CT-2016-002

#### **COMPETITION TRIBUNAL**

**IN THE MATTER OF** the *Competition Act*, R.S.C. 1985, c. C-34, and the *Competition Tribunal Rules*, SOR/2008-141;

**AND IN THE MATTER OF** the proposed acquisition by Teva Pharmaceutical Industries Limited of the generic pharmaceuticals business of Allergan plc;

**AND IN THE MATTER OF** the filing and registration of a consent agreement pursuant to sections 92 and 105 of the *Competition Act*.

#### BETWEEN:



#### THE COMMISSIONER OF COMPETITION

Applicant

- and -

#### TEVA PHARMACEUTICAL INDUSTRIES LIMITED

Respondent

### **CONSENT AGREEMENT**

## **RECITALS:**

- **A.** Teva Pharmaceutical Industries Limited ("Teva") proposes to acquire the generic pharmaceuticals business of Allergan plc (the "Transaction").
- **B.** The Commissioner has concluded that the Transaction is likely to result in a substantial lessening and/or prevention of competition in the supply of buprenorphine:naloxone and tobramycin in Canada, and that the implementation of this Agreement is necessary to ensure that any substantial lessening and/or prevention of competition will not result from the Transaction.
- C. Teva does not admit but will not for the purposes of this Agreement, including execution, registration, enforcement, variation or rescission, contest the Commissioner's conclusions that (i) the Transaction is likely to result in a substantial lessening and/or prevention of competition in the supply of buprenorphine:naloxone and tobramycin in Canada; and (ii) the implementation of this Agreement is necessary to ensure that any

substantial lessening and/or prevention of competition will not result from the Transaction.

**D.** Nothing in this Agreement affects any investigation, inquiry or proceeding other than under section 92 of the Act in respect of the Transaction.

**THEREFORE** Teva and the Commissioner agree as follows:

#### I. **DEFINITIONS**

- [1] Whenever used in this Agreement, the following words and terms have the meanings set out below:
  - (a) "Act" means the Competition Act, R.S.C. 1985, c. C-34, as amended;
  - (b) "Affiliate" means, in respect of a Person, any other Person controlling, controlled by or under common control with such first Person, whether directly or indirectly, and "control" means directly or indirectly hold securities or other interests in a Person (i) to which are attached more than 50% of the votes that may be cast to elect directors or persons exercising similar functions or (ii) entitling the holder to receive more than 50% of the profits of the Person or more than 50% of its assets on dissolution;
  - (c) "Agency" means any government regulatory authority in Canada responsible for granting approvals, clearances, qualifications, license or permits for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product;
  - (d) "Agreement" means this Consent Agreement, including the schedules hereto, and references to a "Part", "Section", "Paragraph" or "Schedule" are, unless otherwise indicated, references to a part, section, paragraph or schedule of or to this Agreement;
  - (e) "Allergan" means Allergan plc and its Affiliates and their directors, officers, employees, agents, representatives, successors and assigns;
  - (f) **"Business Day"** means a day on which the Competition Bureau's Gatineau, Quebec office is open for business;
  - (g) "Closing" means the completion of the Transaction under the Transaction Agreement;
  - (h) "Closing Date" means the date on which Closing occurs;
  - (i) "Commissioner" means the Commissioner of Competition appointed under the Act and includes his authorized representatives;

- (j) "Confidential Information" means competitively sensitive, proprietary and all other information that is not in the public domain, and that is owned by a Person or pertains to a Person's business, and includes, but is not limited to, manufacturing, operations and financial information, customer lists, price lists, contracts, cost and revenue information, marketing methods, patents, technologies, processes, or other trade secrets:
- (k) "Development" means all preclinical and clinical drug and biological research and development activities, including bioequivalence studies, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance and quality control development, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining any and all Product Approvals, and regulatory affairs related to the foregoing;
- (l) "Divested Business" means the business of developing, marketing and selling the Divestiture Products;
- (m) "Divestiture" means the sale, conveyance, transfer, assignment or other disposal of the Divestiture Assets in accordance with the Technology Transfer Standards to a Purchaser or Purchasers pursuant to this Agreement and with the prior approval of the Commissioner, such that Teva will have no direct or indirect interest in the Divestiture Assets;
- (n) "Divestiture Agreement" means a binding and definitive agreement between Teva and a Purchaser to effect the Divestiture pursuant to this Agreement and subject to the prior approval of the Commissioner;
- (o) "Divestiture Applicant" means Teva during the Initial Sale Period or the Divestiture Trustee during the Divestiture Trustee Sale Period;
- (p) "Divestiture Assets" means all of Teva's assets related to the Divestiture Products in Canada, and all of Teva's rights, title and interest in and to all such assets to the extent legally transferrable, including the research, Development, manufacture, distribution, marketing, and sale of the Divestiture Products, including, without limitation, the following:
  - (i) all Divestiture Product Intellectual Property;
  - (ii) licenses to all Divestiture Product Licensed Intellectual Property in relation to the Divestiture Products;
  - (iii) all Product Approvals for the Divestiture Products;
  - (iv) all Divestiture Product Manufacturing Technology that is tangible and exclusive to the Divestiture Products;

- (v) all Divestiture Product Marketing Materials;
- (vi) a list of all customers and targeted customers for the Divestiture Products and the net sales (in either units or dollars) of the Divestiture Products to those customers on a monthly basis during the two year period immediately preceding the Closing Date or such longer period as the Monitor determines is required for ongoing operations on application of the Purchaser;
- (vii) all applications for all Product Approvals for the Divestiture Products granted by any Agency, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Teva or Allergan, as applicable, and the relevant Agency related thereto;
- (viii) a list of all drug identification numbers ("**DINs**"), and rights, to the extent permitted by law, to require Teva to discontinue use of those DINs in respect of any Divestiture Product, other than with respect to returns, rebates, allowances, and adjustments for Divestiture Products sold prior to their Divestiture;
- (ix) all Divestiture Product Development Reports during the two year periods immediately preceding the Closing Date or such longer period as the Monitor determines is required for ongoing operations on application of the Purchaser;
- (x) at the Purchaser's option, subject to any rights of the customer, all unfilled customer purchase orders for the Divestiture Products;
- (xi) at the Purchaser's option, subject to the rights of any Third Party, all Divestiture Product Assumed Contracts;
- (xii) all strategic safety programs submitted to Health Canada related to the Divestiture Products that are designed to decrease product risk by using one or more interventions or tools beyond the package insert;
- (xiii) all patient registries related to the Divestiture Products, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by Health Canada to facilitate the investigation of adverse effects related to the Divestiture Products;
- (xiv) at the Purchaser's option and to the extent approved by the Commissioner in the relevant Remedial Agreement, all inventory (except such inventory that is subject to retention requirements imposed on Teva by applicable law) in existence as of the date of

the Divestiture including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the Divestiture Products; and

(xv) all of Teva's books, records, and files directly related to the foregoing or to the Divestiture Products for the one year period immediately preceding the Closing Date or such longer period as the Monitor determines is required for ongoing operations on application of the Purchaser,

provided, however, that "Divestiture Assets" shall not include: (1) documents relating to Teva's general business strategies or practices relating to research, Development, manufacture, marketing or sales of pharmaceutical Products, where such documents do not discuss with particularity the Divestiture Products; (2) administrative, financial, and accounting records that do not discuss with particularity the Divestiture Products; (3) quality control records that are determined by the Monitor or the Purchaser to not be material to the manufacture of the Divestiture Products; (4) any real estate and the buildings and other permanent structures located on such real estate; and (5) manufacturing assets and equipment not included in the Divestiture Product Manufacturing Technology; provided further, however, that in cases in which documents or other materials included in the relevant assets to be divested contain information: (A) that relates both to the Divestiture Products and to other Products or businesses of Teva and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Divestiture Products; or (B) for which Teva has a legal obligation to retain the original copies, Teva shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Purchaser, Teva shall provide the Purchaser access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes;

- (q) "Divestiture Process Agreement" means the agreement described in Section 6 of this Agreement;
- (r) "Divestiture Products" means the following products:
  - (i) at the election of the Divestiture Applicant, either: (1) buprenorphine:naloxone (tablets), an opiate antagonist and partial opiate agonist that is indicated for substitution treatment in opioid drug dependence in adults, as being developed by or on behalf of Allergan for sale in Canada; or (2) buprenorphine:naloxone (tablets), an opiate antagonist and partial opiate agonist that is indicated for substitution treatment in opioid drug dependence in adults, as sold by or on behalf of Teva in Canada (DINs 02424851 and 02424878); and

- (ii) at the election of the Divestiture Applicant, either: (1) tobramycin (inhalation solution), a respiratory antibiotic that is indicated for the management of cystic fibrosis patients with chronic pulmonary *Pseudomonas aeruginosa* infections, as being developed by or on behalf of Allergan for sale in Canada; or (2) tobramycin (inhalation solution), a respiratory antibiotic that is indicated for the management of cystic fibrosis patients with chronic pulmonary *Pseudomonas aeruginosa* infections, as sold by or on behalf of Teva in Canada (DIN 02389622);
- (s) "Divestiture Product Assumed Contracts" means contracts or agreements (copies of each such contract or agreement to be provided to the Purchaser on or before the Divestiture and segregated in a manner that clearly identifies the purpose(s) of each such contract):
  - (i) that make specific reference to a Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the Divestiture Product from Teva unless such contract applies generally to Teva's sales of Products to that Third Party;
  - (ii) pursuant to which Teva purchases the active pharmaceutical ingredient or other necessary ingredient or had planned to purchase the active pharmaceutical ingredient or other necessary ingredient from any Third Party for use in connection with the manufacture of a Divestiture Product;
  - (iii) relating to any bioequivalence studies, tests or trials involving a Divestiture Product;
  - (iv) with universities or other research institutions for the use of a Divestiture Product in scientific research;
  - (v) relating to the particularized marketing of a Divestiture Product or educational matters relating solely to a Divestiture Product;
  - (vi) pursuant to which a Third Party manufactures or packages a Divestiture Product on behalf of Teva;
  - (vii) pursuant to which a Third Party provides Divestiture Product Manufacturing Technology to Teva;
  - (viii) pursuant to which a Third Party is licensed by Teva to use Divestiture Product Manufacturing Technology;
  - (ix) constituting confidentiality agreements involving a Divestiture Product;

- (x) involving royalty, licensing, or similar arrangements with a Third Party involving a Divestiture Product;
- (xi) pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of a Divestiture Product to Teva including, but not limited to, consultation arrangements; and
- (xii) pursuant to which any Third Party collaborates with Teva in the performance of research, Development, marketing, distribution or selling of a Divestiture Product,

provided, however, that where any such contract or agreement also relates to a Retained Product, Teva shall assign to the Purchaser all such rights under the contract or agreement as are related to the Divestiture Products, but concurrently may retain similar rights for the purposes of the Retained Product;

- (t) "Divestiture Product Copyrights" means rights to all original works of authorship of any kind directly related to a Divestiture Product, and any registrations and applications for registrations thereof, within Canada;
- (u) "Divestiture Product Development Reports" means, in relation to a Divestiture Product:
  - (i) pharmacokinetic, bioavailability, and bioequivalence study reports (including any applicable reference listed drug information);
  - (ii) annual and periodic reports related to any application to any Agency for Product Approvals, including any safety update reports;
  - (iii) Health Canada-approved Product labelling;
  - (iv) currently used Product package inserts (including historical change of controls summaries);
  - (v) Health Canada-approved patient circulars and information related to a Divestiture Product;
  - (vi) adverse event/serious adverse event summaries;
  - (vii) summaries of Product complaints from physicians;
  - (viii) summaries of Product complaints from customers; and
  - (ix) Product recall reports filed with Health Canada;

- (v) "Divestiture Product Intellectual Property" means the following intellectual property owned, controlled, or licensed by Teva existing as of the Closing Date and related to a Divestiture Product (other than Divestiture Product Licensed Intellectual Property):
  - (i) Patents, Divestiture Product Copyrights, Divestiture Product Trade-marks and Divestiture Product Software;
  - (ii) trade dress, industrial designs, distinguishing guises, trade secrets, Divestiture Product Know-How, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information, and all rights in Canada to limit the use or disclosure thereof;
  - (iii) rights to obtain and file for Patents and copyrights and registrations thereof in Canada; and
  - (iv) rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation or breach of any of the foregoing;

provided, however, "Divestiture Product Intellectual Property" does not include the corporate name of Teva or Allergan or the corporate names of any other corporations or companies owned or controlled by Teva or Allergan or the related logos thereof;

- (w) "Divestiture Product Know-How" means all the know-how that is used for the Divestiture Products, including (i) all specifications, processes, designs, plans, trade secrets, ideas, concepts and inventions, (ii) manufacturing, engineering and other manuals and drawings, (iii) standard operating procedures, formulae and flow diagrams, (iv) toxicological, biological and physical analytical studies or reports, (v) information pertaining to safety, stability, supply, selection, constitution, or use of any raw material, (vi) quality assurance, quality control and clinical data, (vii) technical information and (viii) research records;
- (x) "Divestiture Product Licensed Intellectual Property" means the following intellectual property owned, controlled, or licensed by Teva existing as of the Closing Date and related but not exclusive to a Divestiture Product that Teva can demonstrate has been used, as of the Closing Date, for a Retained Product:
  - (i) Patents, Divestiture Product Copyrights, Divestiture Product Trade-marks, trade dress, industrial designs, distinguishing guises, trade secrets, Divestiture Product Know-How, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information; and

(ii) all rights in Canada to limit the use or disclosure thereof

and shall include tangible and intangible Divestiture Product Manufacturing Technology not exclusive to the Divestiture Products;

## (y) "Divestiture Product Manufacturing Technology" means:

- (i) all technology, trade secrets, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of a Divestiture Product that is owned, controlled or licensed by Teva prior to the Closing Date, including, but not limited to: all product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with Product Approval application conformance and GMP compliance, labeling and all other information related to the manufacturing process, and supplier lists:
- (ii) all active pharmaceutical ingredients related to a Divestiture Product that are owned, controlled or licensed by Teva as of the Closing Date; and
- (iii) for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Purchaser's option, all such equipment used to manufacture the Divestiture Products that is owned, controlled or licensed by Teva prior to the Closing Date;
- (z) "Divestiture Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of a Divestiture Product in Canada as of the date of the Divestiture;
- (aa) "Divestiture Product Software" means computer programs, including all software implementation of algorithms, models and methodologies whether in source code or object code form, databases and compilations, including any and all data and collections of data, all documentation, including user manuals and training materials, related to any of the foregoing and the content and information contained on any website, used in connection with the analysis of clinical trial data for a Divestiture Product, other than software that is readily purchasable or licensable and which has not been modified in a manner material to the use or function thereof (other than through user preference settings);
- (bb) "Divestiture Product Trade-marks" means all proprietary names or designations, trade-marks, service marks, trade names, and brand names,

including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, all in Canada, for the Divestiture Products;

- (cc) "Divestiture Trustee" means the Person appointed pursuant to Part [III] of this Agreement (or any substitute appointed thereto) and any employees, agents or other Persons acting for or on behalf of the Divestiture Trustee;
- (dd) "Divestiture Trustee Sale" means the Divestiture to be conducted by the Divestiture Trustee pursuant to Part III of this Agreement;
- (ee) "Divestiture Trustee Sale Period" means the 6 month period commencing upon expiry of the Initial Sale Period;
- (ff) **"First Reference Date"** shall have the meaning set out in Paragraph 22(d) of this Agreement;
- (gg) "GMP" means current Good Manufacturing Practice, as set forth in the *Food and Drugs Act*, R.S.C. 1985, c. F-27, as amended, and all rules and regulations promulgated thereunder;
- (hh) "Initial Sale Period" means the period that commences at Closing and ends at the time set out in Confidential Schedule A to this Agreement;
- (ii) "Monitor" means the Person appointed pursuant to Part X of this Agreement (or any substitute appointed thereto), and any employees, agents or other Persons acting for or on behalf of the Monitor, provided that if no Monitor is appointed, in this Agreement other than Part X Monitor means the Commissioner;
- (jj) "Monitor Agreement" means the agreement described in Section 37 of this Agreement;
- (kk) "Patent" means any Canadian patent or patent application, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Closing Date (except where this Agreement specifies a different time), and includes, without limitation, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Divestiture Product in Canada as of the Closing Date;
- (ll) **"Person"** means any individual, corporation or partnership, sole proprietorship, trust or other unincorporated organization capable of conducting business, and any Affiliates thereof;

- (mm) "Product" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and in any stage of Development, including commercialized Products;
- (nn) **"Product Approvals"** means any approvals, registrations, permits, licences, consents, authorizations, and other approvals, and pending applications and requests therefor, required by any Agency related to the research, Development, manufacture, use, distribution, finishing, packaging, promotion, marketing, sale, storage, transport, import or export of a Product within, into or from Canada;
- (00) **"Purchaser"** means a Person that acquires Divestiture Assets pursuant to this Agreement and a Divestiture Agreement, and includes any Person (other than Teva) that has been designated by a Purchaser to manufacture a Divestiture Product for that Purchaser;
- (pp) "Records" means records within the meaning of subsection 2(1) of the Act;
- (qq) "Remedial Agreement" means any agreement between Teva and a Purchaser, or between a Divestiture Trustee (on behalf of Teva) and a Purchaser or a Third Party (to effect the assignment of assets or rights of Teva related to the Divestiture Products to the benefit of a Purchaser), that has been approved by the Commissioner and that is specifically referenced in this Agreement as constituting a Remedial Agreement;
- (rr) "Retained Product" means any Product of Teva other than the Divestiture Products;
- (ss) **"Second Reference Date"** shall have the meaning set out in Paragraph 22(e) of this Agreement;
- (tt) "Supply Cost" means a cost not to exceed the manufacturer's average direct per unit cost of manufacturing the Divestiture Product for the 24 month period immediately preceding the Closing Date; provided, however, that in each instance where an agreement to contract manufacture becomes a Remedial Agreement for a Divestiture Product, "Supply Cost" means the cost as specified in such Remedial Agreement for that Divestiture Product;
- (uu) "Technology Transfer Standards" means requirements and standards sufficient to ensure that the information and assets required to be delivered pursuant to this Agreement are delivered in an organized, comprehensive, complete, useful, timely, and meaningful manner. Such standards and requirements shall include, among other things:

- (i) designating employees knowledgeable about the Divestiture Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Purchaser and the Monitor, for the purpose of effecting such delivery;
- (ii) preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the Divestiture Products that are acceptable to the Purchaser;
- (iii) preparing and implementing a detailed technological transfer plan, as approved by the Monitor, for the transfer of the Divestiture Product Manufacturing Technology to the Purchaser within specified time lines that provide for the transfer to be complete within 2 years after the Divestiture or such longer period as the Monitor may approve; and
- (iv) providing, in a timely manner, assistance and advice to enable the Purchaser to:
  - 1. manufacture the Divestiture Products in the quality and quantities achieved by or for Teva;
  - obtain any Product Approvals necessary for the Purchaser to manufacture, distribute, market and sell the Divestiture Products in commercial quantities and to meet all Agencyapproved specifications for the Divestiture Products; and
  - 3. receive, integrate and use the Divestiture Product Manufacturing Technology;
- (vv) "Teva" means Teva Pharmaceutical Industries Limited and its Affiliates and their directors, officers, employees, agents, representatives, successors and assigns;
- (ww) "Third Party" means any Person other than the Commissioner, Teva or a Purchaser;
- (xx) **"Transaction"** means the transaction described in the first recital to this Agreement;
- (yy) "Transaction Agreement" means the Master Purchase Agreement dated July 26, 2015 by and between Allergan and Teva; and
- (zz) "**Tribunal**" means the Competition Tribunal established by the *Competition Tribunal Act*, R.S.C. 1985, c.19 (2<sup>nd</sup> Supp.).

#### II. OBLIGATION TO COMPLETE DIVESTITURE

- [2] Teva shall use commercially reasonable efforts to complete the Divestiture.
- [3] During the Initial Sale Period, Teva shall use commercially reasonable efforts to complete the Divestiture in accordance with the provisions of this Part and Confidential Schedule A and subject to Part IV.
- [4] During the Initial Sale Period, Teva shall provide to the Commissioner and to the Monitor every 60 days a written report describing the progress of its efforts to effect the Divestiture. The report shall include a description of contacts, negotiations, due diligence and offers regarding the Divestiture Assets, the name, address and phone number of all parties contacted and of prospective Purchasers who have come forward. Teva shall, within 3 Business Days, respond to any request by the Commissioner for additional information regarding the status of Teva's efforts to complete the Divestiture. An officer or other duly authorized representative of Teva shall certify that he or she has examined the information provided in any such response and that such information is, to the best of his or her knowledge and belief, correct and complete in all material respects.

#### III. DIVESTITURE TRUSTEE SALE PROCESS

- [5] In the event that Teva fails to complete the Divestiture during the Initial Sale Period, the Commissioner shall appoint a Divestiture Trustee to complete the Divestiture in accordance with this Agreement. Such appointment may be made at any time prior to the expiry of the Initial Sale Period or on such later date as the Commissioner determines.
- [6] Within 5 Business Days after the appointment of the Divestiture Trustee, Teva shall submit to the Commissioner for approval the terms of a proposed Divestiture Process Agreement with the Divestiture Trustee and the Commissioner that confers on the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the Divestiture.
- [7] Within 5 Business Days after receipt of the proposed Divestiture Process Agreement referred to in Section 6, the Commissioner shall advise Teva whether or not he approves the terms of the proposed Divestiture Process Agreement. If the Commissioner does not approve the terms of the proposed Divestiture Process Agreement, he shall prescribe alternative terms that confer on the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the Divestiture and Teva shall incorporate them into a final Divestiture Process Agreement with the Divestiture Trustee and the Commissioner.
- [8] Without limiting the Commissioner's discretion to require additional terms, Teva consents to the following terms and conditions regarding the Divestiture Trustee's rights, powers and duties, and shall include such terms in the Divestiture Process Agreement:

- (a) The Divestiture Trustee shall complete the Divestiture as expeditiously as possible, and in any event prior to expiry of the Divestiture Trustee Sale Period.
- (b) The Divestiture Trustee shall use reasonable efforts to negotiate terms and conditions for the Divestiture that are as favourable to Teva as are reasonably available at that time; however, the Divestiture shall not be subject to any minimum price. The Divestiture Trustee's opinion of what constitutes favourable terms and conditions and what constitutes reasonably available terms and conditions, is subject to review and approval by the Commissioner.
- (c) Subject to oversight and approval by the Commissioner, the Divestiture Trustee shall have full and exclusive authority during the Divestiture Trustee Sale Period:
  - (i) to complete the Divestiture in accordance with the provisions of this Part:
  - (ii) to solicit interest in a possible Divestiture by whatever process or procedure the Divestiture Trustee believes is suitable to allow a fair opportunity for one or more prospective good faith Purchasers to offer to acquire the Divestiture Assets, and for greater certainty, in determining whether to pursue negotiations with a prospective Purchaser, may have regard to the approval criteria in Section 23;
  - (iii) to enter into a Divestiture Agreement with a Purchaser that will be legally binding on Teva;
  - (iv) to negotiate reasonable commercial covenants, representations, warranties and indemnities to be included in a Divestiture Agreement; and
  - (v) to employ, at the expense of Teva, such consultants, accountants, legal counsel, investment bankers, business brokers, appraisers, and other representatives and assistants as the Divestiture Trustee believes are necessary to carry out the Divestiture Trustee's duties and responsibilities.
- (d) Where any Person makes a good faith inquiry respecting a possible purchase of Divestiture Assets, the Divestiture Trustee shall notify such Person that the Divestiture is being made and shall provide to such Person a copy of this Agreement, with the exception of the provisions hereof that are confidential pursuant to Section 63 of this Agreement.
- (e) Where, in the opinion of the Divestiture Trustee, a Person has a good faith interest in purchasing Divestiture Assets and has executed a confidentiality agreement, in a form satisfactory to the Commissioner,

with the Divestiture Trustee protecting any Confidential Information that such Person may receive in the course of its due diligence review of the Divestiture Assets, the Divestiture Trustee shall:

- (i) promptly provide to such Person all information respecting the Divestiture Assets that is determined by the Divestiture Trustee to be relevant and appropriate;
- (ii) permit such Person to make reasonable inspection of the Divestiture Assets and of all financial, operational or other non-privileged Records and information, including Confidential Information, that may be relevant to the Divestiture; and
- (iii) give such Person as full and complete access as is reasonable in the circumstances to the personnel involved in managing the Divestiture Assets.
- (f) The Divestiture Trustee shall have no obligation or authority to operate or maintain the Divestiture Assets.
- (g) The Divestiture Trustee shall provide to the Commissioner and to the Monitor, within 14 days after the later of the Divestiture Trustee's appointment and the commencement of the Divestiture Trustee Sales Period and thereafter every 30 days, a written report describing the progress of the Divestiture Trustee's efforts to complete the Divestiture. The report shall include a description of contacts, negotiations, due diligence and offers regarding the Divestiture Assets, the name, address and phone number of all parties contacted and of prospective Purchasers who have come forward. The Divestiture Trustee shall, within 3 Business Days, respond to any request by the Commissioner for additional information regarding the status of the Divestiture Trustee's efforts to complete the Divestiture.
- (h) The Divestiture Trustee shall notify Teva and the Commissioner immediately upon the signing of any letter of intent or agreement in principle relating to the Divestiture Assets, and shall provide to Teva a copy of any executed Divestiture Agreement upon receipt of the Commissioner's approval of the Divestiture contemplated in such Divestiture Agreement.
- [9] Teva shall not be involved in the Divestiture process during the Divestiture Trustee Sale Period or in any negotiations with prospective Purchasers undertaken by the Divestiture Trustee, nor will Teva have contact with prospective Purchasers during the Divestiture Trustee Sale Period, except with the prior approval of the Monitor.
- [10] Subject to any legally recognized privilege, Teva shall provide to the Divestiture Trustee full and complete access to all personnel, Records, information (including

- Confidential Information) and facilities relating to the Divestiture Assets, to enable the Divestiture Trustee to conduct its own investigation of the Divestiture Assets and to provide access and information to prospective Purchasers.
- [11] Teva shall take no action that interferes with or impedes, directly or indirectly, the Divestiture Trustee's efforts to complete the Divestiture.
- [12] Teva shall fully and promptly respond to all requests from the Divestiture Trustee and shall provide all information the Divestiture Trustee may request. Teva shall identify an individual who shall have primary responsibility for fully and promptly responding to such requests from the Divestiture Trustee on behalf of Teva.
- [13] Teva will do all such acts and execute all such documents, and will cause the doing of all such acts and the execution of all such documents as are within its power to cause the doing or execution of, as may be reasonably necessary to ensure that the Divestiture Assets are divested in the Divestiture Trustee Sale Period and that agreements entered into by the Divestiture Trustee are binding upon and enforceable against Teva.
- [14] Teva shall be responsible for all reasonable fees and expenses properly charged or incurred by the Divestiture Trustee in the course of carrying out the Divestiture Trustee's duties and responsibilities under this Agreement. The Divestiture Trustee shall serve without bond or security, and shall account for all fees and expenses incurred. Teva shall pay all reasonable invoices submitted by the Divestiture Trustee within 30 days after receipt and, without limiting this obligation, Teva shall comply with any agreement it reaches with the Divestiture Trustee regarding interest on late payments. In the event of any dispute: (i) such invoice shall be subject to the approval of the Commissioner; and (ii) Teva shall promptly pay any invoice approved by the Commissioner. Any outstanding monies owed to the Divestiture Trustee by Teva shall be paid out of the proceeds of the Divestiture.
- [15] Teva shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation or defence of any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from malfeasance, gross negligence or bad faith by the Divestiture Trustee.
- [16] Teva shall indemnify the Commissioner and hold the Commissioner harmless against any losses, claims, damages, liabilities or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation or defence of any claim, whether or not resulting in any liability.

- [17] If the Commissioner determines that the Divestiture Trustee has ceased to act or has failed to act diligently, the Commissioner may remove the Divestiture Trustee and appoint a substitute Divestiture Trustee. The provisions of this Agreement respecting the Divestiture Trustee shall apply in the same manner to any substitute Divestiture Trustee.
- [18] Teva may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, legal counsel, investment bankers, business brokers, appraisers, and other representatives and assistants to sign an appropriate confidentiality agreement in a form satisfactory to the Commissioner; provided, however, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commissioner.
- [19] The Commissioner may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, legal counsel, investment bankers, business brokers, appraisers, and other representatives and assistants to sign an appropriate confidentiality agreement relating to materials and information the Divestiture Trustee may receive from the Commissioner in connection with the performance of the Divestiture Trustee's duties.
- [20] Notwithstanding any term of this Agreement, the rights, powers and duties of the Divestiture Trustee under this Agreement shall not expire until the Divestiture is completed.

#### IV. COMMISSIONER APPROVAL OF DIVESTITURE

- [21] The Divestiture may proceed only with the prior approval of the Commissioner in accordance with this Part. For greater certainty, if a Divestiture is a notifiable transaction nothing in this Agreement affects the operation of Part IX of the Act.
- [22] The Divestiture Applicant shall comply with the following process for seeking and obtaining a decision of the Commissioner regarding his approval of a proposed Divestiture:
  - (a) The Divestiture Applicant shall promptly:
    - (i) inform the Commissioner of any negotiations with a prospective Purchaser that may lead to a Divestiture; and
    - (ii) forward to the Commissioner copies of any agreement that is signed with a prospective Purchaser, including non-binding expressions of interest.
  - (b) The Divestiture Applicant shall immediately notify the Commissioner that it intends to enter a Divestiture Agreement with a prospective Purchaser, or has entered into an agreement that, if approved by the Commissioner, will be a Divestiture Agreement within the meaning of this Agreement. If

the Divestiture Applicant has entered into or intends to enter into more than one agreement in respect of the same Divestiture Assets, the Divestiture Applicant shall identify the agreement in respect of which it seeks the Commissioner's approval and the remainder of this Part shall apply only to that agreement unless the Divestiture Applicant designates a substitute agreement.

- (c) The notice described in Paragraph 22(b) shall be in writing and shall include: the identity of the proposed Purchaser; the details of the proposed Divestiture Agreement and any related agreements; and information concerning whether and how the proposed Purchaser would, in the view of the Divestiture Applicant, likely satisfy the terms of this Agreement.
- (d) Within 14 days following receipt of the notice described in Paragraph 22(b), the Commissioner may request additional information concerning the proposed Divestiture from any or all of Teva, the Monitor, the prospective Purchaser and, in the Divestiture Trustee Sale Period, the Divestiture Trustee. These Persons shall each provide any additional information requested from them. When they have provided a complete response to the Commissioner's request, these Persons shall comply with the following procedures:
  - (i) the Divestiture Trustee shall provide written confirmation to the Commissioner that the Divestiture Trustee has provided to the Commissioner all additional information requested from the Divestiture Trustee;
  - (ii) the Monitor shall provide written confirmation to the Commissioner that the Monitor has provided to the Commissioner all additional information requested from the Monitor;
  - (iii) an officer or other duly authorized representative of Teva shall certify that he or she has examined the additional information provided by Teva in response to the Commissioner's request and that such information is, to the best of his or her knowledge and belief, correct and complete in all material respects; and
  - (iv) an officer or other duly authorized representative of the prospective Purchaser shall certify that he or she has examined the additional information provided by the prospective Purchaser in response to the Commissioner's request and that such information is, to the best of his or her knowledge and belief, correct and complete in all material respects.

The date on which the last of the Divestiture Trustee, Teva, the Monitor, and the prospective Purchaser provides to the Commissioner a

confirmation or certification required under this Paragraph is the "First Reference Date".

- (e) Within 7 days after the First Reference Date, the Commissioner may request further additional information concerning the proposed Divestiture from any or all of the Persons identified in Paragraph 22(d). These Persons shall each provide any further additional information requested from them. When they have provided a complete response to the Commissioner's request, if any, these Persons shall comply with the procedures outlined in Paragraph 22(d) in regard to the further additional information provided. The date on which the last of the Divestiture Trustee, Teva, the Monitor, and the prospective Purchaser provides to the Commissioner a confirmation or certification required under this Paragraph is the "Second Reference Date".
- (f) The Commissioner shall notify the Divestiture Applicant of the approval of, or the objection to, the proposed Divestiture as soon as possible, and in any event within 14 days after the date on which the Commissioner receives the notice described in Paragraph 22(b) or, if he requests any additional information under Paragraph 22(d) or further additional information under Paragraph 22(e), within 14 days after the later of:
  - (i) the First Reference Date; and
  - (ii) the Second Reference Date, if any.
- (g) The Commissioner's determination as to whether to approve a proposed Divestiture shall be in writing.
- [23] In exercising his discretion to determine whether to approve a proposed Divestiture, the Commissioner shall take into account the likely impact of the Divestiture on competition, and may consider any other factor he considers relevant. Prior to granting his approval, the Commissioner must also be satisfied that:
  - (a) the proposed Purchaser is fully independent of and operates at arm's length from Teva;
  - (b) Teva will have no direct or indirect interest in the Divestiture Assets following the Divestiture;
  - (c) the proposed Purchaser is committed to carrying on the Divested Business;
  - (d) the proposed Purchaser has the managerial, operational and financial capability to compete effectively in the supply of the Divestiture Products; and

(e) the proposed Purchaser will (i) if the Commissioner grants his approval during the Initial Sale Period, complete the Divestiture prior to the expiry of the Initial Sale Period; or (ii) if the Commissioner grants his approval during the Divestiture Trustee Sale Period, complete the Divestiture during the Divestiture Trustee Sale Period.

## V. PRESERVATION OF THE DIVESTITURE ASSETS

- [24] In order to preserve the Divestiture Assets pending completion of the Divestiture, Teva shall maintain the economic viability, marketability and competitiveness of the Divestiture Assets, and shall comply with any decision of or direction given by the Monitor that in the view of the Monitor is required for the preservation of the Divestiture Assets. Until Closing, Teva shall make reasonable efforts to ensure that Allergan preserves the Divestiture Assets in a manner consistent with this Part V of this Agreement. Without limiting the generality of the foregoing, Teva shall:
  - (a) maintain and hold the Divestiture Assets in good condition and repair, normal wear and tear excepted, and to standards that are, in the view of the Monitor, at least equal to those that existed at Closing;
  - (b) ensure that the management and operation of the Divested Business continues in the ordinary course of business and in a manner that is, in the view of the Monitor, reasonably consistent in nature, scope and magnitude with past practices and generally accepted industry practices, and in material compliance with all applicable laws;
  - (c) not knowingly take or allow to be taken any action that, in the view of the Monitor, materially or adversely affects the competitiveness, operations, financial status or value, viability and saleability of the Divestiture Assets;
  - (d) ensure that the Divestiture Assets are not engaged in any type of business other than the type of business conducted as of the date of this Agreement, except with the prior approval of the Monitor and the Commissioner;
  - (e) maintain all approvals, including Product Approvals, registrations, consents, licences, permits, waivers, and other authorizations that are, in Monitor's view subject to consultation with Teva, advisable or necessary for the operation or value of the Divested Business;
  - (f) take commercially reasonable steps to honour all customer contracts and to maintain quality and service standards for customers of the Divested Business that are, in the view of the Monitor, at least equal to the standards that existed during the fiscal year prior to this Agreement;
  - (g) not materially curtail marketing, sales, promotional or other activities of the Divested Business, except with the prior approval of the Monitor;

- (h) not alter, or cause to be altered, the management of the Divested Business as it existed during the two years prior to the date of this Agreement, except with the prior approval of the Monitor;
- (i) not terminate or alter any employment, salary or benefit agreements, as they existed at the date of this Agreement, for Persons employed in connection with the Divested Business, except (i) in accordance with pre-existing plans expressly disclosed to the Commissioner and only in a manner that does not impair the value of the Divestiture Assets, or (ii) with the prior approval of the Monitor;
- (j) ensure that the Divested Business is staffed with sufficient employees to ensure its viability and competitiveness, including by replacing any departing employees with other qualified employees provided that the Monitor has approved both the qualifications and the need for such replacement employees;
- (k) not communicate any Confidential Information related to the Divested Business or the Divestiture Assets to anyone other than Teva's legal or financial advisors (to the extent necessary for the provision of their services), the Monitor, a Person with a good faith interest in purchasing the Divestiture Assets who has executed a confidentiality agreement, or as otherwise permitted in this Agreement;
- (l) maintain inventory levels and payment terms materially consistent with the practices of Teva that existed, with respect to the Divested Business, during the 2 years prior to the date of this Agreement; and
- (m) maintain in accordance with Canadian generally accepted accounting principles, separate and adequate financial ledger books and records of material financial information with respect to the Divested Business.
- [25] Pending completion of the Divestiture, Teva shall not, without the Commissioner's prior written approval:
  - (a) create any new encumbrances on the Divestiture Assets, other than ordinary course obligations that are not due or delinquent;
  - (b) enter into, withdraw from, amend or otherwise take steps to alter any obligations in material contracts relating to the Divestiture Assets, except as necessary to comply with this Agreement; or
  - (c) make any material changes to the Divestiture Assets, except as required to comply with this Agreement.
  - (d) Teva shall provide sufficient financial resources, including general funds, capital funds, working capital and reimbursement for any operating, capital or other losses, to maintain the Divestiture Assets in accordance

with this Part. If the Monitor believes that Teva has not provided, is not providing or will not provide sufficient financial and other resources under this Part, the Monitor shall forthwith refer the matter to the Commissioner, who shall make a final determination respecting the financial and other resources that Teva must provide. The Commissioner may also make such a determination in circumstances where there is no Monitor. Teva shall comply with any determination made by the Commissioner on this issue.

## VI. THIRD PARTY CONSENTS

[26] It shall be a condition in any Divestiture Agreement (whether negotiated by Teva or by the Divestiture Trustee) that Teva shall, as a condition of closing, obtain any consents and waivers from Third Parties and Agencies that are necessary to complete the Divestiture and for the continued research, Development, manufacture, distribution, marketing or sale of the Divestiture Assets; provided, however, that Teva may satisfy this requirement by certifying that the Purchaser has executed agreements directly with one or more Third Parties which make such assignment and assumption unnecessary.

#### VII. CONTRACT MANUFACTURING

- [27] Teva, or the Divestiture Trustee on behalf of Teva, shall:
  - (a) upon reasonable written notice and request from a Purchaser to Teva, contract manufacture (which contract shall constitute a Remedial Agreement) and deliver to the Purchaser, in a timely manner and under reasonable terms and conditions (as recommended by the Monitor and approved by the Commissioner in his sole discretion), a supply of each of the Divestiture Products at Teva's Supply Cost, for a period of time sufficient to allow the Purchaser to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with GMP, the finished Divestiture Product independently of Teva or, at the Purchaser's election, secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and/or necessary components for the Divestiture Products from Persons other than Teva:
  - (b) make representations and warranties to the Purchaser that the Divestiture Product(s) supplied pursuant to the Remedial Agreement meet the relevant Agency-approved specifications for the Divestiture Product(s) to be marketed or sold in Canada. Teva shall agree to indemnify, defend and hold the Purchaser harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Product(s) supplied to the Purchaser pursuant to the Remedial Agreement by Teva to meet GMP. This obligation may be made contingent upon the Purchaser giving Teva prompt written notice of such claim and cooperating fully in the defense of such claim. The Remedial

Agreement shall be consistent with the obligations assumed by Teva under this Agreement; provided, however, that Teva may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with Teva's responsibilities to supply the ingredients and/or components in the manner required by this Agreement; provided further that this obligation shall not require Teva to be liable for any negligent act or omission of the Purchaser or for any representations and warranties, express or implied, made by the Purchaser that exceed the representations and warranties made by Teva to the Purchaser:

- (c) give priority to supplying contract manufacture Divestiture Products to the Purchaser over manufacturing and supplying of Product(s) for Teva's own use or sale;
- (d) make representations and warranties to the Purchaser that Teva shall hold harmless and indemnify the Purchaser for any liabilities or loss of profits resulting from the failure by Teva to deliver the contract manufactured Divestiture Products in a timely manner as required by the Remedial Agreement(s) unless Teva can demonstrate that any failure was entirely beyond the control of Teva and in no part the result of negligence or willful misconduct by Teva; provided, however, that in each instance where an agreement to divest relevant assets becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on Teva's aggregate liability for such a breach;
- (e) during the term of any contract manufacture between Teva and a Purchaser, upon written request of the Purchaser or the Monitor, make available to the Purchaser and the Monitor all Records that relate to the manufacture of the relevant contract manufacture Divestiture Products that are generated or created after the Closing Date;
- (f) during the term of any contract manufacture between Teva and a Purchaser, maintain manufacturing facilities necessary to manufacture each of the relevant contract manufacture Divestiture Products in finished form, *i.e.*, suitable for sale to the ultimate consumer/patient; and
- during the term of any contract manufacture between Teva and a Purchaser, provide consultation with knowledgeable employees of Teva and training, at the written request of the Purchaser and at a facility chosen by the Purchaser, for the purposes of enabling the Purchaser to obtain all Product Approvals to manufacture the Divestiture Products in the same quality achieved by, or on behalf of, Teva and in commercial quantities, and in a manner consistent with GMP independently of Teva, and sufficient to satisfy the Monitor and management of the Purchaser that the Purchaser's personnel are adequately trained in the manufacture of the Divestiture Products.

[28] The foregoing Paragraphs 27(a)-(g) shall remain in effect with respect to each Divestiture Product until the earliest of: (1) the date that the Purchaser of the applicable Divestiture Product is approved to manufacture that Divestiture Product and able to manufacture that Divestiture Product in commercial quantities, in a manner consistent with GMP, independently of Teva; (2) the date that the Purchaser of the applicable Divestiture Product notifies the Commissioner and Teva of its intention to abandon its efforts to manufacture that Divestiture Product; (3) the date of written notification from the Commissioner that the Monitor, in consultation with the Commissioner, has determined that the Purchaser of the applicable Divestiture Product has abandoned its efforts to manufacture that Divestiture Product; or (4) two years from the Closing Date.

### VIII. FAILURE OF DIVESTITURE TRUSTEE SALE

[29] If, by the end of the Divestiture Trustee Sale Period, the Divestiture has not been completed, or if the Commissioner is of the opinion that the Divestiture likely will not be completed prior to the end of the Divestiture Trustee Sale Period, the Commissioner may apply to the Tribunal, at his election, for either (i) such order as is necessary to complete the Divestiture; or (ii) such order as is necessary to ensure that the Transaction is not likely to prevent or lessen competition substantially.

## IX. REMEDIAL AGREEMENTS

- [30] Any Remedial Agreement shall be deemed incorporated into this Agreement.
- [31] Teva shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Agreement and provisions to reflect the full scope and breadth of each of Teva's obligations to the Purchaser pursuant to this Agreement.
- [32] Teva shall also include in each Remedial Agreement a representation from the Purchaser that the Purchaser shall use commercially reasonable efforts to secure the Health Canada approval(s) or other Product Approvals necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each Divestiture Product and to have any such manufacture be independent of Teva, all as soon as reasonably practicable.
- [33] Any failure by Teva to comply with any term of a Remedial Agreement shall constitute a failure to comply with this Agreement.
- [34] Teva shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commissioner.
- [35] Teva shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related

to any of the Divestiture Products, a decision the result of which would be inconsistent with the terms of this Agreement.

#### X. MONITOR

- [36] The Commissioner shall appoint a Monitor, responsible for monitoring compliance by Teva with this Agreement. Such appointment may occur at any time following registration of this Agreement. A reference in this Agreement to specific monitoring functions or tasks that are to be undertaken by the Monitor shall in no way detract from the Monitor's general right, power and duty to monitor all aspects of Teva's compliance with this Agreement.
- [37] Within 5 Business Days after the appointment of the Monitor, Teva shall submit to the Commissioner for approval the terms of a proposed Monitor Agreement with the Monitor and the Commissioner that confers on the Monitor all rights and powers necessary to permit the Monitor to monitor compliance by Teva with this Agreement.
- [38] Within 5 Business Days after receipt of the proposed Monitor Agreement referred to in Section 37, the Commissioner shall advise Teva whether or not he approves the terms of the proposed Monitor Agreement. If the Commissioner does not approve the terms of the proposed Monitor Agreement, he shall prescribe alternative terms that in the Commissioner's view are necessary to permit the Monitor to monitor compliance by Teva with this Agreement, and Teva shall incorporate those terms into a final Monitor Agreement with the Monitor and the Commissioner.
- [39] Teva consents to the following terms and conditions regarding the Monitor's rights, powers and duties, and shall include such terms in the Monitor Agreement:
  - (a) The Monitor shall have the power and authority to monitor Teva's compliance with this Agreement, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of this Agreement and in consultation with the Commissioner.
  - (b) The Monitor shall have the authority to employ, at the expense of Teva, such consultants, accountants, legal counsel and other representatives and assistants as the Monitor believes are necessary to carry out the Monitor's duties and responsibilities.
  - (c) The Monitor shall have no obligation or authority to operate or maintain the Divestiture Assets.
  - (d) The Monitor shall act for the sole benefit of the Commissioner, maintain all confidences and avoid any conflict of interest.

- (e) The Monitor shall have no duties of good faith, of a fiduciary nature, or otherwise, to Teva.
- (f) The Monitor shall provide to the Commissioner every 30 days after the date of the Monitor's appointment until the Divestiture is complete and every six months thereafter, a written report concerning performance by Teva of its obligations under this Agreement. The Monitor shall, within 3 Business Days, respond to any request by the Commissioner for additional information regarding Teva's compliance.
- [40] Subject to any legally recognized privilege, Teva shall provide to the Monitor full and complete access to all personnel, Records, information (including Confidential Information) and facilities relevant to monitoring Teva's compliance with this Agreement.
- [41] Teva shall take no action that interferes with or impedes, directly or indirectly, the Monitor's efforts to monitor Teva's compliance with this Agreement.
- [42] Teva shall fully and promptly respond to all requests from the Monitor and shall provide all information the Monitor may request. Teva shall identify an individual who shall have primary responsibility for fully and promptly responding to such requests from the Monitor on behalf of Teva.
- [43] Teva may require the Monitor and each of the Monitor's consultants, accountants, legal counsel and other representatives and assistants to sign an appropriate confidentiality agreement in a form satisfactory to the Commissioner; provided, however, that such agreement shall not restrict the Monitor from providing any information to the Commissioner.
- [44] The Commissioner may require the Monitor and each of the Monitor's consultants, accountants, legal counsel and other representatives and assistants to sign an appropriate confidentiality agreement relating to materials and information the Monitor may receive from the Commissioner in connection with the performance of the Monitor's duties.
- [45] Teva shall be responsible for all reasonable fees and expenses properly charged or incurred by the Monitor in the course of carrying out the Monitor's duties under this Agreement. The Monitor shall serve without bond or security, and shall account for all fees and expenses incurred. Teva shall pay all reasonable invoices submitted by the Monitor within 30 days after receipt and, without limiting this obligation, Teva shall comply with any agreement it reaches with the Monitor regarding interest on late payments. In the event of any dispute: (i) such invoice shall be subject to the approval of the Commissioner; and (ii) Teva shall promptly pay any invoice approved by the Commissioner. Any outstanding monies owed to the Monitor by Teva shall be paid out of the proceeds of the Divestiture.
- [46] Teva shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities or expenses arising out of, or in connection

with, the performance of the Monitor's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation or defence of any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from malfeasance, gross negligence or bad faith by the Monitor.

- [47] If the Commissioner determines that the Monitor has ceased to act or has failed to act diligently, the Commissioner may remove the Monitor and appoint a substitute Monitor. The provisions of this Agreement respecting the Monitor shall apply in the same manner to any substitute Monitor.
- [48] The Monitor shall serve for such time as is necessary to monitor Teva's compliance with this Agreement.

#### XI. COMPLIANCE

- [49] Within 5 Business Days after the Closing Date, Teva shall provide written confirmation to the Commissioner of the date on which the Transaction was completed.
- [50] Teva shall provide a copy of this Agreement to each of its own and its Affiliates' directors, officers, employees and agents having managerial responsibility for any obligations under this Agreement, within 3 Business Days after the date of registration of this Agreement. Teva shall ensure that its directors, officers, employees and agents with responsibility for any obligations under this Agreement receive sufficient training respecting Teva's responsibilities and duties under this Agreement, and the steps that such individuals must take in order to comply with this Agreement.
- [51] Teva shall not, for a period of 10 years after the date when the Divestiture is completed, directly or indirectly acquire any interest in the Divestiture Assets, without the prior written approval of the Commissioner.
- [52] For a period of 2 years after the date when the Divestiture is completed, Teva shall not, without providing advance written notification to the Commissioner in the manner described in this Section, directly or indirectly:
  - (a) acquire any assets or shares of, or any other interest in, any supplier of buprenorphine:naloxone or tobramycin in Canada or any Person expected to supply buprenorphine:naloxone or tobramycin in Canada within 2 years after the date of such acquisition; or
  - (b) consummate any merger or other combination relating to the buprenorphine:naloxone or tobramycin business in Canada.

If a transaction described in (a) or (b) is one for which notice is not required under section 114 of the Act, Teva shall supply to the Commissioner the information

described in section 16 of the *Notifiable Transactions Regulations* at least 30 days before completing such transaction. Teva shall certify such information in the same manner as would be required if section 118 of the Act applied. The Commissioner may accept a competitive impact brief from Teva instead of such information. The Commissioner may, within 30 days after receiving the information described in this Section, request that Teva supply additional information that is relevant to the Commissioner's assessment of the transaction. In the event that the Commissioner issues such a request for additional information, Teva shall supply information to the Commissioner in the form specified by the Commissioner and shall not complete such transaction until at least 30 days after Teva has supplied all such requested information in the form specified by the Commissioner.

- [53] Six months after the date of registration of this Agreement and annually for the next 5 years on, or within 10 days before, the six month anniversary of the date of registration, and at such other times as the Commissioner may require, Teva shall file an affidavit or certificate, substantially in the form of Schedule B to this Agreement, certifying its compliance with Parts VII and XI of this Agreement and setting out the following information in detail:
  - (a) the steps taken to ensure compliance;
  - (b) the controls in place to verify compliance; and
  - (c) the names and titles of employees who have oversight of compliance.
- [54] If any of Teva, the Divestiture Trustee or the Monitor becomes aware that there has been a breach or possible breach of any of the terms of this Agreement, such Person shall, within 5 Business Days after becoming aware of the breach or possible breach, notify the Commissioner thereof, and shall provide details sufficient to describe the nature, date and effect (actual and anticipated) of the breach or possible breach, provided that notification of a possible breach is not required if such Person determines within those 5 Business Days that it could not reasonably be considered a breach of any of the terms of this Agreement. Teva shall provide confirmation of its compliance with this provision in all affidavits and certificates of compliance filed with the Commissioner pursuant to Section 53 of this Agreement.
- [55] Teva shall notify the Commissioner at least 30 days prior to:
  - (a) any proposed dissolution of Teva; or
  - (b) any other change in Teva if such change may affect compliance obligations arising out of this Agreement including, but not limited to, a reorganization, material acquisition, disposition or transfer of assets, or any fundamental change for purposes of Teva's incorporating statute.

- [56] For the period commencing when this Agreement is registered and ending 10 years after the Divestiture is completed, for purposes of determining or securing compliance with this Agreement, and subject to any legally recognized privilege, Teva shall, upon written request given at least 5 Business Days in advance to Teva, permit any authorized representative(s) of the Commissioner, without restraint or interference:
  - (a) to access, during regular office hours of Teva on any Business Day(s), all facilities and to inspect and copy all Records in the possession or control of Teva related to compliance with this Agreement, which copying services shall be provided by Teva at its expense; and
  - (b) to interview such officers, directors or employees of Teva as the Commissioner requests regarding such matters.

#### XII. DURATION

- [57] This Agreement shall become effective on the date when it is registered, and shall remain in effect for 10 years following the Divestiture, except that:
  - (a) Parts II, III, IV, V and VI of this Agreement shall be effective only until the Divestiture is completed; and
  - (b) Part VII of this Agreement shall be effective only until the time specified in Section 28; and
  - (c) Part IX of this Agreement shall be effective only until each Remedial Agreement is terminated.

#### XIII. NOTICES

- [58] A notice or other communication required or permitted to be given under this Agreement is valid if it is:
  - (a) in writing and delivered by personal delivery, registered mail, courier service, facsimile or electronic mail; and
  - (b) addressed to the receiving party at the address(es) listed below, or to any other address designated by the receiving party in accordance with this Section.

## if to the Commissioner:

Commissioner of Competition Competition Bureau Canada Place du Portage, 21st Floor 50 Victoria Street, Phase I

#### PUBLIC VERSION

Gatineau, Quebec K1A 0C9

Attention: Commissioner of Competition

Fax: (819) 953-5013

Email address: MergerNotification@canada.ca

with a copy to:

**Executive Director and Senior General Counsel** Competition Bureau Legal Services Department of Justice Place du Portage, 22nd Floor 50 Victoria Street, Phase I Gatineau, Quebec K1A 0C9 Fax: (819) 953-9267

Email address: jonathan.chaplan@canada.ca

### if to Teva:

Senior Vice-President and General Counsel Teva Pharmaceutical Industries Limited 5 Basel St., Petach Tikva Israel 49131 Fax: +972-3-9267429

with copies to:

General Counsel Teva Canada Limited 30 Novopharm Court Toronto, Ontario, Canada M1B 2K9 Fax: (416) 291-2842

and:

George Addy and Adam Fanaki Davies Ward Phillips & Vineberg LLP 155 Wellington Street West Toronto, Ontario M5V 3J7

Fax: (416) 863-0871

Email address: GAddy@dwpv.com

[59] A notice or other communication under this Agreement is effective on the day that it is received by the receiving party and is deemed to have been received as follows:

- (a) if it is delivered in person, by registered mail or by courier, upon receipt as indicated by the date on the signed receipt;
- (b) if it is delivered by facsimile, upon receipt as indicated by the time and date on the facsimile confirmation slip; or
- (c) if it is delivered by electronic mail, when the recipient, by an email sent to the email address for the sender stated in this Section or by a notice delivered by another method in accordance with this Section, acknowledges having received that email, with an automatic "read receipt" not constituting acknowledgment of an email for purposes of this Section.

If a notice or other communication is received after 5:00 p.m. local time, or on a day that is not a Business Day, it shall be deemed to have been received on the next Business Day.

[60] Notwithstanding Sections 58 and 59, a notice or other communication that is not communicated in accordance with Sections 58 and 59 is valid if a representative of the party to this Agreement that is the recipient of such communication confirms the receipt of such communication and does not, at the time of such confirmation, request that it be delivered differently.

## XIV. GENERAL

- [61] In this Agreement:
  - (a) **Number and Gender** Unless the context otherwise requires, words importing the singular include the plural and vice versa and words importing gender include all genders.
  - (b) **Time Periods** Computation of time periods shall be in accordance with the *Interpretation Act*, R.S.C. 1985, c. I-21, and the definition of "holiday" in the *Interpretation Act* shall include Saturday.
- [62] The Commissioner shall file this Agreement with the Tribunal for registration in accordance with section 105 of the Act. Teva hereby consents to such registration. Following the filing of this Agreement, the Commissioner shall promptly issue a letter to Teva indicating that, subject to the implementation of this Agreement, the Commissioner does not intend to make an application under section 92 of the Act in respect of the Transaction.
- [63] Information in Confidential Schedule A shall be made public upon the expiry of the Initial Sale Period.
- [64] The Commissioner may, after informing Teva, extend any of the time periods contemplated by this Agreement other than Sections 51, 52 and 57. If any time

- period is extended, the Commissioner shall promptly notify Teva of the revised time period.
- [65] Nothing in this Agreement precludes Teva or the Commissioner from bringing an application under section 106 of the Act. Teva will not, for the purposes of this Agreement, including execution, registration, enforcement, variation or rescission, contest the Commissioner's conclusions that: (i) the Transaction is likely to result in a substantial lessening and/or prevention of competition in the supply of buprenorphine:naloxone and tobramycin in Canada; and (ii) the implementation of this Agreement is necessary to ensure that any substantial lessening and/or prevention of competition will not result from the Transaction.
- [66] Teva attorns to the jurisdiction of the Tribunal for the purposes of this Agreement and any proceeding initiated by the Commissioner relating to this Agreement.
- [67] This Agreement constitutes the entire agreement between the Commissioner and Teva, and supersedes all prior agreements, understandings, negotiations and discussions, whether written or oral, with respect to the subject matter hereof.
- [68] This Agreement shall be governed by and interpreted in accordance with the laws of Ontario and the laws of Canada applicable therein, without applying any otherwise applicable conflict of law rules.
- [69] In the event of a dispute regarding compliance with or the interpretation, implementation or application of this Agreement, the Commissioner or Teva may apply to the Tribunal for directions or an order. In the event of any discrepancy between the English language version of this Agreement and the French language version of this Agreement, the English language version of this Agreement shall prevail. In no event shall any dispute suspend the Initial Sale Period or the Divestiture Trustee Sale Period.
- [70] This Agreement may be executed in two or more counterparts, each of which shall be an original instrument, but all of which shall constitute one and the same Agreement.

The undersigned hereby agree to the filing of this Agreement with the Tribunal for registration.

DATED this 4<sup>th</sup> day of April, 2016

# COMMISSIONER OF COMPETITION

[Original signed by John Pecman]		
Name:	John Pecman	
Title:	Commissioner of Competition	
TEVA PHARMACEUTICAL INDUSTRIES LIMITED		
[Original signed by Eyal Desheh] We have authority to bind the corporation		
Name:	Eyal Desheh	
Title:	Chief Financial Officer	
_[Original signed by Dov Bergwerk] We have authority to bind the corporation		
Name:	Dov Bergwerk	
Title	Company Secretary	

# **PUBLIC VERSION**

# CONFIDENTIAL SCHEDULE A

# INITIAL SALE PERIOD

The Initial Sale Period shall commence at Closing and shall expire 6 months after the Closing Date.

#### **SCHEDULE B**

#### FORM OF COMPLIANCE CERTIFICATION/AFFIDAVIT

- I, [name], of [place], hereby certify¹ in accordance with the terms of the Registered Consent Agreement dated between Teva Pharmaceutical Industries Limited ("Teva") and the Commissioner of Competition, that:
  - 1. I am the **[title]** of Teva, and have personal knowledge of the matters deposed to herein, unless they are stated to be on information and belief, in which cases I state the source of such information and believe it to be true.
  - 2. On **[date]**, Teva entered into a Consent Agreement (the "Consent Agreement") with the Commissioner of Competition (the "Commissioner") in connection with the proposed acquisition of the generic pharmaceuticals business of Allergan plc (the "Transaction").
  - 3. The Transaction closed on [date] (the "Closing Date").<sup>2</sup>
  - 4. The Divestiture (as defined in the Consent Agreement) to **[Purchaser]** was completed on **[date]**.
  - 5. Pursuant to Section 53 of the Consent Agreement, Teva is required to file [annual reports/reports when requested by the Commissioner] certifying its compliance with Parts VII and XI of the Consent Agreement.

## **Oversight of Compliance**

6. [Names/titles] have primary responsibility for overseeing compliance with this Agreement.

#### **Closing Date**

7. Pursuant to Section 49 of the Consent Agreement, Teva is required to provide written confirmation to the Commissioner of the date on which the Transaction was completed. Such notice was provided on [date].

#### **Circulation of Consent Agreement**

8. Pursuant to Section 50 of the Consent Agreement, Teva is required to provide a copy of the Consent Agreement to each of its own and its Affiliates' directors, officers, employees and agents having managerial responsibility for any

If this is drafted as an affidavit, the words "hereby certify" should be removed and should be replaced with "make oath and say". An affidavit should be sworn under oath. A certification should be certified by a Commissioner for taking affidavits.

Paragraphs 3, 4, 7 and 8 need only be included in the first certification/affidavit.

- obligations under the Consent Agreement, within 3 Business Days after the date of registration of the Consent Agreement. The Consent Agreement was circulated by **[whom]** to **[provide list]** on **[dates]**.
- 9. Pursuant to Section 50 of the Consent Agreement, Teva is required to ensure that its directors, officers, employees and agents with responsibility for any obligations under the Consent Agreement receive sufficient training respecting Teva's responsibilities and duties under the Consent Agreement. The following training has been provided: [provide list of who was trained and by whom as well as a general statement of the content of the training]

## **Contract Manufacturing**

10. [Describe compliance with contract manufacturing provisions.]

## **Notification of Breach**

11. Based on my personal knowledge and my inquiries of **[provide names]**, I am not aware of any breach or possible breach of any of the terms of the Consent Agreement within the meaning of Section 54 of the Consent Agreement.

DATED ●.	
Commissioner of Oaths	Name and Title of Certifying Officer