Current Agreements

Dealdoc

Distribution agreement for Entereg (alvimopan)

SmithKline Beecham
Adolor

Jun 29 2004

Distribution agreement for Entereg (alvimopan)

Companies:	SmithKline Beecham Adolor
Announcement date:	Jun 29 2004
Related contracts:	Termination of licensing, co-development and marketing agreement for Entereg (alvimopan) Third amendment to licensing, co-development and marketing agreement for Entereg (alvimopan) First amendment to licensing, co-development and marketing agreement for Entereg (alvimopan) Licensing, co-development and marketing agreement for Entereg (alvimopan) (terminated) Second amendment to licensing, co-development and marketing agreement for Entereg (alvimopan) Fourth amendment to licensing, co-development and marketing agreement for Entereg (alvimopan) Fifth amendment to licensing, co-development and marketing agreement for Entereg (alvimopan) First amendment to distribution agreement for Entereg (alvimopan)

Details

Announcement date:	Jun 29 2004
Start date:	Jun 29 2004
Industry sectors:	Bigpharma Pharmaceutical
Therapy areas:	Hospital care » Surgery Gastrointestinal » Symptoms » Bowel movement
Technology types:	Drug delivery Small molecules
Deal components:	Contract service Distribution
Stages of development:	Phase III

Financials

Termsheet

Not available.

Press Release

Not available.

Filing Data

Not available.

Contract

DISTRIBUTION SERVICES AGREEMENT

BETWEEN

SMITHKLINE BEECHAM CORPORATION

AND

ADOLOR CORPORATION

DATED AS OF

June 29, 2004

DISTRIBUTION SERVICES AGREEMENT

THIS DISTRIBUTION SERVICES AGREEMENT (this “Agreement”) is made and entered into as of the 29th day of June, 2004 (the “Effective Date”) by and between ADOLOR CORPORATION, a Delaware corporation having its principal office at 700 Pennsylvania Drive, Exton, Pennsylvania 19341 (“Adolor”) and SmithKline Beecham Corporation, a Pennsylvania corporation having its principal office at 200 North 16th Street, Philadelphia, Pennsylvania 19102 d/b/a GlaxoSmithKline (“GSK”). GSK and Adolor are sometimes referred to herein individually as a “Party” and collectively as “Parties.”

RECITALS

WHEREAS, Glaxo Group Limited, and Adolor entered into the Collaboration Agreement for the Development and Commercialization of Adolor’s compound known as alvimopan;

WHEREAS, the Collaboration Agreement provides that Glaxo Group Limited will provide certain distribution and commercial services in the Territory with regard to the Adolor Products;

WHEREAS, GSK, as an Affiliate of Glaxo Group Limited, will provide the distribution and commercial services in the Territory with regard to the Adolor Products;

WHEREAS, the Parties wish to memorialize their agreement with regard to the provisions of such distribution and commercial services for the Adolor Products in the Territory, it being understood that the Parties intend to enter into a separate agreement with respect to GSK’s provision of the distribution and commercial services in the territories and possessions of the United States.

NOW, THEREFORE, in consideration of the covenants and agreements contained herein, Adolor and GSK, intending to be legally bound, hereby agree as follows:

ARTICLE 1

DEFINITIONS

Capitalized terms, whether used in the singular or plural, will have the meanings ascribed to them in the Collaboration Agreement unless otherwise defined below for purposes of this Agreement. For the convenience of the Parties, cross-references to the location of some terms that are defined in the Collaboration Agreement that are also used herein have been included below.

1.1 “Adolor Product(s)” has that meaning ascribed to such term in Section 1.10 of the Collaboration Agreement.

1.2 “Adolor Product Promotion Term” has that meaning ascribed to such term in Section 1.8 of the Collaboration Agreement.

1.3 “Adolor Termination Notice” has that meaning ascribed to such term in Section 9.1 below.

1.4 “Adverse Drug Experience” has that meaning ascribed to such term in Section 1.13 of the Collaboration Agreement.

1.5 “Affiliate” has that meaning ascribed to such term in Section 1.14 of the Collaboration Agreement.

1.6 “Business Day” means any day upon which banking institutions in Philadelphia, Pennsylvania are open for business.

1.7 “Calendar Quarter” has that meaning ascribed to such term in Section 1.21 of the Collaboration Agreement.

1.8 “Certificate of Compliance” means a certificate certified by Adolor’s head of Quality Assurance or authorized designee in the form attached hereto as Schedule 1.8 and provided by Adolor to GSK for each batch of Product delivered to GSK.

1.9 “CFR” means the Code of Federal Regulations.

1.10 “cGMP” means current good manufacturing practices of the United States Food and Drug Administration (or any successor entity thereto), or its foreign equivalent, including those set forth in 21 CFR Parts 210 and 211 and all applicable rules, regulations, guides and guidances, and their foreign equivalent.

1.11 “Claims” has that meaning ascribed to such term in Section 1.24 of the Collaboration Agreement.

1.12 “Collaboration Agreement” means that certain agreement between Adolor and GSK dated April 14, 2002 for the development and commercialization of Adolor’s compound known as alvimopan, and all amendments thereto.

1.13 “Confidential Information” has that meaning ascribed to such term in Section 1.30 of the Collaboration Agreement.

1.14 “Cost of Goods” has that meaning ascribed to that term in Section 1.33 of the Collaboration Agreement.

1.15 “Distribution Services” has the meaning ascribed to such term in Section 3.2 of this Agreement.

1.16 “Distribution Services Fee” has that meaning ascribed to such term in Section 1.46 of the Collaboration Agreement.

1.17 “FDA” means the United States Food and Drug Administration and any successor agency thereto.

1.18 “Financial Support Services” has the meaning ascribed to such term in Section 6.1 of this Agreement.

1.19 “Government Contracting Services” has the meaning ascribed to such term in Section 4.3 of this Agreement.

1.20 “Governmental Authority” has that meaning ascribed to such term in Section 1.57 of the Collaboration Agreement.

1.21 “Government Programs” means any Federal and/or State pharmaceutical rebate and/or pricing programs in the Territory, including but not limited to:

1.21.1 The Medicaid Drug Rebate Program (Public Law 101-508 and Section 1927 of the Social Security Act, 41 U.S.C. § 1396-r-8, as amended (the “Medicaid Statute”);

1.21.2 The US Public Health Service Pricing program established under 602 of the Veterans Health Care Act, Public Law 102-585 (the “§340B Programs PHS”);

1.21.3 The Federal Supply Schedule (the “FSS”);

1.21.4 The Federal Ceiling Price established under Section 602 of the Veterans Health Care Act, Public Law 102-585 (the “FCP”);

1.21.5 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-XXX, codified in section 1860D-31 of the Social Security Act referred to as the Medicare Modernization Act;

1.21.6 State Pharmaceutical Assistance Programs; and

1.21.7 State Medicaid Agencies Supplemental Rebate Programs.

1.22 “Government Programs Strategic Plan” has that meaning ascribed to such term in Section 4.1 below.

1.23 “GSK Quality Assurance Requirements” means the requirements as set forth on Schedule 3.1.1.

1.24 “Joint U.S. Marketing Team” or “JMT” has that meaning ascribed to such term in Section 1.81 of the Collaboration Agreement.

1.25 “Joint Steering Committee” or “JSC” has that meaning ascribed to such term in Section 1.83 of the Collaboration Agreement.

1.26 “Launch Date” means the date on which Product is first shipped to GSK by Adolor in commercial quantities for commercial sale to Third Parties in the Territory.

1.27 “Laws” has that meaning ascribed to such term in Section 1.85 of the Collaboration Agreement, and includes, but is not limited to: all laws applicable to federal and state healthcare programs including Medicare Prescription Drug Improvement and

Modernization Act of 2003 (Pub. L. 108-173), the False Claims Act (31 U.S.C. § 3729 et seq.), the anti-kickback provisions of the Social Security Law (42 U.S.C. § 1320a-7b(b)) and comparable state laws, and all other federal and state healthcare fraud statutes.

1.28 “Managed Markets Customers” has that meaning ascribed to such term in Section 5.1 below.

1.29 “MMC Contracting Guidelines” has that meaning ascribed to such term in Section 5.2 of this Agreement.

1.30 “MMC Services” has the meaning ascribed to such term in Section 5.3 of this Agreement.

1.31 “MMC Strategic Plan” has the meaning ascribed to such term in Section 5.1 below.

1.32 “NDC” means the “National Drug Code” which is the eleven digit code registered by Adolor with the FDA.

1.33 “Net Sales” has that meaning ascribed to such term in Section 1.97 of the Collaboration Agreement.

1.34 “Person” means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership, limited liability company, or other business entity, or any government or any agency or political subdivision thereof.

1.35 “Product” means any Adolor Product.

1.36 “Rebate(s)” means any credit, refund, discount, trade allowance, retroactive price adjustment, chargeback, administrative service fee or other payment made pursuant to a Government Program or an agreement with a Managed Markets Customer that is associated with sales of the Product.

1.37 “Services” means the Distribution Services, the Financial Support Services, the Government Contracting Services, the MMC Services and the Wholesaler Support Services, collectively that are performed by GSK pursuant to this Agreement.

1.38 “Term” or “Term of this Agreement” means the period commencing on the Effective Date and ending upon the earlier of (a) termination or expiration of the Adolor Product Promotion Term or (b) the date on which Adolor assumes responsibility for the Services pursuant to Article 9, unless sooner terminated as provided herein.

1.39 “Territory” means[**]

1.40 “Third Party” means any Person whom or which is neither a Party nor an Affiliate of a Party.

1.41 “Wholesaler Support Services” has the meaning ascribed to such term in Section 3.3 of this Agreement.

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ARTICLE 2

APPOINTMENT OF DISTRIBUTOR

2.1 Appointment of GSK. Subject to the terms and conditions of this Agreement, Adolor hereby appoints GSK to exclusively provide the Services for the Products in the Territory during the Term of this Agreement.

2.2 Provision of Services. Adolor and GSK agree that GSK will carry out the Services in accordance with (a) the policies and procedures that GSK uses for its own products of a similar commercial potential, (b) the terms and conditions of this Agreement, (c) any additional plans, policies or procedures set forth in the U.S. Marketing Plan, and (d) in compliance with applicable Laws.

2.3 Nature of Relationship. In carrying out the Services, GSK will act on Adolor’s behalf and specify that GSK is acting as such.

ARTICLE 3

CONSIGNMENT, DISTRIBUTION SERVICES AND WHOLESALER SUPPORT

SERVICES

3.1 Consignment Arrangement.

3.1.1 During the Term, Adolor will ship Product in finished form to GSK to be held on consignment for Adolor. Subject to Section 3.2.5, Adolor will ship, in sufficient quantities to meet the anticipated orders, the Products to a GSK distribution facility as may be designated by GSK in writing to Adolor from time to time (the “GSK Facility”). The written designation from GSK will be sent to Adolor with commercially reasonable lead time to allow Adolor to approve any such proposed GSK Facility in accordance with Adolor’s vendor approval system, such approval not to be

unreasonably withheld, and to allow the Parties to update their systems. Adolor will ship the Product to the GSK Facility via a carrier approved in accordance with Adolor's vendor approval system. For each shipment of Product delivered by Adolor to GSK, Adolor will provide GSK with a Certificate of Compliance for each such shipment. Adolor acknowledges that GSK is entitled to rely on the Certificate of Compliance as part of criteria to release the Products into interstate commerce. GSK will promptly visually inspect each shipment of the Products for external damage or loss in transit and notify Adolor in the event such damage or loss has occurred. Within [**] days following receipt of the Products at the GSK Facility, GSK will notify Adolor whether the shipped Product is in conformity with the GSK Quality Assurance Requirements and, if so, its acceptance, in whole or in part, thereof. GSK will be under no obligation to accept any shipment, in whole or in part, of Product that does not conform to the GSK Quality Assurance Requirements. GSK shall have the right to revoke acceptance of any shipped Product if it later discovers non-obvious defects not reasonably discoverable at the time of receipt.

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3.1.2 Adolor will at all times be the owner of the Products and will retain title and risk of loss to the Product until such time as GSK ships Product to a Third Party on Adolor's behalf.

3.1.3 Adolor and GSK agree to the quality obligations and requirements set forth on Schedule 3.1.1 with respect to the Products.

3.1.4 From time to time as Adolor may elect during the Term [**], during normal business hours and upon reasonable advance notice from Adolor (but not less than ten (10) Business Days' notice), GSK shall permit duly authorized representatives of Adolor to review and inspect, on the premises of GSK, each GSK Facility where such inventory is kept, to ensure compliance with cGMP, quality control standards and with the applicable terms of this Agreement. In the event of an Adverse Drug Experience, any proposed or actual inspection by a Governmental Authority or other emergency involving the Product, Adolor shall have the right at any time upon oral or written notice to GSK of one (1) Business Day to conduct an inspection of each GSK Facility and on the premises of GSK, where such inventory is kept, inventory of the Products, storage documentation and GSK's quality control records relating to the storage of the Products to ensure compliance with cGMPs, quality control standards, and with applicable terms of this Agreement. GSK shall promptly respond to Adolor's request and the Parties shall agree on the time, scope and manner of the inspection.

3.1.5 Within five (5) days after the end of each month during the Term of this Agreement, GSK will send Adolor the following information in the form regularly produced by GSK for its own products: [**]. Adolor may elect during the Term (but no more than once each calendar year), during normal business hours and upon reasonable advance notice from Adolor (but not less than ten (10) Business Days' notice), to perform physical inventory of the Product at each GSK Facility where Product is stored. GSK shall incorporate the Products into its regular cycle count program and, if applicable, provide Adolor with the results of any Adolor Product cycle counts.

3.1.6 GSK will be responsible for Products lost or destroyed due to GSK's negligence or misconduct after GSK's receipt of the Products at the GSK Facility. GSK will reimburse Adolor for [**] for such lost or destroyed Products. If GSK is obligated to pay any such amounts to Adolor pursuant to this Section 3.1.6, such amounts will be payable within thirty (30) days following receipt of an invoice from Adolor.

3.1.7 As to Product so supplied by Adolor, Adolor will be responsible for (i) paying any sales or property taxes that relate to Product, (ii) insuring against loss of Product or any substantial diminution of its value while in GSK Facilities or during transit to customers, and (iii) freight charges not collected from customers that Adolor may authorize from time to time, for the avoidance of doubt, all such costs will not form part of the Distribution Services Fee but will be deducted from Net Sales for calculating Adolor Product Marketing Contribution. Adolor may request in writing that (i) GSK arrange to insure Product upon terms acceptable to Adolor,

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(ii) pay any taxes on behalf of Adolor and (iii) bill Adolor or provide an offset against moneys otherwise due to Adolor at its cost for (i) and (ii), and, for the avoidance of doubt, such costs will not be included in the Distribution Services Fee. Adolor will reimburse GSK within thirty (30) days of receipt of GSK's invoice for such costs.

3.2 Distribution Services. GSK will distribute Product on Adolor's behalf and provide distribution services that include the following activities (the "Distribution Services"):

3.2.1 Receiving, maintaining and storing Product in the GSK Facility on a consignment basis in accordance with the terms and conditions of this Agreement;

3.2.2 Taking, fulfilling, shipping and invoicing orders (priced in accordance with Section 7.3) of Product; provided, however, that Adolor, given a demonstrated concern of a customer's credit worthiness, or non-compliance with contract terms or Laws, may advise GSK and GSK will withhold shipment of Product to said customer for the period of time the concern is relevant;

3.2.3 Processing Product returns from customers;

3.2.4 Adolor will forward orders to GSK as soon as practicable if for any reason Adolor should receive orders for Product in the Territory and notify the customer that it has forwarded such order to GSK;

3.2.5 In the event of a shortage of Product, the JMT will develop a Product allocation strategy for customers that will be implemented by GSK; and

3.2.6 For the avoidance of doubt, GSK will not be obligated to segregate the Products from other GSK products in the GSK warehousing system.

3.3 Wholesaler Support Services. GSK will perform wholesaler support services for Product on Adolor's behalf that include the following activities (the "Wholesaler Support Services"):

3.3.1 The JMT, as part of the U.S. Marketing Plan, will create a strategic wholesaler plan which shall include contracting guidelines, including approved key terms and conditions by targeted customers and the timing relative to expected launch of Product for contracting to be completed (the "Strategic Wholesaler Plan"); provided, however, if the contracting guidelines are to include [**] the JMT's decision to adopt such an arrangement [**];

3.3.2 GSK will enter into new contracts or amend its existing contracts with wholesalers and distributors to include Products (and identify Adolor as the owner of Products) in accordance with the customer-by-customer contracting guidelines approved by the JMT; provided, however, any such contract will provide that the Product may be transferred to Adolor pursuant to Section 9.1 unless otherwise explicitly authorized by the JMT. GSK will not enter into new contracts for the Products or amend existing contracts to include the Products that do not meet the contracting guidelines;

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3.3.3 GSK will provide Adolor a detailed summary of the key terms and conditions of contracts for the Products with wholesalers and distributors entered into, amended or terminated by GSK; and

3.3.4 Notwithstanding the foregoing, if such contractual relationships also include GSK's own products, GSK may preserve the confidentiality of information related to its products and restrict Adolor's access to such information.

3.4 Samples. The Parties acknowledge and agree that GSK will not be distributing any Adolor Product samples nor tracking any Adolor Product samples.

3.5 US Logistics Team.

3.5.1 Members and Meetings. Within thirty (30) days after the Effective Date, the Parties shall establish a US logistics team to coordinate the supply chain aspects of this Agreement (the "US Logistics Team"). The US Logistics Team shall be jointly chaired by a representative of Adolor and GSK and shall meet at least once each Calendar Quarter. US Logistics Team representatives shall include individuals who have supply chain management experience.

3.5.2 Responsibilities. The Parties will provide oversight, review and recommendations regarding Product supply and distribution matters through the US Logistics Team, as applicable, including:

(a) Product sales forecast and supplier production plans;

(b) Product delivery schedule to GSK, including expiration dating available at time of delivery;

(c) Optimal inventory levels, lead-times, space requirements, safety stock targets, pallet and case sizes and configurations;

(d) Technical and logistics review of packaging and manufacturing changes;

(e) Delivery issues from GSK to customers, including back-orders, freight, product returns and short-dating; and

(f) Such other responsibilities as may be as may be mutually agreed upon by the Parties from time to time.

3.5.3 Decision-Making. If the US Logistics Team cannot reach consensus on matters for which it has responsibility, then the JMT will have the final decision in the matter, however the matter will be resolved by the JMT such that GSK is not required to treat the Product in any manner that increases its obligations for the Product beyond its standard operating procedures in effect for its own products of similar commercial potential.

3.5.4 Expenses. Each Party shall be responsible for all travel and related costs and expenses for its members and other representatives to attend meetings of, and otherwise participate on, the US Logistics Team.

ARTICLE 4

GOVERNMENT PROGRAMS; GOVERNMENT SUPPORT SERVICES

4.1 Government Programs Strategic Plan. The Parties will each undertake certain responsibilities, as set forth in this Article 4, for Product in the Territory in connection with the Government Programs. In that regard, subject to Section 7.3, the JMT, as part of the U.S. Marketing Plan, will develop a strategic plan related to Government Programs (the "Government Programs Strategic Plan"). The Government Programs Strategic Plan will include a pricing and contracting strategy, the customers by name, the timing relative to expected launch of Product for contracting to be completed, a reporting and compliance program, as well as responsibilities that will enable the Parties to manage the Government Programs for the Product provided, however, if the contracting guidelines are to include any [**], the JMT's decision to adopt such an arrangement [**].

4.2 Government Program Agreements. Adolor will be responsible for entering into all Government Program agreements in accordance with the strategies set forth in the Government Programs Strategic Plan.

4.3 Government Contracting Services. GSK will perform government contracting support services for Product on Adolor's behalf, which shall include the following activities (the "Government Contracting Services"):

4.3.1 GSK will provide that level of support set forth in Schedule 5.5.2 (sections 2a and 2c) of the Collaboration Agreement to assist Adolor with the management of Government Programs.

4.3.2 GSK will provide to Adolor a written summary describing the applicable portion of GSK's methodology for calculating and reporting, for Adolor Products, (a) the "Best Price" (as defined under the Social Security Act, 42 U.S.C. §1396r-8(c)(1)(C), (b) the "Average Manufacturer Price" (or "AMP") (as defined under the Social Security Act, 42 U.S.C. §1396r-8(k)(1), (c) the "Average Sales Price" (or "ASP") (in the event, and at such time, an ASP must be reported for Adolor Products, under the Medicare Prescription Drug, Improvement and Modernization Act of 2003), (d) the "Federal Ceiling Price" (or "FCP") (as defined in the Veterans Health Care Act) and future reporting requirements (the "Methodology"). Adolor shall confirm to GSK in writing Adolor's approval of the Methodology for the Adolor Products, which approval will not be unreasonably withheld. Adolor acknowledges and agrees that GSK may update its Methodology from time to time to comply with any changes, or changes in interpretation, of Law, regulation or Government Program policy. In the event of such a change

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in the Methodology, GSK will provide Adolor with a copy of the revised Methodology within a reasonable timeframe. Adolor acknowledges and agrees that GSK will not be obligated to make any changes to the Methodology. In the event Adolor does not approve the Methodology or objects to GSK revisions of the Methodology, Adolor will be entitled to terminate this Agreement and the provisions of Article 9 will govern the transfer of the Services to Adolor, provided that Adolor shall be entitled to terminate this Agreement immediately and without regard to the timing provisions of Article 9.

4.3.3 GSK will be responsible for calculating and reporting to the applicable Government Program the Best Price, AMP, ASP (as may be applicable), FCP and future reporting requirements of the Products, consistent with the Methodology and in accordance with applicable Laws. On a quarterly basis during the Term, GSK shall provide Adolor with the Best Price, AMP, ASP (as applicable) and FCP submitted by GSK to the respective Government Programs for the Products.

4.3.4 GSK will be responsible for payment of all chargebacks and Rebates, on Adolor's behalf, that may be due under the Government Programs, in accordance with Articles 6 and 7 herein, consistent with the Methodology.

4.3.5 GSK will provide reasonable assistance to Adolor for completing the necessary applications and forms to obtain state Medicaid reimbursement, participate in state pharmaceutical assistance programs, comply with the Public Health Service (PHS) Section 340B Program price reporting obligations, and comply with the Veterans Health Administration's (VHA's) Federal Supply Schedule program.

4.3.6 Adolor acknowledges that GSK may preserve the confidentiality of information related to its products and restrict Adolor's access to such information.

ARTICLE 5

MMC SERVICES

5.1 Managed Markets Customers. GSK and Adolor will each have certain responsibilities in all dealings related to Product in the Territory with Managed Markets Customers (as defined below) as more particularly described in the strategic plan related to Managed Markets Customers (the "MMC Strategic Plan") as developed by the JMT as part of the U.S. Marketing Plan. "Managed Markets Customers" means health insurers,

health maintenance organizations, pharmacy benefit management companies, any other organization, public or private, that pays or insures health or medical expenses on behalf of beneficiaries or recipients, retail pharmacies, hospitals, hospital group purchasing organizations (GPOs), long term care institutions or pharmacies, nursing homes, and other non-wholesaler purchasers of Product.

5.2 MMC Strategic Plan. The MMC Strategic Plan will include a business plan and a strategy for approaching and managing Managed Markets Customer accounts, pricing and terms to be offered, including contracting guidelines that include approved key terms and conditions by targeted customers and the timing relative to expected launch of Product for contracting to be completed; provided, however, if the contracting guidelines are to include [**]

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[**], the JMT's decision to adopt such an arrangement [**] (the "MMC Contracting Guidelines"). GSK will be responsible for the negotiation and subsequent implementation of all contracts with Managed Markets Customers for Products entered into pursuant to the customer-by-customer MMC Contracting Guidelines approved by the JMT; provided, however, any such contract will provide that the Product may be transferred to Adolor pursuant to Section 9.1 unless otherwise explicitly authorized by the JMT.

5.3 Managed Markets Services. GSK will perform services with respect to Managed Markets Customers which will include the following activities (the "MMC Services"):

5.3.1 GSK will enter into new contracts or amend its existing contracts with Managed Markets Customers to include Products in accordance with the approved MMC Contracting Guidelines. GSK will not enter into new contracts with Managed Markets Customers for the Products or amend existing contracts with Managed Markets Customers to include the Products that do not meet the MMC Contracting Guidelines;

5.3.2 GSK will provide Adolor with a detailed summary of the key terms and conditions of contracts including full disclosure of all financial obligations that may accrue to the Product with Managed Markets Customers entered into, amended or terminated by GSK; and

5.3.3 Notwithstanding the foregoing, if such contractual relationships with Managed Markets Customers also include GSK's own products, GSK may preserve the confidentiality of information related to its products and restrict Adolor's access to such information.

ARTICLE 6

FINANCIAL SERVICES

6.1 Financial Services. GSK will perform financial support services on Adolor's behalf, which shall include the following activities (the "Financial Support Services") in accordance with its operating procedures in place for its own products and consistent with customer contract terms and conditions unless mutually agreed by the Parties at the JMT:

6.1.1 performing credit check functions on customer orders on behalf of Adolor and assigning credit limitations to customers;

6.1.2 collecting payment from customers, maintaining accounts receivable records, posting subsequent cash transactions and pursuing delinquent accounts;

6.1.3 carrying out order pricing (priced in accordance with Section 7.3) and chargeback processing in accordance with Adolor's written guidelines presented to the JMT;

6.1.4 managing contracts, paying for Rebates, discounts, returns, trade and stocking allowances;

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6.1.5 adjudicating on making payments for and retaining records in respect of claims for Rebates; and

6.1.6 meeting annually, or as events dictate, with Adolor to review customer payment histories, receivable aging, credit limits, payment terms, and other customer issues.

ARTICLE 7

PAYMENT PROVISIONS AND REPORTING

7.1 Distribution Services Fee. In consideration for the carrying out of the activities described in this Agreement, Adolor will pay GSK [**] percent ([**]%) of Net Sales of Product in the Territory as the Distribution Services Fee as provided for in Section 1.7 of the Collaboration Agreement. For

the avoidance of doubt, no payments will be made to GSK under this Agreement and the Distribution Services Fee will be paid to GSK as part of the reconciliation process pursuant to and as part of the Collaboration Agreement.

7.2 Booking of Sales. Adolor will have the sole right and responsibility to record and book sales of Products in the Territory, which will be based on the date Product is invoiced by GSK to an independent Third Party on behalf of Adolor consistent with the terms and conditions of the Collaboration Agreement.

7.3 Pricing. The pricing strategy for the Product will be [**]; provided, however, [**], if any, as part of any contracting guidelines adopted by the JMT for the Products for wholesalers and distributors and the MMC Contracting Guidelines.

7.4 Payment. Within [**] of the end of [**], GSK will provide Adolor with a report detailing the gross sales and the calculation of Net Sales as recorded by GSK for such period. Within [**] days of the end of [**] (or the next Business Day if the [**] day in not a Business Day), GSK will remit to Adolor by wire transfer the amount of the Net Sales reported as provided in the preceding sentence excluding any deductions for Rebates that Adolor may be processing and paying on their own behalf. Within [**] days of the expiration of [**], GSK will send to Adolor a reconciliation report that will specify with regard to calculation of Net Sales: (i) each Third Party or Government Program which a Rebate is paid (including any applicable customer or account number), (ii) the period covered by the payment, and (iii) the specific amount of the Rebate paid to any such Third Party or Government Program. GSK will make supporting documentation available to Adolor for its review at a GSK facility during normal business hours upon reasonable prior notice for the purpose of verifying the accuracy of the reconciliation report. GSK and Adolor will meet per GSK's regular schedule to review and set accrual parameters for the subsequent [**].

7.5 Standard Reports. Subject to Sections 3.3.4, 4.3.6 and 5.3.3, GSK will provide to Adolor at no charge those standard reports that GSK uses in the performance and/or management of the Services, as such may be amended from time to time as set forth on Schedule 7.5. The Parties agree to work together in good faith to satisfy each Party's needs with regard to financial audits and compliance.

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7.6 Customer Payments. As provided in the Collaboration Agreement, Adolor will be entitled to receive all monies collected for the sale of Product or gross sales and will be ultimately responsible for any Rebates and other expenses contemplated in this Agreement that are not part of the Distribution Services Fee. To effect the foregoing, GSK will collect gross sales from customers on Adolor's behalf pursuant to Section 6.1.2 and will remit to Adolor Net Sales as calculated by GSK pursuant to Section 7.4, the difference between gross sales and Net Sales being retained by GSK to pay, on Adolor's behalf, any Rebates or other expenses pursuant to the terms of this Agreement. The Parties will, each Calendar Quarter, reconcile Rebate and other payments made by GSK and Adolor pursuant to this Agreement and amounts retained by GSK such that: (a) Adolor will reimburse GSK for all such amounts not previously retained by GSK as part of the calculation of Net Sales that are paid by GSK on Adolor's behalf in accordance with this Agreement (it being understood that such reimbursement will not be a part of GSK's Distribution Services Fee) and (b) Adolor will recoup from GSK amounts previously retained by GSK that have been paid by Adolor.

7.7 Financial Records; Audits. GSK will keep, and will cause its Affiliates to keep, such accurate and complete true books of accounts and other records as are necessary to determine the amounts due to or by Adolor under this Agreement. Such records shall be retained by GSK or any of its Affiliates (in such capacity, the "Recording Party") in accordance with GSK's record retention policy. During normal business hours and with reasonable advance notice to the Recording Party, such records shall be made available for inspection, review and audit, at the request and expense of Adolor, by an independent certified public accountant, or the local equivalent, appointed by Adolor and reasonably acceptable to the Recording Party (the "Auditor") for the sole purpose of verifying the accuracy of the Recording Party's accounting reports and payments made or to be made pursuant to this Agreement; provided, however that such audits may not be performed by Adolor more than [**] and that Adolor [**]. The Auditor will enter into a written confidentiality agreement with the Recording Party. The Auditor will not reveal to Adolor the details of its review, except for (i) such information as is required to be disclosed under this Agreement and (ii) such information presented in a summary fashion as is necessary to report the accountants' conclusions to Adolor, and all such information shall be deemed Confidential Information of the Recording Party; provided, however, that in any event such information may be presented to Adolor in a summary fashion as is necessary to report the accountants' conclusions; provided, further, GSK may preserve the confidentiality of information related to its products and such information will not be provided to Adolor. The Auditor will provide a detailed account of its findings and methodology to the Recording Party. All costs and expenses incurred in connection with performing any such audit shall be paid by Adolor unless the audit discloses at least a [**] percent ([**]%) shortfall, in which case the Recording Party will bear the full cost of the audit for such Calendar Year. Adolor will be entitled to recover any shortfall in payments due to it as determined by such audit, plus interest thereon calculated in accordance with Section 6.12 of the Collaboration Agreement, or alternatively shall have the right to offset and deduct any such shortfall in payments due to it against payments that Adolor is otherwise required to make to the Reporting Party under this Agreement.

[**] =Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

7.8 Government Program Records, Audits. GSK will keep data and records in accordance with GSK standards and practices for retention of records related to reporting to the Government Programs so that the prices reported (i.e., Best Price, AMP, ASP and FCP) to the applicable

Government Programs may be reviewed and audited in accordance with this Section. In the event of an audit, subpoena or civil investigatory demand from a Government Program, or a request from a Government Program for a lower price or for additional rebates or discounts, GSK will cooperate with the Government Program in conducting such audit and, at the request of Adolor, permit a nationally recognized accounting firm with experience in price reporting requirements of the Government Programs, selected by Adolor (except one to whom GSK has some reasonable objection) (the "Government Program Auditor"), to have access (upon prior written reasonable notice given to GSK) during ordinary business hours, to such books and records as may be necessary to review and audit any payment or price report made to the Government Program for Adolor Products or otherwise respond to such Government Program audit. The Government Program Auditor will execute a written confidentiality agreement with GSK and will disclose to Adolor only such information as is necessary to verify the prices reported and/or payments made or otherwise payable to a Government Program under this Agreement. The Government Program Auditor will send a copy of the report to GSK prior to sending the report to Adolor and/or the Government Program so that GSK may have reasonable opportunity to review the report for issues of confidentiality and to clarify any questions of the Auditor. The Government Program Auditor's report sent to GSK will also include the methodology and calculations the Government Program Auditor used to evaluate the prices reported and/or payments made to the Government Program. GSK reserves the right to dispute the Auditor report, or any portion thereof. Adolor will pay the cost of any such Government Program audit.

ARTICLE 8

ACTIVITIES RELATED TO DISTRIBUTION

8.1 Responsibilities. Unless otherwise expressly addressed herein, the Parties rights and obligations with respect to the Products will be governed by the terms and conditions of the Collaboration Agreement and the Pharmacovigilance Agreement, including but not limited to, the Commercialization of the Product, patient safety matters, recalls, refunds, Adverse Drug Experiences, Governmental Authority inspections, approval of labeling and promotional materials, complaints, destruction of returned Product and public statements.

8.2 Resale in Same Packaging. GSK will not alter in any manner any Product or its packaging as delivered to it by Adolor hereunder.

8.3 Compliance with Applicable Law. Each Party will comply with all applicable Laws, provided, that GSK will be solely responsible for compliance with those applicable Laws pertaining to the Services conducted by it hereunder (including, without limitation, those Laws that apply to documentation and records retention pertaining to the distribution and use of Product within the Territory). GSK will store and distribute the Product consistent with Product labeling and in compliance with all applicable Laws. Each Party will cooperate with the other to provide such letters, documentation and other information on a timely basis as the other Party may reasonably require to fulfill its reporting and other obligations under applicable Laws to applicable regulatory authorities. Except for such amounts as are expressly required to be paid by a Party to the other under this Agreement, each Party will be solely responsible for any costs incurred by it to comply with its obligations under applicable Laws.

ARTICLE 9

TRANSFER OF RESPONSIBILITIES TO ADOLOR

9.1 Assumption of Services by Adolor. At anytime after the [**] of the Launch Date, Adolor may elect in its sole discretion to have GSK transfer to Adolor responsibility for the Services and discharge GSK from the obligation to perform the Services; provided, however, that the transfer of the Services to Adolor will be subject to GSK's compliance with obligations contained in agreements concerning the Adolor Products with wholesaler, distributors and Managed Markets Customers. Adolor will give GSK at least ninety (90) days' prior written notice ("Adolor Termination Notice") of Adolor's wish to have GSK transfer to Adolor the Services. The earliest Adolor may send such notice to GSK is the date that is [**] after the Launch Date. In order to assume responsibility for the Services, Adolor must assume [**]. For purposes of clarification, Adolor shall have the right to assume the Services pursuant to Section 4.3.2 without regard to the above notice period.

9.2 GSK's Ability to Dispute Adolor's Assumption of the Services. Before GSK is obligated to transfer such responsibilities to Adolor, GSK will first satisfy itself that Adolor can, and will be able to, comply with, and fulfill, the Services. GSK will be entitled during the ninety (90) day period of such Adolor Termination Notice to carry out such due diligence and auditing of Adolor as GSK may reasonably deem necessary in order to make such determination. If, after conducting such due diligence and auditing in good faith, and giving due consideration to Adolor, GSK determines that Adolor cannot, or will not be able to, perform the Services, then GSK may elect to continue to perform the Services and the matter will be referred to the JMT for discussion and review. If the JMT does not concur with GSK's determination within fifteen (15) days after the matter has been referred to the JMT, the matter will be referred to the JSC for discussion and review for another fifteen (15) day period; provided, however, Adolor will have final decision-making authority with respect to whether or not it will assume and perform the Services and may assume such responsibilities regardless of the finding of the JSC subject to and in accordance with this Article 9. If Adolor assumes responsibility for performance of the Services, Adolor will perform the services in a commercially reasonable manner that is consistent with the performance standards established by the Parties pursuant hereto. The Parties agree that the provisions of preceding sentence will survive termination or expiration of this Agreement so long as the Collaboration Agreement is in effect.

9.3 Termination of Payment of Distribution Services Fee to GSK. Once all the Services have been transferred to Adolor then, in consideration for the performance of the Services, the Distribution Services Fee will no longer be received by GSK and Adolor shall be entitled to receive the Distribution Services Fee in accordance with the provisions of the Collaboration Agreement. For the avoidance of doubt, no payments will be

made to Adolor by GSK for assuming responsibility for the Services and Adolor shall receive the Distribution Services Fee as part of the reconciliation process pursuant to and as part of the Collaboration Agreement.

[**] =Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

ARTICLE 10

REPRESENTATIONS AND WARRANTIES

10.1 Mutual Representations and Warranties. Adolor and GSK each represents and warrants to the other as of the Effective Date that:

10.1.1 Such Party (a) is a company duly organized, validly existing, and in good standing under the Laws of its incorporation; (b) is duly qualified as a corporation and in good standing under the Laws of each jurisdiction where its ownership or lease of property or the conduct of its business requires such qualification, where the failure to be so qualified would have a material adverse effect on its financial condition or its ability to perform its obligations hereunder; (c) has the requisite corporate power and authority and the legal right to conduct its business as now conducted and hereafter contemplated to be conducted; (d) has or will obtain all necessary licenses, permits, consents, or approvals from or by, and has made or will make all necessary notices to, all Governmental Authorities having jurisdiction over such Party, to the extent required for the ownership and operation of its business, where the failure to obtain such licenses, permits, consents or approvals, or to make such notices, would have a material adverse effect on its financial condition or its ability to perform its obligations hereunder; and (e) is in compliance with its charter documents;

10.1.2 The execution, delivery and performance of this Agreement by such Party and all instruments and documents to be delivered by such Party hereunder (a) are within the corporate power of such Party; (b) have been duly authorized by all necessary or proper corporate action; (c) do not conflict with any provision of the charter documents of such Party; (d) will not, to the best of such Party's knowledge, violate any law or regulation or any order or decree of any court of governmental instrumentality; (e) will not violate or conflict with any terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument to which such Party is a party, or by which such Party or any of its property is bound, which violation would have a material adverse effect on its financial condition or on its ability to perform its obligations hereunder;

10.1.3 This Agreement has been duly executed and delivered by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as such enforceability may be limited by applicable insolvency and other Laws affecting creditors' rights generally, or by the availability of equitable remedies; and

10.1.4 Neither Party has, nor will pay, offer or promise to pay, or authorize the payment directly or indirectly of any moneys or anything of value to any government official or employee, or any political party or candidate for political office for the purpose of influencing any act or decision of such official or of the government to obtain or retain business or direct business to any person.

10.2 Additional Adolor Representations, Warranties and Covenants. Adolor further represents, warrants and covenants to GSK that Adolor will ship or have shipped the Product in accordance with applicable Law and the specifications for the Product and that each Certificate of Compliance furnished by Adolor to GSK hereunder is complete and correct.

10.3 Additional GSK Covenants.

10.3.1 GSK further represents, warrants and covenants to Adolor that it will not give or make any, warranties, representations or statements on behalf of Adolor as to the condition, quality, durability, performance, merchantability or fitness for a particular purpose or any other feature of the Products (whether to wholesalers or otherwise) beyond such statements approved by the JMT as part of the MMC Contracting Guidelines, other customer contracting guidelines adopted by the JMT, or the Product labeling.

10.3.2 GSK further represents, warrants and covenants that it will store and ship the Product in accordance with cGMP and applicable Laws.

10.4 Disclaimer of Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS, WAIVES, RELEASES, AND RENOUNCES ANY WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 11

INDEMNIFICATION

11.1 Indemnification by GSK. Subject to the provisions of Section 11.2 below, GSK will defend, indemnify and hold harmless Adolor and its Affiliates and each of their officers, directors, shareholders, employees, successors and assigns from and against all Claims of Third Parties, and all associated Losses, to the extent arising out of (a) GSK's negligence or willful misconduct in performing any of its obligations under this Agreement, or (b) a breach by GSK of any of its representations, warranties, covenants or agreements under this Agreement; provided,

however, that in all cases referred to in this Section 11.1, GSK will not be liable to indemnify Adolor for any Losses of Adolor to the extent that such Losses of Adolor were caused by: (x) the negligence or willful misconduct or wrongdoing of Adolor or (y) any breach by Adolor of its representations, warranties, covenants or agreements hereunder.

11.2 Indemnification by Adolor. Adolor will defend, indemnify and hold harmless GSK and its Affiliates and each of their officers, directors, shareholders, employees, successors and assigns from and against all Claims of Third Parties, and all associated Losses, to the extent arising out of (a) Adolor's negligence or willful misconduct in performing any of its obligations under this Agreement, or (b) a breach by Adolor of any of its representations, warranties, covenants or agreements under this Agreement; provided, however, that in all cases referred to in this Section 11.2, Adolor will not be liable to indemnify GSK for any Losses of GSK to the extent that such Losses of GSK were caused by: (x) the negligence or willful misconduct or wrongdoing of GSK or (y) any breach by GSK of its representations, warranties, covenants or agreements hereunder.

11.3 Product Liability Claims. Notwithstanding anything to the contrary contained in this Article 11, the Parties agree that nothing in this Agreement is meant to modify the provisions of Section 14.5 of the Collaboration Agreement and that all Product Liability Claims will be addressed as provided therein.

11.4 Continued Indemnification Under the Collaboration Agreement. In addition to the indemnification obligations set forth in Section 11.1 and 11.2, each Party will continue to indemnify the other Party in accordance with the terms and conditions of the Collaboration Agreement.

11.5 Indemnification Procedures. The processes and procedures for indemnification will be as provided in the Collaboration Agreement.

11.6 Limitation of Liability. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT. THE FOREGOING SENTENCE WILL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER THIS ARTICLE 11 OR AS OTHERWISE SET FORTH IN THE COLLABORATION AGREEMENT.

ARTICLE 12

CONFIDENTIALITY

All information provided by one Party to the other pursuant to this Agreement, including the terms of this Agreement, will be deemed to be Confidential Information and as such the Parties rights and obligations related thereto will be governed by the provisions of Article 12 of the Collaboration Agreement.

ARTICLE 13

TERMINATION

13.1 Term. This Agreement will become effective as of the Effective Date and, unless sooner terminated as provided herein, expire at the end of the Term.

13.2 Termination for Breach. Either Party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement in the event that the other Party (as used in this subsection, the "Breaching Party") will have materially breached or defaulted in the performance of any of its obligations. The Breaching Party will, if such breach can be cured, have sixty (60) days after written notice thereof was provided to the Breaching Party by the non-breaching Party to remedy such default (or, if such default cannot be cured within such 60-day period, the Breaching Party must commence and diligently continue actions to cure such default during such 60-day period). Any such termination will become effective at the end of such 60-day period unless the Breaching Party has cured any such breach or default prior to the expiration of such 60-day period (or, if such default is capable of being cured but cannot be cured within such 60-day period, the Breaching Party has commenced and diligently continued actions to cure such default provided always that, in such instance, such cure must have occurred within one hundred twenty (120) days after written notice thereof was provided to the Breaching Party by the non-breaching Party to remedy such default).

13.3 Termination of Collaboration Agreement. In the event that the Collaboration Agreement is terminated with respect to the Products in the Territory, this Agreement will similarly terminate.

13.4 Effect of Termination. Upon expiration of this Agreement or upon termination of this Agreement by either Party, GSK will promptly return to Adolor all quantities of Product in its possession and GSK, will treat all Adolor Confidential Information relating to the Product in its possession or control in accordance with the provisions of Article 12 of the Collaboration Agreement, and Adolor will have the right to perform or have performed the Services. The Parties will cooperate to create and implement a transition plan that will promptly transition all Services to Adolor with minimal disruption to either Party and the customers. Except with respect to the performance of the Services by GSK pursuant to Section

5.5.2(b) of the Collaboration Agreement, a termination of this Agreement for any reason is in no way meant to limit, remove or modify any obligation of either Party under the Collaboration Agreement and the Collaboration Agreement will remain in full force and effect in accordance with its terms.

13.5 Accrued Rights; Surviving Obligations. Termination, relinquishment or expiration of this Agreement for any reason will be without prejudice to any rights, which will have accrued to the benefit of either Party prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration will not relieve either Party from obligations, which are expressly indicated to survive termination or expiration of this Agreement. All of the Parties' rights and obligations under Articles 11, 12, 13 and 14 in strict accordance with their respective terms and expressly subject to all time limitations stated therein, will survive expiration or termination of this Agreement.

ARTICLE 14

MISCELLANEOUS PROVISIONS

14.1 Assignment. This Agreement may not be assigned by either Party without the prior consent of the other Party; provided, however that either Party may assign this Agreement, in whole or in part, to any of its Affiliates if such Party guarantees the performance of this Agreement by such Affiliate; and provided further that either Party may assign this Agreement to a successor to all or substantially all of the assets of such Party whether by merger, sale of stock, sale of assets or other similar transaction. Any assignment made contrary to the terms hereof will be void. This Agreement will be binding upon, and subject to the terms of the foregoing sentence, inure to the benefit of the Parties hereto, their permitted successors, legal representatives and assigns.

14.2 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, will be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

14.3 Dispute Resolution. The resolution of all controversies or claims between the Parties arising out of or relating to this Agreement will be governed by the terms and provisions of Section 18.5 of the Collaboration Agreement.

14.4 Entirety of Agreement, Amendments. This Agreement and the Collaboration Agreement, as amended (including the exhibits and schedules hereto and thereto) constitutes the entire agreement between the Parties hereto with respect to the within subject matter and supersedes all previous agreements and understandings between the Parties, whether written or oral. This Agreement may be altered, amended or changed only by a written agreement making specific reference to this Agreement and signed by duly authorized representatives of Adolor and GSK. For the avoidance of doubt, nothing contained herein is intended to limit or remove GSK's obligation to provide distribution and commercial services in the remainder of the United States (as defined in the Collaboration Agreement) outside of the Territory.

14.5 Governing Law. This Agreement will be governed by and construed in accordance with the principles provided in Section 18.4 of the Collaboration Agreement.

14.6 Relationship of the Parties. Each Party will bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither Party will have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party will have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, GSK's legal relationship under this Agreement to Adolor will be that of independent contractor. This Agreement is not a partnership agreement and nothing in this Agreement will be construed to establish a relationship of co-partners or joint venturers between the Parties.

14.7 Headings; Schedules; Counterparts.

14.7.1 Headings. The headings used in this Agreement have been inserted for convenience of reference only and do not define or limit the provisions hereof.

14.7.2 Schedules. All Schedules delivered pursuant to this Agreement will be deemed part of this Agreement and incorporated herein by reference, as if fully set forth herein. All provisions contained in any Schedule delivered by or on behalf of the Parties hereto, or in connection with the transactions contemplated hereby, are an integral part of this Agreement.

14.7.3 Counterparts. This Agreement may be executed in any two counterparts, each of which, when executed, will be deemed to be an original and both of which together will constitute one and the same document.

14.8 Severability. In the event of the invalidity of any provisions of this Agreement, the Parties agree that such invalidity will not affect the validity of the remaining provisions of this Agreement. The Parties will replace an invalid provision with valid provisions which most closely approximate the purpose and economic effect of the invalid provision. In the event that the terms and conditions of this Agreement are materially altered as a result of the preceding

sentences, the Parties will renegotiate the terms and conditions of this Agreement in order to resolve any inequities. Nothing in this Agreement will be interpreted so as to require either Party to violate any applicable laws, rules or regulations.

14.9 Cumulative Rights. Except as expressly provided herein, the rights, powers and remedies hereunder will be in addition to, and not in limitation of, all rights, powers and remedies provided at applicable Law or in equity, or under any other agreement between the Parties, and all of such rights, powers and remedies will be cumulative, and may be exercised successively or cumulatively.

14.10 Expenses. Adolor and GSK will each bear their own direct and indirect expenses incurred in connection with the negotiation and preparation of this Agreement and any related agreements and, except as set forth in this Agreement or any related agreements, the performance of the obligations contemplated hereby and thereby.

14.11 Notices. Any notice required or permitted to be given hereunder will be delivered in accordance with the provisions of Section 18.7 of the Collaboration Agreement.

14.12 Force Majeure. The occurrence of an event which materially interferes with the ability of a Party to perform its obligations or duties hereunder which is not within the reasonable control of the Party affected or any of its Affiliates, not due to malfeasance by such Party or its Affiliates, and which could not with the exercise of due diligence have been avoided (each, a “Force Majeure Event”), including, but not limited to, an injunction, order or action by a Governmental Authority, fire, accident, labor difficulty, strike, riot, civil commotion, act of God, inability to obtain raw materials, delay or errors by shipping companies or change in law, will not excuse such Party from the performance of its obligations or duties under this Agreement, but will merely suspend such performance during the continuation of the Force Majeure Event. The Party prevented from performing its obligations or duties because of a Force Majeure Event will promptly notify the other Party of the occurrence and particulars of such Force Majeure Event and will provide the other Party, from time to time, with its best estimate of the duration of such Force Majeure Event and with notice of the termination thereof. The Party so affected will use commercially reasonable efforts to avoid or remove such causes of nonperformance as soon as is reasonably practicable. Upon termination of the Force Majeure Event, the performance of any suspended obligation or duty will promptly recommence. The Party subject to the Force Majeure Event will not be liable to the other Party for any direct, indirect, consequential, incidental, special, punitive, exemplary or other damages arising out of or relating to the suspension or termination of any of its obligations or duties under this Agreement by reason of the occurrence of a Force Majeure Event, provided such Party complies in all material respects with its obligations under this Section 14.12.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, each of the Parties has caused this Agreement to be executed by its duly authorized representative.

ADOLOR CORPORATION

By:

/s/ Bruce A. Peacock

Name:

Bruce A. Peacock

Title:

President and Chief Executive

Officer

SMITHKLINE BEECHAM CORPORATION

By:

/s/ Donald F. Parman

Name:

Donald F. Parman

Title:

Vice President and Secretary

SIGNATURE PAGE TO

DISTRIBUTION SERVICES AGREEMENT

SCHEDULE 1.8

FORM OF CERTIFICATE OF COMPLIANCE

(see attached)

Certificate of Compliance

Product Description:

Manufacturer:

Manufacturer Assigned Batch/ Lot No.:

Adolor QA Assigned Product Disposition No.:

Statement of Compliance

The above stated product has been determined by Adolor Quality Assurance to have been manufactured and tested in compliance with United States current Good Manufacturing Practice, all applicable Laws and licenses, the specifications for the Product and Adolor approved vendor standard operating procedures. This product meets all requirements for human use and is suitable for release into interstate commerce.

Quality Assurance Approval:

Signature Date

Print Name

SCHEDULE 3.1.1

1. GSK Quality Assurance Requirements.

(a) All shipments of Product will arrive within a delivery window of up to [**], and [**], of its scheduled delivery or its expected delivery date. Any delays must be adequately investigated in accordance with paragraph 5 below.

(b) All shipments of Product must include the appropriate shipping documents, including but not limited to the packing list and bill of ladings.

(c) Adolor shall provide a Certificate of Compliance delivered no later than [**] from receipt of Product at the GSK Facility. The Certificate of Compliance must be signed and approved by Adolor's head of Quality Assurance or authorized designee.

2. Adolor Product shipped to the GSK Facility(ies) will be received under "quarantine" status until GSK releases the Product for distribution in accordance with the requirements of paragraph 4 below of this Schedule 3.1.1.

3. GSK will maintain the Adolor Product under the required storage conditions as provided for by the current Adolor Product label. Pursuant to GSK's policies and procedures, in the event of an incident involving Adolor Product that occurs at the GSK Facility or while the Adolor Product is in the possession of a GSK carrier, GSK will investigate the incident and provide Adolor with a control copy of its completed investigation. GSK may redact any portions of any such investigation that do not relate to Adolor Products.

4. In order to meet "release" status of Adolor Product at the GSK Facility and prior to distribution in accordance with the terms of this Agreement, GSK will, for each shipment of Adolor Product, conduct a visual inspection and confirm compliance with the GSK Quality Assurance Requirements.

5. GSK shall notify Adolor in writing in the event there is any deviation from the acceptance criteria identified in paragraph 4 above for Products based on receipt and inspection at the GSK Facility(ies). GSK shall hold the affected Adolor Product under quarantine status and will consult with Adolor on the disposition of affected Product shipments or parts thereof. GSK shall not take any action (disposition, destruction or return to Adolor) with respect to such affected Product shipment without the written consent of Adolor. Adolor will promptly investigate the affected Product shipment and provide GSK with written notification of Adolor's decision, including a summary of its investigation and conclusion, with

respect to any such affected Product shipment. Adolor shall provide a new Certificate of Compliance for any batch of affected shipped Product, or portion thereof that is to be released.

6. GSK will maintain all Adolor Product related records including receipt verification, release and distribution information in accordance with GSK's record retention policy for records pertaining to its own products in a manner so as to protect and secure the records against damage, destruction, unintended changes, or disposal during the required time of storage.

[**] =Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

7. GSK and Adolor's rights and obligations with respect to Adverse Drug Experiences, complaints and recalls related to the Product will be governed by the terms and conditions of the Collaboration Agreement and Pharmacovigilance Agreement.

8. In the event that either Party reasonably suspects a shipment or lot of Product to be misbranded or adulterated in accordance with the U.S. Federal Food, Drug and Cosmetic Act, either Party may request, and each Party will, as appropriate, quarantine such affected shipments or lots of Products until a corrective action is designated pursuant to the Collaboration Agreement.

SCHEDULE 7.5

Reports

[**]

[**] =Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.