

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 Pfizer Inc. of Hospira, Inc.;

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

B E T W E E N:

THE COMMISSIONER OF COMPETITION

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| COMPETITION TRIBUNAL<br>TRIBUNAL DE LA CONCURRENCE<br><b>REGISTERED / ENREGISTRÉ</b><br><b>FILED / PRODUIT</b><br><br>April 12, 2016<br>CT-2015-008<br><br>Jos LaRose for / pour<br>REGISTRAR / REGISTRAIRE |     |
| OTTAWA, ONT   | # 5 |

Applicant

– and –

PFIZER INC.

Respondent

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CONSENT AGREEMENT

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**RECITALS:**

**A.** Pfizer Inc. (“**Pfizer**”) proposes to acquire Hospira, Inc. (“**Hospira**”). Specifically, and pursuant to an agreement and plan of merger dated February 5, 2015, between Pfizer, Perkins Holding Company (“**Merger Sub**”) and Hospira, Merger Sub will merge with and into Hospira, with Hospira surviving as a wholly-owned subsidiary of Pfizer (the “**Transaction**”).

**B.** The Commissioner has concluded that the Transaction is likely to result in a substantial lessening and/or prevention of competition in Canada for the supply of each of methotrexate sodium tablets, injectable cytarabine, injectable epirubicin hydrochloride and injectable voriconazole, 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. Respondent 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 Canada in the supply of each of methotrexate sodium tablets, injectable cytarabine, injectable epirubicin hydrochloride and injectable voriconazole; 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** Respondent 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) **“Business Day”** means a day on which the Competition Bureau's Gatineau, Quebec office is open for business;
- (f) **“Closing”** means the completion of the Transaction under the Transaction Agreement;
- (g) **“Closing Date”** means the date on which Closing occurs;

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- (h) **“Commissioner”** means the Commissioner of Competition appointed under the Act and includes his authorized representatives;
- (i) **“Confidential Information”** means competitively sensitive, proprietary and all other information that is not in the public domain, and that is owned by or pertains to Respondent, Respondent’s business, Hospira, or Hospira’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;
- (j) **“Develop”** means to engage in Development;
- (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) **“Divestiture”** means the sale, conveyance, transfer, assignment or other disposal of the Divestiture Assets in accordance with Technology Transfer Standards to a Purchaser or Purchasers pursuant to this Agreement and with the prior approval of the Commissioner, such that Respondent will have no direct or indirect interest in the Divestiture Assets, except as permitted herein; **“Divest”** means to implement and complete the Divestiture;
- (m) **“Divestiture Agreement”** means a binding and definitive agreement between Respondent and a Purchaser to effect the Divestiture pursuant to this Agreement and subject to the prior approval of the Commissioner;
- (n) **“Divestiture Applicant”** means Respondent during the Initial Sale Period or the Divestiture Trustee during the Divestiture Trustee Sale Period;
- (o) **“Divestiture Assets”** means all of Respondent’s assets related to the Divestiture Products in Canada, and all of Respondent’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) all Product Approvals for the Divestiture Products;

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- (iii) all Divestiture Product Manufacturing Technology that is tangible and exclusive to the Divestiture Product;
- (iv) all Divestiture Product Marketing Materials;
- (v) a list of all customers and targeted customers for such Divestiture Products and the net sales (in either units or dollars) of such Divestiture Products to such customers on either an annual, quarterly or monthly basis during the two year period immediately preceding the Closing Date or such longer period as Monitor determines is required for ongoing operations on application of the Purchaser;
- (vi) 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 Respondent and the applicable Agency related thereto;
- (vii) a list of all drug identification numbers (“**DINs**”), and rights, to the extent permitted by law, to require Respondent 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 the applicable Divestiture Date;
- (viii) all Divestiture Product Development Reports during the two year periods immediately preceding the Closing Date or such longer period as Monitor determines is required for ongoing operations on application of the Purchaser;
- (ix) at Purchaser’s option, subject to any rights of the customer, all unfilled customer purchase orders for the Divestiture Products;
- (x) at Purchaser’s option, subject to the rights of any Third Party, all Divestiture Product Assumed Contracts;
- (xi) 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;
- (xii) 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;

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- (xiii) at 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 Respondent by applicable law) in existence as of the Divestiture Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the Divestiture Products; and
- (xiv) all of Respondent'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 Monitor determines is required for ongoing operations on application of the Purchaser,

provided, however, that "Divestiture Assets" shall not include: (1) documents relating to Respondent'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 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 Respondent 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 Respondent has a legal obligation to retain the original copies, Respondent 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 Purchaser, Respondent shall provide such Purchaser access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes;

- (p) **"Divestiture Date"** means, in respect of each Divestiture Product, the date on which the Divestiture Assets are Divested to a Purchaser pursuant to this Agreement by Respondent or a Divestiture Trustee;
- (q) **"Divestiture Process Agreement"** means the agreement described in Section [6] of this Agreement;
- (r) **"Divestiture Product"** means each of the following products:

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- (i) methotrexate sodium (tablets), a folic acid analogue that is indicated for the treatment of certain types of cancers of the breast, skin, head and neck, or lung, and as a treatment for severe psoriasis and rheumatoid arthritis, as sold by or on behalf of Pfizer in Canada (DIN 02170698);
  - (ii) cytarabine (injectable), an antimetabolite indicated primarily for use alone or in combination therapy in the induction and maintenance of remission in acute leukemia, as sold by or on behalf of Pfizer in Canada (DINs 02406764, 02406772, 00386715, 00646296 and 00646318);
  - (iii) epirubicin hydrochloride (injectable), an anthracycline antitumor antibiotic used as a single agent and in combination with other approved cancer chemotherapeutic agents to produce regression in a variety of tumour types, as sold by or on behalf of Pfizer in Canada (DIN 02410400); and
  - (iv) voriconazole (injectable), a triazole antifungal medication that is generally used to treat serious, invasive fungal infections and that is currently under development by or on behalf of Hospira, Inc. for sale in Canada;
- (s) **“Divestiture Product Assumed Contracts”** means contracts or agreements (copies of each such contract or agreement to be provided to Purchaser on or before the Divestiture Date 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 Respondent unless such contract applies generally to Respondent’s sales of Products to that Third Party;
  - (ii) pursuant to which Respondent 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;

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- (vi) pursuant to which a Third Party manufactures or packages a Divestiture Product on behalf of Respondent;
- (vii) pursuant to which a Third Party provides Divestiture Product Manufacturing Technology to Respondent;
- (viii) pursuant to which a Third Party is licensed by Respondent 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 Respondent including, but not limited to, consultation arrangements; and
- (xii) pursuant to which any Third Party collaborates with Respondent 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, Respondent shall assign 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) summary of Product complaints from physicians;
  - (viii) summary 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 Respondent existing as of the Closing Date and related to a Divestiture Product (other than Divestiture Product Licensed Intellectual Property):
- (i) Patents;
  - (ii) Divestiture Product Copyrights;
  - (iii) Divestiture Product Trade-marks, 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
  - (iv) rights to obtain and file for Patents and copyrights and registrations thereof in Canada,

provided, however, “Divestiture Product Intellectual Property” does not include the corporate name of Pfizer or abbreviations thereof, or the corporate names of any other corporations or companies owned or controlled by Respondent or the related logos thereof;

- (w) **“Divestiture Product Know-How”** means all the know-how that is used for the Divestiture Products, including all specifications, processes, designs, plans, trade secrets, ideas, concepts, inventions, manufacturing, engineering and other manuals and drawings, standard operating procedures, formulae, flow diagrams, toxicological, biological, physical, analytical studies or reports, safety, stability, supply, selection, constitution, or use of any raw material, quality assurance, quality control and clinical data, technical information, and research records;
- (x) **“Divestiture Product Licensed Intellectual Property”** means the following intellectual property owned, controlled, or licensed by Respondent existing as of the Closing Date:



- (i) Patents, Divestiture Product Copyrights, Divestiture Product Trade-marks, trade dress, industrial design and distinguishing guises that are related to a Divestiture Product that Respondent can demonstrate have been used, as of the Closing Date, for a Retained Product; and
  - (ii) 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, that are related but not exclusive to a Divestiture Product and that Respondent can demonstrate have been used, prior to the Closing Date, for a Retained Product, 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, Divestiture Product Know-How, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of a Divestiture Product that is owned, controlled or licensed by Respondent 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 Respondent as of the Closing Date; and
  - (iii) for those instances in which the manufacturing equipment is not readily available from a Third Party, at Purchaser’s option, all such equipment used to manufacture the Divestiture Products that is owned, controlled or licensed by Respondent 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 Divestiture Date;

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- (aa) **“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;
- (bb) **“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;
- (cc) **“Divestiture Trustee Sale”** means the Divestiture to be conducted by the Divestiture Trustee pursuant to Part [III] of this Agreement;
- (dd) **“Divestiture Trustee Sale Period”** means the six month period commencing upon expiry of the Initial Sale Period;
- (ee) **“First Reference Date”** shall have the meaning set out in Paragraph [22(d)] of this Agreement;
- (ff) **“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;
- (gg) **“Hospira”** means Hospira, Inc., and each of its directors, officers, employees, agents, representatives, successors and assigns; and all joint ventures, subsidiaries, divisions, groups and Affiliates controlled by Hospira, and the directors, officers, employees, agents, representatives, successors and assigns of each;
- (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) **“Merger Sub”** means Perkins Holding Company, and each of its directors, officers, employees, agents, representatives, successors and assigns; and all joint ventures, subsidiaries, divisions, groups and Affiliates controlled by Merger Sub, and the directors, officers, employees, agents, representatives, successors and assigns of each;
- (jj) **“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 Part V of this Agreement, Monitor means the Commissioner;
- (kk) **“Monitor Agreement”** means the agreement described in Section [38] of this Agreement;

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- (ll) **“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 of or owned by Respondent as of the Closing Date (except where this Agreement specifies a different time);
- (mm) **“Parties”** means the Commissioner and Respondent collectively, and **“Party”** means either of them;
- (nn) **“Person”** means any individual, corporation or partnership, sole proprietorship, trust or other unincorporated organization capable of conducting business, and any Affiliates thereof;
- (oo) **“Pfizer”** means Pfizer Inc., and each of its directors, officers, employees, agents, representatives, successors and assigns; and all joint ventures, subsidiaries, divisions, groups and Affiliates controlled by Pfizer, and the directors, officers, employees, agents, representatives, successors and assigns of each;
- (pp) **“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;
- (qq) **“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;
- (rr) **“Purchaser”** means a Person that acquires Divestiture Assets pursuant to this Agreement and a Divestiture Agreement, and includes any Person (other than Respondent) that has been designated by a Purchaser to manufacture a Divestiture Product for that Purchaser;
- (ss) **“Records”** means records within the meaning of subsection 2(1) of the Act;
- (tt) **“Remedial Agreement”** means any agreement between Respondent and a Purchaser, or between a Divestiture Trustee (on behalf of Respondent) and a Purchaser or a Third Party (to effect the assignment of assets or rights of Respondent 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;

- (uu) **“Respondent”** means Pfizer;
- (vv) **“Retained Product”** means any Product of Respondent other than the Divestiture Products;
- (ww) **“Second Reference Date”** shall have the meaning set out in Paragraph [22(e)] of this Agreement;
- (xx) **“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;
- (yy) **“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 Purchaser;
  - (iii) preparing and implementing a detailed technological transfer plan, as approved by the Monitor, that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Divestiture Product Manufacturing Technology to the Purchaser; and
  - (iv) providing, in a timely manner, assistance and advice to enable Purchaser to:
    - A. manufacture the specified Divestiture Product(s) in the quality and quantities achieved by Respondent, or the manufacturer and/or developer of such Divestiture Product;

- B. obtain any Product Approvals necessary for the Purchaser to manufacture, distribute, market and sell the specified Divestiture Product(s) in commercial quantities and to meet all Agency-approved specifications for Divestiture Product(s); and
  - C. receive, integrate and use all such Divestiture Product Manufacturing Technology;
- (zz) **“Third Party”** means any Person other than the Commissioner, Respondent or a Purchaser;
- (aaa) **“Transaction”** means the transaction described in the first recital to this Agreement;
- (bbb) **“Transaction Agreement”** means the Agreement and Plan of Merger between Pfizer, Perkins Holding Company and Hospira dated as of February 5, 2015; and
- (ccc) **“Tribunal”** means the Competition Tribunal established by the *Competition Tribunal Act*, R.S.C. 1985, c.19 (2<sup>nd</sup> Supp.).

All other terms defined in this Agreement have the meanings established elsewhere in this Agreement.

## II. OBLIGATION TO COMPLETE DIVESTITURE

- [2] Respondent shall use commercially reasonable efforts to complete the Divestiture.
- [3] During the Initial Sale Period, Respondent 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, Respondent shall:
- (a) notify the Commissioner as soon as possible of any negotiations with a prospective Purchaser that may lead to a Divestiture and shall forward to the Commissioner copies of any proposed Divestiture Agreement that is signed with a prospective Purchaser. Within five Business Days of receipt of the notice described herein, the Commissioner may request additional information concerning the proposed Divestiture and the proposed Purchaser. The Commissioner may request further additional information within three Business Days of all of the information received from the prior request; and
  - (b) 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. Respondent shall, within three Business Days, respond to any request by the Commissioner for additional information regarding the status of Respondent's efforts to complete the Divestiture. An officer or other duly authorized representative of Respondent 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 Respondent 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 five Business Days after the appointment of the Divestiture Trustee, Respondent 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 five Business Days after receipt of the proposed Divestiture Process Agreement referred to in Section [6], the Commissioner shall advise Respondent 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 Respondent shall incorporate into a final Divestiture Process Agreement with the Divestiture Trustee and the Commissioner.
- [8] Without limiting the Commissioner's discretion to require additional terms, Respondent 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 Respondent 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 Respondent;
  - (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 Respondent, 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].
- (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 21 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 Respondent 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 Respondent a copy of any executed Divestiture Agreement upon receipt of Commissioner approval of the Divestiture contemplated in such Divestiture Agreement.
- [9] Respondent 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 Respondent have contact with prospective Purchasers during the Divestiture Trustee Sale Period except with the prior approval of the Commissioner; provided, however, the Divestiture Trustee may consult with Respondent in the presence of a representative of the Commissioner when the Divestiture Trustee considers such consultation to be appropriate and the Commissioner consents.
- [10] Subject to any legally recognized privilege, Respondent 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.



**REVISED PUBLIC VERSION**

- [11] Respondent shall take no action that interferes with or impedes, directly or indirectly, the Divestiture Trustee's efforts to complete the Divestiture.
- [12] Respondent shall fully and promptly respond to all requests from the Divestiture Trustee and shall provide all information the Divestiture Trustee may request. Respondent shall identify an individual who shall have primary responsibility for fully and promptly responding to such requests from the Divestiture Trustee on behalf of Respondent.
- [13] Respondent 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 Respondent.
- [14] Respondent 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. Respondent shall pay all reasonable invoices submitted by the Divestiture Trustee within 30 days after receipt and, without limiting this obligation, Respondent 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) Respondent shall promptly pay any invoice approved by the Commissioner. Any outstanding monies owed to the Divestiture Trustee by Respondent shall be paid out of the proceeds of the Divestiture.
- [15] Respondent 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] Respondent 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] Respondent 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 10 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 Respondent, 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 Respondent shall certify that he or she has examined any additional information provided by Respondent to the Commissioner 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 any additional information provided by the prospective Purchaser to the Commissioner 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, Respondent, Monitor, and the prospective Purchaser provides to the Commissioner a confirmation or certification required under this Paragraph is the **"First Reference Date"**.

- (e) Within seven 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, Respondent, 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 10 days after the date on which the Commissioner receives that notice described in Paragraph [22(d)] 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 Respondent;
  - (b) Respondent will have no direct or indirect interest in the Divestiture Assets following the Divestiture, subject to Section [52];
  - (c) the proposed Purchaser is committed to carrying on the Divestiture Assets;
  - (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 DIVESTITURE ASSETS**

[24] In order to preserve the Divestiture Assets pending completion of the Divestiture, Respondent 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. Without limiting the generality of the foregoing, Respondent 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 Divestiture Assets 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 Respondent, advisable or necessary for the operation or value of the Divestiture Assets;
- (f) take commercially reasonable steps to honour all customer contracts and to maintain quality and service standards for customers of the Divestiture Assets 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 Divestiture Assets, except with the prior approval of the Monitor;
- (h) not alter, or cause to be altered, the management of the Divestiture Assets 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 Divestiture Assets, 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 Divestiture Assets are staffed with sufficient employees to ensure their 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 Divestiture Assets to anyone other than Respondent's legal or financial advisors (to the extent necessary for the provision of their services), the Monitor or as otherwise permitted in this Agreement;
  - (l) maintain inventory levels and payment terms materially consistent with the practices of Respondent that existed, with respect to the Divestiture Assets, 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 Divestiture Assets;
- [25] Pending completion of the Divestiture, Respondent 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.
- [26] Respondent 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 Respondent 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 Respondent must provide. The Commissioner may also make such a determination in circumstances

where no Monitor has been appointed. Respondent shall comply with any determination made by the Commissioner on this issue.

**VI. THIRD PARTY CONSENTS**

[27] It shall be a condition in any Divestiture Agreement (whether negotiated by Respondent or by the Divestiture Trustee) that Respondent shall, as a condition of closing, obtain any consents and waivers from Third Parties and Agencies that are necessary to Divest the Divestiture Assets to Purchaser, as applicable, or for the continued research, Development, manufacture, distribution, marketing or sale of the Divestiture Assets; provided, however, that Respondent 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**

[28] Respondent, or the Divestiture Trustee on behalf of Respondent, shall:

- (a) upon reasonable written notice and request from a Purchaser to Respondent, contract manufacture (which contract shall constitute a Remedial Agreement) and deliver to 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 Respondent's Supply Cost, for a period of time sufficient to allow such 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 Respondent or, at 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 Respondent;
- (b) make representations and warranties to 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. Respondent shall agree to indemnify, defend and hold 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 Purchaser pursuant to the Remedial Agreement by Respondent to meet GMP. This obligation may be made contingent upon Purchaser giving Respondent 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 Respondent under this Agreement; provided, however, that Respondent 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 Respondent's responsibilities to supply the ingredients and/or components in the manner required by this Agreement; provided further that this obligation shall not require Respondent to be liable for any negligent act or omission of Purchaser or for any representations and warranties, express or implied, made by Purchaser that exceed the representations and warranties made by Respondent to Purchaser;

- (c) give priority to supplying contract manufacture Divestiture Products to Purchaser over manufacturing and supplying of Product(s) for Respondent's own use or sale;
- (d) make representations and warranties to Purchaser that Respondent shall hold harmless and indemnify Purchaser for any liabilities or loss of profits resulting from the failure by Respondent to deliver the contract manufactured Divestiture Products in a timely manner as required by the Remedial Agreement(s) unless Respondent can demonstrate that any failure was entirely beyond the control of Respondent and in no part the result of negligence or willful misconduct by Respondent; 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 Respondent's aggregate liability for such a breach;
- (e) during the term of any contract manufacture between Respondent and a Purchaser, upon written request of such Purchaser or the Monitor, make available to 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 Respondent 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
- (g) during the term of any contract manufacture between Respondent and a Purchaser, provide consultation with knowledgeable employees of Respondent and training, at the written request of Purchaser and at a facility chosen by Purchaser, for the purposes of enabling such Purchaser to obtain all Product Approvals to manufacture the Divestiture Products in the same quality achieved by, or on behalf of, Respondent and in commercial quantities, and in a manner consistent with GMP independently of Respondent, and sufficient to satisfy the Monitor and management of Purchaser that Purchaser's personnel are adequately trained in the manufacture of the Divestiture Products.



- [29] The foregoing Paragraphs [28(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 such Divestiture Product and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with GMP, independently of Respondent; (2) the date that the Purchaser of the applicable Divestiture Product notifies the Commissioner and Respondent of its intention to abandon its efforts to manufacture such 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 such Divestiture Product; or two years from the Closing Date.

#### **VIII. FAILURE OF DIVESTITURE TRUSTEE SALE**

- [30] 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**

- [31] Any Remedial Agreement shall be deemed incorporated into this Agreement.
- [32] Respondent 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 Respondent's obligations to Purchaser pursuant to this Agreement.
- [33] Respondent shall also include in each Remedial Agreement a representation from Purchaser that such 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 such Divestiture Product and to have any such manufacture be independent of Respondent, all as soon as reasonably practicable.
- [34] Any failure by Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Agreement.
- [35] Respondent shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commissioner.
- [36] Respondent 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**

[37] The Commissioner may appoint a Monitor responsible for monitoring compliance by Respondent 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 Respondent's compliance with this Agreement.

[38] Within five Business Days after the appointment of the Monitor, Respondent 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 Respondent with this Agreement.

[39] Within five Business Days after receipt of the proposed Monitor Agreement referred to in Section [38], the Commissioner shall advise Respondent 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 Respondent with this Agreement and such terms shall be incorporated into a final Monitor Agreement with the Monitor and the Commissioner.

[40] Respondent 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 Respondent'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 Respondent, 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 Respondent.
  - (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 Respondent of its obligations under this Agreement. The Monitor shall, within 3 Business Days, respond to any request by the Commissioner for additional information regarding Respondent's compliance.
- [41] Subject to any legally recognized privilege, Respondent shall provide to the Monitor full and complete access to all personnel, Records, information (including Confidential Information) and facilities relevant to monitoring Respondent's compliance with this Agreement.
- [42] Respondent shall take no action that interferes with or impedes, directly or indirectly, the Monitor's efforts to monitor Respondent's compliance with this Agreement.
- [43] Respondent shall fully and promptly respond to all requests from the Monitor and shall provide all information the Monitor may request. Respondent shall identify an individual who shall have primary responsibility for fully and promptly responding to such requests from the Monitor on behalf of Respondent.
- [44] Respondent 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.
- [45] 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.
- [46] Respondent 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. Respondent shall pay all reasonable invoices submitted by the Monitor within 30 days after receipt and, without limiting this obligation, Respondent 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) Respondent shall promptly pay any invoice approved by the Commissioner. Any outstanding monies owed to the Monitor by Respondent shall be paid out of the proceeds of the Divestiture.

- [47] Respondent 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.
- [48] 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.
- [49] The Monitor shall serve such time as the Commissioner considers necessary to monitor Respondent's compliance with this Agreement.

**XI. COMPLIANCE**

- [50] Within 5 Business Days after the Closing Date, Respondent shall provide written confirmation to the Commissioner of the date on which the Transaction was completed.
- [51] Respondent 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 three Business Days after the date of registration of this Agreement. Respondent shall ensure that its directors, officers, employees and agents with responsibility for any obligations under this Agreement receive sufficient training respecting Respondent's responsibilities and duties under this Agreement, and the steps that such individuals must take in order to comply with this Agreement.
- [52] Respondent 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.
- [53] Six months after the date of registration of this Agreement and annually for the next five years on, or 10 days before, the six month anniversary of the date of registration, or at such other times as the Commissioner may relate, Respondent shall file an affidavit or certificate, substantially in the form of Schedule B to this Agreement, certifying its compliance with Parts [VII] [Contract Manufacturing], and [XI] [Compliance] 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 Respondent, 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 five 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 five Business Days that it could not reasonably be considered a breach of any of the terms of this Agreement. Respondent shall provide confirmation of its compliance with this provision in all affidavits and certificates of compliance filed with the Commissioner pursuant to Section [53].

**[55]** Respondent shall notify the Commissioner at least 30 days prior to:

- (a) any proposed dissolution of Respondent;
- (b) any other change in Respondent 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 Respondent'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, Respondent shall, upon written request given at least five Business Days in advance to Respondent, permit any authorized representative(s) of the Commissioner, without restraint or interference:

- (a) to access, during regular office hours of Respondent on any Business Day(s), all facilities and to inspect and copy all Records in the possession or control of Respondent related to compliance with this Agreement, which copying services shall be provided by Respondent at its expense; and
- (b) to interview such officers, directors or employees of Respondent 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, VI] of this Agreement shall be effective only until the Divestiture is complete; and

- (b) Part [VII] 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  
Gatineau, Quebec K1A 0C9

Attention: Commissioner of Competition  
Fax: (819) 953-5013  
Email address: MergerNotification@cb-bc.gc.ca

with copies 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@cb-bc.gc.ca

if to Respondent:

Marc Brotman  
Vice-President & Assistant General Counsel  
Pfizer Inc.  
235 E 42<sup>nd</sup> St  
New York, New York 10017  
Tel: (212) 733-5029  
Fax: (212) 808-8924

with a copy to:

Adam Fanaki  
Davies Ward Phillips & Vineberg LLP  
155 Wellington Street West  
Toronto, Ontario M5V 3J7  
Fax: (416) 863-0871  
Email address: AFanaki@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. Respondent hereby consents to such registration. Following the filing of this Agreement, the Commissioner shall promptly issue a letter to Respondent 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 Respondent, extend any of the time periods contemplated by this Agreement other than Sections [49] (if applicable), [52], and [57]. If any time period is extended, the Commissioner shall promptly notify Respondent of the revised time period.
- [65] Nothing in this Agreement precludes Respondent or the Commissioner from bringing an application under section 106 of the Act. Respondent 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 the Divestiture Products 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] Respondent 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] Until Closing, Respondent shall make reasonable efforts to ensure that Hospira preserves the voriconazole Divestiture Assets in a manner consistent with Part V of this Agreement.
- [68] This Agreement, together with the Monitor Agreement and any Remedial Agreements, constitutes the entire agreement between the Commissioner and Respondent, and supersedes all prior agreements, understandings, negotiations and discussions, whether written or oral, with respect to the subject matter hereof.
- [69] 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.
- [70] In the event of a dispute regarding compliance with or the interpretation, implementation or application of this Agreement, the Commissioner or Respondent 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.



[71] 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.

*[Signature Page Follows]*

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

DATED this day of 13<sup>th</sup> day of August, 2015

**COMMISSIONER OF COMPETITION**

[Original Signed by John Pecman]

Name: John Pecman

Title: Commissioner of Competition

**PFIZER INC.**

[Original Signed by Marc Brotman]

I/We have authority to bind the corporation

Name: Marc Brotman

Title: Vice-President & Assistant General  
Counsel

**CONFIDENTIAL SCHEDULE A**

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

SCHEDULE B

FORM OF COMPLIANCE CERTIFICATION/AFFIDAVIT

I, **[name]**, of **[place]**, hereby certify/make oath and say in accordance with the terms of the Registered Consent Agreement dated • between **[Respondent]** and the Commissioner of Competition, that:

1. I am the **[title]** of **[Respondent]**, 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]**, **[Respondent]** entered into a Consent Agreement (the “Consent Agreement”) with the Commissioner of Competition (the “Commissioner”) in connection with the proposed acquisition by Pfizer Inc. or its direct or indirect subsidiaries of Hospira, Inc. (the “Transaction”).
3. The Transaction closed on **[date]** (the “Closing Date”).
4. The Divestiture (as defined in the Consent Agreement) to **[Purchaser]** was completed on **[date]**.
5. Pursuant to Section [53] of the Consent Agreement, Respondent is required to file an affidavit or certificate certifying its compliance with Parts [VII] [Contract Manufacturing] and [XI] [Compliance] 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 [50] of the Consent Agreement, Respondent 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 [51]XI.[51] of the Consent Agreement, Respondent 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 obligations under the Consent Agreement, within three 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 [51] of the Consent Agreement, Respondent is required to ensure that its directors, officers, employees and agents with responsibility for any

obligations under the Consent Agreement receive sufficient training respecting Respondent'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]**

**Notification of Breach**

10. 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 ●.

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**Commissioner of Oaths**

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**Name and Title of Certifying Officer**