or Fax |
| Non-serious AEs | Day 10 | Source Documents | E-mail or Fax |

Timelines for exchange are presented in calendar days and are subject to the provisions of 1.2.3 above in respect of non English cases.

**Table 2: Timelines for Exchange: From Iroko to Aspen**

| Type of Report | Timeline Iroko to Aspen | Format | Means of Exchange |
|---|---|---|---|
| All SADRs (including fatal & life threatening) originating in the Aspen Allocated Territories | Day 12 | CIOMS I | E-mail or fax |
| Non serious Unexpected ADRs originating in the Aspen Allocated Territories | Day 12 | CIOMS I | E-mail or fax |

Timelines for exchange are presented in calendar days.

3.5 **Regulatory Authority Notifications**

3.5.1 Iroko will provide reports to Aspen on an appropriate form (CIOMS-I) for submission to the appropriate Regulatory Authority in the Allocated Territories by Aspen and in an appropriate timeframe to allow for compliance with Applicable



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Law. Iroko will have assessed the report as potentially fulfilling the criteria for expedited reporting. Where a shorter timeframe is required by Applicable Law Aspen will submit to the Regulatory Authority source documentation for an AE/SAE arising in the Allocated Territory until the CIOMS-1 is available. The CIOMS-1 should be submitted as a follow up to the original submission.

3.5.2 Aspen will be responsible for preparing and sending all relevant individual reports and applicable safety data covered by this Section 3 in accordance with Applicable Law to Regulatory Authorities in their Allocated Territories where required.

3.5.3 Aspen will confirm to Iroko the actual date of submission to the Regulatory Authorities in its Allocated territories as soon as possible but no later than two (2) weeks after the submission date. Where Aspen fails to meet the timeline for submission under Applicable Laws, it will provide Iroko with the documented reason for late submission and a binding action plan detailing how it will perform such submission in the shortest time possible after such missed deadline. For the avoidance of doubt Aspen will bear all liability for any penalty (if any) imposed by the Regulatory Authority in respect to such late submission.

3.6 **Post Marketing Periodic Reports**

3.6.1 Iroko will be responsible for the preparation or provision to Aspen of Periodic Reports (including PSURs, PSUR addenda or PSUR bridging reports) for the Medicinal Products in accordance with ICH E2C (R) Safety Data Management: Periodic Safety Update Reports and Applicable Law.

3.6.2 Iroko will forward electronic copies of any final PSUR, addendum or bridging report to Aspen within fifty-seven (57) days of the Data Lock Point for the PSUR. Where day 57 falls on a day other than a Business Day, Iroko will adjust the timelines accordingly to enable compliance with reporting requirements.

3.6.3 Aspen will be responsible for the submission of any Periodic Report, PSUR, addendum or bridging report in its Allocated Territories if required.

3.6.4 Aspen will confirm to Iroko the actual date of submission in its Allocated Territories as soon as possible but no later than two (2) weeks after the submission date where submission is required.

3.6.5 Aspen will not use, reference or share any information from periodic reports in any marketing presentation, publication or with any external bodies.

3.6.6 Where the Periodic Report, PSUR, addendum or bridging report does not meet local requirements for periodic safety reporting as specified in the Applicable Law of any of the Allocated Territories, Aspen will notify Iroko and Iroko will perform commercially reasonable endeavours to assist Aspen to meet such requirements in collaboration with Regulatory Authorities.

4 **Literature**

4.1 Iroko or its agent will search bio-medical databases for global English language literature reports and Aspen will perform searches for local language reports in its Allocated Territories on a regular basis to identify literature articles containing references to suspected Adverse Drug Reactions or other safety information of relevance in association with the Medicinal Products and forward them to Aspen in the timelines specified in this Agreement.



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4.2 If local literature articles, including any articles from local media/press releases, require translation, the minimum Valid Case criteria must be translated into English and forwarded to Iroko as per the timelines in Section 5.4. The full translation and the full reference of each non-English language article should be forwarded as follow-up in the timelines described in Section 5.4 upon receipt of the translation.

## 5 PRODUCT COMPLAINTS ASSOCIATED WITH AE REPORTS

5.1 Aspen will collect and report all Product Complaints associated with the Medicinal Products in its Allocated Territories where there is an associated AE or ADR in accordance with the format, timelines and method defined in Section 3.4.

5.2 Follow-up of Product Complaints involving AE reports must be carried out according to the same procedures for any other AE report and exchanged in the timelines defined in Section 3.4 above.

5.3 Aspen will be responsible for carrying out the investigation of such Product Complaints involving the Medicinal Products that Aspen manufactures (e.g. through manufacturing QA) and will forward the results on any manufacturing investigation to Iroko as follow up in the timelines defined in Section 3.4.

5.4 Aspen will notify Iroko of any counterfeit activity in its Allocated Territories of which it becomes aware.

5.5 A monthly summary of all product complaints will be sent to Iroko Pharmacovigilance for reconciliation.

## 6 LACK OF EFFECT REPORTS

6.1 Aspen will collect and report all Lack of Effect Reports associated with the Medicinal Products in accordance with the format, timelines and method defined within this Agreement.

6.2 Follow-up of Lack of Effect Reports must be carried out by Aspen according to the same procedures for any other AE report and exchanged with Iroko in the timelines defined within this Agreement.

## 7 Special Situations

### 7.1 Pregnancy Reports

7.1.1 Aspen will collect and report all reports of pregnancy from female patients or partners of male patients exposed to the Medicinal Products of which it becomes aware. Reports should be forwarded as per the timelines in Section 3.4.

7.1.2 Complications of pregnancy or elective termination of pregnancy will be reported by Aspen to Iroko and forwarded as per the timelines in Section 3.4.

7.1.3 Pregnancy outcome data will be sent by Aspen as follow-up in accordance with the timelines in Section 3.4 as applicable.



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7.2 **Post-Authorisation Clinical Trials and Safety Studies**

Should the Parties agree to conduct any post-authorisation Clinical Trials or Safety Studies that may be of relevance to the safety of the Medicinal Products the terms of this Agreement and specifically this Section, will be renegotiated.

8 **Risk management**

8.1 **Ongoing Pharmacovigilance**

8.1.1 Iroko will be responsible for the identification, investigation, monitoring and management of any Safety Issues specific to the Medicinal Products.

8.1.2 Aspen agrees to alert Iroko if they become aware of a Safety Issue that has the possibility to affect the benefit-risk ratio with the Medicinal Products within one (1) Business Day of it becoming aware of such a Safety Issue. Such events include but are not limited to:

A Safety Issue arising from a Clinical Study or from post-marketing safety data;

A clinically important increase in the rate of occurrence of an expected Serious Adverse Event;

A significant new hazard to the patient population e.g. lack of efficacy with a Medicinal Product used in treating a life-threatening disease(s); or

A new safety finding from a newly completed animal study with clinical implications e.g., results indicating a carcinogenic potential.

8.1.3 If Iroko determines that there may be the need for urgent action in relation to a Safety Issue with the Medicinal Products it shall alert Aspen within one (1) Business Day of that determination.

Actions may include, but are not limited to:

A 'Dear Doctor' or 'Dear Healthcare Professional' letter;

A Medicinal Product disposal or recall;

Alteration, suspension or discontinuation of a Clinical Study due to a Safety Issue;

Alteration, suspension or discontinuation of Medicinal Product marketing;

Suspension, modification or discontinuation of Medicinal Product manufacturing; or

A significant change in the Product Labelling.

8.1.4 Aspen is responsible for undertaking communications on pharmacovigilance matters with the relevant Regulatory Authorities in its Allocated Territories in liaison with Iroko.



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8.1.5 Aspen will not involve any external expert or an opinion on any safety matter relating to the Medicinal Products, other than where this is required in the normal course of business, without prior written approval by Iroko and, where such an interaction is approved, Iroko will be fully involved in all discussions. The provisions of this clause shall not apply to consultations with external experts to address medical information related enquiries from doctors or pharmacists.

8.2 **Company Core Safety Information (CCSI)**

8.2.1 The CCSI for the Medicinal Products will be prepared and maintained by Iroko as is reasonable from time to time. The CCSI shall reflect the current safety profile of the Medicinal Products.

8.2.2 An electronic copy of the final approved CCSI and associated documentation to support the reason for any change to the previous version of the CCSI seen by Aspen will be forwarded to Aspen by Iroko no later than five (5) Business Days following Internal approval and sign off within Iroko for such version.

8.2.3 Where amendment to the CCSI is deemed urgent by Iroko, the timelines and process will be altered accordingly and will be managed by Iroko (refer to Section 8.1).

8.3 **Product Labelling**

8.3.1 Aspen will implement the CCSI, and its updates, into the Product Labelling for Aspen Allocated Territories until such time, if any, the Parties agree in writing that Iroko will have these responsibilities.

8.3.2 Where a Regulatory Authority requires Aspen to deviate from the CCSI in its Product Labelling, Aspen shall notify Iroko in writing no later than five (5) Business Days of receipt of the request and the request will be managed as defined in Section 8.1 of this Agreement. Aspen and Iroko shall discuss and agree the revised labeling. For the avoidance of doubt, Aspen will not accept any changes without the prior written consent of Iroko. It is recorded that where the changes are mandated by the Regulatory Authority, Aspen and Iroko are bound to abide by such mandated changes.

8.3.3 Each Party agrees to implement the Medicinal Product Labelling into the Patient Information Leaflet such that the content is consistent with the Product Labelling.

8.4 **Patient Risk Management Plans**

8.4.1 Iroko is responsible for preparation and update of any applicable global Risk Management Plan for the Medicinal Products if required.

8.4.2 Iroko will forward electronic copies of any such final Risk Management Plan to Aspen to enable the submission of the Risk Management Plan to Regulatory Authorities in its Allocated Territories if required.



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## 9 REGULATORY ENQUIRIES/REGULATORY ACTION

### 9.1 Regulatory Safety Enquiries

9.1.1 Aspen will inform Iroko of any safety-related regulatory enquiries relating to the Medicinal Products received from a Regulatory Authority within one (1) Business Day of receipt.

9.1.2 Iroko agrees to provide the response required to Aspen for submission by them to the Regulatory Authorities in the Allocated Territories in the required timeframes set by the respective Regulatory Authority.

### 9.2 Regulatory Action

9.2.1 Aspen agrees to inform Iroko within one (1) Business Day of receipt if it becomes aware of any intention by a Regulatory Authority to take safety-related regulatory action in respect to activities covered by this Agreement in relation to the Medicinal Products.

9.2.2 To the extent that such regulatory action relates to the Medicinal Products each Party agrees to provide support to the other Party in respect to any regulatory action, and will supply all necessary Information as is reasonable to deal with the action.

9.2.3 No less than five (5) Business Days (unless Applicable Law dictates shorter timeframes), prior to the response to the action as specified by the Regulatory Authority in respect of the Medicinal Products, Aspen with respect to such regulatory action will provide details of its proposed plans to Iroko for approval. Iroko will have the right to review and amend the proposed Aspen response prior to its submission to the Regulatory Authority, provided that Aspen is in agreement with changes Iroko may request.

9.2.4 Aspen agrees to provide Iroko with copies of the final communications with and responses to the Regulatory Authority in respect of the Medicinal Products as approved by Iroko in advance of the submission.

## 10 NON REGULATORY AUTHORITY ENQUIRIES

Aspen may respond to enquiries that it receives from healthcare professionals regarding the Medicinal Products that relate to matters of safety in the Allocated Territories where it holds Market Authorisations, provided that the content of the responses is consistent with the local Product Labelling. If such enquiry involves an identifiable patient and a potential adverse reaction, the enquiry will be sent to Iroko pharmacovigilance within one (1) Business Day for potentially serious ADRs and five (5) Business Days for non-serious cases. Aspen will send to Iroko on a monthly basis a summary of all medical information queries for reconciliation.

## 11 EXTERNAL COMMUNICATIONS

Any public statement by Aspen on the safety of the Medicinal Products which goes beyond the scope of the CCSI must be approved by Iroko before publication by Aspen.



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## 12 CONTRACTUAL RELATIONSHIPS

### 12.1 Intra-Company Contractual Relationships

12.1.1 Aspen will ensure that it enters into sufficiently detailed and clear contractual arrangements or have detailed and clear written internal procedures with all of its relevant Affiliates in order to meet its pharmacovigilance obligations under this Agreement.

12.1.2 Iroko or its authorised representatives will have the right to request copies of or to audit or inspect any such contractual arrangements to the extent that they are relevant to the performance of Aspen' s obligations under this Agreement.

### 12.2 Commercial or Third Party Contractual Relationships

12.2.1 Aspen will ensure that it enters into sufficiently detailed and clear contractual arrangements with (a) any commercial or collaboration partners and (b) any Third Parties (including, for the avoidance of doubt, Aspen' s Affiliates as defined in Section 2.2.2.2. of the Exclusive License Agreement) to which pharmacovigilance responsibilities of a Party are delegated hereunder, in each case as necessary in order to meet its obligations under this Agreement. Aspen shall be responsible for ensuring that its contractors and subs comply with the terms of this Agreement. Nothing in this clause shall prejudice the performance of ASPEN' S obligations owed to Iroko pursuant to this Agreement.

12.2.2 Aspen shall ensure that it informs Iroko of any changes to the contractual arrangements described in Section 12.2.1 to the extent that they are relevant to the performance of ASPEN' S obligations pursuant to this Agreement.

12.2.3 Iroko or its authorised representatives shall have the right to request copies of, or to audit or inspect, the provisions of any such contractual arrangements of another Party hereunder to the extent that they are relevant to the performance of such other Party' s obligations pursuant to this Agreement.

## 13 DOCUMENTATION

### 13.1 Record Keeping

Aspen will collect, prepare and maintain complete, current, accurate, organised and legible Documentation in a manner acceptable for the collection of data for submission to, or review by, Regulatory Authorities and in full compliance with this Agreement. For the avoidance of doubt all applicable data protection laws and standards of Good Clinical Practice will be followed by Aspen.

### 13.2 Record Retention

13.2.1 Each Party will retain Documentation for as long as a Marketing Authorisation is held for the Medicinal Products in any country worldwide.

13.2.2 All Documentation will be retained in a secure area reasonably protected from fire, theft and destruction.



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13.2.3 Each Party will make all Documentation available upon request to the other Party for review, copying and audit/ inspection at all times on the provision of reasonable advance notice.

## 14 COMPLIANCE/AUDIT/INSPECTION

### 14.1 Compliance/Audit

14.1.1 Iroko may monitor the conduct of ASPEN' S activities under this Agreement and regularly review compliance with the terms of this Agreement.

14.1.2 Iroko or its authorised representatives shall have the right, exercisable at any time during the term of this Agreement, but no more than twice in any twelve (12) month period, upon reasonable advance notice and at its cost, during regular business hours, to audit the facilities, processes and documentation used by Aspen in its performance of its obligations pursuant to this Agreement. Such activities will include but are not limited to reviews of documentation and staff interviews.

Aspen agrees to take remedial action in a timely manner to correct any omission shown by such audit and avoid repetition.

### 14.2 Regulatory Inspections

14.2.1 Each Party agrees to notify the other Party within two (2) Business Days if any Regulatory Authority contacts it with respect to its intention to conduct or give notice to conduct an inspection in respect to Pharmacovigilance activities including those performed under this Agreement in relation to the Medicinal Products.

14.2.2 Each Party agrees to provide support to the other Party in respect of any Regulatory Authority inspection, and will supply to the other Party all necessary information as is reasonable to enable that Party to deal with the Inspectors requests such that neither Party adversely affects the other Party' s ability to comply with requests.

14.2.3 Each Party agrees to co-operate with the other and provide details of actions required in relation to the Medicinal Products and activities covered by this Agreement at the end of the inspection.

14.2.4 Each Party agrees to take remedial action in a timely manner to correct any act or omission identified by the Regulatory Authority Inspection to the Inspected Party.

## 15 CONFIDENTIALITY

15.1 The terms of this Agreement and any and all information and data disclosed under this Agreement to any Party or its Affiliates shall be deemed "CONFIDENTIAL INFORMATION" of the disclosing Party (or its applicable Affiliate) under any Exclusive License Agreement to which the disclosing Party (or such Affiliate) and the receiving Party (or any of its Affiliates) are parties and, as such, shall be subject to the confidentiality provision' s contained in such Exclusive License Agreement(s) and the receiving Party (and its Affiliates) shall have the right to use and disclose such CONFIDENTIAL INFORMATION solely as permitted thereunder; *provided, however,* that such Party shall have the right to use such information to the extent necessary to perform its obligations, or



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to exercise its rights, hereunder. Notwithstanding the foregoing or anything set forth in any Exclusive License Agreement, a breach of this Section 15.1 (or such confidentiality provisions) by any Party or its Affiliates with respect to any CONFIDENTIAL INFORMATION disclosed to such Party or its Affiliates hereunder shall constitute a breach of this Agreement by such Party and not a breach of such Underlying Agreement.

## 16 DISPUTE MANAGEMENT

Any dispute arising out of or relating to this Agreement will be settled by discussions between the responsible persons outlined in Appendix Two. If the dispute remains unresolved it will be escalated to the Head of Drug Safety Iroko and ASPEN' S Executive of Strategic Business Development and Pharmaceutical Affairs (presently, Mrs. Lorraine Hill). In the event of continued conflict the provisions in Section of the Exclusive License Agreement shall apply.

## 17 MISCELLANEOUS

17.1 Sections 4, 20, 21, 23, 24 and 27 to 32 of the Exclusive License Agreement shall apply to this Agreement.

17.2 Failure to comply with the terms of the SDEA will be managed according to the procedure defined in Section 24 of the Exclusive License Agreement ("Term and Termination").

17.3 Except where the context otherwise requires, wherever used the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders. The words "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement (including the Annexes hereto) as an entirety and not to any particular provision. The word "Including" as used herein shall mean, including, without limiting the generality of any description preceding such term. The word "or" is used in the inclusive sense (and/or). Any reference in this Agreement to a matter or action being subject to the "mutual agreement" or "mutual consultation" of two (2) or more of the Parties, or words of similar import, shall not be construed as an agreement that such Parties shall agree to such matter or action. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against any Party.

17.4 This Agreement (including the Appendices hereto) constitutes, on and as of the Effective Date, the entire agreement of the Parties with respect to the subject matter of this Agreement, and all prior or contemporaneous understandings or agreements, whether written or oral, between the Parties with respect to such subject matter are superseded.

17.5 The agreements, covenants and representations contained herein are for the benefit of the Parties only and are not for the benefit of any Third Parties.

## 18 REVIEW OF AGREEMENT

This SDE Agreement may be amended from time to time as required taking into account changes to Applicable Laws or regulatory guidance to improve compliance with pharmacovigilance activities covered by this Agreement between the parties. Each Party may recommend a change to the Agreement. The amended Agreement will not take effect until reviewed and signed by authorised representatives of each Party.



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**19 TERMINATION OF THE AGREEMENT**

19.1 This Agreement will be co-terminous with the expiration or termination of the Exclusive License Agreement and managed according to the procedures detailed therein.

19.2 This Agreement supersedes any previous version(s), and Is effective upon signatures by authorised representatives of each Party.

19.3 Each Party is bound by Its requirements, and It is in effect until each Party agrees to terminate the Agreement or the Exclusive License Agreement is terminated.

19.4 Should the Exclusive License Agreement be terminated in its entirety, Iroko and Aspen agree to Implement the necessary procedures and practices to ensure that Pharmacovigilance obligations are fulfilled, Including safety reporting obligations for any Medicinal Products that may remain in the marketplace.

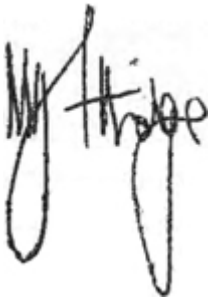
This Agreement represents the entire and Integrated agreement between the Parties In respect of Pharmacovigilance/Safety Issues and supersedes all prior negotiations, representations or agreements either written or oral, regarding Its subject matter.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorised representatives, to be effective as of the Effective Date.

SIGNED for and on behalf of
**Iroko Pharmaceuticals (Luxembourg) SARL**

Name of Signatory
OSAGIE IMASOGIE
Date APRIL 1, 2008

SIGNED for and on behalf of
**Aspen Pharmacare Holdings Limited**



Name of Signatory
MICHAEL GUY ATTRIDGE
Date 1 APRIL 2008



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## APPENDIX ONE: IROKO SAFETY CONTACTS

**Single Case Management**

For Individual case safety reports

Rachael Becker

Drug Safety Specialist

Tel: 44(0) 1985 273433
Fax: 44(0) 1895 231847
E-mail:drugsafety@parexel.com

Parexel PPV
101-105 Oxford Rd.
Uxbridge, Middlesex
UB8 1LZ
UK

**QPPV**

Jonathan West
Associate Director, PAREXEL
PharmacoVigilance
101-105 Oxford Road
Uxbridge, Middlesex
UB8 1LZ
UK

Mobile (for urgent safety and regulatory issues only): 44(0) 7764 143537

Tel: 44(0) 1895 273434
Fax:
E-mail:

**Executive Director**

Olaolu lmasogle, MD
Navy Yard Corporate Center
One Crescent Drive, Suite 400
Philadelphia, PA 19112

Tel:
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Fax: 267/546-3004
E-mail: eoimasogie@iroko.com



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**APPENDIX ONE: ASPEN SAFETY CONTACTS**

| | | |
|---|---|---|
| For Individual case safety reports & medical queries | Carol Sendall<br>Medical Affairs Manager<br>Tel: (0027) 11-2396524<br>Email: sendallc@aspenpharma.com | Aspen Pharmacare,<br>Building 12, Healthcare Park<br>Woodlands Drive,<br>Woodmead<br>Johannesburg<br>South Africa |
| Regulatory | Lorraine Hill<br>Executive : Regulatory Affairs and Responsible Pharmacist<br>Tel : (0027) 31 5808605<br>E-mail : LHill@aspenpharma.com | Aspen Pharmacare,<br>1st Floor Aspen House<br>Aspen Park<br>98 Armstrong Avenue<br>La Lucia Ridge<br>Durban<br>4019<br>South Africa |



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Execution Copy

**SECOND ADDENDUM AGREEMENT TO THE EXCLUSIVE SUBLICENSE AGREEMENT**

**between**

**IROKO PHARMACEUTICALS (LUXEMBOURG) SARL**

**and**

**ASPEN GLOBAL INCORPORATED**

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SECOND ADDENDUM AGREEMENT TO THE EXCLUSIVE SUBLICENSE AGREEMENT

1. DEFINITIONS

Unless otherwise expressly stated, or the context otherwise requires, the words and expressions defined in the AGREEMENT shall bear the same meaning in this SECOND ADDENDUM as those ascribed to them in the AGREEMENT. Unless otherwise expressly stated, or the context otherwise requires, the words and expressions listed below shall when used in this SECOND ADDENDUM, including this introduction, bear the meaning ascribed to them.

1.1 "AGREEMENT" means the Exclusive Sublicense Agreement between IROKO and ASPEN dated December 6, 2007, as amended by the FIRST ADDENDUM.

1.2 "SECOND ADDENDUM" means this second addendum to the Agreement.

1.3 "SECOND ADDENDUM EFFECTIVE DATE" means the 1st day of November 2010.

2. INTRODUCTION

2.1 The PARTIES entered into the AGREEMENT.

2.2 The PARTIES wish to amend the AGREEMENT in accordance with the terms and subject to the conditions set out in this SECOND ADDENDUM.

3. AMENDMENT OF AGREEMENT

The AGREEMENT is hereby amended in the following respects:

3.1 Clause 2.2.2.19

By deleting clause 2.2.2.19 in its entirety and replacing it with the following new paragraph:

"2.2.2.19 "IROKO" means IROKO HOLDINGS LLC, formed under the laws of the State of Delaware, IROKO LLC, IROKO PHARMACEUTICALS (LUXEMBOURG) SARL, a societé a responsabilité limitee formed under the laws of the Grand Duchy of Luxembourg and having its registered office at 65, Boulevard Grande Duchesse Charlotte, L-1331, Luxembourg, LUXEMBOURG and AFFILIATES of the foregoing persons."

4. REMAINDER OF THE AGREEMENT

Save as is expressly set out above or as necessarily implied by the context hereof, all other terms of the AGREEMENT shall remain of full force and effect.

5. THIS SECOND ADDENDUM is effective as of the SECOND ADDENDUM EFFECTIVE DATE.

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For: ASPEN GLOBAL INCORPORATED

SAMER KASSEM, he warranting by his signature that he is duly authorized hereto

For: IROKO PHARMACEUTICALS (LUXEMBOURG) SARL

OSAGIE IMASOGIE, he warranting by his signature that he is duly authorized hereto

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# THIRD ADDENDUM AGREEMENT TO THE EXCLUSIVE SUBLICENSE AGREEMENT

**dated December 6, 2007,**

**between**

**IROKO PHARMACEUTICALS (LUXEMBOURG) SARL**

**and**

**ASPEN GLOBAL INCORPORATED**

**(UNDER ASSIGNMENT FROM ASPEN PHARMACARE HOLDINGS LIMITED)**

**3rd Addendum to ELA**

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**THIRD ADDENDUM AGREEMENT TO THE EXCLUSIVE SUBLICENSE AGREEMENT**

## 1. DEFINITIONS

Unless otherwise expressly stated, or the context otherwise requires, the words and expressions defined in the AGREEMENT shall bear the same meaning in this THIRD ADDENDUM as those ascribed to them in the AGREEMENT. Unless otherwise expressly stated, or the context otherwise requires, the words and expressions listed below shall when used in this THIRD ADDENDUM, including this introduction, bear the meaning ascribed to them in this THIRD ADDENDUM:

1.1 "AGREEMENT" means the Exclusive Sublicense Agreement between IROKO and ASPEN (under assignment from Aspen Pharmacare Holdings Limited), dated 6 December 2007, as amended by the FIRST ADDENDUM and SECOND ADDENDUM;

1.2 "FIRST ADDENDUM" means the First Addendum to the AGREEMENT, dated 1 April 2008;

1.3 "SECOND ADDENDUM" means the Second Addendum to the Agreement, dated 1 November 2010.

1.4 "THIRD ADDENDUM" means this Third Addendum to the Agreement.

1.5 "THIRD ADDENDUM EFFECTIVE DATE" means 1 July 2011.

## 2. INTRODUCTION

2.1 Aspen Pharmacare Holdings Limited and IROKO entered into the AGREEMENT.

2.2 Aspen Pharmacare Holdings Limited assigned its rights and obligations under the AGREEMENT to MAURITIUS HOLDCO. Accordingly, for the avoidance of doubt, MAURITIUS HOLDCO is thus defined and herein referred to as "ASPEN".

2.3 The PARTIES amended the AGREEMENT in accordance with the terms and subject to the conditions set out in the FIRST ADDENDUM.

2.4 The PARTIES amended the AGREEMENT in accordance with the terms and subject to the conditions set out in the SECOND ADDENDUM.

2.5 The PARTIES wish to further amend the AGREEMENT in accordance with the terms and subject to the conditions set out in this THIRD ADDENDUM.



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## 3. AMENDMENT OF AGREEMENT

The AGREEMENT is further amended in the following respects:

### 3.1 New Clause 2.2.2.45

By the incorporation of a new clause 2.2.2.45 to read –

"2.2.2.45 "**PRODUCTS CONTAINING INDOMETHACIN AND/OR METHYLDOPA**" means pharmaceutical products (other than the PRODUCTS) containing one or more of the active pharmaceutical ingredients indomethacin and/or methyldopa;"

### 3.2 Clause 13.2

By amending clause 13.2 to read –

"For purposes of calculating the QUARTERLY ROYALTY FEE set forth in clause 13.1.3, from the EFFECTIVE DATE all sales of PRODUCTS CONTAINING INDOMETHACIN AND/OR METHYLDOPA sold by ASPEN and/or its AFFILIATES in the TERRITORY (other than those PRODUCTS CONTAINING INDOMETHACIN AND/OR METHYLDOPA sold by ASPEN and/or its AFFILIATES in South Africa by public tender) shall be included in the NET SALES computation."

### 3.3 Clause 13.4

By amending clause 13.4 by adding the following sentence –

"Beginning with the quarter starting on January 1, 2010, the QUARTERLY ROYALTY FEE shall be calculated in accordance with Appendix E, as annexed to the THIRD ADDENDUM."

### 3.4 Appendix E to the Agreement

By the deletion of Appendix E to the AGREEMENT and the substitution therefor by the Appendix E as is annexed to this THIRD ADDENDUM.

### 3.5 Appendix E(A) to the Agreement

By the insertion of a new Appendix E(A).



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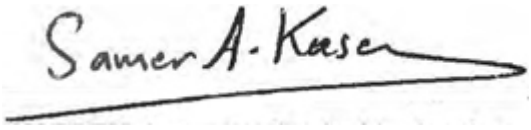
**4. REMAINDER OF AGREEMENT**

Save as is expressly set out above or as necessarily implied by the context hereof, all other terms of the AGREEMENT shall remain of full force and effect.

SIGNED at Mauritius on this 10th day of August 2011.

**For: ASPEN GLOBAL INCORPORATED**

**(UNDER ASSIGNMENT FROM ASPEN PHARMACARE HOLDINGS LIMITED)**



**SAMER KASSEM,** he warranting by his signature that he is duly authorised hereto

SIGNED at Philadelphia, PA, USA on this 17th day of August 2011.

**For: IROKO PHARMACEUTICALS (LUXEMBOURG) SARL**

**OSAGIE IMASOGIE**, he warranting by his signature that he is duly authorised hereto



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**APPENDIX E**

**FORMULA FOR THE DETERMINATON OF THE QUARTERLY ROYALTY FEE**

**[***]**

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If either PARTY disputes the QUARTERLY ROYALTY FEE at any time during the term of the AGREEMENT, the PARTIES shall engage in good faith negotiations to agree on the QUARTERLY ROYALTY FEE. If the PARTIES fail to agree on such fee within ten (10) business days of such dispute, such dispute shall be referred to the respective Presidents and Chief Executive Officers ("CEO") of the PARTIES who shall engage in good faith negotiations to resolve such dispute within ten (10) business days from the date of such referral. If the PARTIES' Presidents and CEOs cannot resolve such dispute, such dispute shall be referred to the respective Chairmen of the Boards of the PARTIES, and if the Chairmen cannot resolve such dispute within ten (10) business days of such referral, such dispute shall be referred to an independent arbitrator for resolution. The arbitrator shall be appointed by agreement between the PARTIES. If no agreement can be reached on appointment of the arbitrator it will be decided by the President of the Institute of Chartered Accountants of England and Wales. Such auditor shall act as an expert and not as an arbitrator and his decision shall, save for any manifest error, be final and binding on the PARTIES. The losing PARTY will bear all the costs of any necessary ARBITRATION including the reasonable costs of the other PARTY.

IROKO shall be entitled, at all reasonable times, either directly or through its duly authorised agents, to undertake an inspection and/or audit of all or any of ASPEN' S reports, books of account, manufacturing facilities and the like in an endeavour to verify that the QUARTERLY ROYALTY FEE has been correctly calculated and ASPEN shall give IROKO and/or its duly authorized agents, its full co-operation in this regard. The authorized agents or representatives of IROKO shall, however, prior to conducting any such inspection and/or audit, enter into a "confidentiality and lock-out agreement" in a form reasonably acceptable to ASPEN that would require the agent or representative to maintain confidentiality of the information obtained and desist from trading in the securities of ASPEN for a period specified therein.

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**APPENDIX E (A)**

**FORMULA FOR THE DETERMINATION OF**

**AFFILIATES' NET PROFITS ("F")**

**[***]**

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[***]

*** This entire page has been omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.



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**Exhibit 10.15**

[***] indicates material that has been omitted pursuant to a Request for Confidential Treatment filed with the Securities and Exchange Commission. A complete copy of this agreement, including redacted portions so indicated, has been filed separately with the Securities and Exchange Commission.

# MANUFACTURING AND SUPPLY AGREEMENT

between

**IROKO PHARMACEUTICALS (LUXEMBOURG) SARL**

and

**ASPEN GLOBAL INCORPORATED**

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**THIS MANUFACTURING AND SUPPLY AGREEMENT is made on the day of , 2008**

BETWEEN:

**IROKO PHARMACEUTICALS (LUXEMBOURG) SARL,** a Société à Responsabilité Limitée formed in accordance with the laws of the Grand Duchy of Luxembourg and having its registered address at 65, Boulevard Grande Duchesse Charlotte, L-1331 Luxembourg, LUXEMBOURG ("IROKO")

and

**ASPEN GLOBAL INCORPORATED,** Company Number 078138, a company registered and incorporated in accordance with the laws of Mauritius and having its registered address at care of Kross Border Trust Services Limited, Manor House, 1st Floor, Corner St George / Chazal Streets, Port Louis, Mauritius ("ASPEN")

**WHEREAS:**

1. IROKO holds the rights, with respect to the Territory, to the DOSSIERS and has the right to MANUFACTURE and sell the PRODUCTS in the Territory.

2. ASPEN is willing to undertake the MANUFACTURE of the PRODUCTS (or procure such MANUFACTURE by way of a TOLL MANUFACTURING AGREEMENT with PHARMACARE) and the supply of the PRODUCTS in accordance with the terms and subject to the conditions set out in this AGREEMENT.

**NOW IT IS HEREBY AGREED AS FOLLOWS:-**

**1. INTERPRETATION**

1.1. In this AGREEMENT and in the annexes to this AGREEMENT: -

1.1.1. clause headings are for convenience and are not to be used in its interpretation;

1.1.2. unless the context indicates a contrary intention an expression which denotes:

1.1.2.1. any gender includes the other genders;

1.1.2.2. a natural person includes a juristic person and vice versa;

1.1.2.3. the singular includes the plural and vice versa.



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1.2. In this AGREEMENT and in the annexes to this AGREEMENT the following expressions bear the meanings assigned to them below and cognate expressions bear corresponding meanings:

1.2.1. "**ADVERSE EVENT**" means any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of the PRODUCT, whether or not considered related to the PRODUCT. An ADVERSE EVENT for the purposes of this AGREEMENT can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of the PRODUCT. It also includes failure to produce expected benefits (i.e. lack of efficacy), abuse or misuse;

1.2.2. "**AFFILIATE/S**" means, in relation to one person, any other person which is controlled by, under common control with, or controls the other. "Control", "controlled" or "controls" means either (i) (x) the ownership of more than 50% (FIFTY PERCENT) of the voting shares or interests of a person carrying the rights to vote at general meetings or (y) the power to nominate the majority of the board of directors of a person; or (ii) the ability to determine the policies and/or management of a person, whether through the ownership of securities, by contract or otherwise;

1.2.3. "**AGREEMENT**" means the agreement set out in this document, incorporating the Appendices hereto;

1.2.4. "**APPLICABLE LAWS**" means all or any:

1.2.4.1.1. statutes, subordinate legislation and common law,

1.2.4.1.2. regulations,

1.2.4.1.3. ordinances and bylaws, and

1.2.4.1.4. directives, codes of practice, circulars, guidance notes, judgments and decisions of any competent authority,

compliance with which is mandatory in relation to the subject matter of this AGREEMENT;

1.2.5. "**ASPEN' S WAREHOUSE**" means the warehouse situated at Mill 1, Bedford Street, Korsten, Port Elizabeth (Erf 6725) or any other address nominated by ASPEN, in the Republic of South Africa;

1.2.6. "**BULK PRODUCTS**" means the PRODUCTS which only require to be PACKAGED in order to enable them to be COMMERCIALISED in the TERRITORY in accordance with the APPLICABLE LAWS;

1.2.7. "**CERTIFICATE OF ANALYSIS**" means a certificate in form and substance satisfactory to IROKO, acting reasonably, signed by a RESPONSIBLE PHARMACIST authenticating the pharmaceutical analysis of each batch of the PRODUCTS in accordance with the TECHNICAL AGREEMENT;

1.2.8. "**CONFIDENTIAL INFORMATION**" means any information including, but not limited to, information regarding a PARTY' S past, current and future services and products, research and development plans and results, customers, sales and



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operating information, marketing plans and strategies, cost and pricing information, data, media, know-how, designs, drawings, specifications, source codes, technical information, concepts, reports, methods, processes, techniques, operations, devices and like, future projections, business plans, software, listings, holdings, alliances, investments, financials, transactions and general business operations, label claims, patents, copyrights, trade secrets, information relating to or underlying such intellectual property rights and other proprietary information, sketches, models, inventions, apparatus, equipment, algorithms, information technology systems and programs, software source documents, formulae, research and development, clinical data, experimental work, design details and specifications and other technical information relating to past, current, future and proposed products and services, engineering data, financial information, procurement requirements, purchasing and manufacturing information, customers and customer lists and profiles, business forecasts and sales, marketing and merchandising plans and data, future projections, fee schedules, stock ownership and all materials prepared on the basis of any of the foregoing, whether or not the foregoing information is patented, tested, reduced to practice, or subject to copyright;

1.2.9. "**COPYRIGHTED MATERIALS**" means such materials as IROKO may from time to time provide to ASPEN pursuant to this AGREEMENT to the extent subject to the copyright of IROKO and/or any of its AFFILIATES anywhere in the world;

1.2.10. "**DOSSIERS**" means the product registration dossiers relating to the PRODUCTS and the MANUFACTURE and PACKAGE thereof, as registered with the REGULATORY AUTHORITY, excluding any intellectual property owned by or licensed to IROKO such as artwork and labelling supplied by IROKO in accordance with clause 10;

1.2.11. "**EFFECTIVE DATE**" means (on a PRODUCT by PRODUCT, country by country basis) in relation to –

1.2.11.1. the PACKING of the BULK PRODUCTS by ASPEN, the later of –

1.2.11.1.1. the date upon which MERCK first delivers the BULK PRODUCTS to ASPEN; and

1.2.11.1.2. the date upon which the relevant REGULATORY AUTHORITY approves ASPEN as a registered packer of the PRODUCTS in accordance with the APPLICABLE LAWS;

1.2.11.2. the MANUFACTURE and PACKING of the PRODUCTS, the later of –

1.2.11.2.1. the date upon which MERCK ceases to deliver to ASPEN the BULK PRODUCTS and ASPEN' S stock of BULK PRODUCTS has been extinguished; and

1.2.11.2.2. the date upon which the relevant REGULATORY AUTHORITY approves ASPEN as a registered manufacturer and packer of the PRODUCTS in accordance with the APPLICABLE LAWS.

Accordingly, the EFFECTIVE DATE shall be staggered in relation to PACKING (on the one hand) and MANUFACTURING and PACKING (on the other hand) and on a PRODUCT by PRODUCT, country by country basis.



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1.2.12. "**EXCLUSIVE LICENSE AGREEMENT**" means the Exclusive Sub-License Agreement between IROKO (as Licensor) and Aspen Pharmacare Holdings Limited (as Licensee) in respect of the LICENSED TERRITORIES;

1.2.13. "**cGMP**" means the current practices as recognised internationally by the pharmaceutical industry with respect to the MANUFACTURE and PACKING of the PRODUCTS and including all applicable standards relating to the manufacturing practices for fine chemicals, bulk products or finished products promulgated by any governmental body having jurisdiction over the MANUFACTURE and PACKING of the PRODUCTS in the form of laws or regulations or promulgated by any governmental body having jurisdiction over the MANUFACTURE and PACKING of the PRODUCTS in the form of guidance documents (including but not limited to advisory opinions, compliance policy guides and guidelines) which guidance documents are being implemented within the manufacturing industry for such PRODUCTS;

1.2.14. "**GOVERNMENT ENTITY**" means any government or state or any department, sub-section or affiliate of a government or state, including without limiting the generality of the foregoing, a local and/or provincial government;

1.2.15. "**IMPROVEMENT/S**" mean any new or improved process, technique, method, formula, invention or know-how relating to the MANUFACTURE and PACKING of PRODUCTS or arising out of the continuous improvement programme referred to in clause 14 made either by IROKO, its AFFILIATES and/or ASPEN;

1.2.16. "**IFRS**" means International Financial Reporting Standards as promulgated by the International Accounting Standards Board and as adopted by ASPEN as its accounting standard;

1.2.17. "**IROKO DATA**" means all knowledge, know-how or other proprietary information and material in relation to the PRODUCTS (whether or not patentable) including, but not limited to, substance, formulations, techniques, methodology, manufacturing process, equipment, data, reports, source of supply, patent position, business plans, research and test results relating to the PRODUCTS owned, developed, licensed to or used by IROKO and those which may belong to third parties for use of which IROKO has made sufficient arrangements;

1.2.18. "**LICENSED TERRITORY**" means the entire African continent, the entire South and Central American continents, including the islands of the Caribbean (excluding Puerto Rico as it is considered part of North America), Ireland, the United Kingdom, Australia and New Zealand, and the entire Asian continent (excluding China (other than Hong Kong), Japan, Pakistan, Korea, any US territories (i.e. Guam) and Sri Lanka (the latter only insofar as it relates to Aldomet®));

1.2.19. "**MANUFACTURE**" or "**MANUFACTURING**" or "**MANUFACTURED**" or "**MANUFACTURES**" means, as applicable, all the production, the procurement of all or any raw materials, excipients, API' s and other inputs of whatever nature, warehousing, quality control testing (including in-process and release) and release of the PRODUCTS;



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1.2.20. "**MANUFACTURING LICENSE**" means all licences issued by REGULATORY AUTHORITIES as are necessary for or in connection with the MANUFACTURE and/or PACKING of the PRODUCTS at the MANUFACTURING SITE(s) and the PACKAGING SITE, respectively;

1.2.21. "**MANUFACTURING PRICE/S**" means the price/s to be paid by IROKO to ASPEN for the MANUFACTURE and PACKAGING of the PRODUCTS, calculated in accordance with clause 7;

1.2.22. "**MANUFACTURING SITE**" means the manufacturing facility as set out in **Appendix 4** for the respective PRODUCTS;

1.2.23. "**MANUFACTURING TERM**" means on a PRODUCT by PRODUCT, country by country basis, the period commencing on the later of the dates referred to in 1.2.11.2.1 and 1.2.11.2.2 and terminating on that date which is: (i) the sixth ($6^{th}$) anniversary of the SIGNATURE DATE *plus* (ii) the earlier of (x) two years or (y) the time necessary to complete the technical transfer of the MANUFACTURING process to new third party manufacturers;

1.2.24. "**MERCK**" means, collectively, Merck & Co., Inc., a corporation organized under the laws of the State of New Jersey and Merck and Company, Incorporated, a corporation organized under the laws of the State of Delaware;

1.2.25. "**PACK**", "**PACKED**", "**PACKING**" or "**PACKAGING**" means the filling, primary and secondary packaging and labelling of the PRODUCTS into sales packs and the procurement of all or any raw materials, packaging materials and other inputs of whatever nature relevant thereto, all in accordance with IROKO' S reasonable requirements and cGMP in effect in the country of PACKING;

1.2.26. "**PACKAGING PRICE/S**" means the price/s to be paid by IROKO to ASPEN for the PACKAGING of the BULK PRODUCTS by ASPEN, calculated in accordance with clause 7;

1.2.27. "**PACKAGING SITE**" means the MANUFACTURING SITE or such other site as may be nominated by ASPEN and agreed to by IROKO, from time to time, acting reasonably;

1.2.28. "**PACKAGING TERM**" means on a PRODUCT by PRODUCT, country by country basis, the period commencing on the later of those dates set out in clauses 1.2.11.1.1 and 1.2.11.1.2 and terminating on the later of those dates set out in clauses 1.2.11.2.1 and 1.2.11.2.2;

1.2.29. "**PARTIES**" means the PARTIES to this AGREEMENT, and "**PARTY**" shall mean any one of such PARTIES;

1.2.30. "**PHARMACARE**" means Pharmacare Limited trading as Aspen Pharmacare, Registration Number 1898/000252/07, a company registered in accordance with the laws of the Republic of South Africa and having its registered address at Building 8 Healthcare Park, Woodlands Drive, Woodmead, Johannesburg, 2052, Republic of South Africa;



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1.2.31. "**PRICE/S**" means the MANUFACTURING PRICE/S and the PACKAGING PRICE/S for the PRODUCTS to be paid by IROKO to ASPEN calculated in accordance with clause 7;

1.2.32. "**PRODUCTS**" means the PRODUCTS PACKED by ASPEN in final form and ready for commercial sale by IROKO as listed in **Appendix 1** (as may be amended in writing by the PARTIES from time to time);

1.2.33. "**REGULATORY AUTHORITY**" means any governmental entity in the respective countries of the TERRITORY with the authority to grant the registration of the PRODUCTS in the relevant country of the TERRITORY;

1.2.34. "**RESPONSIBLE PHARMACIST**" means the person named as such in the TECHNICAL AGREEMENT or any replacement notified by ASPEN, in writing, being a pharmacist and responsible to the South African Pharmacy Council for complying with all provisions of the Pharmacy Act, 1974 of South Africa and other legislation applicable to services which specifically pertain to the scope and practice of a pharmacist and the legislation applicable to the pharmacy, which is under his or her supervision;

1.2.35. "**SIGNATURE DATE**" means the date of signature of this AGREEMENT by the PARTY signing last in time;

1.2.36. "**SPECIFICATIONS**" means the specifications for each of the PRODUCTS as set out in the DOSSIERS and all or any variations thereto as agreed by the PARTIES, in writing, from time to time;

1.2.37. "**TECHNICAL AGREEMENT**" means the document attached hereto as **Appendix 2**, outlining the PARTIES' respective responsibilities on quality and technical matters, as the same may be amended from time to time by written agreement between the PARTIES;

1.2.38. "**TECHNICAL CHANGE CONTROL PROCEDURE**" means the technical change control procedure as set out in the Standard Operating Procedure attached to the TECHNICAL AGREEMENT;

1.2.39. "**TECHNICAL MANAGER**" means, in the case of ASPEN, the RESPONSIBLE PHARMACIST and, in the case of IROKO, means the technical manager appointed by IROKO in accordance with the TECHNICAL AGREEMENT;

1.2.40. "**TERRITORY**" means the LICENSED TERRITORY as well as the following countries/regions: China (PRC) and Korea;

1.2.41. "**TOLL MANUFACTURING AGREEMENT**" means the Toll Manufacturing Agreement which will be entered into between ASPEN and PHARMACARE in terms of which the latter will undertake the PACKAGING and/or MANUFACTURING of the PRODUCTS for and on behalf of ASPEN;

1.2.42. "**TRADEMARKS**" means the trade mark registrations and applications identified in **Appendix 1** together with any further trade marks, trade names, logos and other trade dress appearing on, affixed to or used by IROKO in connection with any of the PRODUCTS.



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1.3. Words and expressions defined in any clause shall, for the purposes of that clause, bear the meaning assigned to such words and expressions in such clause.

1.4. In this AGREEMENT and in the appendices to this AGREEMENT the word "AGREEMENT" refers to this AGREEMENT and the words "clause" or "clauses" and "Appendix" or "Appendices" refer to clauses and appendices to this AGREEMENT.

1.5. The headings are inserted for convenience only and are to be ignored for the purposes of construction.

**2. RECITAL**

2.1. IROKO holds the rights to the DOSSIERS in the Territory and owns or has the right to use the confidential information, know-how, data, intellectual property and trade secrets related thereto on an exclusive basis in the Territory.

2.2. IROKO wishes ASPEN to Initially PACK the BULK PRODUCTS for the supply thereof to IROKO or its designee and subsequently to MANUFACTURE and PACK the PRODUCTS for the supply thereof to IROKO or its designee, both under the terms and subject to the conditions of this AGREEMENT.

2.3. During the PACKAGING TERM, ASPEN undertakes to PACK the BULK PRODUCTS and to supply the same to IROKO or its designee.

2.4. During the MANUFACTURING TERM, ASPEN undertakes to MANUFACTURE and PACK the PRODUCTS and to supply the same to IROKO or its designee.

2.5. Notwithstanding the provisions of clause 2.4, the PARTIES may agree, in writing, from time to time, that during the MANUFACTURING TERM, ASPEN' S obligations may be limited to the MANUFACTURE of the PRODUCTS only and not their PACKING. It is envisaged that circumstances may arise whereby it will be in the interests of both PARTIES to procure the PACKING of BULK PRODUCTS MANUFACTURED by ASPEN by third party designees in territories other than the Republic of South Africa.

**3. APPOINTMENT**

3.1. Subject to the terms and on the conditions contained herein and in the EXCLUSIVE LICENSE AGREEMENT, IROKO hereby appoints ASPEN (i) initially, to PACK the BULK PRODUCTS in respect of the TERRITORY; and (ii) subsequently, to MANUFACTURE and PACK the PRODUCTS, both as its sole and exclusive supplier (except as provided otherwise herein or in the EXCLUSIVE LICENSE AGREEMENT) of the PRODUCTS in respect of the TERRITORY. ASPEN agrees (i) initially, to PACK the BULK PRODUCTS; and (ii) subsequently, to MANUFACTURE and PACK the BULK PRODUCTS and to supply to IROKO the PRODUCTS as ordered from time to time by IROKO under this AGREEMENT and the EXCLUSIVE LICENSE AGREEMENT, in consideration of IROKO paying the PACKAGING PRICE and MANUFACTURING PRICE, respectively, for the PRODUCTS. In addition, for so long as this AGREEMENT is in effect, ASPEN agrees not to MANUFACTURE products equivalent to the PRODUCTS either for competitors of IROKO or for itself for sale in the TERRITORY, other than those products containing Indomethacin and/or Methyldopa sold by ASPEN in South Africa.



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3.2. For so long as this AGREEMENT is in effect, IROKO hereby grants to ASPEN, subject to the terms and conditions set forth herein, a sub-license to use the IROKO DATA for the purpose of MANUFACTURING and/or PACKAGING the PRODUCTS.

3.3. Pursuant to the provisions of the TOLL MANUFACTURING AGREEMENT, ASPEN will procure that PHARMACARE MANUFACTURE the PRODUCTS at the MANUFACTURING SITE and PACKS the PRODUCTS at the PACKAGING SITE in accordance with the terms of this AGREEMENT, the TECHNICAL AGREEMENT, the SPECIFICATIONS, cGMP and all APPLICABLE LAWS relevant to the MANUFACTURE and PACKAGE of the PRODUCTS in the TERRITORY.

3.4. For the avoidance of doubt, ASPEN' S obligations in terms of this AGREEMENT relate only to the TERRITORY and will, in part, be sub-contracted to PHARMACARE in accordance with the provisions of the TOLL MANUFACTURING AGREEMENT, provided that ASPEN shall remain liable to IROKO for the performance of all of PHARMACARE' S obligations, this in accordance with the provisions of clause 26.2.

**4. PERIOD OF AGREEMENT**

4.1. Unless terminated earlier in accordance with clause 18, this AGREEMENT shall commence on the SIGNATURE DATE and endure for an initial term ("the initial term' ' ) of six (6) years.

4.2. Unless terminated earlier in terms of clause 18 or terminated in accordance with clause 4.3 after the initial term, this AGREEMENT shall automatically renew for successive three (3) year terms ("the renewal term").

4.3. Either PARTY shall have the right to terminate this AGREEMENT at the expiry of the initial term or any renewal term on written notice to the other PARTY, upon no less than the shorter of (i) two (2) years' notice; or (ii) such notice as is necessary to complete the technical transfer of the manufacturing process to a new third party manufacturer. For the avoidance of doubt, the aforementioned written notice of termination may be given during the initial period and/or renewal period (as the case may be) provided that it shall only be effective at the expiry of the initial term and/or renewal term (as the case may be).

**5. REGISTRATION OF PRODUCTS**

5.1. ASPEN shall be responsible for ensuring that PHARMACARE obtains and maintains in force a MANUFACTURING LICENSE in respect of the PRODUCT.

5.2. IROKO shall be responsible for obtaining all or any licenses, permits and other approvals which are necessary to enable the PRODUCT to be imported, sold and distributed by IROKO in the TERRITORY, other than the LICENSED TERRITORY.

5.3. IROKO and ASPEN shall be jointly responsible for obtaining and maintaining all or any licenses, permits and other approvals, if any, which are necessary to enable the PRODUCT to be imported, sold and distributed in the LICENSED TERRITORY.



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5.4. IROKO shall be responsible for obtaining and maintaining all licenses, permits and other approvals required by PHARMACARE for the PACKING and MANUFACTURING of the PRODUCT relevant to the TERRITORY, other than the LICENSED TERRITORY; provided, however, that ASPEN shall provide IROKO with reasonable assistance in doing so and will procure that PHARMACARE does likewise.

5.5. IROKO and ASPEN shall be jointly responsible for obtaining and maintaining all licenses, permits and other approvals required by ASPEN for the PACKING and MANUFACTURING of the PRODUCT in the LICENSED TERRITORY.

**6. PACKAGING TERM**

6.1. During the PACKAGING TERM, IROKO shall use its best commercial endeavours to procure that MERCK delivers to ASPEN the BULK PRODUCTS in sufficient quantities to enable ASPEN to timely fulfill its obligations in terms of this AGREEMENT. IROKO shall further use its best commercial efforts to procure that the BULK PRODUCTS delivered by MERCK to ASPEN comply with the SPECIFICATIONS and the APPLICABLE LAWS and that they have been MANUFACTURED in accordance with cGMP. ASPEN shall bear the sole liability to pay MERCK for the BULK PRODUCTS, including without limiting the generality of the aforegoing, all costs and expenses associated with the delivery of the BULK PRODUCTS to the PACKAGING SITE.

6.2. Subject to the minimum quantities set out in clause 9.2, ASPEN shall PACK the BULK PRODUCTS (which comply with the provisions of 6.1) in accordance with the SPECIFICATIONS (insofar as they relate to PACKING), the TECHNICAL AGREEMENT, Good Manufacturing Practice and APPLICABLE LAWS.

6.3. In respect of the PRODUCTS to be supplied by MERCK in bulk, IROKO shall provide MERCK (or shall cause MERCK to be provided) with a written rolling 24 (TWENTY FOUR) month forecast of its requirements, the first 6 (SIX) months of which shall constitute a firm order. MERCK shall deliver such firm order (provided it is consistent with the most recent forecasts) to IROKO or its designee, Ex Works (INCOTERMS 2000), MERCK' S manufacturing plant, at which time title shall pass to IROKO or its AFFILIATES, and IROKO is to notify MERCK (or to cause MERCK to be notified) of any defects within 45 (FORTY FIVE) days thereof. Payment for the PRODUCTS in bulk is to be made to MERCK within 60 (SIXTY) days of delivery.

**7. PRICE AND TERMS OF PAYMENT**

7.1 The PACKAGING PRICE for the PRODUCTS in that part of the TERRITORY other than the LICENSED TERRITORY shall be ASPEN' S costs of procuring and PACKING the BULK PRODUCTS (excluding any profits earned or retained by PHARMACARE pursuant to the provisions of the TOLL MANUFACTURING AGREEMENT), calculated on a [***] basis, determined in accordance with IFRS, plus ten percent (10%) of such costs. ASPEN shall advise IROKO of the PACKAGING PRICE, including details as to how determined, in writing, within forty five (45) days of receipt by ASPEN of a comprehensive forecast of IROKO and/or its designee' s requirements of the PRODUCT for the entire duration of the PACKAGING TERM, or such later date as the PARTIES may agree. The PACKAGING PRICE for the PRODUCTS in the LICENSED TERRITORY shall be ASPEN' S costs of procuring and PACKING the BULK PRODUCTS, calculated on a fully absorbed cost recovery basis, determined in accordance with IFRS.

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7.2 Should IROKO dispute the PACKAGING PRICE at any time during the PACKAGING TERM, then the PARTIES shall enter into negotiations in good faith with regard to agreeing the PACKAGING PRICE and, failing such agreement within ten (10) days after the commencement of such negotiation, either PARTY shall be entitled to refer the dispute/disagreement for determination by an independent auditor appointed by agreement between the PARTIES, in writing, or failing such agreement within five (5) days after either PARTY has required such referral, appointed by the President for the time being of the South African Institute of Chartered Accountants (or his successor-in-title) if IROKO requests such an appointment, or appointed by the then President of the Luxembourg Institut des Réviseurs d' Entreprises (or his successor-in-title), if ASPEN requests such an appointment. Such auditor shall act as an expert and not as an arbitrator and his decision shall, save for any manifest error, be final and binding on the PARTIES.

7.3 The MANUFACTURING PRICE for the PRODUCTS for the first twelve (12) months of the MANUFACTURING TERM (the "**Initial Commercialization Period**") in that part of the TERRITORY other than the LICENSED TERRITORY shall be ASPEN' S costs of MANUFACTURING and PACKING the PRODUCTS, at the commencement of the Initial Commercialization Period (excluding any profits earned or retained by PHARMACARE pursuant to the provisions of the TOLL MANUFACTURING AGREEMENT), calculated on [***] basis, determined in accordance with IFRS, plus ten percent (10%) of such costs. ASPEN shall advise IROKO of such MANUFACTURING PRICE, including details as to how determined, in writing, no later than forty five (45) days prior to the anticipated date of the first supply by ASPEN to IROKO of the commercial release batch of the PRODUCTS MANUFACTURED and PACKED in accordance with the provisions of this AGREEMENT, or such later date as the PARTIES may agree. In the LICENSED TERRITORY, the MANUFACTURING PRICE for the PRODUCTS shall be ASPEN' S costs of MANUFACTURING and PACKING the PRODUCTS, at the commencement of the Initial Commercialization Period, calculated on a fully absorbed cost recovery basis, determined in accordance with IFRS.

7.4 The PARTIES shall meet not less than six (6) months before the expiry of the Initial Commercialization Period and annually thereafter in order to discuss and agree in writing the MANUFACTURING PRICE ("the ADJUSTED MANUFACTURING PRICE") of the PRODUCTS which shall apply after the expiry of the Initial Commercialisation Period. The ADJUSTED MANUFACTURING PRICE in that part of the TERRITORY other than the LICENSED TERRITORY shall exclude any profits earned or retained by PHARMACARE pursuant to the TOLL MANUFACTURING AGREEMENT, and shall be calculated on a fully absorbed cost recovery basis, determined in accordance with IFRS, plus ten percent (10%) of such costs. The ADJUSTED MANUFACTURING PRICE in the LICENSED TERRITORY shall be calculated on a fully absorbed cost recovery basis, determined in accordance with IFRS.

7.5 Should ASPEN incur any extraordinary costs and/or expenses pursuant to an increase in the price actually paid by ASPEN for any manufacturing material, packaging material, active and other ingredients, excipients, raw materials and other components of the PRODUCTS used to MANUFACTURE and/or PACK the PRODUCTS under this AGREEMENT during any twelve (12) month period, then the PRICE of the relevant PRODUCT shall be adjusted by agreement between the PARTIES.

7.6 Should IROKO dispute the MANUFACTURING PRICE for the Initial Commercialization Period or should the PARTIES be unable to agree on the ADJUSTED MANUFACTURING PRICE at any time during the term of this AGREEMENT, then the PARTIES shall enter into good faith negotiations with regard to agreeing the PRICE for the Initial Commercialization Period or the ADJUSTED MANUFACTURING PRICE or, failing such

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agreement within ten (10) days after the commencement of such negotiation, either PARTY shall be entitled to refer the dispute/ disagreement for determination by an independent auditor appointed by agreement between the PARTIES, in writing, or failing such agreement within five (5) days after either PARTY has required such referral, appointed by the President for the time being of the South African Institute of Chartered Accountants (or his successor-in-title) if IROKO requests such an appointment, or appointed by the then President of the Luxembourg Institut des Réviseurs d' Entreprises (or his successor-in-title), if ASPEN requests such an appointment. Such auditor shall act as an expert and not as an arbitrator and his decision shall, save for any manifest error, be final and binding on the PARTIES.

7.7 IROKO or its designee shall be entitled, at all reasonable times, upon reasonable notice and during business hours, either directly or through its duly authorised agents, to undertake an inspection and/or audit of all or any of ASPEN' S reports, books of account, manufacturing facilities, packaging facilities, warehousing and the like in an endeavour to verify that the PACKAGING PRICE and/or MANUFACTURING PRICE have been calculated on [***] basis and ASPEN shall give IROKO and/or its duly authorized agents, its full co-operation in this regard. The authorised agents or representatives of IROKO shall, however, prior to conducting any such inspection and/or audit, enter into a "confidentiality and lock-out agreement" in a form reasonably acceptable to ASPEN that would require the agent or representative to maintain confidentiality of the information obtained and desist from trading in the securities of ASPEN for a period specified therein.

7.8 It is agreed that, save where this AGREEMENT expressly obliges IROKO to pay all or part of ASPEN' S costs, all costs incurred by ASPEN in complying with its obligations under this AGREEMENT are included in the PACKAGING PRICE and MANUFACTURING PRICE, respectively, and ASPEN shall not be entitled to recover any such costs from IROKO.

7.9 ASPEN shall invoice IROKO in United States Dollars (USD$) upon each delivery of the PRODUCT in accordance with the Delivery Terms (defined in clause 9.1).

7.10 IROKO shall pay all amounts due to ASPEN under this AGREEMENT within thirty (30) days of the date of invoice.

7.11 IROKO shall pay all amounts due to ASPEN in United States Dollars (USD$), without any deduction of any nature whatsoever, by making payment into such bank account as ASPEN shall, from time to time, notify to IROKO in writing.

## 8. ORDERS AND REQUIREMENT FORECASTS

**For orders in that part of the TERRITORY other than the LICENSED TERRITORY:**

8.1. IROKO shall from time to time place firm orders with ASPEN for its, and where relevant, its AFFILIATE' S requirements of the PRODUCTS. Subject to the minimum quantities set out in clause 9.2, ASPEN shall fulfill such orders according to the terms of this AGREEMENT upon the agreed delivery dates.

8.2. ASPEN shall keep IROKO informed of the standard lead time which shall in any event not exceed ninety (90) days from the date of IROKO placing a firm order in accordance with the minimum quantities set out in clause 9.2, provided such firm order was included in the Forecast Schedule to be provided pursuant to clause 8.3 below.

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8.3. IROKO shall provide ASPEN by the first working day of each month, with a rolling forecast schedule of demand for the PRODUCTS for the following twelve (12) months ("**Forecast Schedule**"). This shall be updated monthly by IROKO.

8.4. The PRODUCT detailed in the first four (4) months of the Forecast Schedule will constitute a binding commitment by IROKO to purchase all of the PRODUCTS detailed therein. The required delivery date for each order will be specified by IROKO in the related purchase order form ("**Firm Order**").

8.5. Subject to 9.2, ASPEN shall deliver Ex-works ASPEN' S WAREHOUSE (Incoterms 2000) IROKO' S requirements in respect of PRODUCT relating to each Firm Order.

8.6. ASPEN shall use its best endeavors in good faith to satisfy any changes in quantity, delivery phasing or dates requested by IROKO in respect of such Firm Order and otherwise accommodate all updates and revisions by IROKO to the rolling forecasts, but shall not be obliged to do so.

8.7. It is understood that the remaining eight (8) months of the Forecast Schedule constitutes an estimate of the future PRODUCT requirement of IROKO and does not comprise any binding commitment by IROKO to purchase such PRODUCT nor by ASPEN to MANUFACTURE the PRODUCT.

**9. DELIVERY OF PRODUCT**

9.1. The PRODUCTS shall be delivered Ex-works ASPEN' S WAREHOUSE (Incoterms 2000) ("**Delivery Terms**").

9.2. Notwithstanding any other provision of this AGREEMENT, the minimum order quantity of PRODUCTS that IROKO can place and/or that ASPEN is obliged to MANUFACTURE and/or PACK is –

9.2.1. in respect of the PACKING of BULK PRODUCTS, a full PACKAGING batch quantity as is specified by ASPEN, from time to time, acting reasonably; and

9.2.2. in respect of the MANUFACTURE and PACKING of the PRODUCTS, a full MANUFACTURING batch quantity of each PRODUCT as is specified by ASPEN, from time to time, acting reasonably.

9.3. ASPEN shall, until such time as they are delivered, store each batch of the PRODUCTS MANUFACTURED and/or PACKED (as the case may be) hereunder in accordance with the conditions of storage and delivery set out in the TECHNICAL AGREEMENT until instructed to cause the release of such batch(es) by IROKO. If IROKO fails to collect, or cause to be collected, the PRODUCTS within seven (7) days of the scheduled delivery date, then IROKO shall be obliged to pay to ASPEN storage fees in relation to the PRODUCTS until such time as they are so collected at a commercial rate as agreed between the PARTIES, in writing, or failing such AGREEMENT, within five (5) days after either Party has requested such AGREEMENT, determined by an auditor appointed by the President for the time being of the South African Institute of Chartered Accountants (or his successor-in-title) if IROKO requests such AGREEMENT, or appointed by the then President of the Luxembourg Institut des Réviseurs d' Entreprises (or his successor-in-title), if ASPEN requests such an AGREEMENT. Such auditor shall act as an expert and not as an arbitrator and his/her decision shall, save for any manifest error, be final and binding on the PARTIES.



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9.4. Title to the PRODUCTS shall pass to IROKO or its relevant AFFILIATES upon delivery of the PRODUCTS to IROKO or its designee upon delivery thereof in accordance with the Delivery Terms. Risk in any delivery of the PRODUCTS shall pass to IROKO or its relevant AFFILIATES upon delivery in accordance with the Delivery Terms or within seven (7) days of the scheduled delivery date, whichever event shall occur earlier.

**10. ARTWORK AND PACKAGING**

10.1. ASPEN shall supply the PRODUCTS incorporating the design, TRADEMARKS, labelling, package insert and artwork as required and provided by IROKO in writing from time to time. The costs of artwork, labelling compilation, packaging insert compilation and all relevant translations, will be borne by IROKO. IROKO warrants that, to its best knowledge, the artwork, labelling, packaging inserts and translations will comply strictly with all REGULATORY AUTHORITY requirements and APPLICABLE LAWS and regulations.

10.2. Subject to clauses 9.2 and 10.3 and the SPECIFICATIONS, ASPEN will PACK the PRODUCTS in accordance with IROKO' S reasonable requirements from time to time.

10.3. All PACKAGING will reflect IROKO, its AFFILIATE or appointed nominee as the product registration holder in respect of the PRODUCTS and to IROKO' s best knowledge, will comply strictly with all REGULATORY AUTHORITY requirements and APPLICABLE LAWS.

10.4. Where IROKO requires the PACKAGING to reflect a language other than the English language **("other language"),** IROKO shall supply ASPEN with the relevant translation for such PACKAGING, in pdf.format for conversion into the final printed packaging, prior to ASPEN PACKING the PRODUCTS with PACKAGING that reflects the other language.

10.5. ASPEN acknowledges that all intellectual property in the packaging design, TRADEMARKS, labelling, package insert and artwork supplied by IROKO to ASPEN pursuant to clause 10.1 is owned or licensed by IROKO and shall remain IROKO' S property following any termination of this AGREEMENT for any reason, and that nothing in this AGREEMENT grants to ASPEN any right, title or interest in the ownership of such intellectual property. ASPEN will take all reasonable precautions to ensure the protection of IROKO' S rights in such intellectual property and further acknowledges that any IMPROVEMENTS thereto shall also be the sole and exclusive property of IROKO or its AFFILIATES.

**11. TRADE MARKS**

11.1. IROKO hereby sub-licenses to ASPEN, solely to the extent necessary for ASPEN to carry out its obligations hereunder, the non-exclusive rights to use the TRADEMARKS and COPYRIGHTED MATERIALS in the Manufacturing Facility and to supply to IROKO PRODUCTS bearing such TRADEMARKS or using or incorporating such COPYRIGHTED MATERIALS. Such sub-licence is strictly limited to the terms of this AGREEMENT. No right is given to ASPEN to use the TRADEMARKS or COPYRIGHTED MATERIALS (or any adaptations or derivative works or part thereof) to manufacture, sell, export, distribute, or otherwise to copy, make, have made, or dispose of any PRODUCT, packaging, or other materials, other than as expressly permitted under the terms of this AGREEMENT.



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11.2. In addition to any other provisions of this AGREEMENT, ASPEN agrees to all the quality control provisions set out in the Trademark Control Attachment attached as **Appendix 3,** which is hereby incorporated into this AGREEMENT by this reference.

11.3. ASPEN acknowledges that the TRADEMARKS and COPYRIGHTED MATERIALS are the exclusive property of IROKO and/or its AFFILIATES, that the TRADEMARKS and COPYRIGHTED MATERIALS shall remain the exclusive property of IROKO and/or its AFFILIATES following any termination of this AGREEMENT for any reason, and that nothing in this AGREEMENT grants to ASPEN any right, title or interest in the ownership of such TRADEMARKS or COPYRIGHTED MATERIALS. ASPEN will take all reasonable precautions to ensure the protection of IROKO' S and its AFFILIATES' rights in such materials.

11.4. Notwithstanding the foregoing, ASPEN shall not at any time before or after termination of this AGREEMENT do or suffer to be done any act or thing which may impair the rights of IROKO and/or its AFFILIATES in the TRADEMARKS, COPYRIGHTED MATERIALS and/or any other intellectual property and proprietary rights of IROKO or its AFFILIATES.

11.5. ASPEN shall inform IROKO immediately in writing of:

11.5.1. any infringement or alleged infringement of the TRADEMARKS, COPYRIGHTED MATERIALS and/or any other intellectual property and proprietary rights of IROKO which shall come to its attention; and

11.5.2. any action for infringement brought against it by a third party arising from the use of such TRADEMARKS, COPYRIGHTED MATERIALS and/or any other intellectual property and proprietary rights of IROKO.

11.6. IROKO and/or its AFFILIATES shall have the sole and exclusive right, at its expense, to control the defence and/or prosecution of any action involving the TRADEMARKS, COPYRIGHTED MATERIALS and/or any other intellectual property and proprietary rights of IROKO or its AFFILIATES. ASPEN agrees, at IROKO' S cost and expense, to provide any and all reasonable assistance to IROKO or its AFFILIATES with respect to any such actions, to the extent IROKO or its AFFILIATES may request such assistance.

11.7. ASPEN shall not during the currency of this AGREEMENT or thereafter, directly or indirectly, use or register any trade or service mark or trade name, trade dress, symbol or device or packaging (whether external, intermediate or internal) or promotional material in relation to any product (other than the PRODUCTS manufactured for IROKO hereunder) which incorporates or is identical or confusingly similar to or a colourable imitation of any TRADEMARKS used by IROKO in the TERRITORY in respect of the PRODUCTS or any other trade or service mark, trade dress, symbol or device or packaging or promotional material used by IROKO and/or any of its AFFILIATES anywhere in the world.

## 12. REGULATORY ISSUES AND TECHNICAL TRANSFER

12.1. In amplification of the provisions of the TECHNICAL AGREEMENT and the regulatory requirements associated with a technical transfer, all costs relating to stability testing (including stability testing associated with the technical transfer, optimisation, validation and routine maintenance), analytical method transfer and validation, comparative dissolution testing, experimental trial batches, validation batches which are not commercialised and any other associated procedures and testing on the PRODUCTS and any other reasonable costs associated with the above activities, but not limited thereto, will-



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12.1.1. to the extent that they relate to the TERRITORY, other than the LICENSED TERRITORY, be for IROKO' S sole account and payable by IROKO to ASPEN on presentation of invoice;

12.1.2. to the extent that they relate to the LICENSED TERRITORY, be for IROKO and ASPEN' S joint account and accordingly subject to the provisions of the EXCLUSIVE LICENSE AGREEMENT; or

12.1.3. to the extent that they relate, in part, to the TERRITORY, other than the LICENSED TERRITORY (on the one hand), and to the LICENSED TERRITORY (on the other hand), be allocated pro-rata, between the provisions of clauses 12.1.1 and 12.1.2 with reference to the extent of the revenue generated by the underlying PRODUCTS in the then preceding twelve (12) month period in the TERRITORY, other than the LICENSED TERRITORY (on the one hand) and the LICENSED TERRITORY (on the other hand).

12.2. In amplification of the provisions of clause 14, the PARTIES undertake to use their respective commercial reasonable endeavours to identify and target more cost-effective sources of manufacturing material, packaging material, active and other ingredients, excipients, raw materials and other components of the PRODUCTS **("the Component Inputs")** used to MANUFACTURE and/or PACK the PRODUCTS under this AGREEMENT. In the event of a more cost-effective source of the Component Inputs being identified and IROKO, in its sole discretion, being satisfied that the alternative source of Component inputs will not compromise the quality of the PRODUCTS, then IROKO undertakes not to unreasonably withhold or delay its consent for ASPEN MANUFACTURING and/or PACKING the PRODUCTS using the more cost-effective source of the Component Inputs. Changes in relation to the supply of Component Inputs shall be undertaken in accordance with the TECHNICAL CHANGE PROCEDURE.

12.3. Within thirty (30) days of the SIGNATURE DATE, IROKO shall be obliged to deliver or cause to be delivered to ASPEN copies of all of the DOSSIERS for the PRODUCTS, as well as such other methods, formula, procedures, tests and the like as are requested by ASPEN, acting reasonably.

12.4. IROKO shall use its best commercial efforts to undertake or procure the undertaking of all necessary actions, with the utmost dispatch and good faith, to facilitate the transfer of PACKING and MANUFACTURING know-how from MERCK to PHARMACARE, including without limiting the generality of the foregoing, procuring that MERCK provides ASPEN with all reasonable co-operation in this regard.

12.5. All or any costs incurred in procuring the delivery of those documents set out in clauses 12.3 and/or 12.4 and/or in procuring the transfer of the PACKING and/or MANUFACTURING know-how from MERCK to ASPEN in terms of clause 12.4, shall be borne by IROKO. In the event of ASPEN initially paying for such costs and/or expenses IROKO shall be obliged to reimburse the same to ASPEN against the presentation of invoice.

12.6. In the event of it being necessary or becoming necessary (as the case may be) for ASPEN to incur material capital expenditure to enable it to fulfil any of its obligations pursuant to this AGREEMENT, then it shall give IROKO no less than twenty one (21) days notice, in writing, of the nature and estimated extent of such capital expenditure.



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## 13. WARRANTIES, INDEMNITIES AND UNDERTAKINGS

13.1. ASPEN warrants that:

13.1.1 the PRODUCTS will be MANUFACTURED and PACKED in accordance with APPLICABLE LAWS and cGMP and will comply with the terms of this AGREEMENT, the SPECIFICATIONS and the TECHNICAL AGREEMENT;

13.1.2 it has capacity and has taken all necessary action to authorise the execution, delivery and performance of this AGREEMENT in accordance with its terms and so far as it is aware, the execution, performance and delivery of this AGREEMENT will not conflict with any obligation to which ASPEN is subject;

13.1.3 it is carrying on its business in compliance with all APPLICABLE LAWS or regulations;

13.1.4 it has sufficient annual manufacturing capacity at its disposal to meet equivalent volumes of sales of the PRODUCTS to those made in the TERRITORY in the 12 (TWELVE) month period between 1 January 2006 and 31 December 2006;

13.1.5 it and/or PHARMACARE hold or will, in due course, hold all necessary consents, authorisations, registrations, agreements, certificates, licences, approvals, permits, authorities or exemptions from any relevant authority which are required to MANUFACTURE and PACK pharmaceutical products and has paid all fees due in relation to them and is not in breach of any conditions under them where such breach would be likely to have a material and adverse effect on ASPEN' S ability to perform its obligations under this AGREEMENT; and

13.1.6 as at the SIGNATURE DATE, Aspen Pharmacare Holdings Limited, Registration Number 1985/002935/06, a company incorporated in the Republic of South Africa owns 100% (ONE HUNDRED PERCENT) of the capital stock / share capital of PHARMACARE and throughout the term of this AGREEMENT, Aspen Pharmacare Holdings Limited will, and ASPEN will cause Aspen Pharmacare Holdings Limited to, control PHARMACARE. For the purposes of this clause 13.1.6 "control" shall have that meaning set out in clause 1.2.2.

13.2. IROKO warrants that:

13.2.1. it has capacity and has taken all necessary action to authorise the execution, delivery and performance of this AGREEMENT in accordance with its terms and so far as it is aware, the execution, performance and delivery of this AGREEMENT will not conflict with any obligation to which IROKO is subject;

13.2.2. it is carrying on its business in compliance with any APPLICABLE LAWS or regulations; and

13.2.3. it holds all necessary consents, authorisations, registrations, agreements, certificates, licences, approvals, permits, authorities or exemptions from any relevant authority which are required to perform its obligations under this



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AGREEMENT and has paid all fees due in relation to them and is not in breach of any conditions under them where such breach would be likely to have a material and adverse effect on IROKO' S ability to perform its obligations under this AGREEMENT.

13.3. Save as aforesaid, ASPEN has made no representations or warranties (whether express or implied) as to the PRODUCTS to IROKO or any person acting on its behalf and no other warranties or representations as to the PRODUCTS will be binding upon ASPEN unless contained herein or reduced to writing and signed by ASPEN.

WITHOUT LIMITING THE GENERALITY OF THE FOREGOING BUT SUBJECT TO ASPEN' S WARRANTIES ABOVE, ASPEN MAKES NO REPRESENTATIONS OR WARRANTIES, WHETHER EXPRESS OR IMPLIED OF MERCHANTIBILITY, FITNESS OF THE PRODUCTS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, OR REGARDING THE SCOPE, VALIDITY OR ENFORCEABILITY OF THE DOSSIERS AND/OR THE KNOW-HOW, DATA INTELLECTUAL PROPERTY AND TRADE SECRETS WHICH ARE USED BY ASPEN TO MANUFACTURE THE PRODUCTS IN THE TERRITORY.

13.4. ASPEN indemnifies and shall hold IROKO and its AFFILIATES harmless from and against any and all liability for death, illness or injury to any third party or for loss or damage to any third party' s property and against all claims for damages resulting therefrom excluding indirect and/or consequential damages (except, however, that the exclusion of consequential damages shall not apply in the case of a breach of the provisions of this AGREEMENT by ASPEN or in the case of gross negligence or willful misconduct of ASPEN), that may be brought against IROKO or its AFFILIATES arising out of the use of the PRODUCTS provided that -

13.4.1. such claim or liability shall have arisen out of the defective MANUFACTURE or PACKING of the PRODUCTS by ASPEN and/or a breach by ASPEN of its obligations pursuant to this AGREEMENT and shall not relate to the storage or delivery of the PRODUCTS by IROKO;

13.4.2. IROKO shall have notified ASPEN in writing within 10 (TEN) working days of receipt of any claim being made against IROKO or its AFFILIATES in respect of the PRODUCTS; and

13.4.3. neither IROKO nor its AFFILIATES shall be entitled to make any admissions of liability in regard to any claim or to negotiate any settlement without the written consent of ASPEN, which consent shall not be unreasonably withheld or delayed.

13.5. IROKO indemnifies and shall hold ASPEN harmless from and against any and all liability for death, illness or injury to any third party or for loss or damage to any third party' s property and against all claims for damages resulting therefrom excluding indirect and/or consequential damages (except, however, that the exclusion of consequential damages shall not apply in the case of a breach of the provisions of this AGREEMENT by IROKO or in the case of gross negligence or willful misconduct of IROKO), that may be brought against ASPEN arising out of the use of the PRODUCTS provided that -

13.5.1. such claim or liability shall not have arisen out of the defective MANUFACTURE or PACKING of the PRODUCTS by ASPEN and/or a breach by ASPEN of its obligations pursuant to this AGREEMENT;



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13.5.2. ASPEN shall have notified IROKO in writing within 10 (TEN) working days of receipt of any claim being made against ASPEN in respect of the PRODUCTS; and

13.5.3. ASPEN shall not be entitled to make any admissions of liability in regard to any claim or to negotiate any settlement without the written consent of ASPEN, which consent shall not be unreasonably withheld or delayed.

13.6. ASPEN shall maintain at its own cost full and sufficient third party, product liability, public and product recall insurance to cover its actual and potential liabilities hereunder within limits acceptable to IROKO, acting reasonably. In addition, ASPEN shall provide IROKO with at least thirty (30) days' prior written notice of its intent to cancel any such insurance.

13.7. IROKO shall maintain or cause to be maintained at its own cost full and sufficient third party, product liability, public and product recall insurance to cover its actual and potential liabilities hereunder within limits acceptable to ASPEN, acting reasonably.

13.8. In the event that either party receives a claim or demand in respect of a matter which is the subject of an indemnity under this clause 13 it shall give the other party notice thereof as soon as reasonably practicable and shall permit the other party to assist in the defence thereof at the other PARTY' S expense. The PARTIES shall co-operate in such defence by providing reasonable access to evidence available to them and each shall be entitled to participate in the other' s defence to the extent that in its judgement it may be prejudiced thereby.

13.9. IROKO undertakes to ASPEN that –

13.9.1. it will timely and fully comply with all of its obligations arising out of or flowing from all or any agreements concluded between it or its applicable AFFILIATE and MERCK ("the IROKO/MERCK Agreement") relevant to the subject matter of this AGREEMENT;

13.9.2. it shall, at its cost and expense, use its best commercial endeavours to do all things necessary to procure that MERCK fully complies with all of MERCK' s obligations arising out of or flowing from the IROKO/MERCK Agreement and that, against request, it shall appraise ASPEN, in writing, of MERCK' s said compliance or lack thereof (as the case may be).

## 14. CONTINUOUS IMPROVEMENT PROGRAMME

14.1. ASPEN agrees to use its commercially reasonable endeavours to identify and target all potential areas of cost reduction relating to the performance of its obligations. ASPEN further agrees to procure that PHARMACARE is bound by the provision of this 14.1. Examples of such areas of cost reduction include the following:

14.1.1. improvements in quality and technology relating to the MANUFACTURE of PRODUCTS and to cGMP;

14.1.2. reduction of waste associated with MANUFACTURE of PRODUCTS;



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14.1.3. a reduction in all costs associated with the performance of ASPEN' S obligations under this AGREEMENT including the cost of materials and all costs associated with the MANUFACTURE and delivery of the PRODUCTS;

14.1.4. improvements in quality of service provided by ASPEN to IROKO in connection with the performance of this AGREEMENT;

14.1.5. PACKAGING and processing time reduction in respect of the MANUFACTURE of PRODUCTS;

14.1.6. improvements in the supply chain efficiency between ASPEN and IROKO and its AFFILIATES in connection with the performance of this AGREEMENT (including delivery procedures and transport costs where relevant);

14.1.7. best practice in relation to cGMP issues;

14.1.8. increase in ASPEN stock turnover time; and

14.1.9. any other objectives agreed in writing by the technical managers from time to time.

14.2. Each party shall disclose all IMPROVEMENTS of which it is aware to the other Party. ASPEN shall not implement any IMPROVEMENT without IROKO' S written consent obtained through the TECHNICAL CHANGE CONTROL PROCEDURE.

14.3. If the IMPROVEMENT has received (i) IROKO' S written approval through the TECHNICAL CHANGE CONTROL PROCEDURE; and (ii) the relevant REGULATORY AUTHORITY' S written approval, ASPEN shall not unreasonably refuse or delay its implementation of any IMPROVEMENTS.

14.4. The costs associated with any Continuous Improvement Programme shall be incorporated into the PACKAGING PRICE and/or MANUFACTURING PRICE, as the case may be to the extent these costs have not been reimbursed in terms of clause 12.

14.5. In the event of any IMPROVEMENT, the PARTIES shall share equally in the savings resulting from such IMPROVEMENT; provided, however, that ASPEN acknowledges that any IMPROVEMENT to the PRODUCTS (including the MANUFACTURING process) shall belong exclusively to IROKO.

## 15. INSPECTIONS

15.1 Notwithstanding any other provision of this AGREEMENT, IROKO' S representatives may upon reasonable prior notice to ASPEN:

15.1.1 inspect those parts of the MANUFACTURING SITE and the PACKAGING SITE used by PHARMACARE for the MANUFACTURE, PACKAGING and/or testing of the PRODUCTS and/or for generation and disposal of waste including but not limited to any hazardous waste arising from such MANUFACTURE, PACKAGING or testing;



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15.1.2 review PHARMACARE' S procedures for the MANUFACTURE, PACKAGING and testing of the PRODUCTS and for dealing with and disposing of such waste; and

15.1.3 at its own expense take copies of all and any of ASPEN' S and/or PHARMACARE' S records relating to the MANUFACTURE, PACKAGING and testing of the PRODUCTS and to such waste.

15.2 ASPEN shall, upon the receipt of written request, ensure that PHARMACARE permits IROKO' S representatives (including any AFFILIATES or designated partners) and representatives of the REGULATORY AUTHORITY, to enter the MANUFACTURING SITE and/or the PACKAGING SITE at any reasonable time during regular business hours, and to inspect the facilities and procedures used by PHARMACARE in the MANUFACTURE and PACKAGING of the PRODUCTS and to test for standards of quality.

15.3 In the event of any REGULATORY AUTHORITY requiring any fee or a contribution towards its costs and expenses for attending upon inspections of the MANUFACTURING SITE and/or PACKAGING SITE, then such fee, cost and/or expense shall be borne and paid by IROKO, insofar as the inspections of the MANUFACTURING SITE and/or PACKAGING SITE relate to the TERRITORY, other than the LICENSED TERRITORY or by IROKO and ASPEN, jointly, insofar as such attendance relates to the LICENSED TERRITORY.

**16. DEFECTIVE PRODUCTS AND RETURNS**

16.1. IROKO (or its designated partner) shall notify ASPEN in writing or ensure that ASPEN is notified within seventy two (72) hours of any delivery of PRODUCT if the delivery is incomplete in accordance with the terms of this AGREEMENT or if there is an obvious defect with the delivery of PRODUCT ("Rejection Notice"). ASPEN shall then rectify the incomplete or defective delivery within six (6) weeks, running from the first date of notification of the Rejection Notice.

16.2. IROKO shall notify ASPEN within a reasonable period of time, but in no circumstances more than thirty (30) days from the date that it becomes aware, or it receives notice from its customer(s) that a particular delivery of PRODUCT does not or may not comply with the requirements set out in clause 16.4.2.

16.3. IROKO shall have the right, exercisable within the period prescribed under clause 16.2, to reject any such delivery of PRODUCT or any part thereof upon notification in writing to ASPEN. IROKO shall store the delivery of the rejected PRODUCT in accordance with ASPEN' S reasonable directions and, where reasonably requested, provide ASPEN with supporting evidence of the reasons for rejection.

16.4. In the event of a PRODUCT rejection under this clause 16 -

16.4.1. the payment obligations in relation to any such delivery shall be suspended forthwith pending resolution of the dispute;

16.4.2. the PARTIES shall immediately endeavour to agree as to whether or not the delivery in question complies with the requirements of clause 9.3; and



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16.4.3. ASPEN shall be entitled at all reasonable times to inspect and/or analyse the PRODUCTS that comprise the delivery in question.

16.5. The PARTIES shall use their best endeavours to resolve any dispute that may arise pursuant to this clause 16 within 30 (thirty) days of ASPEN being notified of any allegedly defective delivery of PRODUCTS ("**Party Resolution Period**"), failing which the dispute shall be determined by an independent laboratory mutually agreed to by the PARTIES and the decision of the independent laboratory shall be final and binding on the PARTIES. The independent laboratory shall act as an expert and not as an arbitrator and its fees shall be borne by the PARTY against whom the independent laboratory' s decision is given. Should the PARTIES fail to agree on the appointment of the independent laboratory within ten (10) days after the expiry of the Party Resolution Period, the independent laboratory shall be nominated at the request of any PARTY to the dispute by the President for the time being of the South African Institute of Chartered Accountants (or his successor-in-title) if IROKO requests such an appointment, or appointed by the then President of the Luxembourg Institut des Réviseurs d' Enterprises (or his successor-in-title), if ASPEN requests such an appointment.

16.6. If any delivery of the PRODUCTS is agreed by IROKO and ASPEN or is found by the independent laboratory not to have complied with the requirements of clause 9.3, then ASPEN shall:

16.6.1. subject to compliance with any APPLICABLE LAWS and regulations, dispose of the defective PRODUCTS at its own cost;

16.6.2. deliver a replacement delivery of the PRODUCTS to IROKO as soon as practicable and using all reasonable efforts to ensure continuity of the supply of the PRODUCTS to IROKO and if not already paid for by IROKO, IROKO shall pay ASPEN for such replacement delivery in accordance with the payment provisions of clause 7, but subject to deduction of any costs described in clause 16.6.3; and

16.6.3. promptly reimburse IROKO in respect of any cost including but not limited to freight, clearance, duty and storage charges incurred by IROKO in respect of the defective delivery.

16.7. If a consignment of the PRODUCTS is found by the independent laboratory to comply with the requirements of clause 9.3, IROKO shall pay for such consignment in accordance with the payment provisions of clause 9, together with interest thereon at the rate of [***], from the due date of payment.

## 17. ADVERSE EVENTS

17.1. The provisions of this clause 17 are in amplification of the provisions of the TECHNICAL AGREEMENT.

17.2. ASPEN shall promptly notify IROKO of all information coming into its possession concerning any actual or possible ADVERSE EVENT or PRODUCT complaint reports relating to any of the PRODUCTS. Such notice shall be given within no less than one (1) working day after receipt by ASPEN.

*** Portions of this page have been omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.



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17.3. If any of the circumstances described in clause 17.2 arise, the PARTIES shall act promptly and cooperate fully to investigate the matter in accordance with IROKO' S or its AFFILIATES' procedures for investigating complaints in order to determine the validity of product complaints, and to assure the conformity of the PRODUCT to the requirements set out in clause 9.3 and the quality of the PRODUCT.

17.4. IROKO shall be responsible during the term of this AGREEMENT for processing and submitting to the applicable authorities or agencies all individual case ADVERSE EVENT reports and pregnancy reports, and ASPEN shall be responsible for submitting PRODUCT complaint reports regarding the PRODUCT supplied hereunder as may be required by APPLICABLE LAWS. ASPEN will be responsible for following up all ADVERSE EVENT reports, pregnancy reports or PRODUCT complaint reports generated from countries in the LICENSED TERRITORY for the purpose of gathering additional clarifying information and will submit such information to IROKO or its designee. IROKO or its designee will be responsible for following up all ADVERSE EVENT reports, pregnancy reports or PRODUCT complaint reports generated from countries in the TERRITORY, other than the LICENSED TERRITORY. IROKO and ASPEN will collaborate in good faith in developing procedures for providing to IROKO any information coming into ASPEN' S possession concerning ADVERSE EVENTS, pregnancy reports or PRODUCT complaints with respect to the PRODUCT supplied hereunder. ASPEN shall in good faith cooperate with IROKO and any governmental authorities in the investigation and resolution of any ADVERSE EVENT relating to the PRODUCT.

17.5. Under no circumstances shall ASPEN, unless it has first obtained the approval of IROKO, take any action on ADVERSE EVENT reports, pregnancy reports or PRODUCT complaints reported to it relating to the PRODUCT. Any notice to IROKO under this AGREEMENT shall be served on the domicilium specified and provided for on the first page of this AGREEMENT, marked for the General Counsel.

17.6. Should ASPEN become aware of any human safety-related issues relating to the MANUFACTURE of the PRODUCTS, it shall notify IROKO within one (1) working day.

**18. TERMINATION**

18.1. In the event that

18.1.1. either party is placed under judicial management or is wound up, whether compulsorily or voluntarily; or

18.1.2. either party compromises with its creditors or attempts to do so; or

18.1.3. either party falls to observe any of the provisions or perform any of the other terms and conditions of this AGREEMENT, all of which shall be deemed to be material, and in the event such party fails to remedy such breach or persists with such failure within a period of fourteen (14) days of notice to it to remedy such breach or failure,

in any of the aforesaid events, the other party shall have the right, without prejudice to any other rights might thereupon be available to it -

18.2. to enforce the relevant provisions of this AGREEMENT and to proceed against the defaulting party for the recovery of damages, if any, due to it, and



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18.2.1. to declare the whole balance of all amounts owing pursuant to this Agreement, inclusive of interest to date, forthwith to be due, owing and payable;

18.2.2. to terminate this AGREEMENT immediately upon notice and to declare the whole balance of all amounts owing pursuant to this AGREEMENT, inclusive of interest to date, forthwith to be due, owing and payable and to proceed against the defaulting party for the recovery of damages, if any, due to it.

18.3. If at any time during the term of this AGREEMENT there shall be any change in the legal or beneficial ownership or control of IROKO, it shall immediately so notify ASPEN in writing.

For the purposes of this clause, "control" shall mean either the ownership of more than fifty per cent (50%) of the ordinary share capital of IROKO carrying the right to vote at general meetings or the power to nominate a majority of the board of directors of IROKO.

18.4. Notwithstanding anything to the contrary herein contained, the provisions of clauses 11, 13.5, 13.6, 17, 19, 20, 23, 24, 25, 28 and 30 shall survive any termination of this AGREEMENT.

18.5. Neither PARTY (the "OFFENDING PARTY") shall under any circumstances whatsoever (even if advised of a possibility of such damages) be liable for any indirect, special or consequential loss or damage sustained by the other PARTY howsoever caused, including whether or not caused by the negligence of the OFFENDING PARTY, its agents or employees arising out of any contract, tort (delict), negligence, strict liability or otherwise, but excluding, however, any loss or damage arising out of the fraud or wilful misconduct of the OFFENDING PARTY.

**19. EFFECT OF TERMINATION**

Upon the expiration, termination or cancellation of this AGREEMENT for any reason –

19.1. Provided that the termination or cancellation is not due to ASPEN' s breach of clause 13.1.1 or IROKO' s breach of any provisions of this AGREEMENT, ASPEN shall pursuant to clause 8 fill any outstanding orders of the PRODUCTS and pursuant to clause 9 deliver the PRODUCTS MANUFACTURED pursuant to such orders; and

19.2. the whole balance of all or any monies owing by IROKO to ASPEN, inclusive of interest to date, shall forthwith be due, owing and payable, minus, if IROKO is the terminating Party, any damages incurred by IROKO in connection with or arising out of the termination or cancellation; and

19.3. ASPEN shall deliver to IROKO, pursuant to clause 9, all manufacturing materials, packaging materials, active and other ingredients, excipients, raw materials and other components of the PRODUCTS then in ASPEN' S possession (and not required for the purposes of clause 19.1) and IROKO shall, against demand, reimburse to ASPEN its cost price thereof, including freight and insurance costs, if any.

19.4. ASPEN shall, at IROKO' S cost and expense, reasonably co-operate with IROKO and its designated third party in transferring the IROKO DATA and full documentation related thereto to such third party, including permitting observation of the MANUFACTURING of



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the PRODUCTS at the MANUFACTURING SITE and/or of the PACKAGING of the PRODUCTS at the PACKAGING SITE, upon reasonable prior notice during regular business hours.

**20. CUSTOMER COMPLAINTS AND RECALL PROCEDURES**

20.1. ASPEN shall ensure that PHARMACARE maintains adequate manufacturing despatch and analytical records and that they are made available to IROKO in order to assess the quality and destination of the PRODUCTS in the event of a PRODUCT complaint or suspected defect.

20.2. In the event that IROKO requires access to any records, ASPEN shall facilitate immediate access to such records.

20.3. The management of customer complaints and recalls shall be attended to in accordance with the provisions of the TECHNICAL AGREEMENT.

**21. ASSIGNMENT**

Neither party shall be entitled to assign or sub-contract this AGREEMENT nor any part, share or interest therein without the prior written consent of the other party, which consent shall not be unreasonably refused, withheld or delayed: Provided, however, that –

21.1. IROKO shall have the right to assign its rights and obligations under this AGREEMENT to an AFFILIATE under its control or in connection with a merger, a consolidation, a license or sale of substantially all of its assets or other equivalent transaction without obtaining ASPEN' S consent; and

21.2. ASPEN shall have the right to sub-contract its obligations under this AGREEMENT in accordance with the provisions of 26.

**22. NOTICES**

22.1. The PARTIES hereto select as their respective domicilia citandi et executandi the following physical addresses:

| Name | Physical Address | Telefax Number |
|---|---|---|
| ASPEN | c/o Kross Border Trust Services Limited<br>Manor House, 1st Floor<br>Corner St George / Chazal Streets<br>Port Louis<br>Mauritius | +(230) 203 6650 |
| | **With a copy to:**<br>Aspen Pharmacare Holdings Limited<br>1st Floor Aspen House, Aspen Park<br>98 Armstrong Avenue<br>La Lucia Ridge<br>Durban, 4019<br>Republic of South Africa<br>Attn: **Group Chief Executive** | +27 31 5808640 |



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| Name | Physical Address | Telefax Number |
|---|---|---|
| IROKO | 65, boulevard Grande-Duchesse Charlotte, L-1331<br>LUXEMBOURG<br>Attn: **Gérant** | |

provided that a party may change its *domicilium* to any other physical address and its address for the purposes of notices to any other postal address by written notice to the other party to that effect. Such change of address will be effective 7 (seven) days after receipt of notice of the change of *domicilium*.

22.2. All notices to be given pursuant to this AGREEMENT will be in writing and shall be deemed properly served if:-

22.2.1. delivered by hand to a responsible person during normal business hours, be rebuttably presumed to have been received on the date of delivery; or

22.2.2. sent by Federal Express or other like international courier service, be rebuttably presumed to have been received within five (5) business days of posting, or

22.2.3. if sent by facsimile, on the date of receipt of successful facsimile transmission.

**23. CONFIDENTIALITY**

23.1. For the purposes of this clause 23 each PARTY is sometimes referred to as a "**Disclosing Party**" in its capacity as the party providing information to the other PARTY hereunder, and as a "**Receiving Party**" in its capacity as the PARTY receiving information from the other PARTY hereunder.

23.2. Subject to clauses 23.5 and 23.6 and save as required by any law or by any regulatory body to which a Receiving Party is subject, during the period of period of this AGREEMENT and for five years after termination of this AGREEMENT, the Receiving Party shall: -

23.2.1. keep the CONFIDENTIAL INFORMATION confidential and ensure that proper and secure storage is provided for all the CONFIDENTIAL INFORMATION;

23.2.2. not expressly or impliedly, directly or indirectly disclose or allow to be disclosed any of the CONFIDENTIAL INFORMATION to any other person other than with the prior written consent of the Disclosing Party or in accordance with clauses 23.3 and 23.4; and

23.2.3. not expressly or impliedly, directly or indirectly (and whether for its own benefit or the benefit of any other person) use and/or exploit or allow to be used and/or exploited any of the CONFIDENTIAL INFORMATION for any purpose other than the proper performance of its obligations under this AGREEMENT or any other written agreement in connection with the business between the PARTIES.

23.3. During the term of this AGREEMENT, the Receiving Party may disclose the CONFIDENTIAL INFORMATION to its or its AFFILIATES' employees and/or professional advisers to the extent that it is necessary for the purpose of this AGREEMENT or any



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other AGREEMENT current from time to time in connection with the business between the PARTIES ("**the Recipient**"). For the avoidance of doubt, IROKO may disclose necessary CONFIDENTIAL INFORMATION to its appointed nominee for the purpose of obtaining and maintaining certain Health Registrations in accordance with clause 5 and such nominee will be deemed a Recipient for the purpose of this clause 23.

23.4. The Receiving Party shall procure that each Recipient is made aware of and complies with all the Receiving Party' s obligations of confidentiality under this AGREEMENT as if the Recipient was a party to this AGREEMENT. The Receiving Party shall be responsible for the compliance or non compliance of the Recipient with the obligations of confidentiality under this AGREEMENT.

23.5. The obligations contained in clauses 23.2 to 23.4 shall not apply to any CONFIDENTIAL INFORMATION which:-

23.5.1. as at the EFFECTIVE DATE is, or at any time after the EFFECTIVE DATE, comes into the public domain other than through any unlawful act or omission or any breach of this AGREEMENT or any other confidence by the Receiving Party or any Recipient;

23.5.2. can be proved by the Receiving Party to have been known (other than through any unlawful act or omission or any breach of this AGREEMENT or any other confidence by the Receiving Party or any Recipient) to the Receiving Party prior to it being disclosed by the Disclosing Party to the Receiving Party;

23.5.3. subsequently comes lawfully into possession of the Receiving Party from a third party (other than a group undertaking of any Receiving Party); or

23.5.4. can be proved by the Receiving Party to have been developed independently by the Receiving Party other than from information disclosed by the Disclosing Party or disclosed in breach of any of the obligations contained in clauses 23.2 to 23.4 or of any other confidence or pursuant to any unlawful act or omission.

23.6. Upon termination of this AGREEMENT, each party shall, at the other PARTY' S direction, either return or destroy all of the other PARTY' S CONFIDENTIAL INFORMATION which it has in its possession or under its control.

**24. NATURE OF RELATIONSHIP**

24.1. The relationship of the PARTIES pursuant to this AGREEMENT with regard to the PRODUCTS shall be that of purchaser and supplier/manufacturer, neither PARTY being the agent or partner of the other. Neither PARTY shall be entitled to bind the credit of the other.

24.2 Each of the PARTIES undertakes in regard to the carrying out of the provisions of this AGREEMENT that it will act in the utmost good faith in its relationship with the other PARTY.



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## 25. ADVERSE EVENTS AND FORCE MAJEURE

25.1. In the event of either of the PARTIES suffering a material prejudice as a consequence of the tax laws or regulations applicable to either of the PARTIES at any time, the PARTIES will enter into good faith negotiations to re-structure the arrangements (as recorded in this AGREEMENT) between the PARTIES in such a way as to diminish the effect of such prejudice to the greatest extent possible.

25.2. Delay or failure to comply with or breach of any of the terms and conditions of this AGREEMENT if occasioned by or resulting from an act of God or public enemy, fire, explosion, earthquake, perils of the sea, flood, storm or other adverse weather conditions, war declared or undeclared, civil war, revolution, civil commotion or other civil strife, terrorism, riot, strikes, blockade, embargo, sanctions, epidemics, act of an government or other authority, compliance with government orders, demands or regulations, or any circumstances of like or different nature beyond the reasonable control of the PARTY so failing ("**force majeure**"), shall not be deemed to be a breach of this AGREEMENT nor shall it subject either PARTY to any liability to the other.

25.3. If any force majeure occurs in relation to either PARTY which affects or may affect the performance of any of its obligations under this AGREEMENT, it shall notify the other PARTY forthwith as to the nature and extent of the circumstances in question.

25.4. Neither PARTY shall be deemed to be in breach of this AGREEMENT, or shall be otherwise liable to the other PARTY, by reason only of any delay in performance, or the non-performance of any of its obligations hereunder, to the extent that the delay or non-performance is due to any force majeure of which it has duly notified the other PARTY, and the time for performance of that obligation shall be extended accordingly.

25.5. If the performance by either PARTY of any of its obligations under this AGREEMENT is prevented or delayed by force majeure for a continuous period in excess of five (5) working days, the PARTIES shall enter into *bona fide* discussions with a view to alleviating its effects, or to agreeing upon such alternative arrangements as may be fair and reasonable in the circumstances.

25.6. Should either PARTY be prevented from carrying out its contractual obligations by force majeure lasting continuously for a period of six (6) months, and no mutually acceptable arrangement is arrived at within such period, either PARTY shall be entitled to terminate the AGREEMENT forthwith on written notice.

## 26. SUB-CONTRACTORS

26.1 ASPEN shall not, without the prior written consent of IROKO (which consent shall not be unreasonably withheld or delayed), appoint any sub-contractor (other than PHARMACARE in terms of the TOLL MANUFACTURING AGREEMENT), or any other person or persons to carry out its obligations under this AGREEMENT. For clarification purposes, it is recorded that ASPEN shall have the irrevocable rights to sub-contract the whole or any portion of its obligations to MANUFACTURE and/or PACK the PRODUCTS to PHARMACARE in terms of the TOLL MANUFACTURING AGREEMENT.



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26.2 In the event that ASPEN appoints a sub-contractor, including PHARMACARE, or other person to perform its obligations, whether in whole or in part, it shall remain liable to IROKO for the performance of all its obligations and shall ensure that any such sub-contractor, including PHARMACARE, or other person reads and understands the implications of this AGREEMENT.

**27. GOVERNING LAW AND JURISDICTION**

27.1. All matters arising from or in connection with this AGREEMENT, its validity, existence or termination shall be determined in accordance with the laws as in effect from time to time of England and Wales (without reference to rules of conflicts of laws), save to the extent provided for in 27.2.

27.2. Save as provided for in 7.2, 7.6, 9.3 and 16.5, in the event of any dispute or difference arising between the PARTIES relating to or arising out of this AGREEMENT, including the implementation, execution, interpretation, rectification, termination or cancellation of this Agreement, the Chief Executive Officers or Executive Chairperson (as the case may be) of the PARTIES shall forthwith meet to attempt to settle such dispute or difference, and failing such settlement within a period of 21 (twenty one) business days, the said dispute or difference shall, on written demand by any PARTY to the dispute, be submitted to arbitration before 3 (three) arbitrators in London in accordance with the United Nations Commission on International Trade Law (UNCITRAL) Arbitration Rules as are in force at the date of the aforementioned written demand.

27.3. Notwithstanding anything to the contrary contained in this AGREEMENT, nothing in this clause 27 shall preclude any party to the arbitration from seeking interlocutory relief in any court having jurisdiction, pending the institution of appropriate proceedings for the enforcement of any rights under this AGREEMENT.

27.4. The PARTIES to the arbitration undertake to keep the arbitration, including the subject matter of the arbitration and the evidence heard during the arbitration, confidential and not to disclose it to anyone except for the purposes of an order to be made in terms of clause 27.5, subject, however, to any disclosure obligations under APPLICABLE LAWS, including securities laws.

27.5. The majority decision of the arbitrators shall, in the absence of manifest error, be final and binding on the PARTIES to the arbitration and may be made an order of court at the instance of any party to the arbitration.

27.6. The provisions of this clause 27 are separate and severable from the rest of this AGREEMENT and shall remain in effect despite the termination or invalidity for any reason of this AGREEMENT.

**28. ETHICAL STANDARDS AND HUMAN RIGHTS BY IROKO**

28.1. Unless otherwise required or prohibited by the APPLICABLE LAWS, IROKO warrants to ASPEN that, to the best of its knowledge, that in relation to the performance of its obligations in terms of this AGREEMENT –

28.1.1. it does not employ engage or otherwise use any child labour in circumstances such that the tasks performed by any such child labour could reasonably be foreseen to cause either physical or emotional impairment to the development of such child;



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28.1.2. it does not use forced labour in any form (prison, indentured, bonded or otherwise) and its employees are not required to lodge papers or deposits on starting work;

28.1.3. it provides a safe and healthy workplace, presenting no immediate hazards to its employees. Any housing provided by IROKO to its employees is safe for habitation. IROKO provides access to clean water, food, and emergency healthcare to its employees in the event of accidents or incidents at the IROKO' S workplace;

28.1.4. it does not discriminate against any employees on any ground (including race, religion, disability or gender);

28.1.5. it does not engage in or support the use of corporal punishment, mental, physical, sexual or verbal abuse and does not use cruel or abusive disciplinary practices in the workplace;

28.1.6. it pays each employee at least the minimum wage, or a fair representation of the prevailing industry wage, (whichever is the higher) and provides each employee with all legally mandated benefits;

28.1.7. it complies with the laws on working hours and employment rights in the countries in which it operates;

28.1.8. it is respectful of its employees right to join and form independent trade unions and freedom of association.

28.2. IROKO shall ensure that it has ethical and human rights policies and an appropriate complaints procedure to deal with any breaches of such policies. In the case of any complaints, IROKO shall report the alleged complaint and proposed remedy to ASPEN.

**29. ETHICAL STANDARDS AND HUMAN RIGHTS BY ASPEN**

29.1. Unless otherwise required or prohibited by the APPLICABLE LAWS, ASPEN warrants to IROKO that, to the best of its knowledge, that in relation to the performance of its obligations in terms of this AGREEMENT –

29.1.1. it does not employ engage or otherwise use any child labour in circumstances such that the tasks performed by any such child labour could reasonably be foreseen to cause either physical or emotional impairment to the development of such child;

29.1.2. it does not use forced labour in any form (prison, indentured, bonded or otherwise) and its employees are not required to lodge papers or deposits on starting work;



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29.1.3. it provides a safe and healthy workplace, presenting no immediate hazards to its employees. Any housing provided by ASPEN to its employees is safe for habitation. ASPEN provides access to clean water, food, and emergency healthcare to its employees in the event of accidents or incidents at the ASPEN' S workplace;

29.1.4. it does not discriminate against any employees on any ground (including race, religion, disability or gender);

29.1.5. it does not engage in or support the use of corporal punishment, mental, physical, sexual or verbal abuse and does not use cruel or abusive disciplinary practices in the workplace;

29.1.6. it pays each employee at least the minimum wage, or a fair representation of the prevailing industry wage, (whichever is the higher) and provides each employee with all legally mandated benefits;

29.1.7. it complies with the laws on working hours and employment rights in the countries in which it operates;

29.1.8. it is respectful of its employees right to join and form independent trade unions and freedom of association.

29.2. ASPEN shall ensure that it has ethical and human rights policies and an appropriate complaints procedure to deal with any breaches of such policies. In the case of any complaints, ASPEN shall report the alleged complaint and proposed remedy to IROKO.

**30. GENERAL**

30.1. This AGREEMENT constitutes the whole of the agreement between the PARTIES hereto relating to the subject matter hereof and save as otherwise provided herein no amendment, alteration, addition, variation or consensual cancellation shall be of any force or effect unless reduced to writing and signed by the PARTIES hereto or their duly authorized representatives.

30.2. The PARTIES agree that no other conditions, warranties or representations whether oral or written, and whether express or implied whether by statute or otherwise, shall apply hereto.

30.3. No addition to, variation, novation or agreed cancellation of this AGREEMENT shall be of any force or effect unless in writing and signed by or on behalf of the PARTIES.

30.4. The failure of a PARTY in any instance to insist on the strict performance of the terms of this AGREEMENT shall not be construed to be a waiver or relinquishment of any of the terms of this AGREEMENT, either at the time of the PARTY' S failure to insist upon strict performance, or at any subsequent time.

30.5. All costs, charges and expenses of any nature whatever which may be incurred by a PARTY in enforcing its rights pursuant to this AGREEMENT, including legal costs on the scale of attorney and own client and collection commission, irrespective of whether any action has been instituted, shall be recoverable from the PARTY against which such rights are successfully enforced.



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30.6. All provisions in this AGREEMENT are, notwithstanding the manner in which they have been put together or linked grammatically, severable from each other. Any provision of this AGREEMENT which is or becomes unenforceable in any jurisdiction, whether due to voidness, invalidity, illegality, unlawfulness or for any other reason whatsoever, shall, in such jurisdiction only and only to the extent that it is so unenforceable, be treated as pro non scripto and the remaining provisions of this AGREEMENT shall be of full force and effect. The PARTIES declare that it is their intention that this AGREEMENT would be executed without such unenforceable provisions if they were aware of such unenforceability at the time of its execution.

30.7. This AGREEMENT may be signed in separate counterparts, each of which shall be deemed to be an original and all of which taken together shall constitute one and the same instrument. A counterpart of this AGREEMENT in fax form shall be conclusive evidence of the original signature and shall be as effective in law as the counterparts in original form showing the original signatures.

30.8. Termination of this AGREEMENT shall not release either PARTY hereto from any liability or right of action which at the time of termination has already accrued to either PARTY hereto or which may thereafter accrue in respect of any act or omission prior to such termination. Such rights shall include but not be limited to the recovery of any monies due hereunder.

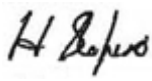
**31. COSTS**

Each PARTY shall bear and pay for its own costs of and incidental to the negotiation, drafting, preparation and execution of this AGREEMENT.

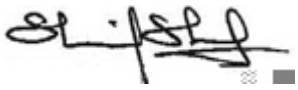
**SIGNED BY ASPEN IN MAURITIUS ON THIS 1st day of APRIL 2008**

**AS WITNESSES:**

For: **ASPEN GLOBAL INCORPORATED**

1. 

2. 



**DHANUN UJOODHA** or **SHARMIL SHAH**,
warranted by his signature that he is duly authorised hereto

SIGNED by IROKO at Philadelphia, PA on this 1st day of April 2008

**AS WITNESSES:**

For: **IROKO PHARMACEUTICALS (LUXEMBOURG) SARL**

1. 

2. 

**OSAGIE IMASOGIE**, warranted by his signature that he is duly authorised hereto

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**APPENDIX 1**

**PRODUCTS AND TRADEMARKS**

| [redacted] | | | |
|---|---|---|---|
| Methyldopa | 250mg, 500mg | Tablets | ALDOMET® |
| Indomethacin | 25mg, 50mg | Capsules | INDOCIN® |



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**APPENDIX 2**

**TECHNICAL AGREEMENT**

Between

**IROKO PHARMACEUTICALS (LUXEMBOURG) SARL**

and

**ASPEN GLOBAL INCORPORATED**

and

**PHARMACARE LIMITED**
**TRADING AS ASPEN PHARMACARE**

In this Agreement, reference to "Aspen" shall mean Aspen Global Incorporated and/or Pharmacare Limited, as the context may require, this having regard to the fact that Aspen Global Incorporated will appoint Pharmacare Limited in terms of a Toll Manufacturing Agreement to manufacture and/or pack the products which are the subject matter of this Agreement.

This document constitutes the TECHNICAL AGREEMENT required in terms of **Good Manufacturing Practice (cGMP).** The agreement defines roles and responsibilities for Iroko and Aspen relating to pharmaceutical manufacture, packaging and assembly of products listed in Appendix 1.

The TECHNICAL AGREEMENT defines the individual responsibilities of IROKO and Aspen and in particular defines who is responsible for the cGMP aspects of manufacturing and specifies the way in which the RESPONSIBLE PHARMACIST releasing product batches for sale ensures they comply with the Marketing Authorisation.

The TECHNICAL AGREEMENT takes the form of a detailed checklist of all the activities associated with pharmaceutical production, analysis and release. Responsibility for each activity is assigned to either Iroko or Aspen or may be a dual responsibility. If any element of the checklist does not apply, it will be denoted as Not Applicable (N/A). A list of the products and countries to which this TECHNICAL AGREEMENT applies is attached as Appendix 1. It is then appended to the legal contract, which covers the commercial and other aspects of the AGREEMENT between the PARTIES.

In general, Iroko will provide, to the best of its knowledge, to Aspen technical know-how and technical documents. Aspen will package or manufacture for distribution/sale by Aspen or supply bulk product or finished packs to an Iroko distribution/partner. Aspen will perform the required activity/tasks using their facilities, equipment, staff and procedures to manufacture the product(s) under cGMP conditions.



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**Packaging by Aspen**

Aspen, using Iroko technical information, will package bulk products supplied to Aspen by iroko from an Iroko third party manufacturing partner (e.g. Merck). In this case, Iroko is responsible to assure to Aspen that Iroko supplied bulk product meets all finished goods specifications and provides Aspen all required technical documentation. This product maybe distributed by Aspen or shipped to an Iroko partner for distribution/sale in agreed upon areas (e.g. Europe)

**Manufacturing by Aspen**

Aspen, using Iroko technical information and formulations, will also manufacture, package and distribute for sale products listed in Appendix 1. In this process, Aspen will assure that all products manufactured by Aspen meet the current finished product specifications. Aspen may also supply to an Iroko partner bulk product that will be shipped to the Iroko partner for packaging and distribution (e.g. Europe).

***Technical Agreement Review Date:*** 3 years (or sooner if the products or activities change)

NOTE: Any changes to any of the steps specified within this TECHNICAL AGREEMENT must be approved, in writing, by both Iroko and Aspen prior to implementation.



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**TECHNICAL AGREEMENT**

TECHNICAL AGREEMENT SIGNATURES

| | | | |
|---|---|---|---|
| Company Name: | PHARMACARE | | |
| Address: | Building 12 | Address of Manufacturing Plant if Different: | 7 Falrclough Road |
| | Healthcare Park | | Korsten, 6014 |
| | Woodlands Drive | | Port Elizabeth |
| | Woodmead | | |
| Position: | RESPONSIBLE PHARMACIST | | RESPONSIBLE PHARMACIST |
| Name: | Lorraine Hill | | Lisa Fleetwood-Jones |
| Signature: | | | |
| Date: | | | |

| | | |
|---|---|---|
| Company Name: | IROKO PHARMACEUTICALS (LUXEMBOURG) SARL | |
| Address: | 65, boulevard Grande-Duchesse Charlotte,<br>L-1331 Luxembourg | |
| Position: | | |
| Name: | | |
| Signature: | | |
| Date: | | |

| | | |
|---|---|---|
| Company Name: | ASPEN GLOBAL INCORPORATED | |
| Address: | c/o Kross Border Trust Services Limited,<br>Manor House, 1st Floor,<br>Corner St George / Chazal Streets,<br>Port Louis, Mauritius | |
| Position: | | |
| Name: | | |
| Signature: | | |
| Date: | | |



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| | | Responsible Party | |
|---|---|---|---|
| | | Iroko | Aspen |
| 1.0 | RESPONSIBILITIES | | |
| | cGMP REQUIREMENTS | | |
| 1.1 | MANUFACTURE and PACKAGE in accordance with Good Manufacturing Practices as defined in the PIC Guide and any locally imposed requirements. | X | X |
| 1.2 | Iroko and Aspen should have a copy of the relevant information from registered PRODUCT dossier for the product on site. Iroko has responsibility for notifying the Aspen of any MCC changes. | X | X |
| 1.3 | Maintain a valid Manufacturing License covering manufacture of the product. | | X |
| 1.4 | MANUFACTURE and PACK product in strict adherence to the approved Marketing Authorisation also known as the PRODUCT dossier (*as defined in footnote 1)*. | | X |
| 1.5 | Permit audits of all relevant facilities, procedures and documentation by the Iroko. Notify Iroko of any adverse regulatory activity that directly impacts on the supplied product. Permit inspection by Regulatory Authorities. | | X |
| 1.6 | Advise Iroko in the event of an inspection by any regulatory agency in respect of any product listed in Appendix 1. Advise Iroko in the event of any critical or major regulatory agency non-conformances concerning facilities, procedures or processes that may affect products listed in appendix 1. | | X |
| 1.7 | Aspen agrees not to subcontract any of the manufacturing or testing work to a third party without prior written agreement from Iroko. All Iroko−Aspen approved third party subcontractors used by Aspen must meet the requirements of this TECHNICAL AGREEMENT. | | X |
| 1.8 | Approve all Master Manufacturing Instructions (Production Operating Instructions), *(as defined in footnote 2)* | X | X |
| 1.9 | Make no changes to the registered product specification or registered manufacturing process without prior written agreement. All changes must follow a documented change control system *(defined in footnote 3)*. | | X |
| 1.10 | Document and notify any deviation, out-of-specification results, non-compliance with cGMP, investigations, complaints or other matters which may impact the decision of the RESPONSIBLE PHARMACIST to certify the finished product batch for release to market. Non Conformance deviation investigations must be conducted following a documented deviation Investigation reporting system *(as defined in footnote 4)* and must include notification to the Iroko. | | X |



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| | | Responsible Party | |
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| | | Iroko | Aspen |
| 1.11 | Make no changes in the sourcing of any actives or excipient materials from the approved vendor list without prior written agreement. All changes must follow a documented change control system (*as defined in footnote 3*). | | X |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 1.12 | Control the quality of all actives and excipients according to specification by the application of approved analytical methods. Should issues occur subsequent to release that would invalidate or compromise results already provided, the Iroko must be immediately notified. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 1.13 | Batch release by an authorised RESPONSIBLE PHARMACIST (or equivalent responsible person) after review of the information specified in sections 2, 3 and 4 to ensure compliance with the PRODUCT dossier, *(as defined in footnote 2)* | | |
| | A full certificate of analysis and a certificate of conformance (release statement) will be supplied to Iroko, | | |
| | PRODUCT failing to meet the general specification may not be dispatched to Iroko without prior written agreement. No product failing to meet the valid PRODUCT dossier specification in full can be dispatched to Iroko without prior AGREEMENT from the relevant Ministry of Health *(as defined in footnote 1)* | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 1.14 | Maintain all batch records for a minimum of 2 years after the expiration date and supply all such records to the Iroko on request. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |



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| | | Iroko | Aspen |
| 1.15 | Not to reprocess (including non-standard inspections) without prior written approval from the Iroko. All reprocessing operations must be validated. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 1.16 | Report all batch failures and major deviations to Iroko within 24 hours even if shipping schedules are not affected. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 1.17 | Investigate product complaints from Iroko within the specified and agreed upon times. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 1.18 | If the active ingredient is listed as a scheduled controlled substance, all the requirements of the Medicines Control Act 101 of 1965 and its amendments and regulations must be adhered to. | | N/A |
| 1.19 | If the product contains a medical device then compliance with directive 93/42/EEC is required. | | N/A |
| 1.20 | Aspen will survey/audit vendors of the primary packaging commodities utilised in the production of PRODUCT. This survey will identify these primary packaging commodities as being of animal origin or not being of animal origin, and shall be completed by *(as detailed in footnote 5)* | | X |
| 1.21 | Aspen agrees to not to manufacture or package any Iroko products in the same facility that is used by Aspen to manufacture highly sensitising materials (e.g. penicillins/cephalosporins), biological preparations (e.g. from live microorganisms), hormones, cytotoxics, cytostatics or other compounds generally regarded as highly potent. | | X |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |



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| | Iroko | Aspen |
| 2.0 RESPONSIBILITIES PRODUCTION AND TESTING OF BULK MATERIAL | | |
| 2.1 Master Formula per unit of product. | | |
| PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| MANUFACTURING AND PACKAGING OF ASPEN BULK | X | X |
| 2.2 Master PRODUCT specification. | | |
| PACKAGING ONLY OF IROKO SUPPLIED BULK | X | X |
| MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.3 Batch identification system for bulk manufacture. | | |
| PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.4 Purchase of active substances (including certificates of analysis). | | |
| PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.5 Storage of active substances. | | |
| PACKAGING ONLY OF IROKO SUPPLIED BULK | | |
| MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.6 Sampling of active substances. | | |
| PACKAGING ONLY OF IROKO SUPPLIED BULK | | |
| MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.7 Test method for active substances. | | |
| PACKAGING ONLY OF IROKO SUPPLIED BULK | | |
| MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |



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| | | Responsible Party | |
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| | | Iroko | Aspen |
| 2.8 | Analysis of active substances (including documentation). | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.9 | Release of active substances. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.10 | Retain reference samples of active substances for at least 5 years after the date of manufacture of the active substance or at least one year after the expiry date of the last lot of product containing the batch of active material, whichever is longest | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.11 | Procurement of excipient substances (including certificates of analysis) | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.12 | Storage of excipient substances. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.13 | Sampling of excipient substances. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.14 | Test method for excipient substances. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |



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| | | Iroko | Aspen |
| 2.15 | Analysis of excipient substances (including documentation, certificate of analysis, etc.) | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | |
| | PRODUCTION AND TESTING OF BULK MATERIAL | | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.16 | Release of excipient substances. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.17 | Retain reference samples of inactive substances for at least 5 years after the release of the inactive substance. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.18 | Process validation | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.19 | Cleaning validation | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.20 | Generation of Bill of Materials for bulk manufacture. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.21 | Adherence to Manufacturing Instructions (Standard Operating Instructions). · | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| | MANUFACTURING AND PACKAGING OF-ASPEN BULK | | X |



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| | | Iroko | Aspen |
| 2.22 | Production of bulk material (including batch documentation). | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.23 | In-process control instructions. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.24 | In process controls (including documentation). | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.25 | Bulk material sampling plan. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.26 | Sampling of bulk material. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.27 | Test method for bulk material. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.28 | Test method validation of bulk | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 2.29 | Analysis of bulk material. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |



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| | | Responsible Party | |
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| | | Iroko | Aspen |
| 2.30 | Release of bulk material for packaging. lroko for lroko supplied bulk, Aspen for Aspen received bulk material and Aspen manufactured bulk | X | X |
| 2.31 | Retain reference samples of bulk material for at least 5 years after the release of the bulk material. | | X |
| 2.32 | Certificate of analysis and conformance for bulk tablets/granulate, to be issued by a responsible pharmacist (or equivalent responsible person). lroko for Iroko bulk supplied to Aspen.<br>Aspen for Aspen manufactured bulk. | X | X |
| 3.0 | PACKAGING OF FINISHED PRODUCT | | |
| 3.1 | Procurement of primary packaging components (including certificates of analysis) | | X |
| 3.2 | Storage of primary packaging components substances. | | X |
| 3.3 | Sampling of primary packaging components substances | | X |
| 3.4 | Test method for primary packaging components substances | | X |
| 3.5 | Analysis of primary packaging components substances (including documentation, COA) | | X |
| 3.6 | Release of primary packaging components substances | | X |
| 3.7 | Finished product specification | X | X |
| 3.8 | Batch identification system for finished product. | | X |
| 3.9 | Artwork and labelling text (blister, carton, leaflet, label, etc) & design | X | |
| 3.10 | Labelling & artwork review and approval | X | |
| 3.11 | SPECIFICATIONS for packaging materials | | X |
| 3.12 | Test methods for packaging materials | | X |
| 3.13 | Procurement of packaging materials | | X |
| 3.14 | Analysis of packaging materials | | X |
| 3.15 | Release of packaging materials | | X |
| 3.16 | Samples of packaging materials to be attached to packaging record | | X |
| 3.17 | Validation of packaging process | | X |



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| | | Responsible Party | |
|---|---|---|---|
| | | Iroko | Aspen |
| 3.18 | Bill of Materials for packaging | | X |
| 3.19 | PACKAGING Instructions | | X |
| 3.20 | PACKAGING operation (including documentation) | | X |
| 3.21 | In-process control instructions | | X |
| 3.22 | In process controls during packaging (including documentation) | | X |
| 3.23 | Finished product-sampling plan | | X |
| 3.24 | Sampling of finished product | | X |
| 3.25 | Retain reference samples of finished product for at least one year after the expiry date | | X |
| 3.26 | Reconciliation of packaging materials | | X |
| 3.27 | Storage of packaging materials | | X |
| 4.0 | RESPONSIBILITIES<br>TESTING AND RELEASE OF FINISHED PRODUCT (Aspen manufactured) | | |
| 4.1 | Test method for finished product. | X | X |
| 4.2 | Analysis of finished product (incl. Documentation) | | X |
| 4.3 | Release to the lroko of finished product by a RESPONSIBLE PHARMACIST (or equivalent Responsible Person). | | X |
| 4.4 | Certificate of analysis for finished product | | X |
| 4.5 | Aspen performed Stability Testing *(Refer footnote 6)* | TBD | TBD |
| | Sampling of product | To be agreed | To be agreed |
| | Sample storage in temperature controlled stability incubators. | To be agreed | To be agreed |
| | Prior to initial supplies place the first batch of product of stability according to the following criteria. | To be agreed | To be agreed |
| | [***] | To be agreed | To be agreed |
| | [***] | To be agreed | To be agreed |

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| | | Responsible Party | |
|---|---|---|---|
| | | Iroko | Aspen |
| | [***] | To be agreed | To be agreed |
| | [***] | To be agreed | To be agreed |
| | [***] | To be agreed | To be agreed |
| | [***] | To be agreed | To be agreed |
| | On a routine, annual, basis place one batch of product on stability for the duration of the shelf life of the product, reporting results to the lroko annually. | To be agreed | To be agreed |
| | [***] | To be agreed | To be agreed |
| | [***] | N/A | N/A |
| | [***] | N/A | N/A |
| 4.6 | Results of 9 months required prior to marketing for a new product. | | N/A |
| 4.7 | Results concurrent with marketing for changes not requiring prior REGULATORY AUTHORITY approval. | X | |
| 4.8 | Pharmacovigilance and reporting of adverse drug events. | X | X |
| 4.9 | Complaints | | |
| | Collection and first logging | X | |
| | Subsequent logging | | X |
| | Investigation and issue of reports | X | X |
| | Follow up corrective action | X | X |
| | Response to the customer | X | |
| 4.10 | Annual product review | X | X |
| 4.11 | PRODUCT Recall *(See footnote 9)* | | |
| | Decision to initiate recall | X | X |
| | Approval of wording of notification to Board of Health | X | |
| | Notification to Board of Health | X | |
| | Management of recall. *(as defined in footnote 9)* | X | X |
| | Reconciliation of returned product | X | |

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| | Responsible Party | |
|---|---|---|
| | Iroko | Aspen |
| 4.12 Responsibility to Authorities | | |
| Liaison with Regulatory Authorities for approval, maintenance and updating of product dossier. | X | |
| Check that lroko has an appropriate Manufacturing License. | X | |
| Maintain safety/hazard and handling data on product and component materials | | X |
| Liaison with Health and Safety Authorities | | X |
| Liaison with Environmental Protection Authorities (Pollution Prevention) | | X |



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| | | Responsible Party | |
|---|---|---|---|
| | | Iroko | Aspen |
| 5.0 | RESPONSIBILITIES | | |
| | BATCH DOCUMENTATION | | |
| 5.1 | Provide complete batch documentation for the first two batches of product to the Iroko. | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK. | X | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 5.2 | Provide the following documentation to Iroko for each batch as specified below: | | X |
| | Certificate of analysis signed by a RESPONSIBLE PHARMACIST (Or Equivalent Responsible Person) | | X |
| | Certificate of conformance (release statement) | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| | Other: Manufacturing Investigation Reports, Laboratory Investigation Reports and Change Controls as related to product Quality | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 5.3 | Provide the following documents if requested for specific batches, within 5 working days of the request: | | |
| | Bill of Materials for bulk manufacture | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| | Analytical results for raw materials | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |



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| | | Responsible Party | |
|---|---|---|---|
| | | Iroko | Aspen |
| | Manufacturing Instructions | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| | In process control record for manufacture | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| | Certificate of analysis for bulk material | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| | Bill of Materials for packaging | | X |
| | PACKAGING Instructions | | X |
| | In-Process Control record for packaging | | X |
| | Reconciliation of packaging material | | X |
| | Stability date for batches included in the stability program *(see footnote 6)* | AS agreed | As agreed |
| | Other (specify). CERTIFICATE OF ANALYSIS of Active raw material | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | X | |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| 5.4 | Maintenance of distribution records (for use in the event of a product recall). | X | |



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| | | Responsible Party | |
|---|---|---|---|
| | | Iroko | Aspen |
| 6.0 | RESPONSIBILITIES<br>STORAGE AND TRANSPORTATION OF BULK MATERIAL, FINISHED PRODUCT AND WASTE DISPOSAL | | |
| 6.1 | Storage of bulk material up to packaging or delivery ex-plant | X | X |
| 6.2 | Storage of finished product, whilst under control of the Iroko. (Conditions as per product requirements) | | X |
| 6.3 | Storage of finished product upon delivery to third party distributor. | | N/A |
| 6.4 | Storage under special conditions, e.g. refrigeration (specify conditions): Below 25°C, protected from light | | N/A |
| 6.5 | Transportation of bulk material to packaging site or designated third party. | X | N/A |
| 6.6 | Transportation of finished product to designated delivery point. | X | N/A |
| 6.7 | Transport under special conditions (specify): In an enclosed container truck | X | N/A |
| 6.8 | Insurance for transportation ex-plant | X | N/A |
| 6.9 | Customs requirements | X | |
| 6.10 | Disposal of waste | | X |
| 6.11 | Disposal of special waste, e.g. toxic waste, solvents, etc. (Specify nature of waste and special disposal methods required) in accordance with the requirements of MCC and Health and Safety Authority | | X |
| | Active raw materials | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| | Excipient raw materials | | |
| | PACKAGING ONLY OF IROKO SUPPLIED BULK | | X |
| | MANUFACTURING AND PACKAGING OF ASPEN BULK | | X |
| | PACKAGING materials: foil, film, cartons etc. | | X |
| | Accessories: bulk tablet containers etc. | | X |



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**TECHNICAL AGREEMENT**

LIST OF QUALIFIED PERSONS AT IROKO

| | | |
|---|---|---|
| **1.** | **TECHNICAL MANAGER / Quality issues:**<br>Joseph C. Crea<br>V.P, Operations | Ph: 267-546-3012<br>Fax: 267-546-3004<br>E-mail: jcrea@iroko.com |
| **2.** | **Regulatory / Legislation:**<br>Hanna Zyruk<br>Director, Regulatory Affairs | Ph: 267-546-3010<br>Fax: 267-546-3004<br>E-Mail: hzyruk@iroko.com |
| **3.** | **Logistics:**<br>Wilma Rivera<br>Director, External Operations | Ph: 267-546-3036<br>Fax: 267-546-3004<br>E-Mail: wrivera@iroko.com |

LIST OF QUALIFIED PERSONS AT ASPEN:

| | | |
|---|---|---|
| **1.** | **TECHNICAL MANAGER / Quality issues:**<br>Lisa Fleetwood-Jones<br>Technical Operations Executive | Ph: 041 4072636<br>Fax: 041 4072691<br>E-Mail: Lisafj@aspenpharma.com |
| **2.** | **Regulatory / Legislation:**<br>Lorraine Hill<br>Group Regulatory Executive | Ph: 031 5808608<br>Fax: 031 5808630<br>E-Mail: LHill@aspenpharma.com |



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**TECHNICAL AGREEMENT-**

APPENDIX 1: PRODUCTS

The products and markets covered by this TECHNICAL AGREEMENT are:

| | INDOCID | INDOCID | ALDOMET | ALDOMET |
|---|---|---|---|---|
| | [redacted] | [redacted] | [redacted] | [redacted] |
| **INTERNATIONAL PRIORITY COUNTRIES** | | | | |
| Algeria | | | | |
| Argentina | | | | 40 |
| Australia | | | | |
| Barbados | | | | 30 |
| Brazil | | | | 30 |
| Burkina Faso (FCP) | | | | |
| Cameroon (FCP) | | | | 30 |
| Colombia | | | | 30 |
| Congo | | | | 30 |
| Costa Rica (SCP) | | | | 30 |
| Dominican Republic (SCP) | | | | 30 |
| Ecuador | | | | |
| El Salvador (SCP) | | | | 30 |
| Ethiopia | | | | |
| Guatemala (SCP) | | | | 30 |
| Honduras (SCP) | | | | 30 |
| Hong Kong | | | | |
| Ireland | | | | 30 |
| Ivory Coast (FCP) | | | | 30 |
| Jamaica | | | | 30 |
| Kenya | | | | 100 |
| Mexico | | | | 30 |
| Morocco (FCP) | | | | 30 |
| Nicaragua (SCP) | | | | 30 |
| Peru | | | | 30 |
| Philippines | | | | |
| Reunion (FCP) | | | | 30 |
| Senegal (FCP) | | | | 30 |
| Singapore | | | | |
| South Africa | | | | |



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| | | | | |
|---|---|---|---|---|
| Trinidad | | | [redacted] | 30 |
| UK | | | | 30 |
| Venezuela | [redacted] | [redacted] | | |
| | | | | |
| **INTERNATIONAL** | | | | |
| **NON PRIORITY COUNTRIES** | | | | |
| Antigua | | | [redacted] | 30 |
| Aruba | | | | |
| Bahamas | | | | 30 |
| Belize | | | | |
| Benin | [redacted] | | | 30 |
| Bermuda | | | | |
| Cayman Islands | | | [redacted] | 30 |
| Central African Emp | | | | |
| China | | | | |
| Chad | [redacted] | | [redacted] | 30 |
| Curacao | | | | |
| Dijibouti | | | | 30 |
| French Guiana | [redacted] | | | 30 |
| French Polynesia | | | | |
| Gabon | | | | 30 |
| Guadeloupe | [redacted] | | | 30 |
| Guyana | | | | |
| Haiti | | | | 30 |
| Korea | | | | |
| Libya | | | [redacted] | |
| Madagascar | | | | 30 |
| Mali | [redacted] | | | 30 |
| Martinique | | | | 30 |
| Mauritania | [redacted] | | | 30 |
| New Caledonia | | | | 30 |
| Niger | | | | 30 |
| Panama | [redacted] | | | 20, 30 |
| Paraguay | | | | |
| Republic of Guiana | | | [redacted] | 30 |
| Taiwan | | | | |
| Togo | [redacted] | | | 30 |
| Uruguay | | | | 20 |
| Zaire | | | | 30 |



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**Notes**

Supply to the Philippines is currently in bulk l000s

Commercialisation plan for non priority countries to be finalised by 15th November

No product sales currently in China and Korea

| Approval of Appendix 1 | Signature | Date |
|---|---|---|
| Iroko: | | |
| Aspen: | | |
| | Lorraine Hill | |
| | Lisa Fleetwood-Jones | |



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**Footnote 1: Product Dossier**

The product dossier includes copies of master specifications.

**Footnote 2: Management of cGMP requirements**

Aspen will at all times have a current and valid cGMP and manufacturing license obtained from the necessary Regulatory Body.

Iroko delegates the responsibility of RESPONSIBLE PHARMACIST as defined in this Contract, to the RESPONSIBLE PHARMACIST appointed by Aspen. This appointment will be reviewed annually during the cGMP and Risk Assessment Audit conducted by Iroko.

**Footnote 3: Change Control**

A documented procedure for the control of changes to manufacturing components, packaging materials, labelling, the method of manufacturing, product specifications, and commodity vendors must be utilised by the Iroko. Any significant changes that may or may not affect the quality, purity, safety, effectiveness or regulatory status of PRODUCT (i.e. requiring prior- approval by a REGULATORY AUTHORITY) shall be reviewed and approved by Iroko and Aspen prior to implementation.

When a change authorised through the change control system may or may not have the potential to require a regulatory submission; appropriate representatives from each firm will develop a joint strategy to secure the appropriate regulatory approval(s), as necessary. The change, if jointly approved by both companies in the change control system, may be approved and secured in Aspen documentation system prior to regulatory approval.

Batch record change control must be governed by the guidelines and procedures of the appropriate manufacturing plant. Original batch records will be maintained on site by the Aspen' s Manufacturing and Quality Assurance functions and must be available for inspection and review by Iroko in accordance with the provisions of the Manufacturing AGREEMENT.

Change Control Process should account for changes including, but not limited to approved vendor, raw materials, components specifications, and primary packaging components.

Guidelines for Change Control Notification:

1) No notification required:
Change which does not obviously impact Iroko' s product, process, equipment etc., i.e. general repairs and preventative maintenance.

2) Notification; review and the Iroko approval required:
Change which may have a minor impact on aspect(s) of the Iroko' s product, process, etc., e.g. upgrade of electrical system wiring; new vial washer; new autoclave; change to secondary packaging specs; change to the media fill SOP; change to batch records; maintenance required on dedicated equipment, etc.

3) Notification, review, and the Iroko and Regulatory approval required:
Change that has a direct impact on Iroko' s product, process, or equipment, etc., e.g. changes to raw material and primary component, etc.

**Footnote 4: Manufacturing, PACKAGING and/or Analytical Deviations, and Investigations**

Aspen will utilize a documented exception reporting procedure for the identification and disposition of non-conforming materials and/or processes used in the manufacture of product. The procedure will include processes for batch specific corrective actions and for long-term preventative actions.



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The procedure will also include provision and process for assuring the performance of adequate and appropriate failure investigations. Aspen will notify Iroko, by an established system, of deviations, excursions, and investigations within 5 days of occurrence. Should an investigation extend beyond 30 days, Iroko and Aspen shall mutually agree upon the communication requirements concerning the status and timing of the investigation.

Aspen shall approve all deviations and supply a copy with each batch certificate of analysis.

Investigation documents will be made available to Iroko during an on-site audit. Copies of reports will be made available to the Iroko upon request.

**Footnote 5: Source and supply of Vendors or Raw Materials and PACKAGING Components**

Iroko will survey vendors of all materials (including media fills and cleaning solutions) utilized in the production of PRODUCT. This survey will identify these PRODUCT related materials as being of animal origin or not being of animal origin, and shall be completed by the end of 2004.

At the completion of the aforementioned surveys, if all materials (including media fills and cleaning solutions) utilised in the manufacture of product at the Aspen facility are identified as not being of animal origin, then each CERTIFICATE OF ANALYSIS for such product will include the following statement:

"The material does not derive from, nor has it been in contact with, at any stage during manufacturing, raw materials, chemicals and/or excipients of animal origin. Material is defined as media fill supplies, cleaning agents, product ingredients and primary packaging components."

At the completion of the aforementioned surveys, if any of the materials (including media fills and cleaning solutions) utilised in the manufacture of PRODUCT at the Aspen facility are identified being of animal origin, then each CERTIFICATE OF ANALYSIS for such PRODUCT will include the following information:

Species of animal

Tissue used

Country/countries of origin

Age of animals

Manufacturing process

Availability of any recognised certification for the material to national or international TSE control guidelines

Measures taken to reduce the risk of TSE contamination

Existence of Quality systems to ensure on-going accuracy of the above information

This information must be sufficiently detailed to confirm that the material complies with the relevant regulatory requirements (ref: CPMP note for guidance, EMEA/410/01 rev. 1). Aspen will establish and maintain a TSE assessment for all PRODUCT related materials (including media fills and cleaning solutions) and notify Iroko of changes in TSE status.

**Footnote 6: Stability**

Stability required by the APPLICABLE LAWS and/or precipitated by changes to products will be the responsibility of Iroko. Should Iroko require Aspen to perform such stability (and should Aspen have the required capacity and capabilities to perform such stability), then this will necessitate a separate agreement being reached between Iroko and Aspen.



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**Footnote 7: Management of Adverse Drug Reactions**

While the overall management of the Adverse Drug Reactions would be Iroko' s responsibility, this is noted a shared responsibility as Aspen would need to supply the factory level information.

**Footnote 8: Management of Complaints**

While the overall management of the complaints would be Iroko' s responsibility, this is a shared responsibility as Aspen would need to supply the factory level information.

Apsen will promptly supply all relevant information required for the investigation of customer complaints, or other queries with respect to the quality of the product. Aspen will investigate all customer complaints and will report to the Quality Assurance Manager at Iroko of the findings of such an investigation. Iroko will undertake to reply to the complainant.

Guidelines for immediate notification of a customer complaint:

incorrect labeling

bacteriological or other contamination, stability failures etc

complaint by third party

product does not comply with product specifications, cGMP, laws and regulations

**Footnote 9: Management of Recall**

While the overall management of the recall would be Iroko' s responsibility, this is noted a shared responsibility as Aspen would need to supply the factory level information.

Aspen and Iroko will notify the other promptly if any batch of the product is alleged or proven to be the subject of a recall, market withdrawal or removal.

If the reason for the recall or withdrawal is due to the quality of product as supplied by Aspen, the decision to recall must be by mutual consent, unless a national authority requires a batch recall to be implemented. In the first instance, the Quality Assurance Manager (or nominated deputy), Iroko and the Quality Assurance Manager (or nominated deputy), Iroko must be contacted and receive all essential, relevant information.

Any recall will be in accordance with both lroko and Aspen' s Company Policies. The recall procedures, which ensure prompt action and which identifies the respective staff to be involved in the event of a recall will be followed.

Appropriate records will be kept by both Iroko and Aspen in a suitably accessible form to allow for timely and accurate retrieval of information in the event of a recall situation. The effectiveness of the recall procedure should be challenged at regular pre-determined intervals.



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## APPENDIX 3

## TRADEMARK CONTROL ATTACHMENT

1.1 ASPEN shall use the TRADEMARKS strictly in accordance with IROKO' S standards and specifications (i) as provided in the AGREEMENT to which this Trademark Control Attachment is attached, and (ii) as may be supplied or otherwise designated from time to time by IROKO.

1.2 IROKO or its authorized representatives shall have the right to inspect at any time during normal business hours and after reasonable notice, the business premises of ASPEN to ensure that the character and quality of the goods used or services offered in association with the TRADEMARKS are satisfactory to IROKO.

1.3 ASPEN will, upon the request of IROKO and at IROKO' S cost and expense, supply to IROKO or its authorized representatives, samples of the goods in association with which it uses the TRADEMARKS together with samples of labeling, publicity advertising and promotional or other material used by it in the distribution, advertising, offering for sale and sale of such goods; and samples of materials employed in conjunction with services carried out under the TRADEMARKS.



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## APPENDIX 4

## MANUFACTURING SITE

MANUFACTURER:

Aspen Pharmacare Oral Solid Dosage Facility
7 Fairclough Road
Port Elizabeth
6001
South Africa



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**FIRST ADDENDUM TO**
**THE MANUFACTURING AND SUPPLY AGREEMENT**
**BETWEEN ASPEN GLOBAL INCORPORATED AND IROKO**
**PHARMACEUTICALS, LLC**



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EXECUTION VERSION

**THIS FIRST ADDENDUM TO THE MANUFACTURING AND SUPPLY AGREEMENT ("First Addendum")** is made and executed on this 17th day of August, 2011 ("Effective Date")

**AMONG:**

**ASPEN GLOBAL INCORPORATED**, a company incorporated under the laws of the Republic of Mauritius, bearing registration number 078138 and having its registered office and principal place of business at GBS Plaza, Corner La Salette and Royal Roads, Grand Bay, Mauritius;

**AND**

**IROKO PHARMACEUTICALS, LLC**, a limited liability company formed in accordance with the laws of the State of Delaware and having its registered address at the Navy Yard Corporate Center, One Crescent Drive, Suite 400, Philadelphia, PA 19112 and AFFILIATES of the foregoing persons.

**NOW THEREFORE THE PARTIES AGREE AS FOLLOWS:**

**1. DEFINITIONS**

Unless otherwise expressly stated, or the context otherwise requires, the words and expressions defined in the AGREEMENT shall bear the same meaning in this First Addendum as those ascribed to them in the AGREEMENT. Unless otherwise expressly stated, or the context otherwise requires, the words and expressions listed below shall, when used in this First Addendum, including this introduction, bear the meaning subscribed to them:

1.1. "First Addendum" means this Addendum to the AGREEMENT;

1.2. "AGREEMENT" means the Manufacturing and Supply Agreement between ASPEN and Iroko Pharmaceuticals, LLC dated 1 April 2008.

**2. RECORDAL**

2.1. The Parties entered into the AGREEMENT.

2.2. The Parties wish to amend the AGREEMENT on the terms and subject to the conditions set out in this First Addendum.

**3. AMENDMENT OF AGREEMENT**

Notwithstanding the date of signature of this First Addendum, the following terms are effective as 1 January 2011:

3.1 The definitions PACKAGING PRICE, PACKAGING SITE and PACKAGING TERM and all references to such definitions shall be deleted from the AGREEMENT.



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3.2 Clause 6 of the AGREEMENT is deleted in its entirety.

3.3 Clause 7.2 of the AGREEMENT is deleted in its entirety.

3.4 Clause 7.4 of the AGREEMENT is replaced with –

"7.4 During the term of this AGREEMENT, by no later than 7 May of each year, ASPEN shall provide to IROKO a proposed MANUFACTURING PRICE for the next fiscal year commencing on 1 July ("MANUFACTURING PRICE PROPOSAL"), calculated on a [***] basis, determined in accordance with IFRS, plus a mark-up of ten percent (10%) of such costs. These costs shall include the actual cost of API, raw material, excipients, conversion costs or any other inputs of whatever value and exclude any freight costs and warehousing costs or any other direct costs that will be charged back from ASPEN to IROKO on an actual cost basis. As part of such MANUFACTURING PRICE PROPOSAL, ASPEN will provide IROKO with supporting documentation that provides the basis for the API costs. The supporting documentation should be presented in sufficient detail to enable IROKO to determine how such costs were calculated by ASPEN. For illustration purposes only, a sample report showing the level of detail that ASPEN should provide to IROKO is set forth in Appendix 6 of this AGREEMENT. Only during the annual cost review period or should ASPEN provide IROKO with an EXTRAORDINARY COST PROPOSAL, at IROKO' s specific request, ASPEN will provide additional detail on an SKU basis limited to the breakdown by component of API, excipients, packaging material, exchange rates, and manufacturing yield factors. For illustration purposes only, a sample report showing the additional level of detail which may be required by IROKO is attached as Appendix 7 to this AGREEMENT. IROKO will provide ASPEN with a written response to the MANUFACTURING PRICE PROPOSAL within ten (10) business days of receipt of such proposal from ASPEN. ASPEN will provide a written response to IROKO' s response to such proposal within ten (10) business days of receipt of IROKO' s response. IROKO and ASPEN will then discuss and agree on the new MANUFACTURING PRICE for the relevant PRODUCT which will apply, prospectively, from 1 July of that year. . If the PARTIES' fail to agree on the new MANUFACTURING PRICE for the relevant

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PRODUCT, such dispute will be resolved in accordance with the dispute resolution mechanism set forth in clause 7.6 of this AGREEMENT.

3.5 Clause 7.5 of the AGREEMENT is replaced with –

"7.5 If at any time ASPEN incurs a material increase in cost directly resulting from the purchase of raw materials, excipients, API or any other inputs included in the current computation of the PRICE for the relevant PRODUCT that are MANUFACTURED at the MANUFACTURING SITE ("EXTRAORDINARY COST") then the PRICE of the relevant PRODUCT shall be adjusted by mutual written consent of the PARTIES not to be unreasonably withheld. ASPEN will provide a written proposal of the actual EXTRAORDINARY COST and the proposed new PRICE for the relevant PRODUCT which shall include this EXTRAORDINARY COST ("EXTRAORDINARY COST PROPOSAL") and subject to IROKO' s written consent, not to be unreasonably withheld; the PRICE of the relevant PRODUCT will be adjusted accordingly to reflect the EXTRAORDINARY COST. As part of the EXTRAORDINARY COST PROPOSAL, ASPEN will provide to IROKO detailed documentation of all costs included in such proposal. IROKO will respond to this EXTRAORDINARY COST PROPOSAL within ten (10) business days of receipt of such proposal. If the PARTIES fail to agree on the EXTRAORDINARY COST and the new PRICE for the relevant PRODUCT which incorporates the EXTRAORDINARY COST, such dispute will be resolved in accordance with the dispute resolution mechanism set forth in clause 7.6 of this AGREEMENT.

3.6 Clause 7.6 of the AGREEMENT is replaced with –

"7.6. If either PARTY disputes the MANUFACTURING PRICE at any time during the term of this AGREEMENT, the PARTIES shall engage in good faith negotiations to agree on the MANUFACTURING PRICE. If the PARTIES fail to agree on one or both of such prices, within ten (10) business days of such dispute, the dispute shall be referred to the BOARD as defined by the Exclusive Sublicense Agreement between Aspen Pharmacare Holdings Limited and Iroko Pharmaceuticals (Luxembourg) SARL dated 6 December 2007 who shall engage in good faith negotiations to resolve the dispute within ten (10)



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business days from the date of such referral. If requested by the BOARD, ASPEN will provide additional information in sufficient detail to enable the BOARD to determine how such costs were computed. If the BOARD cannot resolve the dispute, such dispute shall be referred to the respective Chairmen of the Boards of Directors of the PARTIES, and if the Chairmen cannot resolve the dispute within ten (10) business days of such referral, such dispute shall be referred to an independent arbitrator for resolution. The arbitrator shall be appointed by agreement between the PARTIES. If no agreement can be reached on appointment of the arbitrator it will be decided by the President of the Institute of Chartered Accountants of England and Wales. Such auditor shall act as an expert and not as an arbitrator and his decision shall, save for any manifest error, be final and binding on the PARTIES. The losing PARTY will bear all the costs of any necessary ARBITRATION including the reasonable costs of the other PARTY."

3.7 The following new clause 7.12 is added to the AGREEMENT –

"7.12 Unless the PARTIES agree otherwise in writing, on 15 January and 15 July of each year, ASPEN will provide to IROKO a statement to reconcile the financial impact of exchange rate fluctuations for both PARTIES on an equitable basis ("EXCHANGE RATE STATEMENT"). This EXCHANGE RATE will not apply to any PRODUCT/S, raw materials, excipients, API or any other inputs of whatever nature (that have been previously agreed to by the PARTIES) and that have been purchased in USD. The PARTIES will engage in good faith negotiations and agree on the amount of the payments (if any) to be paid to the other PARTY to reflect the impact of exchange rate fluctuations within ten (10) business days of receipt of the EXCHANGE RATE STATEMENT and make such payments by 15 February for the EXCHANGE RATE STATEMENT sent in January and by 15 August for the EXCHANGE RATE STATEMENT sent in July. If the PARTIES fail to agree on the amount of payments due to the other PARTY based upon the EXCHANGE RATE STATEMENT, such dispute will be resolved in accordance with the dispute resolution mechanism set forth in clause 7.6 of this AGREEMENT."

3.8 New Appendices 5, 6 and 7, attached hereto are hereby added to the AGREEMENT.



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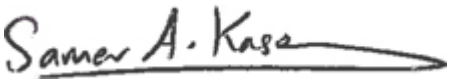
**4. REMAINDER OF THE AGREEMENT**

Save as expressly set out above or as necessarily implied by the context thereof all the other terms of the AGREEMENT shall remain of full force and effect.

SIGNED by ASPEN at Mauritius on this 8th day of AUG 2011

For **ASPEN GLOBAL INCORPORATED**



**SAMER KASSEM,** warranted by his signature that he is duly authorised hereto

SIGNED by IROKO PHARMACEUTICALS, LLC at Philadelphia, PA USA on this 17th day of August 2011

For **IROKO PHARMACEUTICALS, LLC**

**Osagie Imasogie,** warranted by his signature that he is duly authorised hereto



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APPENDIX 5

Commencing on January 1, 2011 and ending on June 30, 2011, the PRICE/S for the PRODUCTS will be as set forth in this Appendix 5. In addition, the PRICE/S for the PRODUCTS for the period commencing on July 1, 2011 and ending on June 30, 2012 are also set forth in this Appendix 5. During the term of this Agreement, these PRICES may be adjusted (i) after good-faith negotiations between the PARTIES and (ii) upon mutual agreement of the PARTIES in accordance with clause 7.4 of this AGREEMENT.

MANUFACTURING PRICE FOR PERIOD JANUARY 1, 2011 to JUNE 30, 2011

| Item no. | Item Description | Iroko Cost USD |
|---|---|---|
| 906502 | ALDOMET 500 MG BULK (IROKO) | [***] |
| 906501 | ALDOMET 250 MG BULK (IROKO) | [***] |
| 931801 | INDOCID 25 MG CAPS BULK (IROKO) | [***] |

MANUFACTURING PRICE FOR PERIOD JULY 1, 2011 to JUNE 30, 2012

| Item no. | Item Description | Iroko Cost USD | PURPOSES ONLY |
|---|---|---|---|
| 906502 | ALDOMET 500 MG BULK (IROKO) | [***] | |
| 906501 | ALDOMET 250 MG BULK (IROKO) | [***] | |
| 931801 | INDOCID 25 MG CAPS BULK (IROKO) | [***] | |

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APPENDIX 6 SAMPLE REPORT NO. 1

**SAMPLE REPORT SHOWING SUPPORTING DOCUMENTATION REQUIRED AS THE BASIS FOR MANUFACTURING PRICE PROPOSAL**

| | | | | | | | | 2011 Prices | | | | | 2012 Prices | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Item No. | Item Description | API | API 2011 Prices | API 2012 Prices | Strength | Pack Size | Budget 2012 Volume | API | Other Mat | Total Mat | Conv | Iroko Cost | API | Other Mat | Total Mat | Conv | Iroko Cost |
| 906502 | ALDOMET 500 MG BULK TABS (IROKO) | Methyldopa - Egis | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] |
| 906501 | ALDOMET 250 MG BULK (IROKO) | Methyldopa - Egis | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] |
| 931801 | INDOCID 25MG CAPS BULK (IROKO) | Indomethacin (FIS) | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] | [***] |

**Notes:**

Prices are based on actual confirmed API and Material Prices as at July 1st 2011

Prices exclude any freight or inflation assumptions

[***]

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APPENDIX NO. 7 SAMPLE REPORT NO. 2

**SAMPLE REPORT SHOWING SUPPORTING DOCUMENTATION REQUIRED AS THE BASIS OF API, EXCIPIENTS, PACKAGING MATERIALS, EXCHANGE RATE, AND MANUFACTURING YIELD FACTORS FOR EXTRAORDINARY COST PROPOSAL**

[***]



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[***] indicates material that has been omitted pursuant to a Request for Confidential Treatment filed with the Securities and Exchange Commission. A complete copy of this agreement, including redacted portions so indicated, has been filed separately with the Securities and Exchange Commission.

**Execution Version**

# CAPITAL PROJECT AGREEMENT

This Agreement (the "Agreement"), is effective May 10, 2012 (the "Effective Date") and is made by and between Iroko Pharmaceuticals, LLC, a Delaware limited liability company, whose principal place of business is at The Navy Yard Corporate Center, One Crescent Drive, Suite 400, Philadelphia, Pennsylvania 19112 ("Iroko") and Catalent CTS, Inc., formerly known as Aptuit, Inc., a Delaware corporation, with offices located at 10245 Hickman Mills Drive, Kansas City, MO 64137 ("Catalent").

## RECITALS

WHEREAS Iroko has proposed that Catalent become the commercial manufacturer and supplier of Iroko' s certain Nano-formulated pharmaceutical products (together, the "Products" and the "Proposal"), with such relationship between the parties to be set forth in a binding commercial term sheet on terms reasonably satisfactory to both parties and negotiated in good faith, which the parties intend to execute on or prior to June 30, 2012 (the "Term Sheet") followed by a commercial manufacturing agreement which Iroko and Catalent also intend to negotiate in good faith subsequent to the execution of such Term Sheet (collectively, the "Commercial Manufacturing Agreements");

WHEREAS pursuant to such Proposal, Iroko and Catalent have agreed that Catalent would commence renovations and equipment purchases at its Kansas City manufacturing facility (the "Facility") in order to allow Catalent to perform its obligations under the Commercial Manufacturing Agreements, the scope and timelines of which are set forth on Schedule A attached hereto (the "Capital Project");

WHEREAS, Iroko and Catalent signed an Initiation Agreement on November 3, 2011, pursuant to which Iroko paid Catalent a non-refundable amount of [***] to be applied towards the Capital Project (the "Capital Improvement Allowance");

WHEREAS, Catalent has commenced the Capital Project and expended the full amount of the Capital Improvement Allowance in furtherance thereof;

WHEREAS, the parties desire to enter into this Agreement to set forth the basis on which Catalent will proceed with the Capital Project before the date on which the Commercial Manufacturing Agreements are executed.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants, promises and agreements herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, Iroko and Catalent hereby agree as follows.

1. **Capital Project Acknowledgements**

Iroko acknowledges that a portion of the Capital Project (which portion has an expected value of $[***]) represents the estimated cost of Facility modifications that will be required to accommodate Iroko Equipment as set forth in Schedule A that will be

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provided by Iroko (the "Specialty Equipment Fit Out") solely in reliance on Iroko' s representations that it will seek in good faith to enter into the binding Commercial Manufacturing Agreements with Catalent on terms reasonably satisfactory to both parties. Catalent represents and warrants to Iroko that the Specialty Equipment Fit Out shall be used solely for the manufacture of the Products.

Iroko further acknowledges that Catalent may enter into commitments to secure equipment and contracting services as set forth in Schedule A in furtherance of the Capital Project solely in reliance on Iroko' s representations that it will seek in good faith to enter into the binding Commercial Manufacturing Agreements with Catalent on terms reasonably satisfactory to both parties. Upon a Separation Event (as defined below), Catalent may sell all Catalent Equipment as set forth in Schedule A to Iroko. Furthermore, upon the occurrence of a Separation Event (as defined below) Iroko shall reimburse Catalent for the cost of the Specialty Equipment Fit Out and reasonable cancellation fees associated with the Specialty Equipment Fit Out (collectively, "Breakage Costs").

"Separation Event" shall mean the failure of the parties to enter into a binding commercial Term Sheet on terms reasonably satisfactory to both parties by June 30, 2012.

In addition, Catalent will transfer all the rights to, title and interest in all the Catalent Equipment as set forth in Schedule A to Iroko as long as Iroko purchases the minimum volume of Product from Catalent as agreed by the parties in the Commercial Manufacturing Agreements to be executed by the parties. In the event of such transfer of rights, title, and interest in the Catalent Equipment to Iroko in accordance with this Agreement, Catalent warrants that it shall transfer the Catalent Equipment to Iroko free of all and any lien and/or encumbrance in the Catalent Equipment.

2. **Catalent Obligations**

Catalent hereby agrees to use commercially reasonable efforts to progress the Capital Project according to the scope and timelines set forth in Schedule A, [***]

Catalent shall be responsible for all Facility-related regulatory obligations and approvals where the Products are manufactured. Iroko shall be responsible for all regulatory obligations and approvals relating to the Products' filings and approvals (excluding Catalent' s Facility related obligations as set forth above) as required to market the Products in the United States and any other jurisdictions.

Catalent' s regulatory obligations relate solely to Facility renovation and utility qualification specific for supporting Iroko' s intended commercial manufacturing process and equipment train. Catalent will be responsible for Catalent Equipment (as defined herein) installation/operational qualifications. Catalent shall, at Iroko' s request, Iroko' s

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cost, and with Iroko' s reasonable assistance, be responsible for Iroko Equipment (as defined herein) installation/operational qualifications. In addition, the parties acknowledge and agree that process validation necessary to establish a robust commercial manufacturing process will need to be established and agreed between the parties as soon as practicable.

As described is United States Food and Drug Administration "Guidance for Industry, Process Validation: General Principles and Practices," conclusions about a commercial manufacturing process can only be made after the process validation protocol ("PPQ") is fully executed and the data are fully evaluated. If process qualification is not successful (i.e., does not demonstrate that the process as designed is capable of reproducible performance at commercial scale), then it is understood by Iroko that additional design studies and qualification may be necessary.

Catalent shall not be liable to Iroko nor be deemed to have breached this Agreement for errors, delays or other consequences arising from Iroko' s failure to provide necessary documents, materials or information as agreed and/or in a timely manner. Nor will Catalent be liable to Iroko if Iroko fails to otherwise reasonably cooperate in order for Catalent to perform its obligations and any such failure by the Iroko will automatically extend any timelines affected by a time period that reasonably takes into account such failure in providing documents, materials, information or cooperation.

3. **Iroko Obligations**

Upon the occurrence of a Separation Event, Iroko shall be responsible for all Breakage Costs. Within 30 days of a Separation Event, Catalent will submit its invoice to Iroko (with complete documentation of all items in the invoice) for, all Breakage Costs. Iroko shall have 15 days to reconcile its accounts. Iroko will pay each undisputed invoice issued by Catalent within [***] of the date such invoice is received by Iroko in fell. If any portion of an invoice is disputed, Iroko will pay the undisputed amounts and promptly notify Catalent in writing of the nature of the dispute, upon which the parties will use good faith efforts to reconcile the disputed amount as soon as practicable, and upon such resolution, Iroko will pay Catalent within thirty (30) days of the resolution.

In furtherance of the Capital Project, Iroko shall furnish [***] as specifically set forth in Schedule A or as mutually agreed by the parties in writing (collectively, "Iroko Equipment"). Iroko will be responsible for the costs associated with purchase, shipping, installation and qualification of Iroko Equipment to be installed at the Facility unless otherwise agreed by the parties in writing.

Iroko must provide Catalent engineering shop drawings on all Iroko Equipment within a reasonable time to support Catalent' s obligation to meet agreed timelines. Catalent, in collaboration with Iroko, shall be responsible for providing all IQOQ and qualifying all Iroko Equipment being installed.

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If (a) during the term of the Capital Project Iroko provides technical information and/or specifications needed by Catalent to progress the Capital Project ("Specs"), (b) Catalent takes actions and incurs costs and expenses to further the Capital Project in accordance with such Specs, and (c) the Specs are subsequently determined to have been erroneous or Iroko otherwise makes amendments to the Specs, then Iroko shall reimburse Catalent for any reasonable incremental costs and expenses incurred by Catalent to rectify/rework any impacted aspect of the Capital Project upon Catalent' s presentation of reasonable supporting documentation in a form agreed by the parties

4. **Joint Obligations**

Should any technical issue arise which could not have been foreseen earlier and which results in a change to the scope, timelines or current estimated costs of the Capital Project as set forth in Schedule A, Iroko and Catalent will jointly agree on a resolution to the issue and a revision to the Capital Project and if necessary this Capital Project Agreement including Breakage Costs. Additionally, the parties further agree to use commercially reasonable efforts to identify ways in which to shorten the timelines where reasonably possible. In furtherance therefore, both parties agree to discuss, within one week of execution of the Agreement, how to achieve a shortening of the timelines. For purpose of clarity and notwithstanding the foregoing, all costs related to expedited shipment shall be at Iroko' s cost.

5. **Equipment**

Catalent shall have no liability for any defects in Iroko Equipment or other inability of the Iroko Equipment to perform in accordance with the manufacturer' s specifications, except for defects and damages caused by Catalent resulting from Catalent' s negligence or wilful misconduct. Iroko acknowledges and agrees that Catalent shall be the sole and exclusive owner of all right, title and interest in any equipment or component either purchased by Catalent from third party manufacturers or paid for by Catalent pursuant to this Capital Project Agreement or the Initiation Agreement (excluding Iroko Equipment) as set forth in Schedule A (collectively, "Catalent Equipment"). Iroko shall have no liability for any defects in Catalent Equipment or other inability of the Catalent Equipment to perform in accordance with the manufacturer' s specifications. Catalent acknowledges and agrees that Iroko shall be the sole and exclusive owner of all right, title and interest in the Iroko Equipment. Catalent shall at all times maintain its Facility(ies) and the Catalent Equipment and Iroko Equipment used in the performance of services hereunder in accordance with applicable laws and registrations. Catalent shall not move the Iroko Equipment and the Catalent Equipment to any other Facility, without Iroko' s prior written consent which shall not be unreasonably withheld. The parties agree that the Iroko is entitled to file any document necessary to demonstrate and secure its ownership in Iroko Equipment, including, without limitation, a UCC-1 financing statement, and Catalent shall cooperate with Iroko, at Iroko' s sole cost and expense, in completing and filing and executing any documents necessary to demonstrate and secure Iroko' s ownership interest in the Equipment.



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Each party shall, at its own cost and expense, obtain and maintain in full force and effect from the commencement of services hereunder and during the term of the Commercial Manufacturing Agreement the following: (A) Commercial General Liability Insurance with a per-occurrence limit of not less than $1,000,000; (B) Products and Completed Operations Liability Insurance with a per-occurrence limit of not less than $10,000,000; (C) Workers' Compensation Insurance with statutory limits and Employers Liability Insurance with limits of not less than $1,000,000 per accident; and (D) All Risk Property Insurance, including transit coverage, in an amount equal to the full replacement value of its property while in, or in transit to, a Catalent facility as required under this Agreement. Each party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth is greater than $100 million or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than $75 million. Each required insurance policy, other than self-insurance, shall be obtained from an insurance carrier with an A.M. Best rating of at least A-VII. If any of the required policies of insurance are written on a claims made basis, such policies shall be maintained throughout the term and for a period of at least 3 years thereafter. Each party shall obtain a waiver of subrogation clause from its property insurance carriers in favor of the other party. Each party shall be named as an additional insured within the other party' s products liability insurance policies; provided, that such additional insured status will apply solely to the extent of the insured party' s indemnity obligations under this Agreement. Such waivers of subrogation and additional insured status obligations will operate the same whether insurance is carried through third parties or self-insured. Upon the other party' s written request from time to time, each party shall promptly furnish to the other party a certificate of insurance or other evidence of the required insurance.

6. **Term and Termination**

This Agreement shall commence on the Effective Date and remain valid until either (i) the occurrence of a Separation Event and the fulfilment by each party of its related obligations thereafter or (ii) execution of a binding Term Sheet by June 30, 2012 (or other date as agreed by the. parties in writing).

7. **Assignment**

Catalent shall have the right to assign this Agreement, in whole or in part, with the written consent of Iroko, to any of its affiliates or in connection with a merger, consolidation, license or sale of substantially all of its assets to which this Agreement relates or other equivalent transaction. Iroko shall have the right to assign this Agreement, in whole or in part, without the written consent of Catalent, to any of its affiliates or in connection with a merger, consolidation, license or sale of substantially all of its assets or Products to which this Agreement relates or other similar transaction and in all events such assignee, licensee, or purchaser shall be bound by Iroko' s obligations hereunder.



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8. **Applicable laws**

   This Agreement will be governed by the laws of the Commonwealth of Pennsylvania, without consideration to its conflicts of laws provisions. Further, the parties agree to submit to the exclusive jurisdiction of the federal and state courts in the Commonwealth of Pennsylvania.

9. NEITHER PARTY SHALL HAVE ANY LIABILITY HEREUNDER FOR ANY INDIRECT, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES INCLUDING, WITHOUT LIMITATION, LOSS OF PROFIT OR BUSINESS OPPORTUNITIES, WHETHER OR NOT THE PARTY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

10. This Agreement may not be changed, modified, amended or supplemented except by a written instrument signed by both parties.



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**IN WITNESS WHEREOF** this Agreement has been executed by the parties hereto through their duly authorised officers on the date(s) set forth below.

| **Catalent CTS, Inc.** | | **Iroko Pharmaceuticals, LLC** | |
|---|---|---|---|
| **Signature:** |  | **Signature:** |  |
| **Name:** | Scott Houlton | **Name:** | Fred Krieger |
| **Title:** | President, Development & Clinical | **Title:** | CFO |
| **Date:** | 10-May-2012 | **Date:** | 5/10/12 |



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**Schedule A**

**Scope and Timing**

**Facility Modifications for Specialty Equipment Fit Out − Iroko Equipment**

**Scope:** The scope is outlined in documents "Drawings − Bid Documents Phase 1" and "Scope of Work − Bid Documents Phase 1" provided to Iroko January 5, 2012, which outlines the facility modifications of [***] to support the Iroko Equipment. The Iroko Equipment shall mean the following specialized equipment to be supplied by Iroko at Iroko' s cost and expense: [***]

| Facility Modifications | Estimated Completion Dates |
|---|---|
| Demolition/Trench Cuffing | **7-Feb-12** |
| Above Ground MEP Rough-in Work | **24-Feb-12** |
| Walls/Doors/Floors/Paint/Fire Protection | **16-Mar-l2** |
| Final Punch List Items | **6-Apr-12** |
| Facility Validations | **20-Apr-12** |
| Change Controls/Final Quality Approval | **27-Apr-12** |

[***]

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**Cost Estimates**

**Facility Modifications for Specialty Equipment Fit Out**

| **Construction** | **Estimated Costs** |
|---|---|
| Purdum Company for labor costs far construction | |
| Passivation of purified water system | |
| Hagard company for equipment moving | **$[***]** |
| Siemens monitoring | |
| Other miscellaneous construction | |
| **Project Support** | |
| Warehouse mapping | |
| Insite facility/utility validation | |
| Micro support | **$[***]** |
| Maintenance support | |
| Pro Pharma validation plan | |
| Other miscellaneous project support | |
| **Environmental Health & Safety** | |
| Flex Containment | |
| Surrogate Sampling | |
| Grounding and Electrical Adds | **$[***]** |
| Dust Containment | |
| Signage | |
| Other miscellaneous Environmental Health & Safety | |
| **Estimated Total Facility Modifications for Specialty Equipment Fit Out** | **$[***]** |

[***]

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**EXECUTION VERSION**
**SEPTEMBER 14, 2012**

**Binding Term Sheet for Submicron-formulated Pharmaceutical Products**
**Exclusive Commercial Manufacturing Agreement**
**Iroko Pharmaceuticals, LLC**

Summary

This term sheet ("**Term Sheet**") is a binding agreement between Iroko Pharmaceuticals, LLC ("**Client**" or "**Iroko**") and Catalent CTS, Inc. ("Catalent") regarding a commercial supply arrangement for the Product (as defined below). It is the expressed intent of the parties hereto that this Term Sheet be a binding agreement and the parties expressly state that this Term Sheet contains all material terms of the Agreement between the parties for commercial supply of the Product.

Product

"**Product**" means certain formulations of specified submicron-formulated pharmaceutical products that contains Client' s active pharmaceutical ingredient(s) ("**API**"), as agreed by the parties in writing and as more fully described in specifications to be agreed by the parties (the "**Specifications**"). For purposes of clarity all references to the nano and nano-formulated-technology in prior agreements shall have the same meaning as the term submicron-formulated used in this Term Sheet to describe the Product. A "**Unit**" of Product is one hard shell capsule.

Supply

Catalent shall be the exclusive manufacturer and supplier of Client' s and Client' s Affiliates submicron-formulated pharmaceutical products that contain the API as set forth above for the first [***] Units for each year of the Agreement until Iroko purchases a cumulative total of [***] Units after which such exclusivity shall expire. Notwithstanding the expiration of exclusivity as set forth in the preceding sentence, Iroko shall still be responsible for the minimum purchase requirements throughout the term of the Agreement as set forth in this Term Sheet. In addition, Catalent shall have a right of first refusal to manufacture and supply all additional volume during each year of the Agreement. An independent third party auditor will be agreed by both parties to review competing bids and Catalent shall have five (5) business days within which to match the competing bid. Should Catalent decide to match the competing bid, Catalent shall supply the additional volume set forth in the competing bid, provided Catalent has a regulatory compliance and quality record (with respect to the Facility (as defined below)) that is at least comparable to that of the competing bidder. Catalent shall be responsible for the reasonable fees of the independent auditor which shall be agreed by Catalent and such auditor in advance of any such audit.

Catalent will provide:

qualification and stability services agreed upon by parties in writing for Product;
certain Product maintenance services, as agreed upon by the parties in writing;
API testing and Release agreed upon by the parties in writing; and
other Product-related services as also may be agreed from time to time.

The costs of the above-referenced services are not included in the commercial Supply Price estimates set forth in this Term Sheet. Services will be provided from Catalent' s Kansas City, MO plant (the "**Facility**") unless otherwise agreed by the parties.

In the event that Client does not receive regulatory approval for any of the Products hereunder or fails to launch any of such Products commercially or materially breaches this Term Sheet (and is unable to cure such material breach within [***] days of Catalent' s written

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| | |
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| | notice to Iroko of the occurrence of such breach and request to cure), then the parties agree that: 1) Client shall reimburse Catalent for [***] (collectively, "**Breakage Costs**") as set forth in the Capital Project Agreement dated May 10, 2012 executed by the parties (the "**Capital Project Agreement**"); 2) Client will pay Catalent [***] and 3) at Catalent' s option, Catalent may sell (but is not required to sell) to Client the Catalent Equipment as that term is defined in the Capital Project Agreement and in such instance where Catalent elects to sell, then Client shall buy the Catalent Equipment. Upon Iroko' s fulfillment of the obligations set forth in 1 through 3 above, Iroko shall be excused from all of its obligations under this Term Sheet and all related agreements. For purpose of clarity, Iroko' s obligation to pay the Breakage Costs in this Term Sheet and the Capital Project Agreement shall be terminated, become void and of no effect upon Iroko' s launch of any of the Product. |
| Materials | Client will provide API and other Client supplied materials to Catalent free of charge, together with certificates of analyses and safe handling information. Catalent will perform ID testing on all incoming API unless otherwise agreed to by the Parties and the commercial pricing will be revised based on the agreed testing and confirmation of API lot size. Client retains title to API and Client supplied materials, however, the risk of loss shall pass to Catalent upon delivery to Catalent-designated facility/location subject to the limitations on liability set forth in this Term Sheet. Client is responsible for Product defects due to API and materials supplied by Client, except where such defect is caused by the gross negligence or willful misconduct of Catalent or its contractors while the Product is in the possession of Catalent or its contractors. Catalent will obtain all other raw materials consistent with Client' s forecasts. Client will bear cost of obsolescence of materials due to change in Specifications, insufficient orders based on forecast, and termination of the Agreement.<br><br>Catalent shall maintain at least [***] of inventory of materials to meet Client' s Firm Commitment. |
| Artwork & Packaging | Client will provide and be responsible for content of all artwork, advertising and packaging information, including approvals of same, if applicable. |
| Forecasting & Ordering | Client shall provide a written 12 month rolling forecast of the quantities of Product that Client intends to order from Catalent during such period ("**Rolling Forecast**").<br><br>The first [***] of Rolling Forecast is a binding order for the quantities of Product specified therein ("**Firm Commitment**") and the following [***] of the Rolling Forecast shall be non-binding, good faith estimates excluding the Launch period prior to the approval of the Product which shall be mutually agreed by the parties. |
| Minimum Purchase Requirement | Client must order and purchase a minimum of [***] Units in year one and a minimum of [***] Units in year two (2), and [***] Units in each of years three (3), four (4) and five (5) of the Agreement. [***] |

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| | In no event shall Client order and purchase less than [***] Units of Product in any one contract quarter during year one of the Agreement and not less than [***] Units per contract quarter in years two through five of the Agreement. [***] |
| | "**Year**" shall be defined under the Agreement as successive twelve calendar months, with first "year" starting from [***]. |
| Inspection | Client will have access to the portion of the Facility where Catalent processes the Product, upon two weeks prior written notice and at reasonable times during regular business hours. Such access shall be for the purpose of inspecting and verifying that Catalent is processing Product in accordance with applicable Specifications and cGMPs. |
| | Iroko shall have immediate access to the Facility in case of "for cause" inspection. |
| Testing and Rejection | After manufacture of Product, Catalent will deliver certificates of analysis to Client. Client will be responsible for final release of Product (including testing), at its cost. Client must notify Catalent of any rejection of Product within 30 days after receipt of shipment. Catalent shall be responsible for Product that does not meet warranty at the time of tender of delivery due solely to Catalent' s negligence, willful misconduct, or breach of this Agreement. Catalent shall not be responsible for Product that does not meet warranty at the time of tender of delivery due to defective API or other materials supplied by Client. If the parties disagree as to whether Product is defective or the reason for non-conformity, and cannot resolve their differences within 30 days after Client notifies Catalent of rejection, the parties will submit the matter to a mutually acceptable independent third party laboratory to test Product and its components. The findings of such laboratory will be binding, and the losing party bears costs. |
| Non-Conforming Product | If Product is defective due solely to Catalent' s negligence, willful misconduct or breach of this Agreement, Catalent will replace the Product at Catalent' s cost or credit Client for payments made for such Product, subject to the limitation of liability. |
| Delivery | Catalent will segregate and store Product at the Facility until tender of delivery. Delivery is ExWorks (Incoterms 2010) the Facility. If Client does not take delivery on the scheduled date, Catalent will store the Product at no additional charge for 15 days. Thereafter Catalent will charge an administrative fee to continue to store the Product. |
| Pricing | Product pricing assumes standard manufacturing and storage processes for Diclofenac and Indomethacin. |
| | Product pricing will be subject to annual adjustments on [***] days written notice from Catalent. Such pricing adjustments shall be effective January 1 of each calendar year during the term of this Agreement, and pricing adjustments shall be [***]. |

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Assuming [***] estimated pricing shall be:

1) Supply Price per Unit: Low dose = [***] per Unit for the first 300 million Units of the Products; High dose = [***] per Unit for the first 300 million Units of the Products.

2) [***] After the first [***] Units are purchased, the price per Unit above will be reduced by [***] per Unit of the then current Supply Price [***]

3) For the five year term of the Agreement and in addition to the [***] set forth in 2) immediately above, Iroko is entitled to the [***] as set forth below:
[***]

This is meant to be a cumulative count not annual and is to share our efficiencies as we gain experience with the manufacturing. Also, the cost will continue to have the annual [***] adjustment as described above.

Final pricing shall be agreed by the parties in writing within [***] Any variation from the estimated prices set forth in this Term Sheet will be supported with quantified analysis in writing.

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| Iroko Specialty Equipment | Iroko shall be responsible for all maintenance, repairs, and normal wear and tear of such Iroko Equipment (as defined under the Capital Project Agreement) unless Catalent is grossly negligent in its use of such equipment resulting in required equipment repairs. |
| Payment Terms | Payments to be made in USD, net 30 days. Unpaid amounts accrue interest at [***] per month. Client will be responsible for taxes and duties on API and Product. Invoice issues upon tender of delivery. |
| Changes to Specifications | Specifications may be changed only upon written agreement of the parties. Both parties must use commercially reasonable, good faith efforts to agree to such changes, including any implementation costs, which Client will bear. |
| Records | Catalent will maintain books and records as required by Applicable Laws and Catalent standard operating procedure. Catalent will keep such records for 2 years from relevant Product expiration date or such longer period as required by law. |
| Regulatory Compliance | Client will be responsible for obtaining and maintaining all Product-related regulatory approvals. Catalent will be responsible for obtaining and maintaining all approvals for the Facility in the jurisdiction where Catalent manufactures or packages the Product. Catalent will assist Client in regulatory matters (beyond covered Product maintenance services) as |

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| | requested, at Client' s cost. Catalent will notify Client of any regulatory inspections and provide a copy of any reports (redacted of any other customer or third party confidential information) that relate directly to or mention the Products. |
| Recall | If a Regulatory Authority orders or requires the recall of any Product supplied hereunder or if either Catalent or Client believes a recall, field alert, Product withdrawal or field correction ("**Recall**") may be necessary with respect to any Product supplied under this Agreement, the party receiving the notice from the Regulatory Authority or that holds such belief shall promptly notify the other party in writing. With respect to any Recall, Catalent shall provide all necessary cooperation and assistance to Client. Client shall provide Catalent with an advance copy of any proposed submission to a Regulatory Authority in respect of any Recall, and shall consider in good faith any comments from Catalent. The cost of any Recall shall be borne by Client, and Client shall reimburse Catalent for expenses incurred in connection with any Recall, in each case unless such Recall is caused solely by Catalent' s breach of its manufacturing obligations under this Agreement or Catalent' s violation of Applicable Laws or the negligence or willful misconduct of Catalent or its contractor, then such cost shall be borne by Catalent, For purposes hereof, such Catalent cost shall be limited to reasonable, actual and documented administrative costs incurred by Client for such Recall and if applicable, replacement of the Product subject to Recall both in accordance with the Non-Conforming Product Section. "**Applicable Laws**" means all laws, ordinances, rules and regulations within the Territory of the United States applicable to the mixing, encapsulation, producing and/or packaging of the Product or any aspect thereof and the obligations of Catalent or Client, as the context requires under the Agreement, including, without limitation, (A) all applicable federal, state and local laws and regulations of the United States; (B) the U.S. Federal Food, Drug and Cosmetic Act, and (C) cGMP or Good Laboratory Practices ("**GLPs**") promulgated by the Regulatory Authorities, as amended from time to time, as applicable to the manufacture of the Product; provided that cGMP shall not constitute Applicable Laws except to the extent expressly stated in the Agreement. |
| Quality | The parties will enter into a Quality Agreement on Catalent' s standard form within 6 months after executing the Agreement, but in any event prior to commencing manufacture of Product. |
| Confidentiality | Confidentiality provisions to be consistent with confidentiality provisions contained in the Master Services Agreement dated September 10, 2010 between Iroko and Catalent CTS Inc. (f/k/a Aptuit, Inc.) (the "**MSA**"). The Patent and Confidential Information License Agreement between iCeutica Inc. and iCeutica Pty Ltd. (together, iCeutica) and Catalent CTS Inc. (f/k/a Aptuit Inc.) dated March 20, 2010 (as may be amended) ("**iCeutica Agreement**") shall govern and control all matters regarding or related to confidentiality in this Term Sheet and the Agreement. |
| Intellectual Property | IP provisions to be consistent with the IP provisions contained in the MSA. The iCeutica Agreement shall govern and control all matters regarding intellectual property rights in this Term Sheet and the Agreement. Catalent shall comply with all iCeutica/Iroko policy and procedures agreed by the Parties regarding the safeguarding of iCeutica Confidential Information, including but not limited to iCeutica' s trade secret and Know-How, as those terms are defined in the iCeutica Agreement. |



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Representations and Warranties

Catalent represents that:

at the time of delivery, Product will have been manufactured in accordance with laws (including cGMP) and the Specifications, and will not be adulterated, misbranded or mislabeled; excluding any defects attributable to API or other materials supplied by Client (including artwork, advertising and labeling).

As of the Effective Date hereof and through the term of the Agreement, Catalent holds, and shall continue to hold, all licenses and permits of regulatory authorities necessary for Catalent to perform the manufacturing and supply of the Products in the jurisdiction where Catalent manufactures or packages the Product as contemplated in this Term Sheet and the Agreement.

Client represents that:

API and other materials supplied by Client will have been manufactured in accordance with laws (including cGMP) and applicable specifications, and will not be adulterated, misbranded or mislabeled by Client; all artwork provided complies with laws;

Client has provided all relevant safety materials for Product and API;

Client will hold, use and dispose of the Product in accordance with laws and otherwise comply with laws in connection with its performance under the Agreement; and will not release any Product if the certificates of analysis indicate that it does not comply with Specifications, and will use reasonable efforts to ensure that the Product is safe and effective; and

Client has all necessary authority to use and permit Catalent to use intellectual property relating to the Product; and the work to be performed by Catalent does not violate or infringe any intellectual property of others.

Client has all necessary license, permits, and registrations to transport API to Catalent' s facility.

The warranties and representations contained in the Agreement shall be the sole warranties and representations of the parties and exclude any other express or implied warranties or representations.

Indemnification

Catalent will indemnify, defend, and hold harmless Client and certain related parties against losses in connection with any third party action arising out of:

any breach of its representations, warranties or obligations under the Agreement; or

any negligence or willful misconduct by Catalent;

except to the extent that any of the foregoing arises out of or results from any Client or related party negligence, willful misconduct or breach of the Agreement.

Client will indemnify, defend, and hold harmless Catalent and certain related parties against losses in connection with any third party action arising out of:

any breach of its representations, warranties or obligations under the Agreement;

any manufacture, packaging, sale, promotion, distribution or use of or exposure to Product, API or any other materials supplied by Client;

Client' s exercise of control over manufacture, to the extent that Client' s written instructions or directions violate law;

the conduct of any clinical trials utilizing Product or API;

any actual or alleged infringement of intellectual property provided by Client; or

any negligence or willful misconduct by Client;

except to the extent that any of the foregoing arises out of or results from any Catalent or related party negligence, willful misconduct or breach of the Agreement. Procedures shall be detailed in the Agreement.

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Limitation of Liability

A. Catalent' s liability under the Agreement for lost, damaged or destroyed API or other materials supplied by Client, whether or not incorporated into Product shall not exceed the lesser of the actual replacement cost of such API or other Client-supplied materials giving rise to the claim (including transportation cost and taxes paid by Iroko) or [***] per batch, except where the loss directly results from the gross negligence or willful misconduct of Catalent.

B. Notwithstanding the above, Catalent' s total liability per year for lost, damaged or destroyed API or other materials supplied by Client, whether or not incorporated into Product shall not exceed [***] except where losses directly result from the gross negligence or willful misconduct of Catalent.

C. Except for third party claims arising from death or bodily injury caused by Catalent' s negligence or willful misconduct or third party claims arising from Catalent' s gross negligence or willful misconduct, Catalent' s total liability under the Agreement is limited to total fees paid by Client for the batch giving rise to the claim.

D. Neither party will be liable for indirect, incidental, special or consequential damages.

Insurance

Each party shall, at its own cost and expense, obtain and maintain in full force and effect during the Term the following: (A) Commercial General Liability Insurance with a per-occurrence limit of not less than $1,000,000; (B) Products and Completed Operations Liability Insurance with a per-occurrence limit of not less than $10,000,000; (C) Workers' Compensation Insurance with statutory limits and Employers Liability Insurance with limits of not less than $1,000,000 per accident; and (D) All Risk Property Insurance, including transit coverage, in an amount equal to the full replacement value of its property while in, or in transit to, a Catalent facility as required under this Agreement. Each party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth is greater than $100 million or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than $75 million. Each required insurance policy, other than self-insurance, shall be obtained from an insurance carrier with an A.M. Best rating of at least A-VII. If any of the required policies of insurance are written on a claims made basis, such policies shall be maintained throughout the Term and for a period of at least 3 years thereafter. Each party shall obtain a waiver of subrogation clause from its property insurance carriers in favor of the other party. Each party shall be named as an additional insured within the other party' s products liability insurance policies; provided, that such additional insured status will apply solely to the extent of the insured party' s indemnity obligations under this Agreement. Such waivers of subrogation and additional insured status obligations will operate the same whether insurance is carried through third parties or self-insured. Upon the other party' s written request from time to time, each party shall promptly furnish to the other party a certificate of insurance or other evidence of the required insurance.

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| Term and Termination | The Term of the Agreement will be for 5 years, with automatic 2 year renewal terms unless terminated earlier in accordance with the terms below. Either party may terminate after 60 days for the uncured breach of a material term (10 days for payment breach), or 30 days of undismissed bankruptcy of the other party. Either party may terminate the Agreement for any reason upon twenty-four (24) months prior written notice to the other party, provided, that in the event that Iroko terminates the Agreement, Iroko shall remain liable for the minimum purchase requirements under this Term Sheet. Upon termination, Client shall pay Catalent for all invoiced amounts, plus inventory and WIP and non-cancelable commitments made consistent with Client' s forecasts. Catalent shall promptly return to Client, at Client' s expense and at Client' s direction, any remaining inventory of Product, API or other Client-supplied materials; *provided*, that Catalent shall have no obligation to so return such items until all outstanding invoices sent by Catalent to Client have been paid in full.<br><br>This Term Sheet shall remain in full force and effect until the execution of the Agreement. This Term Sheet may only be terminated in the event of a material breach by the other party and only after providing the breaching party with written notice of such breach and an opportunity to cure such breach within 30 additional days following written notice of such breach. |
| Capital Project Agreement | Notwithstanding anything to the contrary herein, the parties agree that the terms of the Capital Project Agreement between the parties shall remain valid and in full effect. To the extent there is a conflict between any provision of the Capital Project Agreement and the Term Sheet, the Term Sheet shall control. |
| Force Majeure | Neither party will be liable for performance defaults caused by events beyond the defaulting party' s reasonable control. Events constituting "force majeure" shall include but are not limited to, strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, lack of or inability to obtain fuel, power or components, or compliance with any order or regulation of any government entity acting within color of law. |
| Governing Law | Commonwealth of Pennsylvania law, excluding conflicts of laws provisions. UN Convention on Contracts for the International Sale of Goods is disclaimed. |
| Dispute Resolution | Disputes that cannot be resolved between the parties will be submitted to binding arbitration to be held in English, in New York, New York, pursuant to the rules of CPr. The prevailing party will be entitled to recover its reasonable attorney' s fees and costs. |
| Assignment | Neither party may assign the Agreement without the prior written consent of the other party, except that either party may, without the other party' s consent, assign the Agreement to an Affiliate or to a successor to substantially all of the business or assets of the assigning company or the assigning company' s business unit responsible for performance of the Agreement. |
| Miscellaneous | The Agreement will contain such other terms and conditions as are customary for agreements of this nature. |



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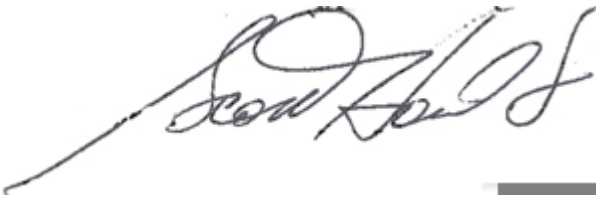
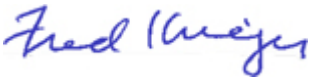
| Attachments to Commercial Supply Agreement | Stability Services |
| | API Specifications |
| | Product Specifications |
| | Packaging Specifications |
| | Pricing, Minimum Requirement and Additional Fees (if agreed) |
| | Form of Quality Agreement |
| | Capital Project Agreement |

**IN WITNESS WHEREOF** this Term Sheet has been executed by the parties hereto through their duly authorized officers on the date(s) set forth below.

| **Catalent CTS, Inc. (f/k/a Aptuit Inc.)** | | **Iroko Pharmaceuticals, LLC** | |
|---|---|---|---|
| **Signature:** |  | **Signature:** |  |
| **Name:** | Scott Houlton | **Name:** | Fred Krieger |
| **Title:** | President | **Title:** | CFO |
| **Date:** | 20-Sep-2012 | **Date:** | 9/19/12 |



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