

LISTING AGREEMENT

STANDARD TERMS AND CONDITIONS

Date: September 9, 2022

ARTICLE 1

Definition

1.1 Definitions. In this Agreement, the following words shall have the following meanings:

“Agreement” means this agreement between the Executive Officer and the Manufacturer consisting of the Contract Particulars and this Listing Agreement Standard Terms and Conditions, including all Schedules and attachments to the Contract Particulars document, as the same may be amended or supplemented from time to time;

“Applicable Law” means, with respect to any Person, transaction, event or other matter, any law, rule, statute, regulation, order, judgment, decree, treaty or other requirement having the force of law relating or applicable to such Person, transaction, event or other matter and includes any rule or order of any existing commission, board or other administrative agency;

“Contractual Payment” means an amount specified in Article 4 that is owing to the Executive Officer and payable by the Manufacturer to the Ontario Minister of Finance in consideration for the listing or continued listing of a Drug Product or Drug Products, as the case may be, on the Formulary or the funding of a Drug Product under the Ontario Public Drug Programs and/or such other form of value;

“Day” means calendar day; and **“Days”** has the corresponding meaning;

“Drug Benefit Price” means the drug benefit price of the Drug Product as listed in Schedule “A” of the Contract Particulars; and **“Drug Benefit Prices”** has the corresponding meaning;

“Drug Product” means the drug product listed in Schedule “A” of the Contract Particulars, and **“Drug Products”** has the corresponding meaning;

“Fiscal Year” means from April 1st of one calendar year to March 31st of the following calendar year;

“**FIPPA**” means the *Freedom of Information and Protection of Privacy Act*, R.S.O. 1990 c. F.31 as may be amended or replaced from time to time;

“**Formulary**” means the Formulary that the Executive Officer is required to keep, maintain and publish under the *Ontario Drug Benefit Act*;

“**Indemnified Parties**” means His Majesty the King in right of Ontario, his advisors, agents, appointees and employees (including the Executive Officer) and the members of the Executive Council of Ontario and their advisers and staff;

“**IPC**” means the Information and Privacy Commissioner of Ontario;

“**Manufacturer’s Personnel**” means the directors, officers, employees, agents, subcontractors, independent contractors or other representatives of the Manufacturer;

“**Ministry**” means the Ontario Ministry of Health;

“**Notice**” means any notice, request, demand, consent, approval, authorization, correspondence, or other communication required pursuant to or permitted under this Agreement given in accordance with Article 10;

“**Ontario Public Drug Programs**” means the Ontario Drug Benefit Program, including the Trillium Drug Program and Exceptional Access Program, administered by the Ministry and governed by the *Ontario Drug Benefit Act* or any other drug program funded by the Ministry;

“**Person**” shall be broadly interpreted and includes an individual, a corporation, a partnership, a trust, a joint venture, an unincorporated or incorporated organization, an unincorporated or incorporated association, the government of a country or any political subdivision thereof, or any agency or department of any such government, and the executors, administrators or other legal representatives of an individual in such capacity, and includes the Manufacturer;

“**Quarter**” means, in any Fiscal Year and as applicable, any of the following periods: (i) April 1st to June 30th; (ii) July 1st to September 30th; (iii) October 1st to December 31st; or (iv) January 1st to March 31st; and “**Quarterly**” has a corresponding meaning; and;

“**Schedule**” means a schedule listed in the Contract Particulars and “**Schedules**” shall have the corresponding meaning.

ARTICLE 2

Manufacturer Representations and Warranties

- 2.1 Representations and Warranties.** The Manufacturer represents, warrants, and covenants as follows:
- (a) the Manufacturer is duly incorporated pursuant to Applicable Law;
 - (b) the Manufacturer has the full power and authority to enter into this Agreement and to carry out its obligations under this Agreement;
 - (c) the Manufacturer shall not, in the performance of its obligations under the Agreement, contravene or violate any provisions of the by-laws of the Manufacturer or any provision of Applicable Law;
 - (d) the Manufacturer shall give the Executive Officer Notice of any change made to the Drug Product, including a formulation change, and of any change in the ownership of the Manufacturer;
 - (e) the Drug Products are authorized for sale under the *Food and Drugs Act* (Canada); and
 - (f) if a Drug Product is listed under the *Ontario Drug Benefit Act*, the Manufacturer meets the conditions of the *Ontario Drug Benefit Act* and its regulations with respect to the Drug Products.

ARTICLE 3

Term of the Agreement

[Intentionally deleted – See Contract Particulars]

ARTICLE 4

Contractual Payment

- 4.1 Payment for Changes in Drug Benefit Prices.** The Manufacturer shall pay the Executive Officer a Contractual Payment in consideration for having the Drug Product funded under the Ontario Public Drug Programs at the Drug Benefit Price set out in Schedule “A” of the Contract Particulars.
- 4.2 Calculation of Payment.** The amount of the Contractual Payment that the Manufacturer is required to pay under section 4.1 in respect of a Drug Product shall be calculated:
- (a) on the basis of quarterly ODB Program expenditure data in respect of that Drug Product;
 - (b) as of and including the date on which the Drug Product is funded under the Ontario Public Drug Programs; and
 - (c) in accordance with the formula and other specifications set out in Schedule “B” of the Listing Agreement Contract Particulars.
- 4.3 Details of Contractual Payment to be Made Public.** The Executive Officer may, in the Executive Officer’s sole discretion and in accordance with Article 6, make public the following:
- (a) the name of the Manufacturer;
 - (b) the subject-matter of this Agreement; and
 - (c) the fact of entering into or terminating this Agreement.
- 4.4 Debt Owing to Crown.** If the Executive Officer demands payment of a Contractual Payment by the Manufacturer under section 4.1, the amount demanded shall be deemed to be a debt owing to the Ontario Minister of Finance by the Manufacturer.
- 4.5 Interest Rate.** The Executive Officer may charge the Manufacturer interest on any amount owing by the Manufacturer under this Agreement after the expiry of the time period set out in section 4.6(a) at the then current interest rate charged by the Province of Ontario on accounts receivable.

- 4.6 Contractual Payment Payable To.** The Manufacturer shall pay any amounts owing to the Executive Officer under this Agreement:
- (a) within 30 Days after receiving an invoice;
 - (b) in Canadian dollars;
 - (c) to the “Ontario Minister of Finance”; and
 - (d) in accordance with any instructions set out in the invoice.

ARTICLE 5

Terms and Conditions of Listing / Continued Listing

- 5.1 Manufacturer to Comply with Terms and Conditions.** The Manufacturer shall comply with the terms and conditions of this Agreement in consideration for having the Drug Products funded by the Ontario Public Drug Programs at the Drug Benefit Prices set out in Schedule “A” of the Contract Particulars.
- 5.2 Terms and Conditions in addition to statutory and regulatory requirements.** The terms and conditions set out in this Agreement are in addition to, and not in substitution for, any requirements for listing, continued listing or designation of interchangeability of the Drug Products on the Formulary under the *Ontario Drug Benefit Act*, the *Drug Interchangeability and Dispensing Fee Act*, and their respective regulations.

ARTICLE 6

Confidentiality

- 6.1 Definitions.** For the purpose of this Article 6, the following terms shall have the following meanings:

“**Aggregate Program Data**” means Ontario Public Drug Program fiscal data in aggregate form which: (a) relates to multiple manufacturers and products, but does not identify or reveal any individual manufacturer or product; and (b) is derived, in part, from information resulting from this Agreement.

“**Confidential Information**” means: (i) any and all information or data that was submitted, supplied or communicated by the other party or obtained in any way pursuant to the Agreement or the negotiation of the Agreement, including such information, aggregate or otherwise, which would reveal the quantum of the Contractual Payment, the effective unit price of a Drug Product, payments made by the Manufacturer under the Agreement, aggregate or otherwise, and any other benefit, service or undertaking which the Manufacturer agrees to provide under this Agreement in consideration of having a Drug Product reimbursed or funded under Ontario Public Drug Programs, and (ii) any Reports under Article 7 containing information described in (i) above. The term excludes Aggregate Program Data and the information specified in section 4.3.

6.2 Confidential Information. The Executive Officer and the Manufacturer shall:

- (a) treat as confidential and hold in confidence all Confidential Information; and
- (b) not publish or disclose Confidential information, nor permit the Confidential information to be published or disclosed, without the prior written consent of the other party, except as necessary to enable the party in possession of the Confidential Information to fulfil its obligations under this Agreement or as required by Applicable Law.

6.3 Mutual Notice Obligation. If a party is required by Applicable Law to disclose Confidential Information under section 6.2(b), the disclosing party shall notify the other party at least thirty (30) Days prior to disclosing the information, where the giving of such Notice is possible in the circumstances. If the minimum 30 Day notice is not possible, the disclosing party shall notify the other party as soon as possible prior to disclosing the information.

6.4 Executive Officer to Notify Manufacturer of Access Requests under FIPPA. The Executive Officer shall notify the Manufacturer in writing of any access requests received under FIPPA for Confidential Information or Aggregate Program Data (“Requested Information”) to enable the Manufacturer to make written submissions to the Executive Officer about the potential disclosure within the timelines set out under FIPPA.

6.5 Executive Officer to Notify Manufacturer of Decision. If the Manufacturer makes submissions under section 6.4 opposing the release of the Requested Information and the Executive Officer decides nevertheless that it should be released either in whole or in part, the Executive Officer will not proceed to release any of the Requested Information until the Manufacturer has received written notice of the decision, thereby enabling the Manufacturer to exercise its right to appeal the Executive Officer’s decision to the IPC in accordance with the timelines set out under FIPPA.

- 6.6 Where Disclosure is Ordered by the IPC.** Where Requested Information is required to be disclosed by order of the IPC, the Manufacturer will be notified immediately, and no disclosure will be made until the Manufacturer has been notified, the timing of such notification, at a minimum, providing sufficient time to enable the Manufacturer to initiate any proceedings it may deem necessary to protect its interests.
- 6.7 Executive Officer and Manufacturer May Publish.** Notwithstanding Article 6.2, the Executive Officer and the Manufacturer may each publish and disclose any Confidential Information that is in the public domain other than through a breach of this Agreement, or contrary to other laws, including FIPPA.
- 6.8 Information Submitted or Supplied in Confidence.** The Executive Officer and the Manufacturer agree and acknowledge that Confidential Information submitted or supplied by the Manufacturer to the Executive Officer for purposes of this Agreement is supplied or submitted in confidence and its disclosure would allow for an accurate inference to be made about the value of the Contractual Payment and would reasonably be expected to result in commercial or competitive harm to the Manufacturer and to the interests of the Ministry of Health and the Province of Ontario and its disclosure would likely result in similar information no longer being supplied or submitted to the Executive Officer.
- 6.9 No Public Announcements.** The Manufacturer shall not communicate publicly any information under this Agreement concerning the new or revised funding of any Drug Product until such time as the new or revised Drug Product funding is issued, announced, or otherwise made public by the Executive Officer.

ARTICLE 7

Reports

- 7.1 Reports.** The Manufacturer shall submit to the Executive Officer any reports pertaining to this Agreement which the Executive Officer may reasonably request from time to time (“Reports”).
- 7.2 Preparation and Submission.** The Manufacturer shall:
- (a) prepare its Reports using the forms which may be specified by the Executive Officer from time to time;
 - (b) ensure that all Reports are completed to the reasonable satisfaction of the Executive Officer;
 - (c) include with all Reports any documentation which may be required to substantiate the content of the Reports; and
 - (d) submit all Reports on the dates specified by the Executive Officer to the address set out in the Contract Particulars.

ARTICLE 8

Limitation of Liability

- 8.1 Limitation of Liability.** The Indemnified Parties shall not be liable to the Manufacturer, the Manufacturer’s Personnel, or any other person for any costs, losses, claims, liabilities, damages or expenses howsoever caused (including any incidental, indirect, special or consequential damages, injury or any loss of use or profit of the Manufacturer) arising out of or in any way related to the listing, delisting, designation or de-designation of the Manufacturer’s Drug Products or otherwise in connection with the Agreement, unless caused by the gross negligence or willful misconduct of an officer, employee or agent of the Ministry which includes, for greater clarity, the Executive Officer.

ARTICLE 9

Termination

- 9.1 Termination Without Reason.** Either party may terminate the Agreement at any time, for any reason, upon giving at least thirty (30) Days Notice to the other party.

Where there is more than one Drug Product under this Agreement, either party may terminate the application of this Agreement to one or more Drug Products at any time, for any reason, upon giving at least thirty (30) Days Notice to the other party. The Agreement shall continue in force in respect of other Drug Products under this Agreement. For clarity, if the Agreement is terminated in respect of a Drug Product under this clause, section 13.1 (Survival) applies to the termination in respect of that Drug Product.

- 9.2 Immediate Termination by Executive Officer.** The Executive Officer may terminate the Agreement immediately upon giving Notice to the Manufacturer if:

- (a) in the opinion of the Executive Officer acting reasonably:
 - (i) the Manufacturer has knowingly provided false or misleading information in any communication with the Executive Officer;
 - (ii) the Manufacturer breaches any provision of this Agreement; or
 - (iii) termination is necessary for reasons concerning the protection of public health or safety;
- (b) the Manufacturer makes an assignment, proposal, compromise, or arrangement for the benefit of creditors, or is petitioned into bankruptcy, or files for the appointment of a receiver; or
- (c) the Manufacturer ceases to carry on business.

- 9.3 Opportunity to Remedy.** If the Executive Officer considers that it is appropriate to allow the Manufacturer the opportunity to remedy a breach of the Agreement, the Executive Officer may give the Manufacturer an opportunity to remedy the breach by giving the Manufacturer Notice:

- (a) of the particulars of the breach;
- (b) of a reasonable period of time within which the Manufacturer is required to remedy the breach; and

- (c) that the Executive Officer shall terminate the Agreement:
 - (i) at the end of the notice period provided for in the Notice if the Manufacturer fails to remedy the breach within the time specified in the Notice; or
 - (ii) prior to the end of the notice period provided for in the Notice if it becomes apparent to the Executive Officer that the Manufacturer cannot completely remedy the breach within that time or such further period of time as the Executive Officer considers reasonable, or the Manufacturer is not proceeding to remedy the breach in a way that is satisfactory to the Executive Officer, acting reasonably.

9.4 Manufacturer not Remediating. If the Executive Officer has provided the Manufacturer with an opportunity to remedy the breach, and

- (a) the Manufacturer does not remedy the breach within the time period specified in the Notice;
- (b) it becomes apparent to the Executive Officer that the Manufacturer cannot completely remedy the breach within the time specified in the Notice or such further period of time as the Executive Officer considers reasonable; or
- (c) the Manufacturer is not proceeding to remedy the breach in a way that is satisfactory to the Executive Officer, acting reasonably;

the Executive Officer may immediately terminate the Agreement by giving Notice of termination to the Manufacturer.

9.5 Effective Date. The effective date of any termination under this Article shall be the last Day of the notice period, the last Day of any subsequent notice period or immediately, whichever applies.

ARTICLE 10

Notices

10.1 Notice. Any Notice shall be:

- (a) in writing;
- (b) delivered personally or by pre-paid courier, or sent by facsimile, certified or registered mail or postage pre-paid mail with receipt notification requested; and,
- (c) addressed to the other party as provided in the Contract Particulars or as either party shall later designate to the other in writing.

10.2 Notices Effective From. All Notices shall be effective:

- (a) at the time the delivery is made if the Notice is delivered personally, by pre- paid courier or by facsimile; or
- (b) three Days after the Day the Notice was deposited in the mail if the Notice is sent by certified, registered or postage prepaid mail, unless the Day the Notice is effective falls on a Day when the Ministry is normally closed for business, in which case the Notice shall not be effective until the next Day that is a Day when the Ministry is normally open for business.

ARTICLE 11

Indemnity and Insurance

11.1 Indemnification. The Manufacturer hereby agrees to indemnify and hold harmless the Indemnified Parties from and against any and all liability, loss, costs, damages and expenses (including reasonable legal, expert and consultant fees), causes of action, actions, claims, demands, lawsuits or other proceedings, (collectively "Claims"), by whomever made, sustained, brought or prosecuted, including for third party bodily injury (including death), personal injury and property damage, in any way based upon, occasioned by or attributable to anything done or omitted to be done by the Manufacturer or the Manufacturer's Personnel in the course of performance of the Manufacturer's obligations under, or otherwise in connection with, the Agreement. The Manufacturer further agrees to indemnify and hold harmless the Indemnified Parties for any incidental, indirect, special or consequential damages, or any loss of use, revenue or profit, by any Indemnified Party, including without limitation the Executive Officer, claimed or resulting from such Claims. This indemnity does not apply to the extent that a third party claim arises from the gross negligence or wilful misconduct of an Indemnified Party.

- 11.2 Comprehensive General Liability Insurance.** The Manufacturer shall put in effect and maintain, either with self-insurance or with insurers acceptable to the Executive Officer, for the duration of the Agreement at its own expense, all the necessary and appropriate insurance that a prudent Person in the business of the Manufacturer would maintain including, but not limited to, Comprehensive General Liability Insurance on an occurrence basis for third party bodily injury, personal injury and property damage, to an inclusive limit of not less than two million dollars (\$2,000,000) per occurrence. Upon request, the policy shall include the Indemnified Parties as additional insured with respect to liability arising in the course of performance of the Manufacturer's obligations under or otherwise in connection with, the Agreement.
- 11.3 Certificates of Insurance.** If requested by the Executive Officer, the Manufacturer shall provide the Executive Officer with proof of the insurance required under this Agreement in the form of a valid certificate of insurance that references the Agreement and confirms the required coverage.

ARTICLE 12

General

- 12.1 Execution.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 12.2 Severability.** The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement and any invalid or unenforceable provision shall be deemed to be severable.
- 12.3 Independent Parties.** The parties hereto are, and shall at all times remain, independent and are not, shall not be deemed to be, and shall not represent themselves to be the agent, joint venture, partner or employee of the other. Neither party shall be bound in any manner whatsoever by any agreements, warranties or representations made by the other party to any other Person nor with respect to any other action of the other party.
- 12.4 Applicable Law.** This Agreement and the rights, obligations and relations of the parties hereto shall be governed by and construed in accordance with the laws of the Province of Ontario and the federal laws applicable therein. The parties irrevocably and unconditionally submit to the non-exclusive jurisdiction of the courts of the Province of Ontario and all courts competent to hear appeals from them.

- 12.5 Further Assurances.** The parties agree to promptly do or cause to be done all acts or things (including executing and delivering further documentation) necessary to implement and carry into effect this Agreement to its full extent.
- 12.6 Waiver.** A waiver of any failure to comply with any term of this Agreement must be written and signed by the party purporting to give such waiver. Each waiver must refer to a specific failure to comply and shall not have the effect of waiving any subsequent failures to comply or of any other failures to comply.
- 12.7 Rights and Remedies cumulative.** The rights and remedies of the parties hereto are cumulative and are in addition to and not in substitution for any rights and remedies provided at law or in equity.
- 12.8 Time of the Essence.** Time shall be of the essence in the performance of the obligations under this Agreement.
- 12.9 Entire Agreement.** This Agreement consisting of the Contract Particulars (and attached Schedules) and these Standard Terms and Conditions constitutes the entire agreement between the parties hereto with respect to the subject matter contained in this Agreement and supersedes all prior oral or written representations, agreements and understandings.
- 12.10 Written Amendments by Mutual Agreement.** This Agreement may be amended at any time at the discretion of either party and subject to their mutual agreement. No modification of this Agreement shall be binding upon the parties to this Agreement unless it is in writing and executed by an authorized signing officer for the Manufacturer and the Executive Officer.
- 12.11 Executive Officer's Authority Maintained.** Nothing in this Agreement shall limit the authority of the Executive Officer to list or delist any drug product under the *Ontario Drug Benefit Act*, or to designate or remove the designation of any drug product under the *Drug Interchangeability and Dispensing Fee Act*.
- 12.12 Assignment.** Except as provided in this section, the Manufacturer shall not assign this Agreement (either in whole or in part) to any other Person without the prior written consent of the Executive Officer which such consent shall not be unreasonably withheld. The Manufacturer may assign this Agreement in whole or in part in the following circumstances and under the following conditions:
- (a) in the case of a corporate reorganization of the Manufacturer, the Manufacturer may assign this Agreement in whole or in part to a related corporation of the Manufacturer by providing at least 30 Days Notice to the Executive Officer. Such an assignment does not release the Manufacturer of its obligations under this Agreement; or

- (b) In the case of the sale of the rights respecting one or more Drug Products to an unrelated Person of the Manufacturer, the Manufacturer may assign this Agreement in whole or in part to an unrelated Person by providing at least 30 Days Notice to the Executive Officer so long as the unrelated Person also provides Notice to the Executive Officer that it is assuming the rights and liabilities of the Manufacturer in respect of the Drug Product on a date specified in the Notice. If that is done, then the Manufacturer shall be released of its obligations under this Agreement in respect of the Drug Product(s) being assigned on and after the date of the assumption of liabilities by the unrelated Person.

ARTICLE 13

Survival

- 13.1 Survival.** The provisions in Articles 8 (Limitation of Liability), 11 (Indemnity and Insurance), 10 (Notices), sections 4.4 (Debt Owing to Crown), 12.4 (Applicable Law), and 12.11 (Executive Officer's Authority Maintained) shall survive termination or expiry of this Agreement for a period of seven (7) years from the date of expiry or termination of this Agreement. The provisions of Article 6 (Confidentiality) shall survive the termination or expiry of this Agreement perpetually.