GENERIC LISTING SUBMISSION APPLICATION

("the Application")

SUBMITTED TO:

HER MAJESTY THE QUEEN IN RIGHT OF THE PROVINCE OF BRITISH COLUMBIA
AS REPRESENTED BY THE MINISTER OF HEALTH
1515 BLANSHARD STREET, VICTORIA, BC V8W 3C8

("the Province")

BY:

SUPPLIER NAME:_____

SUPPLIER ADDRESS:_____

("the Supplier")

1.0 Throughout this Application, the following definitions apply:

"*Accepted*" means, in relation to any generic drug product, a product which the Province lists on a PharmaCare formulary and makes eligible for PharmaCare reimbursement during part or all of the Pricing Period.

"Affiliate" means an "affiliate" as defined in the *Business Corporations Act*, S.B.C. 2002, c. 57.

"Agreed Price" means the unit price at which a Product that is designated as Accepted will be available for sale from the Supplier to distributors in British Columbia during the Pricing Period, and more specifically means:

(a) in relation to a Product designated as Accepted pursuant to section 3.0, the Manufacturer's List Price; and
(b) in relation to a Product designated as Accepted pursuant to section 4.0, the price determined by the Province.

"Allowance" means any monetary or non-monetary consideration related to the purchase or distribution of Accepted Products by a distributor or retail pharmacy and which is provided, directly or indirectly, to, or on account of, that distributor or retail pharmacy by the Supplier, an Affiliate or an agent of the Supplier or Affiliate.

"*Application Date*" means the date this Application is received by the Province from the Supplier.

"Competitor Product" means a generic drug product that is supplied by an entity other than the Supplier, and that is part of the same Tiered Pricing Category as a Product.

"Cross Licensed Product" means a generic drug product that is the subject of a Cross Licensing Agreement.

"Cross Licensing Agreement" means an agreement between two or more entities which enables a generic drug product to be sold under a different name, under a different manufacturer / supplier name, or with different packaging, appearance or drug identification number.

"LCA Category" means a category of drugs established under section 3(1)(a) of the Drug Price Regulation that is included in the low cost alternative program of the Province.

"Manufacturer's List Price", in relation to a Product or a Competitor Product, is the price which the Supplier (or, in the case of a Competitor Product, the supplier of the Competitor Product) proposes to the Province as the published unit price at which the Product (or the Competitor Product), upon being designated as Accepted, will be available for sale from the Supplier (or, in the case of a Competitor Product, the supplier of the Competitor Product) to distributors in British Columbia during the Pricing

Period, and shall be considered the "manufacturer's list price" as defined in the *Drug Price Regulation*, B.C. Reg.233/2012 ("the Drug Price Regulation").

"*MALP*" means the Maximum Accepted List Price, as determined by the Province pursuant to the *Pharmaceutical Services Act* and the Drug Price Regulation, B.C. Reg. 344/2012.

"Modified Release Drug" means a drug product that is in a dosage form for which the drug-release characteristics of time-course and drug-release location are chosen to accomplish therapeutic or convenience objectives not offered by conventional dosage forms.

"Non-Oral Solid" means a drug product that is in a form other than oral solid form, including but not limited to liquid, cream, suspension, patch, injectable or inhaler form, and for the purposes of this Application, does not include a Modified Release Drug.

"Oral Solid" means a drug that

(a) is available in a solid form, including as a gel capsule, chewable tablet or wafer;
(b) is intended to be taken orally and for the purposes of this Application, does not include a Modified Release Drug.

"PharmaCare" means the public drug plan funded by the Province through its Ministry of Health.

"Pricing Period" means the period commencing on the Application date and continuing until and including March 31, 2017, inclusive.

"Pricing Tier" means the applicable Pricing Tier set out in Exhibit B.

"Product" means a drug that is supplied by the Supplier.

"Tiered Pricing Category" means a LCA Category included in the Tiered Pricing Framework during the Pricing Period.

"Tiered Pricing Framework" means the pricing arrangement utilized by the Province whereby, for specific categories of generic drug products, the price per unit of a product to be listed on the PharmaCare formulary may be determined based on certain criteria, including the number of suppliers of products in that category.

"*Unaccepted"* means, in relation to any generic drug product, a product which the Province determines will not be eligible for listing on a PharmaCare formulary and for PharmaCare reimbursement during the Pricing Period or that otherwise loses the status of Accepted at any time prior to the end of the Pricing Period.

2.0 By signing and submitting this Application to the Province and in consideration of the Province agreeing to consider for designation as Accepted each Product listed in the Generic Listing Submission Workbook (attached hereto as "Exhibit A") for which the Supplier proposes a Manufacturer's List Price, the Supplier acknowledges and agrees to all terms, conditions and stipulations set out in this Application. The Supplier understands and acknowledges that each Product listed in Exhibit A will be considered on an individual basis by the Province for designation as Accepted, and that designation of a Product as Accepted will be at the sole discretion of the Province, as will the cancellation of any such designation. The Supplier acknowledges that this Application shall constitute an offer and a decision by the Province to designate a Product as Accepted shall, in relation to that Product, constitute acceptance by the Province of such offer. More specifically, the Parties intend for this Application to form a legally binding agreement in relation to any Product that is designated as Accepted.

3.0 For each Product listed in Exhibit A for which the Manufacturer's List Price proposed by the Supplier is equal to or less than the applicable MALP and which the Province designates as Accepted, the Supplier

agrees to supply the Product in British Columbia throughout the Pricing Period at the Agreed Price that is equal to the Manufacturer's List Price proposed in Exhibit A, in accordance with the *Pharmaceutical Services Act* and its associated regulations, and on the terms and conditions set out in this Application.

4.0 For each Product listed in Exhibit A for which the Manufacturer's List Price proposed by the Supplier is greater than the applicable MALP, the Province will consider whether the Product meets the criteria set out in the Drug Price Regulation to be designated as a provisional drug. If the Province, in its sole discretion, determines that the Product does not meet the criteria, the Product will be designated as Unaccepted. If the Province, in its sole discretion, determines that the Product does meet the criteria, the Province may designate the Product as Accepted. If the Product is designated as Accepted, the Supplier agrees to supply the Product in British Columbia throughout the Pricing Period (in accordance with the *Pharmaceutical Services Act* and its associated regulations, and on the terms and conditions set out in this Application) at the Agreed Price that is determined by the Province in its sole discretion, such Agreed Price to be either

(a) the Manufacturer's List Price proposed by the Supplier, in the case of a Product that is not included in a Tiered Pricing Category; or

(b) the price calculated pursuant to Exhibit B, in the case of a Product that is included in or is becoming included in a Tiered Pricing Category.

Pursuant to section 14(2) of the Drug Price Regulation, the Province may cancel the designation of a Product as a provisional drug at any time during the Pricing Period, and the Product will then be designated as Unaccepted for the remainder of the Pricing Period.

5.0 Notwithstanding any other provision of this Application, the Province may require the Agreed Price of a Product designated as Accepted pursuant to section 4.0 that is included in or is becoming included in a Tiered Pricing Category to be changed for any reason, including but not limited to:

(a) a product that has been designated Accepted becoming included in a Tiered Pricing Category during the Pricing Period;

(b) a product that has been designated as Accepted and is included in a Tiered Pricing Category becoming subject to a different Pricing Tier during the Pricing Period;

(c) the Province designating a Competitor Product as Accepted or cancelling such a designation during the Pricing Period.

If the Supplier does not consent to the Agreed Price of an Accepted Product being changed as required by the Province, the Province may, in its sole discretion, designate the Product as Unaccepted.

6.0 The Supplier warrants that each Product, at the applicable Agreed Price, is available in sufficient amounts for delivery to pharmacies in British Columbia starting on the Application Date and shall remain available as such through to the end of the Pricing Period. If, at any time, the Supplier foresees that it may not meet demand in British Columbia for any Accepted product during the Pricing Period, it shall, as soon as is reasonably practicable, notify the Province in writing. The Supplier shall further take all reasonable steps necessary to rectify the aforementioned situation as quickly as possible. Notwithstanding the above, the Supplier understands and acknowledges that the Province may, in its sole discretion and without notice, determine that the Supplier is unable to meet demand in British Columbia for an Accepted product, and change the designation for such Product from Accepted to Unaccepted, thereby cancelling the listing of the Product on a PharmaCare formulary and making the Product no longer eligible for PharmaCare reimbursement. Once such Product is designated as

Unaccepted, the Province is under no obligation to reconsider its designation of that Product until the next pricing period.

7.0 In relation to any Product that is designated as Accepted pursuant to section 4.0, the Supplier acknowledges that:

(a) the determination of the number of generic drug products in each Tiered Pricing Category is in the sole discretion of the Province;

(b) the determination of the number of generic drug products in each Tiered Pricing Category is subject to change during the Pricing Period, and therefore the Pricing Tier (as described in Exhibit B) applicable to any Tiered Pricing Category is subject to change; and

(c) the Pricing Tier applicable to the Product will be determined by the Province.

Subject to Section 9.0, if, during the Pricing Period, there is a change to the Pricing Tier applicable to a Product that has been designated as Accepted, the Supplier will be provided with an opportunity to submit a different Manufacturer's List Price for the Product than the Manufacturer's List Price submitted in Exhibit A, and the Province will consider that new Manufacturer's List Price to determine whether to continue the designation of the Product as Accepted or whether to designate the Product as Unaccepted.

8.0 In relation to any Product which is included in or becomes included in a Tiered Pricing Category and for which the Manufacturer's List Price proposed by the Supplier is greater than:

(a) for Oral Solids, twenty-five percent (25%) of the manufacturer's list price of the LCA drug comparator for the LCA category of the Product, as determined by the Province pursuant to the Drug Price Regulation;
(b) for Non-Oral Solids, thirty-five percent (35%) of the manufacturer's list price of the LCA drug comparator for the LCA category of the Product, as determined by the Province pursuant to the Drug Price Regulation,

if one or more suppliers submits a Manufacturer's List Price for a Competitor Product that is:

(a) for Oral Solids, equal to or greater than twenty-five percent (25%) of the manufacturer's list price of the LCA drug comparator for the LCA category of the Product, as determined by the Province pursuant to the Drug Price Regulation; or

(b) for Non-Oral Solids, equal to or greater than thirty-five percent (35%) of the manufacturer's list price of the LCA drug comparator for the LCA category of the Product, as determined by the Province pursuant to the Drug Price Regulation,

the Supplier will be provided with an opportunity to submit a Manufacturer's List Price for the Product that is equal to or less than the Manufacturer's List Price submitted for that Competitor Product. If the Supplier submits a Manufacturer's List Price for the Product that is equal to or less than the Manufacturer's List Price submitted for the Competitor Product, the Province will consider that reduced Manufacturer's List Price to determine whether to designate the Product as Accepted or, if the Product had already been designated as Accepted, to continue to designate the Product as Accepted. If the Supplier fails to submit a Manufacturer's List Price for the Product that is equal to or less than the Manufacturer's List Price submitted for the Competitor Product, the Product may be designated as Unaccepted by the Province.

9.0 The Supplier acknowledges that if any supplier submits a Manufacturer's List Price for a Competitor Product that:

(a) in the case of an Oral Solid or Modified Release Drug, is less than twenty-five percent (25%) of the manufacturer's list price of the LCA drug comparator for the LCA category of the Product, as determined by the Province pursuant to the Drug Price Regulation; or

(b) in the case of a Non-Oral Solid, is less than thirty-five percent (35%) of the manufacturer's list price of the LCA drug comparator for the LCA category of the Product, as determined by the Province pursuant to the Drug Price Regulation,

(in either case, "Below Tiered Pricing MLP"),

all other products in the Tiered Pricing Category for which the Manufacturer's List Price submitted is:

a) in the case of an Oral Solid or Modified Release Drug, greater than the Below Tiered Pricing MLP,
b) in the case of a Non-Oral Solid, greater than the Below Tiered Pricing MLP and greater than 35%,

may be designated as Unaccepted, and neither the subsequent addition of a generic drug product to a public drug plan formulary in any jurisdiction in Canada, nor the subsequent removal of a generic drug product from a public drug plan formulary in any jurisdiction in Canada will cause the implementation of the pricing calculation outlined in Exhibit B. Despite Section 7.0, in the circumstances outlined above, the Supplier will not be provided with an opportunity to provide a different Manufacturer's List Price than the Manufacturer's List Price provided in Exhibit A.

10.0 The Supplier acknowledges that the Province has full discretion to designate as Unaccepted any Product for which a Manufacturer's List Price, as proposed by the Supplier in Exhibit A, is greater than the applicable MALP. The Supplier further acknowledges that once a Product is designated as Unaccepted for any reason, the Province is under no obligation to reconsider its designation of that Product at any time prior to the beginning of the next pricing period regardless of any subsequent change related to the Product, including but not limited to a change to:

(a) the Manufacturer's List Price for the Product;

(b) the name of the Product;

(c) the packaging or appearance of the Product;

(d) the Drug Identification Number of the Product; or

(e) the manufacturer or supplier of the Product.

Without limiting the foregoing, if any product is a Cross Licensed Product and the Province has designated that product as Unaccepted for the Pricing Period (whether or not, at the time it was so designated, it had the same name, packaging, appearance, Drug Identification Number, or supplier or manufacturer), the Province is under no obligation to reconsider its designation of that product until the next pricing period.

11.0 The Supplier acknowledges that the Province is under no obligation to consider for designation as an Accepted Product any Product for which a Notice of Compliance has been issued by Health Canada on or before November 9, 2015.

12.0 The Supplier shall, if requested by the Province, report to the Province the value of all Allowances provided by the Supplier, its agents, its Affiliates and its Affiliate's agents, directly or indirectly to, or on

account of, each distributor and retail pharmacy in British Columbia for each period of time specified by the Province. Each such report shall be provided in a format determined by the Province and shall clearly show for each distributor or retail pharmacy involved, in relation to the period of time specified, the total value of Accepted Products supplied to the distributor or retail pharmacy and the total value of Allowances provided to the distributor or retail pharmacy. Each such report will be provided by a date to be determined by the Province, but will not be required by the Province more than once in any calendar year.

13.0 The Supplier warrants and represents that all information provided by the Supplier to the Province in relation to a Product is accurate and complete, and the Supplier acknowledges that the Province will rely on the information provided by the Supplier to determine whether to designate a Product as Accepted.

If:

(a) the Supplier provides inaccurate or incomplete information in relation to a Product;

(b) the Province designates the Product as Accepted, and in doing so, relies in whole or in part on the inaccurate or incomplete information provided by the Supplier; and

(c) the Province subsequently designates the Product as Unaccepted on the basis that the information provided by the Supplier was inaccurate or incomplete

the Supplier, if required by the Province, will indemnify the Province for any costs (including costs relating to securing and/or subsidizing, or increasing the subsidy for, products provided by another supplier, additional dispensing fees, and all actual legal expenses) incurred, directly or indirectly, by the Province in relation to the change in designation of the Product.

14.0 Failure on the part of the Supplier to comply with the provisions of the *Pharmaceutical Services Act* and its associated regulations, or with the terms and conditions of this Application, including but not limited to the obligation to maintain the Agreed Price for Accepted products throughout the Pricing Period and the obligation to submit reports on Allowances, shall constitute material breach of this Agreement, and may result in the Province taking any action or exercising any rights available, including changing the designation of Products from Accepted to Unaccepted. Any such action taken by the Province shall be in addition to, and not in the place of, any remedy or action available under the *Pharmaceutical Services Act* and its associated regulations.

15.0 The Supplier is under no obligation in regard to the Manufacturer's List Price of any Product that is designated as Unaccepted.

16.0 The Supplier confirms that it has obtained all approvals needed to market and distribute each Product within Canada and British Columbia, including without limitation, the valid and current Notice of Compliance(s) issued by Health Canada, which Supplier has attached hereto as "Exhibit C".

17.0 The Supplier consents to the Province engaging in unrestricted communication with its agents, contractors, Health Canada, other provinces and territories including their ministries, agencies and departments, the Canadian Agency for Drugs and Technologies in Health, the Patented Medicines Prices Review Board, health authorities and health care practitioners in relation to any of the Products.

18.0 Notwithstanding anything in this Application, actual PharmaCare reimbursement is subject to the *Pharmaceutical Services Act* and its association regulations, PharmaCare policies, plan rules, and reimbursement practices, as may be amended from time to time at the sole discretion of the Province. The Supplier further acknowledges that the Province, when deciding whether to make a generic drug

eligible for PharmaCare coverage, has sole discretion in determining whether any generic drug meets eligibility criteria other than list price, as may be amended from time to time.

19.0 Nothing contained within this Application is intended to supersede the *Pharmaceutical Services Act* or its associated regulations, and nothing contained within this Application prevents the Government of British Columbia from enacting or amending legislation respecting or relating to any matter contained in this Application. If there is a conflict between any provision of this Application or the *Pharmaceutical Services Act* or its associated regulations, then such conflict will be resolved as follows:

(a) a provision in the *Pharmaceutical Services Act* will prevail over any conflicting provision in its associated regulations, and over any conflicting provision in this Application; and

(b) a provision in an associated regulation to the *Pharmaceutical Services Act* will prevail over any conflicting provision in this Application.

20.0 The Province is subject to the British Columbia *Freedom of Information and Protection of Privacy Act* and must comply with any order of the Office of the Information and Privacy Commissioner.

21.0 Any Exhibits to this Application are an integral part of this Application.

22.0 This Application and any contractual arrangement resulting from such shall be governed by and construed under the laws of British Columbia and the parties agree to attorn to the exclusive jurisdiction of the courts of the province of British Columbia.

23.0 The terms and provisions of this Application shall be construed fairly as to each party and without regard to which party was generally responsible for the preparation of this Application.

24.0 This Application may be executed by facsimile and will be binding upon the Supplier, the Supplier's successors and assigns.

Agreed to for and on behalf of the Supplier by a duly authorized representative:

_____

(signature)

Name & Title: _____ Date: _____

EXHIBIT B

CALCULATION OF AGREED PRICE

1. Calculation of Agreed Price

Subject to Section 2 of this Exhibit, the Agreed Price for an Accepted product that is included in or that becomes included in a Tiered Pricing Category will be determined based on the Pricing Tier which the Province determines will apply to a particular Tiered Pricing Category, and more specifically, as follows:

Pricing Tier 1:

Where the Product is an Oral Solid, a Non-Oral Solid, or a Modified Release Drug, it is the only generic drug product included in the Tiered Pricing Category, and the equivalent brand name drug product is not the subject of a formulary listing agreement in any province or territory in Canada other than Quebec, the Agreed Price will be the lesser of:

(a)

(i) for LCA categories established prior to April 1, 2013, eighty-five percent (85%) of the base price set out in Column 2 of the Drug Price Regulation Schedule opposite the applicable LCA category;

(ii) for LCA categories established after April 1, 2013, eighty-five percent (85%) of the manufacturer's list price of the LCA drug comparator for the LCA category of the Product, as determined by the Province pursuant to the Drug Price Regulation

and

(b) the Manufacturer's List Price for the product.

Notwithstanding the foregoing, the Province may, in its sole discretion, determine that the Agreed Price will be some amount other than as calculated above. In such a circumstance, the Province will provide the Supplier with written notification of the Agreed Price and the Supplier will be permitted an opportunity to withdraw its request for a listing prior to the Product being designated as Accepted by the Province.

Pricing Tier 1A:

Where the Product is an Oral Solid, a Non-Oral Solid, or a Modified Release Drug, it is the only generic drug product included in the Tiered Pricing Category, and the equivalent brand name drug product is the subject of a formulary listing agreement in any province or territory in Canada other than Quebec, the Agreed Price will be the lesser of:

(a)

(i) for LCA categories established prior to April 1, 2013, seventy-five percent (75%) of the base price set out in Column 2 of the Drug Price Regulation Schedule opposite the applicable LCA category;

(ii) for LCA categories established after April 1, 2013, seventy-five percent (75%) of the manufacturer's list price of the LCA drug comparator for the LCA category of the Product, as determined by the Province pursuant to the Drug Price Regulation

and

(b) the Manufacturer's List price for the product.

Notwithstanding the foregoing, the Province may, in its sole discretion, determine that the Agreed Price will be some amount other than as calculated above. In such a circumstance, the Province will provide the Supplier with written notification of the Agreed Price and the Supplier will be permitted an opportunity to withdraw its request for a listing prior to the Product being designated as Accepted by the Province.

Pricing Tier 2:

Where the Product is an Oral Solid, a Non-Oral Solid, or a Modified Release Drug, and it is one of two generic drug products included in the Tiered Pricing Category, the Agreed Price will be the lesser of:

(a)

(i) for LCA categories established prior to April 1, 2013, fifty percent (50%) of the base price set out in Column 2 of the Drug Price Regulation Schedule opposite the applicable LCA category;

(ii) for LCA categories established after April 1, 2013, fifty percent (50%) of the manufacturer's list price of the LCA drug comparator for the LCA category of the Product, as determined by the Province pursuant to the Drug Price Regulation

and

(b) the lowest Manufacturer's List Price for a generic drug product in that Tiered Pricing Category.

Notwithstanding the foregoing, the Province may, in its sole discretion, determine that the Agreed Price will be some amount other than as calculated above. In such a circumstance, the Province will provide the Supplier with written notification of the Agreed Price and the Supplier will be permitted an opportunity to withdraw its request for a listing prior to the Product being designated as Accepted by the Province.

Pricing Tier 3:

Where the Product is an Oral Solid or a Modified Release Drug, and it is one of three or more generic drug products included in the Tiered Pricing Category, the Agreed Price will be the lesser of:

(a)

(i) for LCA categories established prior to April 1, 2013, twenty-five percent (25%) of the base price set out in Column 2 of the Drug Price Regulation Schedule opposite the applicable LCA category;

(ii) for LCA categories established after April 1, 2013, twenty-five percent (25%) of the manufacturer's list price of the LCA drug comparator for the LCA category of the Product, as determined by the Province pursuant to the Drug Price Regulation

and

(b) the lowest Manufacturer's List Price for a generic drug product in that Tiered Pricing Category.

Notwithstanding the foregoing, the Province may, in its sole discretion, determine that the Agreed Price will be some amount other than as calculated above. In such a circumstance, the Province will provide the Supplier with written notification of the Agreed Price and the Supplier will be permitted an opportunity to withdraw its request for a listing prior to the Product being designated as Accepted by the Province.

Pricing Tier 4:

Where the Product is a non-Oral Solid and it is one of three or more generic drugs included in the Tiered Pricing Category, the Agreed Price will be the lesser of:

(a)

(i) for LCA categories established prior to April 1, 2013, thirty-five percent (35%) of the base price set out in Column 2 of the Drug Price Regulation Schedule opposite the applicable LCA category;

(ii) for LCA categories established after April 1, 2013, thirty-five percent (35%) of the manufacturer's list price of the LCA drug comparator for the LCA category of the Product, as determined by the Province pursuant to the Drug Price Regulation

and

(b) the lowest Manufacturer's List Price for a generic drug product in that Tiered Pricing Category.

Notwithstanding the foregoing, the Province may, in its sole discretion, determine that the Agreed Price will be some amount other than as calculated above. In such a circumstance, the Province will provide the Supplier with written notification of the Agreed Price and the Supplier will be permitted an opportunity to withdraw its request for a listing prior to the Product being designated as Accepted by the Province.

2. <u>Pan-Canadian Pricing at Eighteen Percent (18%)</u>

Where the Province has entered into an agreement with the Canadian Generic Pharmaceutical Association and one or more provincial or territorial governments in Canada, and that agreement provides that a LCA Category is to be subject to pan-Canadian pricing at eighteen percent (18%), the Agreed Price for any Accepted product in that LCA Category will be as set out in the agreement.