Yukon

ATIPP Request: 25-145

Source of Records: Insured Health Services

Health and Social Services

AGREEMENT

BETWEEN:

GOVERNMENT OF YUKON represented by the Minister of Health and Social Services (GY)

And

MANUFACTURER NAME TO BE WRITTEN

(the Manufacturer)

(GY and the Manufacturer individually referred to hereafter as a "Party" and collectively referred to hereafter as the "Parties")

WHEREAS:

1. The Manufacturer requests that certain of its Drug Products be covered at a predetermined price under various programs operated by the Yukon Department of Health and Social Services (HSS), as defined in Article 1 ("the PEB programs");
2. HSS has authority to determine the amounts payable for drugs under the PEB programs;
3. The Parties wish to enter into an Agreement that specifies the amount payable by GY in respect of certain of the Manufacturer's Drug Products; and
4. The Parties acknowledge that the Manufacturer is providing to GY commercial and financial information that is supplied in confidence, the disclosure of which could reasonably be expected to:

    (i) harm significantly the competitive position, or interfere significantly with the negotiating position of the Manufacturer,

    (ii) result in similar information no longer being supplied to GY when it is in the public interest that similar information continues to be supplied, or

    (iii) result in undue financial loss or gain to the Manufacturer.

NOW THEREFORE in consideration of the mutual covenants and agreements contained herein and for other good and valuable consideration, the sufficiency and receipt of which are hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1
Definitions

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

"**Accepted**" is defined as where the dollar amount, for a claim that goes towards the coverage/reimbursement or any amount of one or more of the patient's deductible or co-payment obligations, is greater than $0.00.

"Agreement" means this agreement between GY and the Manufacturer and all Schedules and attachments to this Agreement, as amended from time to time and any mutually agreed assignments;

"Applicable Law", with respect to any Person, transaction, event or other matter, includes, but is not limited to, 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;

"Attachment" means any attachment to this Agreement which forms part of this Agreement and "**Attachments**" has the corresponding meaning;

"Brand Name Drug" means a drug synthesized by chemical reactions and sold under a specific name or trademark and is protected by a patent,

"**Business Day**" means a day that is not a Saturday, a Sunday or statutory holiday in Yukon.

"Biologic" means a drug derived through the metabolism of living organisms, rather than being synthesized by chemical reactions

"Biologic originator" means the first version of a biologic patented and approved for sale in Canada.

"Biosimilar" means a highly similar version of a biologic drug that comes to the Canadian market after the patent for the biologic originator has expired.

"Day" means calendar day and **"days"** has the corresponding meaning;

"Drug Benefit Price" means the drug benefit price of the Drug Product listed in Schedule "B" and **"Drug Benefit Prices"** has the corresponding meaning;

"Drug Product" means the drug product listed in Schedule "B" 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, provided that the initial Fiscal Year shall start on the first day of the term of this Agreement and end on March 31st of the following calendar year and the final Fiscal Year shall start on April 1st of that calendar year and end on the last day of the term of this Agreement, which shall be no later than March 31st of the following calendar year;

"Generic Drug" means a prescription drug synthesized by chemical reactions, has the same active ingredient formula as a Brand Name drug and is sold after the patent for the brand name drug expires.

"HSS" means the Government of Yukon Department of Health and Social Services;

"List Price" is the price set out as "List Price" in the attached LOI.

"LOI" means the Letter of Intent, including amendments, if any, attached as Schedule "A"

"Manufacturer's Personnel" means the directors, officers, employees, agents, subcontractors, independent contractors or other representatives of the Manufacturer;

"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 7 of this Agreement;

"Patient Access Program" means a set of services, if any, operated by the Manufacturer designed to support a patient through a number of therapy-related needs. Services may include, but are not limited to, drug supply, financial assistance, nursing and pharmacy services and clinical services. For clarity, if a Manufacturer does not, at the time of signing this agreement, have a Patient Access Program for the Drug Product identified in this agreement, this agreement does not require that a Patient Access Program be commenced.

"PEB programs" means Pharmacare and Extended Benefits programs and includes one

or more of the following programs operated by HSS:

- the Yukon Pharmacare Plan;
- the Extended Health Care Benefits program;
- the Chronic Disease and Disability program; and
- the Children's Drug and Optical program;

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

"Personal Health Information" means personal health information as defined in the *Health Information and Privacy Management Act*;

"Personal Information" means personal information as defined in the *Access to Information and Protection of Privacy Act*;

"Schedule" means a schedule listed in Article 9 and which forms part of this Agreement and **"Schedules"** has the corresponding meaning; and

"Volume Discount" means an amount determined in accordance with Article 4 that is payable from time to time by the Manufacturer to the Yukon Minister of Finance.

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 and execute this Agreement and to carry out its obligations under the Agreement;

c) each individual signing this Agreement on behalf of the Manufacturer has been properly authorized and empowered to enter into and execute this Agreement;

d) 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, any rights related to intellectual property or property rights or any other rights, or any provision of Applicable Law;

e) the Manufacturer shall give GY immediate notice of any change made to the Drug Product, including a formulation change, and of any change in the ownership of the Manufacturer or of any change in the ownership of rights to the Drug Product;

f) the Drug Products are authorized for sale under the *Food and Drugs Act (Canada)*;

g) the Manufacturer will supply the Drug Product or Drug Products in quantities that are sufficient to allow all pharmacies within Yukon to dispense the Drug Product to all patients presenting prescriptions for the Drug Product.

h) the Manufacturer must notify GY in writing as soon as it has reasonable cause to believe that it will fail to supply the Drug Product on the terms set out in, and in accordance with, this Agreement.

2.2 The Manufacturer will:

a) market and promote the Drug Product or Drug Products in accordance with the Health Canada label and will educate physicians when conducting its marketing about the inclusion and exclusion criteria set out in Schedule "D", and

b) provide, pay for, and maintain the following insurance with minimum policy limits as specified:

Commercial General Liability insurance with a limit not less than two million ($2M) dollars (CAD) per occurrence and ten million ($10M) dollars (CAD) in aggregate per policy year. The commercial general liability insurance shall cover bodily injuries (including death, sickness, or disease), personal injury, and property loss or damage, which shall at a minimum cover liabilities associated with or arising from the Manufacturer's Drug Product or Drug Product(s), and shall include GY as an additional insured.;

c) pay all deductibles for any of the insurance policies required under this Agreement. No later than thirty (30) days after the Manufacturer signs this Agreement, the

Manufacturer shall submit a certificate of insurance showing compliance with 2.2(b). The certificate of insurance shall be delivered to the Director, Insured Health services. Upon or prior to expiry of the policies listed on the certificate of insurance the Manufacturer shall submit an updated certificate. The Manufacturer shall notify of any lapse, cancellation, or other material change to the Manufacturer's insurance coverage within thirty (30) days of the Manufacturer being notified of the material change;

d) indemnify and hold harmless GY from and against all claims, liabilities, demands, or costs (including reasonable legal costs) to the extent arising from or related to: errors, omissions or negligence by the Manufacturer; breach of this Agreement or, breach of any statutory or professional duty by the Manufacturer; or any injury (including death) to persons, damage to or loss of property, infringement of rights (including intellectual property rights) or any claims, liabilities, demands, or costs in any way to the extent arising from or related to the fault or legal responsibility of the Manufacturer. For greater certainty, the term "Manufacturer" for the purposes of this clause includes the Manufacturer and its officers, employees, subcontractors, agents, and successors or assigns. This indemnity clause shall survive the expiry or termination of this Agreement.

PATIENT ACCESS PROGRAM

2.3 If the Manufacturer has a Patient Access Program, whether the Patient Access Program is commenced before or after the signing of this agreement:

a) The Manufacturer will continue to enroll new patients into its existing Patient Access Program until six (6) months after the latest date that the LOI is signed, or until individual jurisdictional listing, whichever is sooner.

b) The Parties will cooperate to facilitate the transfer of existing patients who meet provincial listing criteria upon listing or six (6) months following the execution of the LOI, whichever is later.

c) The Manufacturer acknowledges and agrees that currently enrolled Patients who do not meet the inclusion and exclusion criteria outlined in Schedule "D" of a Participating Jurisdiction will remain enrolled in its Patient Access Program.

d) The Manufacturer will not make patient enrollment in a Patient Access Program a condition of supplying the Drug Product to the pharmacy of the patient's choice. For

clarity, consistent with Section 2.1(g), if a patient decides to not enroll or opt out of the Manufacturer's Patient Access Program, the Manufacturer will continue to ensure the patient has access to the Drug Product at the pharmacy of their choice

2.4 Infusion Service

a) If administration of the Drug Product requires infusion, the Manufacturer will collaborate with GY to find solutions for establishing, maintaining, and funding drug administration (infusion) services for the Drug Product. The Manufacturer will work with GY to adequately address unmet infusion service requirements or new service demands and other related service issues in a timely manner

ARTICLE 3
Term of the Agreement

3.1 Subject to Article 3.2, below, the initial term of this Agreement shall commence on the date determined under Article 11.1 and shall remain in effect for three (3) years or terminated pursuant to Article 6, whichever is earlier.

3.2 Upon completion of the initial term, but subject to earlier termination in accordance with Article 6, the Agreement shall automatically renew for no more than two (2) successive three (3) year periods (each a renewal term), unless one party provides the other party with written notice at least ninety (90) days prior to the expiry of the initial term or any renewal term of its intention not to renew the Agreement.

3.3 GY may re-negotiate the terms of this Agreement with the Manufacturer if there are significant market changes or if the drug expenditures on the Drug Product significantly exceed the budget impact estimates submitted to the GY, c/o the Director, Insured Health Services.

3.4 GY reserves the right, in its absolute discretion and without notice, to establish, review or change the inclusion and exclusion criteria in relation to the Drug Product, as well as to alter substantially the extent to which it provides reimbursement for the Drug Product.

ARTICLE 4
Volume Discount

4.1 **Payment of Volume Discount.** In consideration of GY providing coverage under PEB programs for the Drug Product at the Drug Benefit Price (subject to any inclusion or exclusion criteria generally accepted in respect of a particular Drug Product, including

any inclusion or exclusion criteria set out in Schedule "D", the Manufacturer shall pay to GY a Volume Discount.

4.2 Calculation of Payment. The amount of the Volume Discount that the Manufacturer shall pay in accordance with Article 4.1 in respect of a Drug Product shall be calculated:

a) on the basis of annual (fiscal year) PEB programs' drug quantity data in respect of that Drug Product;

b) as of and including the date on which this Agreement comes into effect, which may be a date earlier than the date upon which this Agreement is signed; and

c) in accordance with the formula and other specifications set out in Schedule "C".

4.3 Provision of Data.

a) GY shall provide the Manufacturer with drug quantity data to allow the Manufacturer to calculate and confirm the amount of the Volume Discount. Provision of any other information to the Manufacturer shall be at the sole discretion of GY.

b) The Manufacturer will provide to GY all significant clinical data relating to efficacy of the Drug Products ("Data") within thirty (30) days of that Data becoming available to the Manufacturer and being capable of disclosure by the Manufacturer under applicable law. In any case, where Data raises issues concerning patient safety, the Manufacturer will provide that Data to GY immediately once it becomes capable of disclosure under applicable law.

4.4 Dispute Resolution. In the case of a dispute, the Parties shall make all reasonable efforts to resolve the dispute by amicable negotiations in a respectful manner.

If the Parties fail to resolve the dispute, then they may each pursue whatever remedies are available to them under this Agreement or at law.

4.5 Debt Owing to GY. Any amount payable under this Agreement shall be deemed to be a debt owing to GY, payable by the Manufacturer to the Yukon Minister of Finance.

4.6 Payment. The Manufacturer shall pay any amounts owing under this Agreement to the Yukon Minister of Finance

a) within thirty (30) days after receiving the drug quantity data supplied under Article 4.3;

b) in Canadian dollars; and

c) by cheque payable to the GY "Minister of Finance" addressed to GY in accordance with Article 7.1, or such other manner as agreed to by the Parties.

4.7 **Interest Rate.** GY 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 GY on overdue accounts receivable.

4.8 **Discrepancies.** Any potential discrepancies identified by the Manufacturer with respect to the amount of the Volume Discount that the Manufacturer is required to pay must be presented to GY in writing within 90 days of the Manufacturer receiving the section 4.2 calculation. Such notification shall NOT relieve the Manufacturer of the obligation to make the section 4.1 payment, including the amount disputed by the due date as outlined in section 4.6. Where the amount of Discount that the Manufacturer is required to pay is modified following review of the discrepancies raised, and agreed to by GY, the adjustment will be applied to the subsequent invoice or invoices.

ARTICLE 5
Confidentiality

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

"Aggregate Program Data" means Yukon PEB Programs drug quantity data in aggregate form which: **(a)** relates to multiple manufacturers and products but does not identify or reveal any individual person, manufacturer or product; and **(b)** is derived, in part, from information resulting from this Agreement;

"ATIPPA" means the Yukon *Access to Information and Protection of Privacy Act* as amended from time to time;

"Confidential Information" means any and all information or data that were supplied or communicated to one Party 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 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, but excludes Aggregate Program Data; and

"HIPMA" means the Yukon *Health Information and Privacy Management Act*.

5.2 Confidential Information. GY 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.

5.3 Mutual Notice Obligation. If a Party is required by Applicable Law to disclose Confidential Information under Article 5.2(b), the disclosing Party shall notify the other Party at least thirty (30) days prior to the disclosure, where the giving of such notice is possible in the circumstances. If it is not possible in the circumstances for a Party to comply with the minimum thirty (30)-day notice requirement, the disclosing Party shall notify the other Party as soon as possible following receipt of the disclosure requirement made under Applicable Law.

5.4 GY to Notify Manufacturer of Access Requests under ATIPPA. GY shall promptly notify the Manufacturer in writing if it becomes aware that an access request has been made under ATIPPA for Confidential Information.

5.5 ATIPPA Notice, Submissions and Appeal Provisions. The Parties acknowledge the notice requirements and submission and appeal provisions of ATIPPA as they apply to "*Disclosure harmful to third party business interests*".

5.6 GY and Manufacturer May Publish. Notwithstanding Article 5.2, GY 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 Applicable Law.

5.7 No Public Announcements. The Manufacturer shall not communicate publicly any information under this Agreement concerning the coverage or funding of any Drug Product under the PEB programs until such time as the PEB programs' Drug Product coverage or funding is announced or otherwise made public by GY.

5.8 Acquisition of Personal Health Information. In the event that the Manufacturer finds itself in possession of personal health information, the Manufacturer will immediately forward that information to GY. Immediately upon request by GY, the Manufacturer will

delete the personal health information from its records.

ARTICLE 6
Termination

6.1 Termination Without Cause.

a) Where this Agreement pertains to only one Drug Product, GY may terminate this Agreement at any time, without cause, upon giving at least thirty (30) days notice to the Manufacturer.

b) Where this Agreement pertains to more than one Drug Product, GY may terminate the application of this Agreement to one or more Drug Products at any time, without cause, upon giving at least thirty (30) Day Notice to the Manufacturer. The Agreement shall continue to have effect in respect of any remaining Drug Products to which the termination does not apply. For clarity, if the Agreement is terminated in respect of a Drug Product under this clause, Article 10 (Survival) applies to the termination in respect of that Drug Product.

6.2 Immediate Termination by GY. GY may terminate the Agreement immediately upon giving notice to the Manufacturer if:

a) in the opinion of GY acting reasonably:

(i) the Manufacturer has knowingly provided false or misleading information in any communication with GY;

(ii) the Manufacturer has breached any provision of this Agreement; or

(iii) termination is necessary for reasons concerning the protection of public health or safety;

b) any agency/department of Canada or Yukon:

(i) requires the termination of this Agreement; or

(ii) requires the Manufacturer to withdraw, suspend the sale of, or recall the Product from the entire Canadian market;

c) the Manufacturer decides to withdraw, suspend the sale of, or recall all of the Product from the entire Canadian market

d) the Manufacturer makes an assignment, proposal, compromise or arrangement for the benefit of creditors, becomes insolvent or is petitioned into bankruptcy, or files for the appointment of a receiver; or

e) the Manufacturer ceases to carry on business.

ARTICLE 7
Notices

7.1 **Notice.** The Parties shall provide addresses for any notices under this Agreement. Notices will be sent to the address provided by the other Party. The delivery of a notice may be by hand, courier, mail, or electronic mail. A notice delivered by one Party in accordance with this Agreement will be deemed to have been received by the other Party:

1. if delivered in person or by courier, on the date of delivery;

2. if sent by mail, five (5) calendar days after the date on which it was mailed;

3. if sent by electronic mail, on the date of its transmission if there is no indication of failure of receipt communicated to the sender and the date of transmission is a Business Day and received at the place of receipt during the hours of 8:00 am to 5: 00 pm, and if not received on a Business Day or during such hours, then it shall be deemed to have been received at the opening of business at the place of receipt on the next Business Day following the transmission thereof.

Contact information for a party may be changed by notice to the other party setting out the new address in accordance with this clause. For the purposes of this Agreement.

To GY:	**To the Manufacturer:**
Department of Health and Social Services	NAME
Insured Health Services (H-2)	ADDRESS
4th Floor, 204 Lambert Street	ADDRESS
Whitehorse, YT Y1A 1Z4	

Summary of Comments on 25-145 Working Records.pdf

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Number: 1 Author: Marie Claire.Savoie Date: 2024-07-12 3:10:00 PM

Manufacturer to complete

Attention: Director, Insured Health Programs	**Attention:** NAME
Fax: (867) 393-6486	**Fax:**
Telephone: (867) 667-5202	**Telephone:**
Email: marieclaire.savoie@yukon.ca	**Email:**

ARTICLE 8
General

8.1 **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.

8.2 **Severability.** If any provision of this Agreement is held to be invalid, unenforceable or illegal to any extent, such provision may be severed and such invalidity, unenforceability or illegality will not prejudice or affect the validity, enforceability and legality of the remaining provisions of this Agreement.

8.3 **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 venturer, 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.

8.4 **Applicable Law.** This Agreement will be deemed to have been made in Yukon and will be governed, interpreted, and enforced by the laws of Yukon and Canada without regard to conflict of law principles that would impose a law of another jurisdiction, and both Parties irrevocably submit and attorn to the exclusive jurisdiction of the courts in Yukon.

8.5 **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.

8.6 **Waiver.** No action or failure to act by a Party shall constitute a waiver of any right or duty afforded to it under the Agreement, nor shall any such action or failure to act

constitute an approval of or acquiescence in any breach thereunder, except as may be specifically agreed to in writing by the Party.

8.7 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.

8.8 Time of the Essence. Time shall be of the essence in the performance of the obligations under this Agreement.

8.9 Entire Agreement. This Agreement together with the attached Schedules and any other Attachments 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.

8.10 Written Amendments by Mutual Agreement. This Agreement may be amended at any time at the discretion of either Party and subject to the Parties' mutual agreement. With the exception of Article 3.4, above, 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 GY.

8.11 GY's Authority Maintained. Nothing in this Agreement shall limit the authority of GY to extend or revoke coverage of any drug product under the PEB programs.

8.12 Assignment. The Manufacturer shall not assign this Agreement (either in whole or in part) to any other Person without the prior written consent of GY, which consent shall not be unreasonably withheld.

8.13 Ethical Conduct. Neither Party shall perform any actions that are prohibited by local and other anti-corruption laws that may be applicable to one or both Parties to this Agreement.

8.14 Conflict with LOI. The terms of the LOI are incorporated into this Agreement. However, if any term or terms of this Agreement conflict with any term or terms of the LOI, this Agreement prevails.

ARTICLE 9
Schedules

9.1 Schedules. The following are the Schedules attached to and forming part of this Agreement.

a) Schedule "A" – Letter of Intent dated_____,2024

b) Schedule "B" – Drug Benefit Prices

c) Schedule "C" – Calculation of Volume Discount

d) Schedule "D" – Inclusion and Exclusion Criteria (by Drug Product)

ARTICLE 10
Survival

10.1 Survival. The Parties intend that those sections of this Agreement which, by their nature, are intended to survive, shall survive the termination or expiry of this Agreement.

ARTICLE 11

Effective date of Agreement

11.1 Effective Date of Agreement. This agreement is effective [month, day, year]

IN WITNESS WHEREOF the Parties have executed this Agreement made on the date(s) set out below.

NAME OF COMPANY	**GOVERNMENT OF YUKON represented by the Minister of Health and Social Services**
_____	_____
NAME:	Shauna Demers
TITLE: I have the authority to bind the Manufacturer	Director under the Yukon *Health Care Insurance Plan Act*
EMAIL:	
Witness Signature:	Witness Signature: _____
Witness Name: (Please print)	Witness Name: _____ (Please print)
EMAIL:	
Signature Date: _____	Signature Date: _____

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Number: 1 Author: Marie Claire.Savoie Date: 2024-07-12 3:12:00 PM
Manufacturer to complete. Please note we require two signatures and two emails to have the signatures done via Adobe Sign.

SCHEDULE "A"

Letter of Intent dated_____,20_

Schedule "B"

Drug Benefit Prices

As per section _____of the LOI attached hetero as Schedule A

SCHEDULE "C"

Calculation of Drug Product Volume Discount

As per Section __ of the LOI attached hetero as Schedule A

Except that, for this Product Listing Agreement, the following definition of "MP" is:

MP = the maximum reimbursement amount per unit, which is LP plus the maximum allowable markup(s) but excluding dispensing fee.

SCHEDULE "D"

INCLUSION AND EXCLUSION CRITERIA

(by Drug Product)