LIST PRICE PROPOSAL AGREEMENT

("the Agreement")

BETWEEN:

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")

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NAME OF SUPPLIER: APOTEX INC.

ADDRESS OF SUPPLIER: 150 Signe 4 Deve Toward

(collectively, "the Parties")

WHEREAS:

- A. The Province is responsible for the operation and funding of the PharmaCare program ("PharmaCare"), including the establishment of terms and conditions for the determination, to be made by the Province, of which pharmaceutical products will be eligible for reimbursement through PharmaCare;
- B. The Supplier supplies one or more generic pharmaceutical products for sale in the British Columbia market:
- C. The Province requires that any supplier seeking to have a generic pharmaceutical product determined as eligible for reimbursement through PharmaCare as of April 2, 2012 must submit a proposed List Price for such product, with the Province to subsequently make a determination of whether that product will be eligible for reimbursement through PharmaCare;
- D. The Supplier seeks a determination that certain of the Supplier's pharmaceutical products are eligible for reimbursement through PharmaCare as of April 2, 2012;

NOW THEREFORE in consideration of the mutual promises and covenants set forth in this Agreement, the Parties agree as follows:

1.0 Throughout this Agreement, the following definitions apply: "Accepted Product" means any Product which the Province makes eligible for PharmaCare reimbursement during part or all of the Pricing Period.

"Affiliate" means any corporation or entity that is directly or indirectly controlled by, or controls or is under common control with, the Supplier, provided that control shall mean ownership of more than fifty percent (50%) of another corporation or entity, or the power to direct major decisions of another corporation or entity, including, without limitation, the power to direct management and policies of another corporation or entity, whether by reason of ownership, agreement or otherwise.

"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.

"List Price", in relation to a Product shall be the published unit price at which the Product, upon becoming an Accepted Product, is available for sale from the Supplier to distributors in British Columbia.

"MALP" means the Maximum Accepted List Price, as communicated by the Province.

"Pre-Populated Data" means all data pre-populated by the Province into the orange-coloured columns grouped under the overall heading of "Manufacturer's Product Information" within the spreadsheet entitled "Submission Sheet" contained in Exhibit A.

"Pricing Period" means the period commencing on March 3, 2012 and continuing until and including March 31, 2013 unless this Agreement is terminated pursuant to section 14.0, in which case the Pricing Period ends on the effective date of the termination.

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

"Supplier Confidential Information" means any technical, business, financial, personal, employee, operations, scientific or other information or data, findings, documents, reports, plans, working plans and other material of the Supplier that is supplied to or obtained by the Province as a result of this Agreement.

"Unaccepted Product" means any Product which the Province determines will not be eligible for PharmaCare reimbursement during the Pricing Period-or that otherwise loses the status of Accepted Product prior to the end of the Pricing Period.

- 2.0 For each of the Products listed in the Price Confirmation Workbook (attached hereto as "Exhibit A") that the Province designates to be an Accepted Product, the Supplier agrees to supply the Product in British Columbia at the List Price proposed by the Supplier in Exhibit A, and on the terms and conditions set out in this Agreement.
- 3.0 Notwithstanding Section 2.0, if, during the Pricing Period, the Supplier seeks to have a Product not listed in Exhibit A designated as an Accepted Product, the Supplier shall submit to the Province, in the

form and manner required by the Province, information about the Product, including but not limited to the List Price proposed by the Supplier for the Product. If the Province designates the Product to be an Accepted Product, the Supplier agrees to supply the Product in British Columbia at the List Price proposed by the Supplier, and on the terms and conditions set out in this Agreement. For greater clarity, this section 3.0 applies only to Products that are not already listed in Exhibit A and that have received their Notice of Compliance (NOC) from Health Canada after January 13, 2012.

- 4.0 The Supplier shall ensure that the List Price of each Accepted Product shall be in effect throughout the duration of the Pricing Period. The Supplier understands and acknowledges that the supplying of any Accepted Product at a price higher than the List Price during the Pricing Period will cause harm to the Province as it would likely result, whether directly or indirectly, in an increase to the PharmaCare program's reimbursement expenditures.
- 5.0 The Supplier warrants that each Product listed in Exhibit A shall be available in sufficient amounts for delivery to pharmacies in British Columbia commencing on March 3, 2012 and continuing to the end of the Pricing Period. Despite the foregoing, if a Product listed in Exhibit A will not be available in sufficient amounts by March 3, 2012, the Supplier must provide, in Exhibit A, an estimated date by which the Product will be available. When the Province receives confirmation from the Supplier that such Product is available in sufficient amounts, the Province will consider the Product for designation as an Accepted Product.
- 6.0 If at any time the Supplier foresees that it may not meet demand in British Columbia for any Accepted Product during the Pricing Period, the Supplier 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, 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 Product to Unaccepted Product, thereby making the Product no longer eligible for PharmaCare reimbursement.
- 7.0 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.
- 8.0 The Province will consider for designation as an Accepted Product and on an individual basis:
 - (a) each Product listed in Exhibit A for which the Supplier submits the required information, including but not limited to a List Price; and

(b) each Product which the Supplier seeks to have designated as an Accepted Product pursuant to section 3.0 and for which the Supplier submits the required information, including but not limited to a List Price.

For greater clarity, designation of an Accepted Product will be at the sole discretion of the Province.

- 9.0 The Province has full discretion to designate as an Unaccepted Product any Product for which the List Price, as proposed by the Supplier in Exhibit A, or as proposed by the Supplier pursuant to section 3.0, is greater than the applicable MALP. Once such Product is designated as an Unaccepted Product, the Province is under no obligation to reconsider its designation of that Product regardless of any subsequent change to the Supplier's proposed List Price for that Product.
- 10.0 The Supplier is under no obligation in regard to the List Price of any Product that is or becomes an Unaccepted Product.
- 11.0 Failure on the part of the Supplier to comply with the terms and conditions of this Agreement, including but not limited to the obligation to maintain List Prices for Accepted Products throughout the Pricing Period and the obligation to submit reports on Allowances, shall constitute material breach of the Agreement, and may result in the Province taking any action or exercising any rights available, including changing the designation of Accepted Products to Unaccepted Products.
- 12.0 In the event that no supplier's List Price for a product is equal to or lower than the applicable MALP or in a case in which the Province has concerns with the sufficiency of supply for those suppliers that meet the applicable MALP, the Province may, in its sole discretion, take any action or actions it deems appropriate, including provisionally designating one or more Products as an Accepted Product, and subsequently removing that designation.
- 13.0 The Supplier understands and acknowledges that all Pre-Populated Data are supplied by the Province without any guarantee, assurance or representation as to its accuracy or completeness, and that such data has been supplied in response to requests received from one or more manufacturers of pharmaceuticals for such information. The Supplier further understands and acknowledges that no reliance can or should be placed upon the Pre-Populated Data, that the Supplier itself is the appropriate party to review and verify the accuracy and completeness of all Pre-Populated Data given that the Pre-Populated Data relate directly to products believed to be marketed by the Supplier, and that the Supplier is solely responsible for ensuring the accuracy and completeness of all Product-related data that the Supplier submits to the Province, whether as part of Exhibit A or pursuant to Section 3.0, in order to propose List Prices.
- 14.0 This Agreement may be terminated by the Province upon sixty (60) days written notice to the Supplier.
- 15.0 Except where required by law, or unless provided with the express written consent of the Supplier, the Province agrees that it will not disclose any Supplier Confidential Information other than in a form and manner whereby information particular to a specific supplier cannot be identified with that supplier.

 Notwithstanding the foregoing, the Parties acknowledge that should a Product be designated as an Accepted Product, the identity of the Supplier and List Price of that Product will be publicly disclosed.

- 16.0 The Parties acknowledge that notwithstanding anything in this Agreement, actual PharmaCare reimbursement is subject to PharmaCare policies, plan rules, and reimbursement practices, as may be amended from time to time in the sole discretion of the Province. The Parties further acknowledge 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 the eligibility criteria other than list price, and those eligibility criteria may be amended from time to time.
- 17.0 The Parties acknowledge that 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.
- 18.0 The Parties acknowledge that nothing contained within this Agreement prevents the Government of British Columbia from enacting legislation respecting or relating to any matter contained in this Agreement.
- 19.0 Any written communication between the Parties, including any notice contemplated by this Agreement, is to be mailed, delivered, or faxed to the following addresses:

To the Supplier:

At the address and facsimile number noted above

To the Province:

Pharmaceutical Services Division Ministry of Health 301 – 960 Quayside Drive New Westminster, BC V3M 6G2

Facsimile No.: 604-660-5405

Attention: Executive Director, Business Management and Supplier Relations

Any written communication from either Party will be deemed to have been received by the other Party on the fifth business day after mailing if mailed, or on the date of personal delivery if delivered, or on the date of transmission if faxed.

Either-Party-may, from time to-time, notify-the-other Party in writing of a change of address or facsimile number, and following receipt of such notice, the new address or facsimile number will, for the purposes of this Agreement, be deemed to be the address or facsimile number of the Party that gave notice.

- 20.0 Any Exhibits to this Agreement are an integral part of this Agreement.
- 21.0 This Agreement shall be governed by and construed under the laws of the Province of British Columbia and the Parties agree to attorn to the exclusive jurisdiction of the courts of the Province of British Columbia.
- 22.0 The Parties acknowledge and agree that the terms and provisions of this Agreement shall be construed fairly as to each Party and not in favor of or against either Party regardless of which Party was generally

responsible for the preparation of this Agreement.

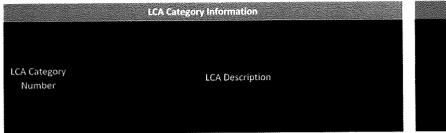
- 23.0 A waiver by either Party of any term of this Agreement or of any breach of this Agreement is effective only if that waiver is in writing and signed by the waiving Party. Such a waiver is not to be interpreted as a waiver of any other term or any other breach.
- 24.0 This Agreement may be executed by facsimile and simultaneously in two or more counterparts, each of which shall be deemed an original, but both of which together shall constitute a single agreement.

IN WITNESS WHEREOF, the Parties have each caused this Agreement to be duly executed as of the dates written below.

Agreed to for and on behalf of Her Majesty)		Agreed to for and on behalf of)
The Queen in Right of the Province of British)		HOPEX INC.
Columbia by a duly authorized representative)		by a duly authorized representative)
of the Minister of Health)		of the Supplier)
Pharmaceutical Services Division)		
Ву:		Ву:	ATow
Name:		Name:	ART TRAMONTS.
Title:		Title:	Director, Markehne
Date:		Date:	JANUARY 12,2012
		Ву:	
		Name:	
		Title:	
		Date:	

Manufacturer Submission Sheet - Data for April 2012 LCA Pricing

All data pre-populated into the orange-coloured columns grouped under the overall heading of "Manufacturer's Product Info guarantee, assurance or representation as to accuracy or completeness. No reliance can or should be placed upon such data.

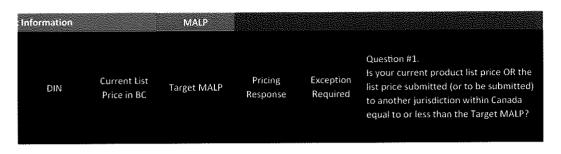




Not Responsive

1286 923 1043 922	OXYCODONE HCL SUPP.RECT 20MG OXYCODONE HCL TAB 10MG OXYCODONE HCL TAB 20MG OXYCODONE HCL TAB 5MG	
431	OXYCODONE/ACET TAB 5/325MG	APO-OXYCODONE/ACET
432	OXYCODONE/ASA TAB 5/325MG	

rmation" are supplied by the Province without any
The Supplier is solely responsible for satisfying itself as to



Not Responsive

\$1.4746 \$0.1327 \$0.2305 \$0.0901

S. 21, S. 17

2324628 \$0.1285 \$0.0450

\$0.3093 \$60.7551

Question #2. Question #3. To your knowledge, is the product the Do the costs of producing only generic product available in and distributing the British Columbia in the applicable LCA generic drug exceed the category? MALP?

MALP Calculation Information

Not Responsive

equivalent to 53.8% of the lowe	392472	SUPEUDOL 2C	\$2.7408
equivalent to 35% of the brand	2240131	OXY.IR	\$0.3792
equivalent to 35% of the brand	2240132	OXY.IR	\$0.6586
equivalent to 35% of the brand	2231934	OXY.IR	\$0.2574
equivalent to 35% of the brand	1916548	ENDOCET	\$0.1285

From:

David Young

To:

PSD BMSRS - Generic Submissions HLTH:EX;

cc:

Art Tramonte; Peter Hardwick; Elie Betito; Heather West;

Moneo, Mitch HLTH:EX; Tan, Dominic HLTH:EX; David Young;

Subject:

List Price Confirmation - APOTEX INC. Friday, January 13, 2012 4:13:12 PM

Date: Attachments:

<u>Apotex - List Price Proposal Agreement.pdf</u> <u>Apotex BC Round 3 Price Submission FINAL.xlsx</u>

BC Exclusive Products Supporting Documents Summary FINAL.xlsx

Cover letter to BC jan 13 2012 apotex.pdf Discontinuation Notices confirmation.pdf

Please find attached our submission for round 3 of the generic pricing reform. Included in this email is the following documents:

- The completed price confirmation workbook (PCW)
- · A scanned version of the signed LPPA, in PDF format
- A cover letter concerning our submission
- An excel file in support of the exclusive products in our submission
- Documentation of brand and generic discontinuation in PDF format

If you have any questions regarding our submission, please feel free to contact us anytime.

Thanks and best regards,

David Young

Marketing Manager, Pricing

Tel: (416) 749-9300 x 8400 Toll Free: (800) 268-4623 x 8400

Fax:

(416) 401-3835

www.apotex.com



From:

To:

PSD BMSRS - Generic Submissions HLTH:EX
PSD BMSRS - Generic Submissions HLTH:EX;

Subject:

В.

C. PharmaCare Message for Generic Manufacturers: List Price Proposal Agreement

Date:

Tuesday, January 10, 2012 4:09:00 PM

Attachments: List Price Proposal Agreement - April 2012.pdf

IMPORTANT COMMUNICATION FROM THE BRITISH COLUMBIA MINISTRY OF HEALTH – PHARMACEUTICAL SERVICES DIVISION

PLEASE DIRECT ALL REPLIES TO generic.submissions@gov.bc.ca

This is a very important communication that affects the eligibility of generic pharmaceuticals for coverage from B.C. PharmaCare.

Further to the communication sent to manufacturers on December 16, 2011, we are herewith enclosing the List Price Proposal Agreement (LPPA) for the upcoming pricing period.

In accordance with the aforementioned communication to manufacturers, the completed Price Confirmation Workbook (PCW), in Excel format and a scanned version of the signed LPPA, in PDF format, must be sent as electronic attachments together in one email directly back to the Province, at generic.submissions@gov.bc.ca bearing the subject heading "List Price Confirmation – (MANUFACTURER NAME)" by no later than 5:00PM (Pacific Daylight Saving Time) January 13, 2012.

Important: For manufacturers who have already submitted their completed PCWs to PSD, please **resubmit** your PCW together with a signed copy of the LPPA.

We look forward to receiving your submissions.

Regards, PSD

LCA Price List

A "Y" is found in column G for those LCA Categories where the Province granted an exception to the MALP in Round 2 of the Pharmacy Services Agreement (PSA). The Pricing Period for Round 2 is July 2011 to March 2012.

LCA Category Information Round 2 of PSA Exception Pricing Round
April 2012 to March 2013

Pages 17 through 25 redacted for the following reasons:

Not Responsive

1286	OXYCODONE HCL SUPP.RECT 20MG	\$1.6856	\$2.7408	Υ	\$1,4746
923	OXYCODONE HCL TAB 10MG	\$0.1517	\$0.1517		\$0.1327
1043	OXYCODONE HCL TAB 20MG	\$0.2634	\$0.2634		\$0.2305
922	OXYCODONE HCL TAB 5MG	\$0.1030	\$0.1030		\$0.0901
431	OXYCODONE/ACET TAB 5/325MG	\$0.0514	\$0.1285	Υ	\$0.0450
422	OVYCODONE/ASA TAR 5/325MG	\$0.3220	\$0.3220		\$0.3093

Pages 27 through 29 redacted for the following reasons:

Questions & Answers Concerning the Price Confirmation Process for Generic Drugs Effective April 2, 2012

Questions and Answers circulated on December 23, 2011:

Question 1:

Can the submission deadline for the price confirmation be extended from January 11, 2012 to January 13, 2012?

Response 1:

Yes – PSD will be extending the price confirmation submission deadline to **5:00 pm Pacific Standard Time, Friday, January 13, 2012**. In order to accommodate this extension and still meet the required timeframes, however, PSD will only be able to provide manufacturers with two days to review the DRAFT pricing spreadsheets.

Question 2:

Is it possible to have a delisted product reconsidered for coverage within the pricing period (April 2, 2012 to March 31, 2013), since the upcoming pricing period is longer than previous pricing periods?

Response2:

Where a manufacturer submits a price for a generic drug that exceeds the MALP and requests a pricing exception, and where the Province declines to grant the exception, the generic drug in question will be ineligible for PharmaCare coverage, effective April 2, 2012 through to March 31, 2012.

Question 3:

In respect to the policy provided directly below, how can a manufacturer submit for a product in the price confirmation workbook if the Notice of Compliance (NOC) is not yet available? Also, even if the NOC is available prior to the submission deadline, the manufacturer may not have supply available.

New Drug Submissions from April 2, 2012 to March 31, 2013

Starting April 2, 2012, the Province will no longer accept for review a new generic drug product submission for a generic drug in an existing LCA category, where all existing Full Benefit products are priced at or below the MALP. Manufacturers will have an opportunity to be considered for coverage during the next pricing period. However, the Province will continue to review a new generic drug product submission for a generic drug in an existing LCA category, where the list price submitted is below the list price of an existing Full Benefit drug that did not meet the MALP for the LCA category.

Response 3:

PSD has taken your concerns into consideration and we are pleased to inform you that we will be amending the policy. Please see below for the updated language.

New Drug Submissions from April 2, 2012 to March 31, 2013

Starting April 2, 2012, the Province will no longer accept for review a new generic drug product submission for a generic drug in an existing LCA category, where all existing Full Benefit

Questions & Answers Concerning the Price Confirmation Process for Generic Drugs Effective April 2, 2012

products are priced at or below the MALP, except in situations where the generic drug product's Notice of Compliance (NOC) was obtained after the price confirmation submission deadline. Manufacturers will have an opportunity to be considered for coverage during the next pricing period. However, the Province will continue to review a new generic drug product submission for a generic drug in an existing LCA category, where the list price submitted is below the list price of an existing Full Benefit drug that did not meet the MALP for the LCA category.

Where the NOC is available prior to the submission deadline and the manufacturer does not have supply available, the manufacturer must confirm the list price for the generic product in the Price Confirmation Workbook and indicate the date when the product will be available for sale in the province of British Columbia in column 'O' of the Price Confirmation Workbook (in the space reserved for Question 4). Please note that such product will not be eligible for coverage until this date is confirmed.

Question 4:

Why can't single-source or provisional generics be granted partial benefit status, similar to brand products?

Response 4:

We appreciate your input on this, and PSD will take this under advisement. Pending any decision in relation to this matter, no changes will be made to the current price confirmation process.

From:

PSD BMSRS - Generic Submissions HLTH:EX

PSD BMSRS - Generic Submissions HLTH:EX:

Subject: Date: Attachments: IMPORTANT COMMUNICATION FROM THE BRITISH COLUMBIA MINISTRY OF HEALTH - PHARMACEUTICAL SERVICES DIVISION - FINAL LCA AND REMOVAL SPREADSHEETS

Tuesday, February 28, 2012 11:02:38 AM LCA Spreadsheet for April 2012 xls
Removal Spreadsheet for April 2012 xls

IMPORTANT COMMUNICATION FROM THE BRITISH COLUMBIA MINISTRY OF HEALTH -

PHARMACEUTICAL SERVICES DIVISION CONCERNING THE IMPLEMENTATION OF

THE APRIL 2012 GENERIC PRICING PERIOD

Further to various communications sent to manufacturers since December 16, 2011, this email communication provides two attached files. The first attached file ("LCA Spreadsheet for April 2012") lists the drugs that will be included within the Low Cost Alternative (LCA) program as of April 2, 2012. The second attached file ("Removal Spreadsheet for April 2012") sets out the drugs that will be removed from the PharmaCare Formulary, and thus become ineligible for PharmaCare reimbursement, as of April 2, 2012. The two attached files are further described in subsequent sections below.

1) LCA Spreadsheet for April 2012

On February 16, 2012, Pharmaceutical Services Division (PSD) distributed to manufacturers of generic drugs a draft spreadsheet that set out those drugs which remained under consideration for PharmaCare reimbursement for the upcoming Reimbursement Period (April 2, 2012 to March 31, 2013), as well as the applicable maximum reimbursement limits being considered for each of those drugs. PSD distributed the spreadsheet in order to provide generic manufacturers with an opportunity to notify PSD of any items in the spreadsheet that were inconsistent with the data submitted by them in their respective Price Confirmation Workbooks (deadline for those workbooks was January 13, 2012). We thank those manufacturers that submitted such notifications.

PSD undertook to confirm by February 28, 2012 which generic products would be eligible for PharmaCare reimbursement for the Reimbursement Period, as well as the maximum reimbursement prices that would apply to them. The first attached file bearing the file name "LCA Spreadsheet for April 2012" provides such confirmation. Please note that since the draft spreadsheet sent out on February 16, 2012, the attached LCA Spreadsheet for April 2012 may contain updated information which may impact your respective products. Therefore, we encourage you to review this attached LCA Spreadsheet for April 2012 and ensure to take note of any such changes.

As contemplated in the February 16, 2012 communication, some generic products listed in the attached LCA Spreadsheet for April 2012 are accorded Full Benefit status on a provisional basis only (identified by an "X" in the column entitled "PROV"). Generic products that are accorded a provisional Full Benefit status may potentially not remain eligible for PharmaCare reimbursement throughout the entirety of the Reimbursement Period. PSD will have the discretion to delist these products at any time prior to the end of the Reimbursement Period.

In the attached LCA Spreadsheet for April 2012, brand and generic products are listed in their respective LCA categories. Only those generic products accorded Full Benefit status under the LCA program shall be eligible for PharmaCare reimbursement effective April 2, 2012. Generic products enjoying Full Benefit status (indicated by an "F" or a "P*" in the column entitled "Full/Partial LCA Benefit") under the LCA program shall be reimbursed up to the maximum price, unless subject to a Reference Price under the Reference Drug Program. The maximum price is equal to the manufacturer list price plus, in general, an 8% mark-up (5% for certain drugs subject to the Reduced Mark-up for High Cost Drugs policy). Generic products not listed in the attached LCA Spreadsheet for April 2012 will be ineligible for PharmaCare reimbursement during the Reimbursement Period.

Brand products may be accorded Full Benefit or Partial Benefit status. Partial Benefit status under the LCA program is indicated by a "P" in the column entitled "Full/Partial LCA Benefit". Those that are a Full Benefit shall be reimbursed up to the maximum price (unless subject to a Reference Price under the Reference Drug Program), while those that are Partial Benefit will be reimbursed up to the LCA price (shown in the column entitled "LCA Price", where applicable).

Manufacturers are again advised that, as in the past, maximum prices, LCA prices and PharmaCare reimbursement in general, remain subject to eligibility criteria, as well as other reimbursement limiting measures, such as those of PharmaCare's programs (i.e. Reference Drug Program and Special Authority program), plan rules, policies, pricing exceptions and reimbursement practices.

We strongly urge manufacturers to, based on the data in the LCA Spreadsheet for April 2012, communicate and take note of the reimbursement limits and list prices applicable to their drugs. Should they notice any data that is inconsistent with the Price Confirmation Workbooks they submitted along with their List Price Proposal Agreement (deadline for such submission was January 13, 2012), they should notify PSD immediately, at generic.submissions@gov.bc.ca with an email bearing the subject heading "LCA Spreadsheet for April 2012 Concern".

Please note the following headings for the columns in the attached spreadsheet.

LCA CATEGORY NO.: The Low Cost Alternative (LCA) category number, as assigned by PSD.

DIN: The Drug Identification Number (DIN) assigned to each of the products by the Health Protection Branch of

Health Canada.

CHEMICAL NAME: The chemical name for each drug.

DRUG NAME: The product name associated with a specific manufacturer's version of a drug.

MAN: The manufacturer code assigned by Health Canada. While this information is from sources believed to be accurate, it is important to note that the accuracy of these manufacturer codes and names cannot be guaranteed.

FULL/PARTIAL LCA BENEFIT: This column indicates whether or not a product will be automatically and fully covered by PharmaCare.

- "F" indicates that the product is a "Full Benefit" and will be fully covered by PharmaCare, subject to the Maximum Pricing Policy.
- "P" indicates that the product is a "Partial Benefit" and coverage is limited according to LCA or RDP pricing policy.
- "P*" identifies a product that will be recognized as a full benefit if a Special Authority has been granted for exemption to the RDP.

PLAN B ONLY: An "X" in this column indicates that the product is a benefit for Plan B patients only. These drugs are subject to LCA or RDP rules.

RDP: This column identifies a drug that is subject to the rules of the RDP. Claims for drugs that are designated as "RDP" will be reduced to the RDP price. The RDP price is determined by the cost of the reference drug. "REF" refers to the reference drug(s) in the category. If this column is blank, the drug is not included in the RDP.

SA: This column identifies a drug that is a **LIMITED COVERAGE DRUG** covered only with an approved Special Authority. Claims for "SA" drugs adjudicate to zero unless a Special Authority has been granted and entered on PharmaNet before the prescription is filled. All valid claims for an "SA" drug adjudicate according to LCA Program rules.

MAX PRICE: The price entered in PharmaNet as the maximum price that PharmaCare will reimburse for the drug. When there is a price in both the MAX PRICE and LCA PRICE column, claims adjudicate to the lower of the two prices. Please note that if a product is an RDP product it will be adjudicated at the lesser of the MAX PRICE, LCA PRICE or RDP PRICE.

LCA PRICE: This is the Low Cost Alternative price for each drug. If this column is blank, the drug is not subject to the LCA orice for that category.

PROV: An "X" in this column indicates that the generic drug has been accorded Full Benefit status on a provisional basis only.

As communicated in the December 16, 2011 letter to manufacturers, and further to an update in the December 23, 2011 Question and Answers document, starting April 2, 2012, PSD will no longer accept for review a new generic drug product submission for a generic drug in an existing LCA category, where all existing Full Benefit products are priced at or below the MALP, except in situations where the generic drug product's Notice of Compliance (NOC) was obtained after the price confirmation submission deadline. Manufacturers will have an opportunity to be considered for coverage during the next pricing period. However, PSD will continue to review a new generic drug product submission for a generic drug in an existing LCA category, where the list price submitted is below the list price of an existing Full Benefit drug that did not meet the MALP for the LCA category.

Where the NOC was available prior to the submission and where the manufacturer confirmed pricing for the generic product in the Price Confirmation Workbook, such products will not be eligible for PharmaCare coverage until the supply date is formally confirmed to PSD.

2) Drugs to be Removed from the PharmaCare Formulary

The second attached file bearing the file name "Removal Spreadsheet for April 2012" lists out the drugs that will be removed from the PharmaCare formulary, and thus made ineligible for PharmaCare reimbursement, effective April 2, 2012. These drugs will be removed for reasons that include, without limitation, the following:

- A price confirmation for the drug was not submitted by the manufacturer in accordance with the process and timeframes set out in earlier communications
- > A price confirmation was submitted for the drug by the manufacturer that did not meet the MALP eventually established for the LCA Category
- Discontinuation of the drug by the manufacturer

We strongly encourage all manufacturers to review the data in the Removal Spreadsheet for April 2012 to satisfy themselves that such spreadsheet does not contain any drug that should not be removed. Column headings in the spreadsheet have the same meaning as those in the LCA Spreadsheet for April 2012, as described above in this communication. Should any drug not belonging in this spreadsheet be found, the manufacturer should immediately notify PSD at generic.submissions@gov.bc.ca with an email bearing the subject heading "Removal

Spreadsheet for April 2012 Concern", so as to prevent any removal that would be inconsistent with the process outlined by PSD in this and other prior communications. Such notification must clearly state the LCA Category number, the DIN of the drug, and the reason why the removal would be inconsistent.

These documents will also be available on the PharmaCare website by February 29, 2012.

Should you any other questions concerning the above, please email them to us at generic.submissions@gov.bc.ca.

Regards,

PSD

From:

PSD BMSRS - Generic Submissions HLTH:EX

To:

PSD BMSRS - Generic Submissions HLTH:EX;

Subject:

Important Message from BC Ministry of Health - Identification of Potential Inconsistencies Thursday, February 16, 2012 6:18:54 PM

Date: Attachments:

Draft LCA Spreadsheet For Manufacturer Review (February 16, 2012).xls

IMPORTANT COMMUNICATION FROM THE BRITISH COLUMBIA MINISTRY OF HEALTH –

PHARMACEUTICAL SERVICES DIVISION CONCERNING THE IMPLEMENTATION OF

THE APRIL 2012 GENERIC PRICING PERIOD

The Pharmaceutical Services Division (PSD) thanks all manufacturers that submitted a signed List Price Proposal Agreement and a completed Price Confirmation Workbook (Exhibit A to the List Price Proposal Agreement).

As referenced in earlier communications, PSD shall confirm by February 28, 2012 which generic products shall be eligible for PharmaCare reimbursement from April 2, 2012 through to March 31, 2013 (the Pricing Period), as well as the maximum reimbursement prices that shall apply. PSD has started reviewing manufacturer price confirmations and is in the process of finalizing the list of eligible generic drugs and the maximum reimbursement prices.

As part of PSD's process for finalizing such lists, we attach below a spreadsheet that sets out those drugs which remain under consideration for PharmaCare reimbursement during the Pricing Period, as well as the maximum reimbursement limits being considered for each of those drugs. PSD is disseminating this spreadsheet in order to provide manufacturers with an opportunity to notify PSD of any items in the spreadsheet that are **inconsistent** with the data submitted by them in their respective Price Confirmation Workbooks. Any such notification, in order to be considered prior to the publication of the next LCA documents, must be received in an email sent to generic.submissions@gov.bc.ca no later than 5:00pm Pacific Daylight Standard Time on Tuesday, February 21, 2012, and must:

- 1) bear the subject heading "Notification Concerning Spreadsheet of February 16, 2012",
- 2) clearly identify the specific LCA category number, DIN and name of the relevant product,
- 3) clearly state why the information in the spreadsheet is inconsistent with the price confirmation submitted by the manufacturer in their Price Confirmation Workbook, and

4) clearly state how the spreadsheet should be amended so as to accurately reflect the price confirmation submitted by the manufacturer in their Price Confirmation Workbook.

Manufacturers are strongly encouraged to carefully review the data in the attached spreadsheet and to provide notifications promptly so as to avoid any erroneous information being published in the eventual LCA documents that may affect the eligibility of their products and applicable maximum reimbursement prices.

Manufacturers should note that the information in the attached spreadsheet is still subject to change, as PSD has yet to finalize which generic products will be eligible during the Pricing Period, as well what the maximum reimbursement limits will be. Therefore, the attached spreadsheet does **not** constitute confirmation of which products will be eligible for PharmaCare reimbursement during the Pricing Period nor does it constitute confirmation of the maximum reimbursement prices that will apply during the Pricing Period. Such confirmations will be provided by February 28, 2012.

As set out in the December 16, 2011 letter, the Province retains sole discretion to take whatever action it deems appropriate to address situations where within an LCA category, no manufacturer commits to sell a generic product at or below a MALP or where the Province has concerns relating to the sufficiency of supply offered by those manufacturers confirming prices that meet or fall below a MALP. One of the possibilities is that some generic products listed in the attached spreadsheet may be accorded Full Benefit status on a provisional basis only.

While changes to PharmaCare reimbursement limits for eligible generic drugs will not be implemented until April 2, 2012, please note that where the list price submitted for a generic drug in accordance with this process represents a change to the current list price, the new list price must take effect in British Columbia no later than March 2, 2012.

Generic products that are accorded a provisional Full Benefit status may potentially not remain eligible for PharmaCare reimbursement throughout the entirety of the Pricing Period. PSD will have the discretion to delist these products at any time prior to the end of the Pricing Period. PSD shall confirm by February 28, 2012 which products will be accorded Full Benefit status on a provisional basis only.

In the attached spreadsheet, brand and generic products are listed in their respective LCA categories. Only those generic products accorded Full Benefit status shall be eligible for PharmaCare reimbursement on April 2, 2012. Generic products enjoying Full Benefit status shall be reimbursed up to the maximum price (shown as "Max Price", or Column J in the attached spreadsheet). Subject to finalization of the upcoming LCA documents, generic products not listed in the attached spreadsheet will be ineligible for PharmaCare reimbursement during the Pricing Period.

Brand products may be accorded Full Benefit or Partial Benefit status. Those that are a Full Benefit shall be reimbursed up to the maximum price, while those that are Partial Benefit will be reimbursed up to the LCA price (Column K in the attached spreadsheet).

Manufacturers are also advised that, as in the past, maximum prices, LCA prices, and PharmaCare reimbursement in general remain subject to eligibility criteria, as well as other reimbursement limiting measures, such as those of PharmaCare's programs (i.e. Reference Drug Program and Special Authority program), plan rules, policies, pricing exceptions, and reimbursement practices.

Please forward any questions that you may have regarding the above to generic. submissions@gov.bc.ca.

Regards,

PSD

From:

Nicole Neveu

To:

PSD BMSRS - Generic Submissions HLTH:EX;

cc:

Gestiondesprix;

Subject:

List Price Confirmation - Pharmascience Inc.

Date:

Friday, January 13, 2012 1:45:35 PM

Attachments:

LIST PRICE PROPOSAL AGREEMENT - PHARMASCIENCE.pdf

Pharmascience Inc.xls

Good day,

Please find attached the completed list price confirmation workbook for Pharmascience Inc.

Should you have any questions, please do not hesitate to call me at your earliest convenience.

Sincerely,

Nicole

Nicole Neveu Chef, Gestion des Prix Manager, Pricing Administration (514) 340-5043

LIST PRICE PROPOSAL AGREEMENT

("the Agreement")

BETWEEN:

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")

AND:

NAME OF SUPPLIER: Phar mascience Inc

ADDRESS OF SUPPLIER: 6111 ROYALMOUNT AVE. SUITE 100

MONTRÉAL, QUEBEC H4P 274 ("the Supplier")

(collectively, "the Parties")

WHEREAS:

- A. The Province is responsible for the operation and funding of the PharmaCare program ("PharmaCare"), including the establishment of terms and conditions for the determination, to be made by the Province, of which pharmaceutical products will be eligible for reimbursement through PharmaCare;
- B. The Supplier supplies one or more generic pharmaceutical products for sale in the British Columbia market:
- C. The Province requires that any supplier seeking to have a generic pharmaceutical product determined as eligible for reimbursement through PharmaCare as of April 2, 2012 must submit a proposed List Price for such product, with the Province to subsequently make a determination of whether that product will be eligible for reimbursement through PharmaCare;
- D. The Supplier seeks a determination that certain of the Supplier's pharmaceutical products are eligible for reimbursement through PharmaCare as of April 2, 2012;

NOW THEREFORE in consideration of the mutual promises and covenants set forth in this Agreement, the Parties agree as follows:

1.0 Throughout this Agreement, the following definitions apply:

- "Accepted Product" means any Product which the Province makes eligible for PharmaCare reimbursement during part or all of the Pricing Period.
- "Affiliate" means any corporation or entity that is directly or indirectly controlled by, or controls or is under common control with, the Supplier, provided that control shall mean ownership of more than fifty percent (50%) of another corporation or entity, or the power to direct major decisions of another corporation or entity, including, without limitation, the power to direct management and policies of another corporation or entity, whether by reason of ownership, agreement or otherwise.
- "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.
- "List Price", in relation to a Product shall be the published unit price at which the Product, upon becoming an Accepted Product, is available for sale from the Supplier to distributors in British Columbia.
- "MALP" means the Maximum Accepted List Price, as communicated by the Province.
- "Pre-Populated Data" means all data pre-populated by the Province into the orange-coloured columns grouped under the overall heading of "Manufacturer's Product Information" within the spreadsheet entitled "Submission Sheet" contained in Exhibit A.
- "Pricing Period" means the period commencing on March 3, 2012 and continuing until and including March 31, 2013 unless this Agreement is terminated pursuant to section 14.0, in which case the Pricing Period ends on the effective date of the termination.
- "Product" means a pharmaceutical that is supplied by the Supplier.
- "Supplier Confidential Information" means any technical, business, financial, personal, employee, operations, scientific or other information or data, findings, documents, reports, plans, working plans and other material of the Supplier that is supplied to or obtained by the Province as a result of this Agreement.
- "Unaccepted Product" means any Product which the Province determines will not be eligible for PharmaCare reimbursement during the Pricing Period or that otherwise loses the status of Accepted Product prior to the end of the Pricing Period.
- 2.0 For each of the Products listed in the Price Confirmation Workbook (attached hereto as "Exhibit A") that the Province designates to be an Accepted Product, the Supplier agrees to supply the Product in British Columbia at the List Price proposed by the Supplier in Exhibit A, and on the terms and conditions set out in this Agreement.
- 3.0 Notwithstanding Section 2.0, if, during the Pricing Period, the Supplier seeks to have a Product not listed in Exhibit A designated as an Accepted Product, the Supplier shall submit to the Province, in the

form and manner required by the Province, information about the Product, including but not limited to the List Price proposed by the Supplier for the Product. If the Province designates the Product to be an Accepted Product, the Supplier agrees to supply the Product in British Columbia at the List Price proposed by the Supplier, and on the terms and conditions set out in this Agreement. For greater clarity, this section 3.0 applies only to Products that are not already listed in Exhibit A and that have received their Notice of Compliance (NOC) from Health Canada after January 13, 2012.

- The Supplier shall ensure that the List Price of each Accepted Product shall be in effect throughout the duration of the Pricing Period. The Supplier understands and acknowledges that the supplying of any Accepted Product at a price higher than the List Price during the Pricing Period will cause harm to the Province as it would likely result, whether directly or indirectly, in an increase to the PharmaCare program's reimbursement expenditures.
- The Supplier warrants that each Product listed in Exhibit A shall be available in sufficient amounts for delivery to pharmacies in British Columbia commencing on March 3, 2012 and continuing to the end of the Pricing Period. Despite the foregoing, if a Product listed in Exhibit A will not be available in sufficient amounts by March 3, 2012, the Supplier must provide, in Exhibit A, an estimated date by which the Product will be available. When the Province receives confirmation from the Supplier that such Product is available in sufficient amounts, the Province will consider the Product for designation as an Accepted Product.
- 6.0 If at any time the Supplier foresees that it may not meet demand in British Columbia for any Accepted Product during the Pricing Period, the Supplier 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, 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 Product to Unaccepted Product, thereby making the Product no longer eligible for PharmaCare reimbursement.
- 7.0 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.
- 8.0 The Province will consider for designation as an Accepted Product and on an individual basis:
 - (a) each Product listed in Exhibit A for which the Supplier submits the required information, including but not limited to a List Price; and

(b) each Product which the Supplier seeks to have designated as an Accepted Product pursuant to section 3.0 and for which the Supplier submits the required information, including but not limited to a List Price.

For greater clarity, designation of an Accepted Product will be at the sole discretion of the Province.

- 9.0 The Province has full discretion to designate as an Unaccepted Product any Product for which the List Price, as proposed by the Supplier in Exhibit A, or as proposed by the Supplier pursuant to section 3.0, is greater than the applicable MALP. Once such Product is designated as an Unaccepted Product, the Province is under no obligation to reconsider its designation of that Product regardless of any subsequent change to the Supplier's proposed List Price for that Product.
- 10.0 The Supplier is under no obligation in regard to the List Price of any Product that is or becomes an Unaccepted Product.
- 11.0 Failure on the part of the Supplier to comply with the terms and conditions of this Agreement, including but not limited to the obligation to maintain List Prices for Accepted Products throughout the Pricing Period and the obligation to submit reports on Allowances, shall constitute material breach of the Agreement, and may result in the Province taking any action or exercising any rights available, including changing the designation of Accepted Products to Unaccepted Products.
- 12.0 In the event that no supplier's List Price for a product is equal to or lower than the applicable MALP or in a case in which the Province has concerns with the sufficiency of supply for those suppliers that meet the applicable MALP, the Province may, in its sole discretion, take any action or actions it deems appropriate, including provisionally designating one or more Products as an Accepted Product, and subsequently removing that designation.
- 13.0 The Supplier understands and acknowledges that all Pre-Populated Data are supplied by the Province without any guarantee, assurance or representation as to its accuracy or completeness, and that such data has been supplied in response to requests received from one or more manufacturers of pharmaceuticals for such information. The Supplier further understands and acknowledges that no reliance can or should be placed upon the Pre-Populated Data, that the Supplier itself is the appropriate party to review and verify the accuracy and completeness of all Pre-Populated Data given that the Pre-Populated Data relate directly to products believed to be marketed by the Supplier, and that the Supplier is solely responsible for ensuring the accuracy and completeness of all Product-related data that the Supplier submits to the Province, whether as part of Exhibit A or pursuant to Section 3.0, in order to propose List Prices.
- 14.0 This Agreement may be terminated by the Province upon sixty (60) days written notice to the Supplier.
- 15.0 Except where required by law, or unless provided with the express written consent of the Supplier, the Province agrees that it will not disclose any Supplier Confidential Information other than in a form and manner whereby information particular to a specific supplier cannot be identified with that supplier. Notwithstanding the foregoing, the Parties acknowledge that should a Product be designated as an Accepted Product, the identity of the Supplier and List Price of that Product will be publicly disclosed.

- The Parties acknowledge that notwithstanding anything in this Agreement, actual PharmaCare reimbursement is subject to PharmaCare policies, plan rules, and reimbursement practices, as may be amended from time to time in the sole discretion of the Province. The Parties further acknowledge 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 the eligibility criteria other than list price, and those eligibility criteria may be amended from time to time.
- 17.0 The Parties acknowledge that 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.
- 18.0 The Parties acknowledge that nothing contained within this Agreement prevents the Government of British Columbia from enacting legislation respecting or relating to any matter contained in this Agreement.
- Any written communication between the Parties, including any notice contemplated by this Agreement, is to be mailed, delivered, or faxed to the following addresses:

To the Supplier:

At the address and facsimile number noted above

To the Province:

Pharmaceutical Services Division Ministry of Health 301 – 960 Quayside Drive New Westminster, BC V3M 6G2

Facsimile No.: 604-660-5405

Attention: Executive Director, Business Management and Supplier Relations

Any written communication from either Party will be deemed to have been received by the other Party on the fifth business day after mailing if mailed, or on the date of personal delivery if delivered, or on the date of transmission if faxed.

Either Party may, from time to time, notify the other Party in writing of a change of address or facsimile number, and following receipt of such notice, the new address or facsimile number will, for the purposes of this Agreement, be deemed to be the address or facsimile number of the Party that gave notice.

- 20.0 Any Exhibits to this Agreement are an integral part of this Agreement.
- 21.0 This Agreement shall be governed by and construed under the laws of the Province of British Columbia and the Parties agree to attorn to the exclusive jurisdiction of the courts of the Province of British Columbia.
- 22.0 The Parties acknowledge and agree that the terms and provisions of this Agreement shall be construed fairly as to each Party and not in favor of or against either Party regardless of which Party was generally

responsible for the preparation of this Agreement.

- 23.0 A waiver by either Party of any term of this Agreement or of any breach of this Agreement is effective only if that waiver is in writing and signed by the waiving Party. Such a waiver is not to be interpreted as a waiver of any other term or any other breach.
- 24.0 This Agreement may be executed by facsimile and simultaneously in two or more counterparts, each of which shall be deemed an original, but both of which together shall constitute a single agreement.

IN WITNESS WHEREOF, the Parties have each caused this Agreement to be duly executed as of the dates written below.

Agreed to for and on behalf of Her Majesty)	Agreed to for and on behalf of)		
The Queen in Right of the Province of British Columbia by a duly authorized representative of the Minister of Health Pharmaceutical Services Division		Pharmascience Inc)		
		by a duly authorized representative		
		of the Supplier)		
Ву:	,	By: //		
Name:		Name: Manie Weschange		
Title:		Title: fresident/coo		
Date:		Date: Jan 12, 2012		
		Name: LARBY MACGIRR		
		Title:		
		Date: 5m 12/2012		



S. 21, S. 17

Not Responsive



LIST PRICE PROPOSAL AGREEMENT

("the Agreement")

BETWEEN:

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")

AND:

NAME OF SUPPLIER: Kunhaxy Phorna entrals Carnola Inc

ADDRESS OF SUPPLIER: 2680 Matheon Blvd. East, Suite 200 MISSISSOUS, and L4W OAS

("the Supplier")

(collectively, "the Parties")

WHEREAS:

- A. The Province is responsible for the operation and funding of the PharmaCare program ("PharmaCare"), including the establishment of terms and conditions for the determination, to be made by the Province, of which pharmaceutical products will be eligible for reimbursement through PharmaCare;
- B. The Supplier supplies one or more generic pharmaceutical products for sale in the British Columbia market:
- C. The Province requires that any supplier seeking to have a generic pharmaceutical product determined as eligible for reimbursement through PharmaCare as of April 2, 2012 must submit a proposed List Price for such product, with the Province to subsequently make a determination of whether that product will be eligible for reimbursement through PharmaCare;
- D. The Supplier seeks a determination that certain of the Supplier's pharmaceutical products are eligible for reimoursement through PharmaCare as of April 2, 2012;

NOW THEREFORE in consideration of the mutual promises and covenants set forth in this Agreement, the Parties agree as follows:

4.0 Throughout this Agreement, the following definitions apply:

- "Accepted Product" means any Product which the Province makes eligible for PharmaCare reimbursement during part or all of the Pricing Period.
- "Affiliate" means any corporation or entity that is directly or indirectly controlled by, or controls or is under common control with, the Supplier, provided that control shall mean ownership of more than fifty percent (50%) of another corporation or entity, or the power to direct major decisions of another corporation or entity, including, without limitation, the power to direct management and policies of another corporation or entity, whether by reason of ownership, agreement or otherwise.
- "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.
- "List Price", in relation to a Product shall be the published unit price at which the Product, upon becoming an Accepted Product, is available for sale from the Supplier to distributors in British Columbia.
- "MALP" means the Maximum Accepted List Price, as communicated by the Province.
- "Pre-Populated Data" means all data pre-populated by the Province into the orange-coloured columns grouped under the overall heading of "Manufacturer's Product Information" within the spreadsheet entitled "Submission Sheet" contained in Exhibit A.
- "Pricing Period" means the period commencing on March 3, 2012 and continuing until and including March 31, 2013 unless this Agreement is terminated pursuant to section 14.0, in which case the Pricing Period ends on the effective date of the termination.
- "Product" means a pharmaceutical that is supplied by the Supplier
- "Supplier Confidential Information" means any technical, business, financial, personal, employee, operations, scientific or other information or data, findings, documents, reports, plans, working plans and other material of the Supplier that is supplied to or obtained by the Province as a result of this Agreement.
- "Unaccepted Product" means any Product which the Province determines will not be eligible for PharmaCare reimbursement during the Pricing Period or that otherwise loses the status of Accepted Product prior to the end of the Pricing Period.
- 2.0 For each of the Products listed in the Price Confirmation Workbook (attached hereto as "Exhibit A") that the Province designates to be an Accepted Product, the Supplier agrees to supply the Product in British Columbia at the List Price proposed by the Supplier in Exhibit A, and on the terms and conditions set out in this Agreement
- 3.0 Notwithstanding Section 2.0, if, during the Pricing Period, the Supplier seeks to have a Product not listed in Exhibit A designated as an Accepted Product, the Supplier shall submit to the Province, in the

form and manner required by the Province, information about the Product, including but not limited to the List Price proposed by the Supplier for the Product. If the Province designates the Product to be an Accepted Product, the Supplier agrees to supply the Product in British Columbia at the List Price proposed by the Supplier, and on the terms and conditions set out in this Agreement. For greater clarity, this section 3.0 applies only to Products that are not already listed in Exhibit A and that have received their Notice of Compliance (NOC) from Health Canada after January 13, 2012.

- 4.0 The Supplier shall ensure that the List Price of each Accepted Product shall be in effect throughout the duration of the Pricing Period. The Supplier understands and acknowledges that the supplying of any Accepted Product at a price higher than the List Price during the Pricing Period will cause harm to the Province as it would likely result, whether directly or indirectly, in an increase to the PharmaCare program's reimbursement expenditures.
- The Supplier warrants that each Product listed in Exhibit A shall be available in sufficient amounts for delivery to pharmacies in British Columbia commencing on March 3, 2012 and continuing to the end of the Pricing Period. Despite the foregoing, if a Product listed in Exhibit A will not be available in sufficient amounts by March 3, 2012, the Supplier must provide, in Exhibit A, an estimated date by which the Product will be available. When the Province receives confirmation from the Supplier that such Product is available in sufficient amounts, the Province will consider the Product for designation as an Accepted Product.
- 6.0 If at any time the Supplier foresees that it may not meet demand in British Columbia for any Accepted Product during the Pricing Period, the Supplier 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, 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 Product to Unaccepted Product, thereby making the Product no longer eligible for PharmaCare reimbursement.
- 7.0 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.
- 8.0 The Province will consider for designation as an Accepted Product and on an individual basis:
 - (a) each Product listed in Exhibit A for which the Supplier submits the required information, including but not limited to a List Price; and

(b) each Product which the Supplier seeks to have designated as an Accepted Product pursuant to section 3.0 and for which the Supplier submits the required information, including but not limited to a List Price.

For greater clarity, designation of an Accepted Product will be at the sole discretion of the Province.

- 9.0 The Province has full discretion to designate as an Unaccepted Product any Product for which the List Price, as proposed by the Supplier in Exhibit A, or as proposed by the Supplier pursuant to section 3.0, is greater than the applicable MALP. Once such Product is designated as an Unaccepted Product, the Province is under no obligation to reconsider its designation of that Product regardless of any subsequent change to the Supplier's proposed List Price for that Product.
- 10.0 The Supplier is under no obligation in regard to the List Price of any Product that is or becomes an Unaccepted Product.
- 11.0 Failure on the part of the Supplier to comply with the terms and conditions of this Agreement, including but not limited to the obligation to maintain List Prices for Accepted Products throughout the Pricing Period and the obligation to submit reports on Allowances, shall constitute material breach of the Agreement, and may result in the Province taking any action or exercising any rights available, including changing the designation of Accepted Products to Unaccepted Products.
- 12.0 In the event that no supplier's List Price for a product is equal to or lower than the applicable MALP or in a case in which the Province has concerns with the sufficiency of supply for those suppliers that meet the applicable MALP, the Province may, in its sole discretion, take any action or actions it deems appropriate, including provisionally designating one or more Products as an Accepted Product, and subsequently removing that designation.
- The Supplier understands and acknowledges that all Pre-Populated Data are supplied by the Province without any guarantee, assurance or representation as to its accuracy or completeness, and that such data has been supplied in response to requests received from one or more manufacturers of pharmaceuticals for such information. The Supplier further understands and acknowledges that no reliance can or should be placed upon the Pre-Populated Data, that the Supplier itself is the appropriate party to review and verify the accuracy and completeness of all Pre-Populated Data given that the Pre-Populated Data relate directly to products believed to be marketed by the Supplier, and that the Supplier is solely responsible for ensuring the accuracy and completeness of all Product-related data that the Supplier submits to the Province, whether as part of Exhibit A or pursuant to Section 3.0, in order to propose List Prices.
- 14.0 This Agreement may be terminated by the Province upon sixty (60) days written notice to the Supplier.
- 15.0 Except where required by law, or unless provided with the express written consent of the Supplier, the Province agrees that it will not disclose any Supplier Confidential Information other than in a form and manner whereby information particular to a specific supplier cannot be identified with that supplier. Notwithstanding the foregoing, the Parties acknowledge that should a Product be designated as an Accepted Product, the identity of the Supplier and List Price of that Product will be publicly disclosed

- 16.0 The Parties acknowledge that notwithstanding anything in this Agreement, actual PharmaCare reimbursement is subject to PharmaCare policies, plan rules, and reimbursement practices, as may be amended from time to time in the sole discretion of the Province. The Parties further acknowledge 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 the eligibility criteria other than list price, and those eligibility criteria may be amended from time to time.
- 17.0 The Parties acknowledge that the Province is subject to the British Columbia *Fréedom of Information* and *Protection of Privacy Act* and must comply with any order of the Office of the Information and Privacy Commissioner.
- 18.0 The Parties acknowledge that nothing contained within this Agreement prevents the Government of British Columbia from enacting legislation respecting or relating to any matter contained in this Agreement.
- 19.0 Any written communication between the Parties, including any notice contemplated by this Agreement, is to be mailed, delivered, or faxed to the following addresses:

To the Supplier:

At the address and facsimile number noted above

To the Province:

Pharmaceutical Services Division Ministry of Health 301 – 960 Quayside Drive New Westminster, BC V3M 6G2

Facsimile No.: 604-660-5405

Attention: Executive Director, Business Management and Supplier Relations

Any written communication from either Party will be deemed to have been received by the other Party on the fifth business day after mailing if mailed, or on the date of personal delivery if delivered, or on the date of transmission if faxed.

Either Party may, from time to time, notify the other Party in writing of a change of address or facsimile number, and following receipt of such notice, the new address or facsimile number will, for the purposes of this Agreement, be deemed to be the address or facsimile number of the Party that gave notice.

- 20.0 Any Exhibits to this Agreement are an integral part of this Agreement.
- 21.0 This Agreement shall be governed by and construed under the laws of the Province of British Columbia and the Parties agree to attorn to the exclusive jurisdiction of the courts of the Province of British Columbia.
- 22.0 The Parties acknowledge and agree that the terms and provisions of this Agreement shall be construed fairly as to each Party and not in favor of or against either Party regardless of which Party was generally

responsible for the preparation of this Agreement.

- 23.0 A waiver by either Party of any term of this Agreement or of any breach of this Agreement is effective only if that waiver is in writing and signed by the waiving Party. Such a waiver is not to be interpreted as a waiver of any other term or any other breach.
- 24.0 This Agreement may be executed by facsimile and simultaneously in two or more counterparts, each of which shall be deemed an original, but both of which together shall constitute a single agreement.

IN WITNESS WHEREOF, the Parties have each caused this Agreement to be duly executed as of the dates written below.

Agreed to for and on behalf of Her Majesty)	Agreed to for and on behalf of)
The Queen in Right of the Province of British)	Run baxy Pharmacroticals Canada Inc.)
Columbia by a duly authorized representative)	by a duly authorized representative)
of the Minister of Health)	of the Supplier)
Pharmaceutical Services Division)	ALL.
Ву:		By:
Name:		Name: PAUL DRAKE
Title:		Title: PRES. + 6M
Date:		Date: <u>SAN. 13/12</u>
		By: 100 100.
		Name: Joe Buttice
	•	Title: S-Repulatory Affairs Associate Date: January 13, 2012
		Date: January 13, 2012
		· V

Manufacturer Submission Sheet - Data for April 2012 LCA Pricing

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LIST PRICE PROPOSAL AGREEMENT

("the Agreement")

BETWEEN:

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")

A	N	D	:
•		_	

NAME OF SUPPLIER: Sandoz Canada Inc.	
--------------------------------------	--

ADDRESS OF SUPPLIER: 145 Jules - Leger St.

Boucherville, Quebec ("the Supplier")

J4B 7K8 Canada

(collectively, "the Parties")

WHEREAS:

- A. The Province is responsible for the operation and funding of the PharmaCare program ("PharmaCare"), including the establishment of terms and conditions for the determination, to be made by the Province, of which pharmaceutical products will be eligible for reimbursement through PharmaCare;
- B. The Supplier supplies one or more generic pharmaceutical products for sale in the British Columbia market:
- C. The Province requires that any supplier seeking to have a generic pharmaceutical product determined as eligible for reimbursement through PharmaCare as of April 2, 2012 must submit a proposed List Price for such product, with the Province to subsequently make a determination of whether that product will be eligible for reimbursement through PharmaCare;
- D. The Supplier seeks a determination that certain of the Supplier's pharmaceutical products are eligible for reimbursement through PharmaCare as of April 2, 2012;

NOW THEREFORE in consideration of the mutual promises and covenants set forth in this Agreement, the Parties agree as follows:

1.0 Throughout this Agreement, the following definitions apply:

"Accepted Product" means any Product which the Province makes eligible for PharmaCare reimbursement during part or all of the Pricing Period.

"Affiliate" means any corporation or entity that is directly or indirectly controlled by, or controls or is under common control with, the Supplier, provided that control shall mean ownership of more than fifty percent (50%) of another corporation or entity, or the power to direct major decisions of another corporation or entity, including, without limitation, the power to direct management and policies of another corporation or entity, whether by reason of ownership, agreement or otherwise.

"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.

"List Price", in relation to a Product shall be the published unit price at which the Product, upon becoming an Accepted Product, is available for sale from the Supplier to distributors in British Columbia.

"MALP" means the Maximum Accepted List Price, as communicated by the Province.

"Pre-Populated Data" means all data pre-populated by the Province into the orange-coloured columns grouped under the overall heading of "Manufacturer's Product Information" within the spreadsheet entitled "Submission Sheet" contained in Exhibit A.

"Pricing Period" means the period commencing on March 3, 2012 and continuing until and including March 31, 2013 unless this Agreement is terminated pursuant to section 14.0, in which case the Pricing Period ends on the effective date of the termination.

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

"Supplier Confidential Information" means any technical, business, financial, personal, employee, operations, scientific or other information or data, findings, documents, reports, plans, working plans and other material of the Supplier that is supplied to or obtained by the Province as a result of this Agreement.

"Unaccepted Product" means any Product which the Province determines will not be eligible for PharmaCare reimbursement during the Pricing Period or that otherwise loses the status of Accepted Product prior to the end of the Pricing Period.

- 2.0 For each of the Products listed in the Price Confirmation Workbook (attached hereto as "Exhibit A") that the Province designates to be an Accepted Product, the Supplier agrees to supply the Product in British Columbia at the List Price proposed by the Supplier in Exhibit A, and on the terms and conditions set out in this Agreement.
- 3.0 Notwithstanding Section 2.0, if, during the Pricing Period, the Supplier seeks to have a Product not listed in Exhibit A designated as an Accepted Product, the Supplier shall submit to the Province, in the

form and manner required by the Province, information about the Product, including but not limited to the List Price proposed by the Supplier for the Product. If the Province designates the Product to be an Accepted Product, the Supplier agrees to supply the Product in British Columbia at the List Price proposed by the Supplier, and on the terms and conditions set out in this Agreement. For greater clarity, this section 3.0 applies only to Products that are not already listed in Exhibit A and that have received their Notice of Compliance (NOC) from Health Canada after January 13, 2012.

- 4.0 The Supplier shall ensure that the List Price of each Accepted Product shall be in effect throughout the duration of the Pricing Period. The Supplier understands and acknowledges that the supplying of any Accepted Product at a price higher than the List Price during the Pricing Period will cause harm to the Province as it would likely result, whether directly or indirectly, in an increase to the PharmaCare program's reimbursement expenditures.
- The Supplier warrants that each Product listed in Exhibit A shall be available in sufficient amounts for delivery to pharmacies in British Columbia commencing on March 3, 2012 and continuing to the end of the Pricing Period. Despite the foregoing, if a Product listed in Exhibit A will not be available in sufficient amounts by March 3, 2012, the Supplier must provide, in Exhibit A, an estimated date by which the Product will be available. When the Province receives confirmation from the Supplier that such Product is available in sufficient amounts, the Province will consider the Product for designation as an Accepted Product.
- 6.0 If at any time the Supplier foresees that it may not meet demand in British Columbia for any Accepted Product during the Pricing Period, the Supplier 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, 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 Product to Unaccepted Product, thereby making the Product no longer eligible for PharmaCare reimbursement.
- 7.0 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.
- 8.0 The Province will consider for designation as an Accepted Product and on an individual basis:
 - (a) each Product listed in Exhibit A for which the Supplier submits the required information, including but not limited to a List Price; and

(b) each Product which the Supplier seeks to have designated as an Accepted Product pursuant to section 3.0 and for which the Supplier submits the required information, including but not limited to a List Price.

For greater clarity, designation of an Accepted Product will be at the sole discretion of the Province.

- Price, as proposed by the Supplier in Exhibit A, or as proposed by the Supplier pursuant to section 3.0, is greater than the applicable MALP. Once such Product is designated as an Unaccepted Product, the Province is under no obligation to reconsider its designation of that Product regardless of any subsequent change to the Supplier's proposed List Price for that Product.
- 10.0 The Supplier is under no obligation in regard to the List Price of any Product that is or becomes an Unaccepted Product.
- 11.0 Failure on the part of the Supplier to comply with the terms and conditions of this Agreement, including but not limited to the obligation to maintain List Prices for Accepted Products throughout the Pricing Period and the obligation to submit reports on Allowances, shall constitute material breach of the Agreement, and may result in the Province taking any action or exercising any rights available, including changing the designation of Accepted Products to Unaccepted Products.
- 12.0 In the event that no supplier's List Price for a product is equal to or lower than the applicable MALP or in a case in which the Province has concerns with the sufficiency of supply for those suppliers that meet the applicable MALP, the Province may, in its sole discretion, take any action or actions it deems appropriate, including provisionally designating one or more Products as an Accepted Product, and subsequently removing that designation.
- 13.0 The Supplier understands and acknowledges that all Pre-Populated Data are supplied by the Province without any guarantee, assurance or representation as to its accuracy or completeness, and that such data has been supplied in response to requests received from one or more manufacturers of pharmaceuticals for such information. The Supplier further understands and acknowledges that no reliance can or should be placed upon the Pre-Populated Data, that the Supplier itself is the appropriate party to review and verify the accuracy and completeness of all Pre-Populated Data given that the Pre-Populated Data relate directly to products believed to be marketed by the Supplier, and that the Supplier is solely responsible for ensuring the accuracy and completeness of all Product-related data that the Supplier submits to the Province, whether as part of Exhibit A or pursuant to Section 3.0, in order to propose List Prices.
- 14.0 This Agreement may be terminated by the Province upon sixty (60) days written notice to the Supplier.
- 15.0 Except where required by law, or unless provided with the express written consent of the Supplier, the Province agrees that it will not disclose any Supplier Confidential Information other than in a form and manner whereby information particular to a specific supplier cannot be identified with that supplier. Notwithstanding the foregoing, the Parties acknowledge that should a Product be designated as an Accepted Product, the identity of the Supplier and List Price of that Product will be publicly disclosed.

- 16.0 The Parties acknowledge that notwithstanding anything in this Agreement, actual PharmaCare reimbursement is subject to PharmaCare policies, plan rules, and reimbursement practices, as may be amended from time to time in the sole discretion of the Province. The Parties further acknowledge 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 the eligibility criteria other than list price, and those eligibility criteria may be amended from time to time.
- 17.0 The Parties acknowledge that 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.
- 18.0 The Parties acknowledge that nothing contained within this Agreement prevents the Government of British Columbia from enacting legislation respecting or relating to any matter contained in this Agreement.
- 19.0 Any written communication between the Parties, including any notice contemplated by this Agreement, is to be mailed, delivered, or faxed to the following addresses:

To the Supplier:

At the address and facsimile number noted above

Fax: (450) 641-8615

Attention: Vice-President, Legal and Governmental Affairs

To the Province:

Pharmaceutical Services Division Ministry of Health 301 – 960 Quayside Drive New Westminster, BC V3M 6G2

Facsimile No.: 604-660-5405

Attention: Executive Director, Business Management and Supplier Relations

Any written communication from either Party will be deemed to have been received by the other Party on the fifth business day after mailing if mailed, or on the date of personal delivery if delivered, or on the date of transmission if faxed.

Either Party may, from time to time, notify the other Party in writing of a change of address or facsimile number, and following receipt of such notice, the new address or facsimile number will, for the purposes of this Agreement, be deemed to be the address or facsimile number of the Party that gave notice.

- 20.0 Any Exhibits to this Agreement are an integral part of this Agreement.
- 21.0 This Agreement shall be governed by and construed under the laws of the Province of British Columbia and the Parties agree to attorn to the exclusive jurisdiction of the courts of the Province of British Columbia.
- 22.0 The Parties acknowledge and agree that the terms and provisions of this Agreement shall be construed fairly as to each Party and not in favor of or against either Party regardless of which Party was generally

responsible for the preparation of this Agreement.

- 23.0 A waiver by either Party of any term of this Agreement or of any breach of this Agreement is effective only if that waiver is in writing and signed by the waiving Party. Such a waiver is not to be interpreted as a waiver of any other term or any other breach.
- 24.0 This Agreement may be executed by facsimile and simultaneously in two or more counterparts, each of which shall be deemed an original, but both of which together shall constitute a single agreement.

IN WITNESS WHEREOF, the Parties have each caused this Agreement to be duly executed as of the dates written below.

Agreed to for and on behalf of Her Majesty)		Agreed to for and on behalf of)
The Queen in Right of the Province of British)		Sandoz Canada Inc.	.)
Columbia by a duly authorized representative)		by a duly authorized representative)
of the Minister of Health)		of the Supplier)
Pharmaceutical Services Division)			
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Title:		Title:	UP FIRMER (IT	
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LIST PRICE PROPOSAL AGREEMENT

("the Agreement")

BETWEEN:

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")

AND:

NAME OF SUPPLIER: Teva Canada L'mited

ADDRESS OF SUPPLIER: 30 Novo pharm Court

Toponto ON ("the S

("the Supplier")

MIB 2K9

(collectively, "the Parties")

WHEREAS:

- A. The Province is responsible for the operation and funding of the PharmaCare program ("PharmaCare"), including the establishment of terms and conditions for the determination, to be made by the Province, of which pharmaceutical products will be eligible for reimbursement through PharmaCare;
- B. The Supplier supplies one or more generic pharmaceutical products for sale in the British Columbia market:
- C. The Province requires that any supplier seeking to have a generic pharmaceutical product determined as eligible for reimbursement through PharmaCare as of April 2, 2012 must submit a proposed List Price for such product, with the Province to subsequently make a determination of whether that product will be eligible for reimbursement through PharmaCare;
- D. The Supplier seeks a determination that certain of the Supplier's pharmaceutical products are eligible for reimbursement through PharmaCare as of April 2, 2012;

NOW THEREFORE in consideration of the mutual promises and covenants set forth in this Agreement, the Parties agree as follows:

1.0 Throughout this Agreement, the following definitions apply:

- "Accepted Product" means any Product which the Province makes eligible for PharmaCare reimbursement during part or all of the Pricing Period.
- "Affiliate" means any corporation or entity that is directly or indirectly controlled by, or controls or is under common control with, the Supplier, provided that control shall mean ownership of more than fifty percent (50%) of another corporation or entity, or the power to direct major decisions of another corporation or entity, including, without limitation, the power to direct management and policies of another corporation or entity, whether by reason of ownership, agreement or otherwise.
- "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.
- "List Price", in relation to a Product shall be the published unit price at which the Product, upon becoming an Accepted Product, is available for sale from the Supplier to distributors in British Columbia.
- "MALP" means the Maximum Accepted List Price, as communicated by the Province.
- "Pre-Populated Data" means all data pre-populated by the Province into the orange-coloured columns grouped under the overall heading of "Manufacturer's Product Information" within the spreadsheet entitled "Submission Sheet" contained in Exhibit A.
- "Pricing Period" means the period commencing on March 3, 2012 and continuing until and including March 31, 2013 unless this Agreement is terminated pursuant to section 14.0, in which case the Pricing Period ends on the effective date of the termination.
- "Product" means a pharmaceutical that is supplied by the Supplier.
- "Supplier Confidential Information" means any technical, business, financial, personal, employee, operations, scientific or other information or data, findings, documents, reports, plans, working plans and other material of the Supplier that is supplied to or obtained by the Province as a result of this Agreement.
- "Unaccepted Product" means any Product which the Province determines will not be eligible for PharmaCare reimbursement during the Pricing Period or that otherwise loses the status of Accepted Product prior to the end of the Pricing Period.
- 2.0 For each of the Products listed in the Price Confirmation Workbook (attached hereto as "Exhibit A") that the Province designates to be an Accepted Product, the Supplier agrees to supply the Product in British Columbia at the List Price proposed by the Supplier in Exhibit A, and on the terms and conditions set out in this Agreement.
- 3.0 Notwithstanding Section 2.0, if, during the Pricing Period, the Supplier seeks to have a Product not listed in Exhibit A designated as an Accepted Product, the Supplier shall submit to the Province, in the

form and manner required by the Province, information about the Product, including but not limited to the List Price proposed by the Supplier for the Product. If the Province designates the Product to be an Accepted Product, the Supplier agrees to supply the Product in British Columbia at the List Price proposed by the Supplier, and on the terms and conditions set out in this Agreement. For greater clarity, this section 3.0 applies only to Products that are not already listed in Exhibit A and that have received their Notice of Compliance (NOC) from Health Canada after January 13, 2012.

- 4.0 The Supplier shall ensure that the List Price of each Accepted Product shall be in effect throughout the duration of the Pricing Period. The Supplier understands and acknowledges that the supplying of any Accepted Product at a price higher than the List Price during the Pricing Period will cause harm to the Province as it would likely result, whether directly or indirectly, in an increase to the PharmaCare program's reimbursement expenditures.
- The Supplier warrants that each Product listed in Exhibit A shall be available in sufficient amounts for delivery to pharmacies in British Columbia commencing on March 3, 2012 and continuing to the end of the Pricing Period. Despite the foregoing, if a Product listed in Exhibit A will not be available in sufficient amounts by March 3, 2012, the Supplier must provide, in Exhibit A, an estimated date by which the Product will be available. When the Province receives confirmation from the Supplier that such Product is available in sufficient amounts, the Province will consider the Product for designation as an Accepted Product.
- 6.0 If at any time the Supplier foresees that it may not meet demand in British Columbia for any Accepted Product during the Pricing Period, the Supplier 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, 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 Product to Unaccepted Product, thereby making the Product no longer eligible for PharmaCare reimbursement.
- 7.0 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.
- 8.0 The Province will consider for designation as an Accepted Product and on an individual basis:
 - (a) each Product listed in Exhibit A for which the Supplier submits the required information, including but not limited to a List Price; and

(b) each Product which the Supplier seeks to have designated as an Accepted Product pursuant to section 3.0 and for which the Supplier submits the required information, including but not limited to a List Price.

For greater clarity, designation of an Accepted Product will be at the sole discretion of the Province.

- 9.0 The Province has full discretion to designate as an Unaccepted Product any Product for which the List Price, as proposed by the Supplier in Exhibit A, or as proposed by the Supplier pursuant to section 3.0, is greater than the applicable MALP. Once such Product is designated as an Unaccepted Product, the Province is under no obligation to reconsider its designation of that Product regardless of any subsequent change to the Supplier's proposed List Price for that Product.
- 10.0 The Supplier is under no obligation in regard to the List Price of any Product that is or becomes an Unaccepted Product.
- 11.0 Failure on the part of the Supplier to comply with the terms and conditions of this Agreement, including but not limited to the obligation to maintain List Prices for Accepted Products throughout the Pricing Period and the obligation to submit reports on Allowances, shall constitute material breach of the Agreement, and may result in the Province taking any action or exercising any rights available, including changing the designation of Accepted Products to Unaccepted Products.
- 12.0 In the event that no supplier's List Price for a product is equal to or lower than the applicable MALP or in a case in which the Province has concerns with the sufficiency of supply for those suppliers that meet the applicable MALP, the Province may, in its sole discretion, take any action or actions it deems appropriate, including provisionally designating one or more Products as an Accepted Product, and subsequently removing that designation.
- 13.0 The Supplier understands and acknowledges that all Pre-Populated Data are supplied by the Province without any guarantee, assurance or representation as to its accuracy or completeness, and that such data has been supplied in response to requests received from one or more manufacturers of pharmaceuticals for such information. The Supplier further understands and acknowledges that no reliance can or should be placed upon the Pre-Populated Data, that the Supplier itself is the appropriate party to review and verify the accuracy and completeness of all Pre-Populated Data given that the Pre-Populated Data relate directly to products believed to be marketed by the Supplier, and that the Supplier is solely responsible for ensuring the accuracy and completeness of all Product-related data that the Supplier submits to the Province, whether as part of Exhibit A or pursuant to Section 3.0, in order to propose List Prices.
- 14.0 This Agreement may be terminated by the Province upon sixty (60) days written notice to the Supplier.
- 15.0 Except where required by law, or unless provided with the express written consent of the Supplier, the Province agrees that it will not disclose any Supplier Confidential Information other than in a form and manner whereby information particular to a specific supplier cannot be identified with that supplier. Notwithstanding the foregoing, the Parties acknowledge that should a Product be designated as an Accepted Product, the identity of the Supplier and List Price of that Product will be publicly disclosed.

- The Parties acknowledge that notwithstanding anything in this Agreement, actual PharmaCare reimbursement is subject to PharmaCare policies, plan rules, and reimbursement practices, as may be amended from time to time in the sole discretion of the Province. The Parties further acknowledge 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 the eligibility criteria other than list price, and those eligibility criteria may be amended from time to time.
- 17.0 The Parties acknowledge that 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.
- 18.0 The Parties acknowledge that nothing contained within this Agreement prevents the Government of British Columbia from enacting legislation respecting or relating to any matter contained in this Agreement.
- 19.0 Any written communication between the Parties, including any notice contemplated by this Agreement, is to be mailed, delivered, or faxed to the following addresses:

To the Supplier:

At the address and facsimile number noted above

To the Province:

Pharmaceutical Services Division Ministry of Health 301 – 960 Quayside Drive New Westminster, BC V3M 6G2

Facsimile No.: 604-660-5405

Attention: Executive Director, Business Management and Supplier Relations

Any written communication from either Party will be deemed to have been received by the other Party on the fifth business day after mailing if mailed, or on the date of personal delivery if delivered, or on the date of transmission if faxed.

Either Party may, from time to time, notify the other Party in writing of a change of address or facsimile number, and following receipt of such notice, the new address or facsimile number will, for the purposes of this Agreement, be deemed to be the address or facsimile number of the Party that gave notice.

- 20.0 Any Exhibits to this Agreement are an integral part of this Agreement.
- 21.0 This Agreement shall be governed by and construed under the laws of the Province of British Columbia and the Parties agree to attorn to the exclusive jurisdiction of the courts of the Province of British Columbia.
- 22.0 The Parties acknowledge and agree that the terms and provisions of this Agreement shall be construed fairly as to each Party and not in favor of or against either Party regardless of which Party was generally

responsible for the preparation of this Agreement.

- 23.0 A waiver by either Party of any term of this Agreement or of any breach of this Agreement is effective only if that waiver is in writing and signed by the waiving Party. Such a waiver is not to be interpreted as a waiver of any other term or any other breach.
- 24.0 This Agreement may be executed by facsimile and simultaneously in two or more counterparts, each of which shall be deemed an original, but both of which together shall constitute a single agreement.

IN WITNESS WHEREOF, the Parties have each caused this Agreement to be duly executed as of the dates written below.

Agreed to for and on behalf of Her Majesty)		Agreed to for and on behalf of)
The Queen in Right of the Province of British)			.)
Columbia by a duly authorized representative)		by a duly authorized representative)
of the Minister of Health)		of the Supplier)
Pharmaceutical Services Division)			
Ву:		By:		
Name:		Name:	Daug Sommerville Vice President	
Title:		Title:	Sales & Marketing	
Date:		Date:	1/13/2012.	
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From:

Liliana Polcari

To:

<u>PSD BMSRS - Generic Submissions HLTH:EX;</u> Terry Creighton; Houri Ohan; Gayle Peddle;

Subject:

List Price Confirmation - Teva Canada Limited

Date:

Friday, January 13, 2012 5:03:14 PM

Attachments:

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Teva Canada Limited.xls 20120113194535273.pdf

ATT00001.txt

Dear Sir or Madam:

BC PharmaCare Coverage for Generic Drugs - Reimbursement Effective April 2, 2012

Please find attached the following as part of our List Price Confirmation for Round 3 of BC's Drug Reform:

- 1. Teva Canada Limited's completed Price Confirmation Workbook
- 2. Scanned version of the signed List Price Proposal Agreement
- 3. Request for Exceptions, supporting documentation (pdf)

Please do not hesitate to contact me directly for questions,

Best Regards,

Liliana

Liliana Polcari

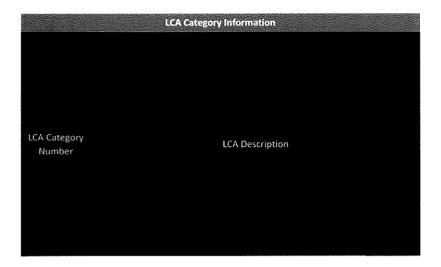
Director Govt and Econ Affr

liliana.polcari@tevacanada.com

T 416 .940.6426 30 Novopharm Court Toronto, Ontario Canada M1B 2K9 your global advantage

Manufacturer Submission Sheet - Data for April 2012 LC

All data pre-populated into the orange-coloured columns grouped under the overall he as to accuracy or completeness. No reliance can or should be placed upon such data. The spreadsheet that it submits to the Province as part of the process of proposing List Price.



Not Responsive

Not Responsive

1286	OXYCODONE HCL SUPP.RECT 20MG
923	OXYCODONE HCL TAB 10MG
1043	OXYCODONE HCL TAB 20MG
922	OXYCODONE HCL TAB 5MG
431	OXYCODONE/ACET TAB 5/325MG
432	OXYCODONE/ASA TAB 5/325MG

Not Responsive

A Pricing

eading of "Manufacturer's Product Information" are supplied by the Province without any guarantee, assurance or representation he Supplier is solely responsible for satisfying itself as to ensuring the accuracy and completeness of all data contained in this ces, whether such data was pre-populated by the Province or inputted by the Supplier.

Manufacturer's Product Information

4 4 4 3 10

\$0.0126

Not Responsive

			\$0.0901	
RATIO-OXYCOCET	608165	\$0.1285	\$0.0450	
RATIO-OXYCODAN	608157	\$0.3220	\$0.3093	S. 21
			\$60.7551	
			\$182.2618	
			\$6.0755	
			\$9.8668	
			\$18.2262	

Not Responsive

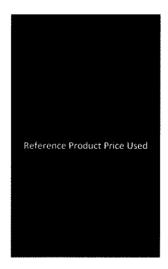
Manufacturer's Response

S. 21, S. 17

Page 85 redacted for the following reason:
Not Responsive

MALP Calculation Information

Not Responsive



Not Responsive

From:

Moneo, Mitch HLTH:EX

Sent:

Friday, December 16, 2011 8:46 PM

To:

Tan, Dominic HLTH:EX; Ghouse, Ray HLTH:EX; Hosick, David HLTH:EX; Kwok, Jess

HLTH:EX; Shin, Sophia HLTH:EX

Subject:

Fw: B.C. PharmaCare Message for Generic Manufacturers RE: Generic Pricing

Confirmation

Attachments:

Cover Letter - Dec 16 2011.pdf; Guideline for Completing the Price Confirmation

Workbook (Exhibit A).pdf; Generic Price Confirmation Workbook.xls

Thank you all for making this happen in such a timely manner despite the obstacles that were thrown up.

I learned some valuable lessons along the way that may have come at the expense of all of you and I appreciate your perseverance.

Mitch

From: PSD BMSRS - Generic Submissions HLTH:EX

Sent: Friday, December 16, 2011 08:29 PM

To: Kozubenko, Vitali HLTH:EX; Lun, Eric HLTH:EX; Moneo, Mitch HLTH:EX; Nakagawa, Bob HLTH:EX; Taylor, Suzanne C HLTH:EX; Walsh, Sara M HLTH:EX; Bethel, John HLTH:EX; Pop, Sorin HLTH:EX; Wilmer, Brett D HLTH:EX; Hosick, David HLTH:EX; Fazlagic, Tijana HLTH:EX; Moneo, Mitch HLTH:EX; Campbell, Diane E HLTH:EX; Capelli, John HLTH:EX; Munro, Deborah HLTH:EX; Healey, Susan HLTH:EX; Chong, Elaine HLTH:EX; Therrien, Darlene HLTH:EX; XT:Vasseur, Melissa SSBC:IN; Arenson, Darlene H HLTH:EX; Hardy, Jillian HLTH:EX; Yamaguchi, Jesse HLTH:EX; Voggenreiter, Christine HLTH:EX; Day, Patrick HLTH:EX; de Boer, Cheryl HLTH:EX

Cc: Guillen, Emy HLTH:EX; Shin, Sophia HLTH:EX; Kwok, Jess HLTH:EX; Tan, Dominic HLTH:EX; Ghouse, Ray HLTH:EX

Subject: FW: B.C. PharmaCare Message for Generic Manufacturers RE: Generic Pricing Confirmation

Hi All,

Please see below the email communication sent today to generic manufacturers for the upcoming generic pricing confirmation.

Regards,

BMSRS

From: PSD BMSRS - Generic Submissions HLTH:EX

Sent: Friday, December 16, 2011 8:21 PM **To:** PSD BMSRS - Generic Submissions HLTH:EX

Subject: B.C. PharmaCare Message for Generic Manufacturers RE: Generic Pricing Confirmation

Importance: High

IMPORTANT COMMUNICATION FROM THE BRITISH COLUMBIA MINISTRY OF HEALTH – PHARMACEUTICAL SERVICES DIVISION

PLEASE DIRECT ALL REPLIES TO generic.submissions@gov.bc.ca

This is a very important communication that affects whether your company's pharmaceutical products are eligible for coverage from B.C. PharmaCare

In order to ensure that your company receives all updates, corrections, answers, and other items relating to this letter, you must confirm receipt of this communication by email to generic.submissions@gov.bc.ca and identify yourself as the appropriate contact person within your organization for the issues addressed in the letter. If you are not the appropriate contact, it is important that we receive from you or your company an email confirming receipt of this communication and identifying the appropriate contact person with their contact details (including email address). Failure to provide such notification could result in your company not receiving crucial information.

In order to seek, to obtain, or maintain PharmaCare coverage for your generic products, it is essential that you read this entire letter carefully.

Attached are the following four documents:

- 1. Cover letter to generic manufacturers
- 2. Price Confirmation Workbook (this is "Exhibit A" to the List Price Proposal Agreement* and includes two spreadsheets in one Excel workbook file)
- 3. Guideline For Completing Price Confirmation Workbook (Exhibit A)

*Please note that the List Price Proposal Agreement will be forwarded to manufacturers at a later date.

If you have received this communication in error, please notify us immediately by email to generic.submissions@gov.bc.ca

Regards, PSD



December 16, 2011

Dear Manufacturer,

RE: BC PharmaCare Coverage for Generic Drugs - For Reimbursement Effective April 2, 2012

The Province of British Columbia (the Province) continues to rationalize the cost of generic drugs by reducing PharmaCare's generic drug costs, in partnership with generic drug manufacturers. All generic drugs subject to the Low Cost Alternative (LCA) will be eligible for PharmaCare reimbursement only if the manufacturer list price for such drug does not exceed a defined Maximum Accepted List Price (MALP) threshold. The upcoming BC PharmaCare reimbursement period is to commence on April 2, 2012.

For information regarding LCA categories, prices and products subject to the LCA policy, manufacturers are encouraged to review the online LCA booklet. The LCA booklet is posted online at: http://www.health.gov.bc.ca/pharmacare/lca/lcabooklets.html.

Requirements for PharmaCare Coverage Eligibility for Generic Drugs

Generic drugs included in an LCA category have one of two benefit statuses: Full Benefit or Non-Benefit. Pharmacy claims for Full Benefit products will be reimbursed up to a maximum of the manufacturer list price, plus a mark-up of eight percent for most drugs and five percent for certain drugs subject to the Reduced Mark-up for High-Cost Drugs policy. PharmaCare does not cover generics as Partial Benefits. To confirm, generic drugs subject to the Reference Drug Program will still be subject to limitations on maximum reimbursement cost.

Brand drugs included in an LCA category will remain eligible for reimbursement as Partial Benefits, unless they have a list price that is equal to or less than the applicable MALP, in which case they will be eligible for reimbursement as Full Benefits. Reimbursement for brand drugs will be limited to the LCA price for the category. The LCA price will continue to be set at the price of the generic products covered in the LCA category, plus the applicable mark-up of either eight or five percent.

Implementation of Maximum Accepted List Prices for Generic Drugs

Subject only to specific exceptions, as set out below, the MALP for generic drugs in each LCA category are determined as a percentage of the list price of the equivalent brand drug in the LCA category.

Drug coverage decisions will be based on manufacturer list prices in effect approximately thirty days before the start of the pricing period. This requirement is intended to provide pharmacies

with a period for inventory adjustment before the new PharmaCare reimbursement comes into effect. Table 1 below outlines the percentage to be applied to determine the MALPs for the upcoming pricing period.

Table 1: Percentages Used to Determine Maximum Accepted List Prices

Timeframe (Reimbursement Period)	MALP
April 2, 2012 to March 31, 2013*	35 percent of brand list price as of January 1, 2010

^{*}Subject to change

Calculation of Maximum Accepted List Prices for April 2, 2012 to March 31, 2013

The Province has calculated the MALP that will apply to generic drugs in each LCA category. For the upcoming period, the MALP for each category is listed in the Price Confirmation Workbook accompanying this letter as Exhibit A to the List Price Proposal Agreement.

<u>NOTE:</u> The List Price Proposal Agreement will be sent at a later date, separate from the Price Confirmation Workbook and this letter.

As set out above, the MALP for a generic drug is generally calculated as a percentage of the manufacturer's list price for a brand drug in the same LCA category. Since there are LCA categories in which there is not a sole brand drug, the Province has applied the following guidelines in its calculations:

- If there was only one brand product currently available in an LCA category, the MALP is based on the manufacturer's list price in existence on January 1, 2010 for the one brand product;
- If there was more than one brand product available in an LCA category on January 1, 2010, the MALP is based on the lowest priced brand product;
- If the list price of the brand product in an LCA category decreased by more than 20 percent from July 1, 2008 to July 1, 2010, the MALP is based on the list price of the brand product on July 1, 2008;
- If the brand product in an LCA category was discontinued prior to January 1, 2010, the MALP is calculated on the basis of the last known list price of the brand product;
- If there is no brand product in an LCA category or no pricing information was available for the brand product, the MALP is calculated to be 53.8 percent of the LCA price in place on July 1, 2010 (53.8 percent is derived from 35 percent as a percentage of 65 percent, which was the average list price of generic drugs as a percentage of the list price of their equivalent brand drug, on July 1, 2010); and
- If the list price on July 1, 2010 for any brand or generic drug included in an LCA category was less than the calculated MALP, the MALP for the category shall be such list price of such brand or generic drug on July 1, 2010

Submission of Price Confirmation Workbook and List Price Proposal Agreement

Manufacturers seeking to obtain or maintain coverage for any generic drug must submit the following documents no later than 5:00 pm (Pacific Daylight Saving Time) on January 11, 2012:

- 1) The accompanying Price Confirmation Workbook (this is compiled of two spreadsheets in one Excel file and forms the "Exhibit A" attachment to the List Price Proposal Agreement) with all requested information for each generic drug for which the manufacturer is seeking coverage, including confirmed list prices for the period of March 3, 2012 to March 31, 2013 in the Province that are less than or equal to the applicable MALP (subject to approved exceptions);
- 2) The signed List Price Proposal Agreement (to be sent to manufacturers separately at a later date) which undertakes that the published list prices submitted to the Province will remain in effect in the Province for the duration of March 3, 2012 to March 31, 2013.

Please note that where the list price submitted for a generic drug in accordance with this process represents a change to the current list price, the new list price must take effect in British Columbia no later than March 3, 2012.

NOTE: The Province has no obligation to consider list price confirmations for a manufacturer's products unless both the required documents noted above are received by the Province.

The Province will accept price confirmations only if they are inputted into the accompanying Price Confirmation Workbook in the required format. It is the manufacturer's responsibility to input properly all requested information into the Price Confirmation Workbook and to communicate such back to the Province in the format required. Also accompanying this letter is a document entitled "GUIDELINE FOR COMPLETING THE PRICE CONFIRMATION WORKBOOK (EXHIBIT A)", which explains how to input information into the Price Confirmation Workbook in the required format.

The completed Price Confirmation Workbook in Excel format and a scanned version of the signed List Price Proposal Agreement in Portable Document Format (PDF) must be sent as electronic attachments together in one email directly back to the Province, at generic.submissions@gov.bc.ca bearing the subject heading "List Price Confirmation-(MANUFACTURER NAME)."

For information regarding PharmaCare's LCA categories, prices and products subject to the LCA policy, manufacturers are encouraged to review the online LCA booklet that is posted online at: http://www.health.gov.bc.ca/pharmacare/lca/lcabooklets.html.

Submissions for Generic Drugs Not Presently Covered

Manufacturers seeking to have a new product become eligible for coverage should continue to follow the existing drug submission procedures. Confirmation that the list price for a generic

drug shall be equal to or less than the applicable MALP is one requirement for coverage approval.

In cases where a manufacturer has already provided the Province with submissions requesting the listing of a generic drug and merely awaits a listing decision, such manufacturer must also confirm pricing for the generic drug for April 2, 2012 in accordance with the process outlined in this letter. If the pending submission meets all other listing requirements and the manufacturer confirms a list price that is equal to or less than the applicable MALP, the drug will become eligible for coverage for the applicable period.

Requests for Exceptions to Generic Pricing Requirements

The Province recognizes that there may be truly exceptional circumstances where the application of the percentages as outlined in Table 1 above generates a MALP that exceeds a manufacturer's cost to produce and distribute a generic product. Where such exceptional circumstances are properly documented, the Province, at its sole discretion, may grant an exception to the pricing requirements set out above and increase the effective MALP for the LCA category.

It is important to note that PharmaCare will not consider a request for an exception to the generic pricing requirements where the drug is being supplied (or where the drug is intended to be supplied) in another jurisdiction in Canada at a list price that is equal to or lower than the MALP as initially calculated by the Province.

Manufacturers seeking an exception to the MALP as calculated by the Province must submit adequate information in accordance with the questions found in the attached Price Confirmation Workbook, the answers to which must be completed fully by the manufacturer. Failure to provide adequate information may result in the manufacturer's exception request not being considered by the Province. The Province may also seek further evidence and information from the manufacturer.

All exception requests must be received by the Province no later than the deadline of 5:00 pm (Pacific Daylight Saving Time) on January 11, 2012, along with all other information, price confirmations and other exception requests sought in the Price Confirmation Workbook.

For any LCA category where no manufacturer commits to sell a generic drug at or below the MALP as calculated above, or where the Province has significant concerns with the sufficiency of supply offered by those manufacturers committing to sell at or below the MALP, the Province will review the exception requests and prices submitted by manufacturers for generic drugs in the category. Based on its review, the Province may, at its sole discretion, take whatever action it deems appropriate, which may include without limitation one or more of the following:

• The Province may grant an exception to the maximum accepted list price requirement to the manufacturer(s) submitting the lowest list price, or a lower list price for any drug in the LCA category. Where necessary to ensure sufficient supply for PharmaCare beneficiaries, the Province may grant exceptions to more than one drug in the LCA category. In such instance, drugs will be considered for coverage in order of submitted list price, with the lowest priced drug receiving first consideration. Such exceptions may also be granted on a provisional basis, meaning that the exception may be removed at any time during the applicable period;

- The Province may deem all generic drugs in the LCA category ineligible for PharmaCare coverage;
- The Province may deem all drugs in the LCA category ineligible for PharmaCare coverage;
- The Province may undertake a competitive process to ascertain the lowest price at which a manufacturer is prepared to supply the drug in question for PharmaCare beneficiaries.

Where a manufacturer submits a price for a generic drug that exceeds the MALP and requests a pricing exception, and where the Province declines to grant the exception, the generic drug in question will be ineligible for PharmaCare coverage, effective April 2, 2012.

New Drug Submissions from April 2, 2012 to March 31, 2013

Starting April 2, 2012, the Province will no longer accept for review a new generic drug product submission for a generic drug in an existing LCA category, where all existing Full Benefit products are priced at or below the MALP. Manufacturers will have an opportunity to be considered for coverage during the next pricing period. However, the Province will continue to review a new generic drug product submission for a generic drug in an existing LCA category, where the list price submitted is below the list price of an existing Full Benefit drug that did not meet the MALP for the LCA category.

Confirmation of Coverage for Generic Drugs as of April 2, 2012

Following the review of the information received from all manufacturers, the Province will publish documents confirming the specific products eligible for coverage in each LCA category as of April 2, 2012, the maximum reimbursement price for each product and the LCA price for the category (i.e. the maximum reimbursement price for brand drugs in the category). The Province will publish the above information on or before **March 3, 2012**.

All generic drugs confirmed as eligible for coverage will be Full Benefit drugs, while any generic drugs not referenced in the document will be Non-Benefits.

Questions, Requests or Other Communications

Please direct all questions, requests or other communications regarding this letter or the accompanying documents to generic.submissions@gov.bc.ca.

We strongly encourage you to pose any questions concerning the issues addressed by this letter, or the accompanying documents, at the earliest possible opportunity. As much as is practicable, updates or other communications provided by the Province shall be communicated by email to all persons identified as the appropriate contacts for their companies in emails confirming receipt of this letter. Please check email inboxes regularly for correspondence from the Province, as information forthcoming over the coming months regarding this process could be very important.

As an additional forum for information exchange, the Province will also hold a conference call on **December 22**, 2011 to address questions or comments from manufacturers of generic drugs.

The call will start at 9:00am (Pacific Daylight Saving Time) and shall last up to two hours. The call details for each conference call shall be:

Dial-in number:

Participant Code

s. 15

We appreciate the ongoing relationship between your organization and the Province and we look forward to receiving your pricing submission.

Sincerely,

Original Signed

Mitch Moneo A\Executive Director Business Management, Supplier Relations & Systems Branch

Company Name Primary Contact	
Primary Contact	
Primary Contact	
all Still ame	
Last Name	
Job Title	
Ewa	
Phone	
Notes	
Secondary Contact	
First Name	
Last Name	
Job Title	
E-Wall	
Phone	
Notes	
Further Contacts	
E-mail	



GUIDELINE FOR COMPLETING THE PRICE CONFIRMATION WORKBOOK (EXHIBIT A)

Pharmaceutical Services Division December 16, 2011

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Section 1: Outline of Tasks

- 1) Upon receipt of the cover letter of December 16, 2011 and the Price Confirmation Workbook (the Workbook), send a confirmation of receipt to the Province via email to generic.submissions@gov.bc.ca
- 2) In your confirmation of receipt email, be sure to verify your company's contact information in the 'Contact' sheet of the Workbook. Update if necessary.
- 3) Gather a list of the generic drug products your company wishes to confirm list prices for.
 - Identify the appropriate Low Cost Alternative (LCA) categories for each of these
 products. For information on which products are currently included in each LCA
 category, manufacturers are encouraged to review the LCA Booklet. The LCA Booklet is
 posted online at http://www.health.gov.bc.ca/pharmacare/lca/lcabooklets.html.
- 4) In the appropriate LCA category row of the 'Submission Sheet', enter details into the 'Manufacturer's Product Information' and 'Manufacturer's Response' sections for each of the generic drug products that you are confirming list prices for.
 - If the manufacturer received a pre-populated Workbook, confirm that the details in the
 orange 'Manufacturer's Product Information' section are correct and then enter your
 response in the blue 'Manufacturer's Response' section. Amend, delete or add any
 details pre-populated into the orange 'Manufacturer's Product Information' section as
 may be needed to ensure accurate entries on your products that you may or may not
 want to confirm prices for.
- 5) Save the file using your company's name as the file name (i.e. ABCPharma.xls).
- 6) The completed Workbook must be sent in Excel format, along with a scanned version of the signed List Price Proposal Agreement in Portable Document Format (PDF), as electronic attachments together in one email to the Province at generic.submissions@gov.bc.ca with "List Price Confirmation" as the subject of the email in the manner and by the time stipulated in the cover letter of December 16, 2011.

Section 2: Frequently Asked Questions

1	Question	I represent more than one company. Can I simply fill in and return a single Workbook?
*	Answer	No, if you represent more than one company, you must use a separate Workbook for each company.
	Question	Is it important to format the Workbook so that it is more 'presentable'?
2	Answer	No, the data supplied by the Workbook will be loaded into a database, as part of an
_		automated process. Do not format the Workbook differently as the Province will only
		accept price confirmations that are inputted in the required format.
	Question	I have two DINs that belong to the same LCA category, how do I submit information for both DINs?
3	Answer	You will have to duplicate the row containing the LCA category that contains both DINs. Then, you can modify the DIN number of the duplicated row and enter its respective list price, along with other necessary information.
4	Question	PharmaCare generally allows for an 8% mark-up on top of list prices. Do I include the 8% mark-up in my submission?
	Answer	No, only submit to us the prices as public list prices, without the mark-up.

Section 3: Walkthrough of the Price Confirmation Workbook

Section 3.1: Overview of Sheets Contained In the Workbook

You will notice that the Workbook is made up of the following two sheets:

Sheet Name	Action Required	Description
Contact	Yes	Contains information on who PharmaCare should contact
Contact	162	regarding the manufacturer's price submission.
Submission Sheet	Yes	This is the sheet used by the manufacturer to submit
Submission sheet	162	prices for individual DINs.

Table 1: Summary of sheets in the Workbook

Section 3.2: Contact Sheet

This sheet contains the contact information for your company. Please ensure that the information in this contact sheet is properly completed. Include all applicable information, including telephone line extension numbers and anticipated holiday schedules (in the Notes section).

Should there be any changes after the submission of prices, please send an email with the relevant details to the Province at *generic.submissions@gov.bc.ca* as soon as possible.

Contact Informa	ition
Company Name	Sample Company
Primary Contact	
First Name	John
Last Name	Smith
Job Title	Director, Government Relations
E-mail	john.smith@sample.com
Phone	(514) 555-1234
Notes	On holidays Jan-15-2012 until Jan-31-2012
econdary Contact	
First Name	Jane
Last Name	Doe Statistics
Job Title	Director, Marketing
	jane.doe@sample.com
	(514) 555-5678 ext. 321
Notes	
Further Contacts	
	formulary@sample.com; bob@sample.com
Signification of the second	and the sample texts boom sample to the

Figure 1: Example of a completed contact sheet

We have provided space for two detailed contacts. But, you may submit additional e-mail addresses in the 'Further Contacts' section. As demonstrated in the example, e-mails entered in this section are to be separated by a semi-colon.

Formatting Requirements for the Contact Sheet

The automated program used to extract information is pre-determined. Therefore, please ensure that, apart from entering in the required fields, no other modifications are made to the sheet.

Section 3.3: Submission Sheet

- 1. Some manufacturers will receive a pre-populated Workbook. All other manufacturers will receive a standard Workbook.
- 2. The Workbook is not locked or password-protected. However, it is essential that manufacturers refrain from altering the format for the Workbook and to only enter information where designated. The Province will only accept price submissions that are in the required format.



Figure 2: Sample of how the submission sheet looks before being completed

How the Submission Sheet Is Set Up

The submission sheet consists of five sections:

Section#	Section Name	Section Color	Section Details
1	LCA Category Information	Grey	 LCA Category Number (Column 'A') LCA Category Description (Column 'B')
2	Manufacturer's Product Information	Orange	 Supplier Product Name (Column 'D') Supplier Product DIN (Column 'E') Supplier Product List Price (Column 'F')
3	MALP	Green	 Target MALP (Maximum Accepted List Price) (Column 'H')
4	Manufacturer's Response	Blue	 Pricing Response (Column 'J') Exception Request prompt based on Pricing Response (Column 'K') Question 1 (Column 'L') Question 2 (Column 'M') Question 3 (Column 'N') Question 4 (Column 'O')
5	MALP Calculation Information	Purple	 Rationale for MALP (Column 'Q') Reference Product DIN used to calculated MALP where applicable (Column 'R') Reference Product Name Used (Column 'S') Reference Product Price used to calculate MALP (Column 'T')

Table 2: Submission sheet layout

IMPORTANT NOTE: Limitations on Accuracy and Completeness of Pre-populated Data

For those manufacturers who receive a pre-populated Workbook, please note the following limitations: It is important to note that all of the pre-populated information relating to the manufacturer's products is prepared and sent without any guarantee or assurance as to accuracy and completeness. Therefore, manufacturers need to conduct their own due diligence to ensure that all of their intended products and the data related to such are accurately contained in the Workbook as they use the Workbook to submit their price confirmations.

The Province is under no obligation to accept changes post-submission whatever the reasons, including, but not limited to, missing and/or incorrect DINs or DINs submitted in error, even where incorrect DINs are the result of inaccurate details supplied by the Province in the 'Manufacturer's Product Information' columns. Manufacturers are solely responsible for ensuring the accuracy of all information in the Price Confirmation Workbook relating to their products, whether the information was pre-populated by the Province or inputted by the manufacturer.

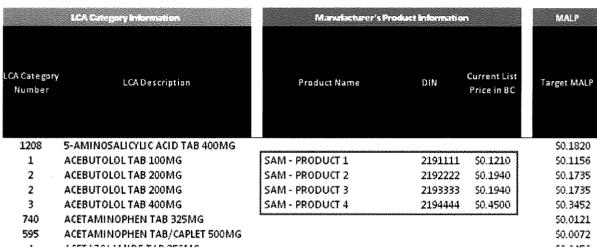


Figure 3: Sample of a company with pre-populated data. The pre-populated information has been highlighted in the red box.

How to Submit Pricing

1) Locate grey 'LCA Category Information' section for which product belongs to:

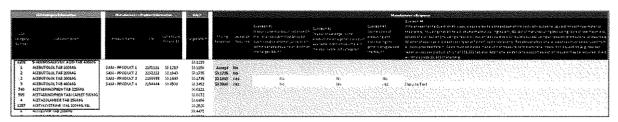


Figure 4: Finding LCA category information on the Workbook

2) Fill in the corresponding orange 'Manufacturer's Product Information' section. This includes Product Name and DIN. Manufacturers who were provided with a pre-populated Workbook need to ensure that all cells in this section contain the correct information or are correctly not populated, and must amend, delete or add information as needed to ensure accuracy and completeness.

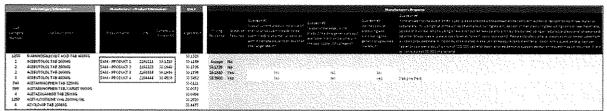


Figure 5: Filling in Manufacturer Product Information

3) Review the corresponding green 'Target MALP'. Remember that all MALPs are exclusive of mark-up.

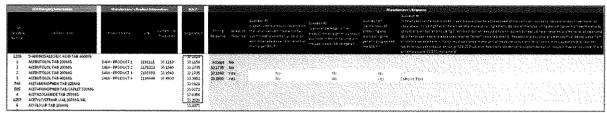


Figure 6: Finding the Target MALP on the Workbook

- 4) If you wish to submit a price confirmation for the applicable product that is equal to the Target MALP (Maximum Accepted List Price), enter the word 'Accept' into column 'J' within the blue section (the column entitled 'Pricing Response'). The value in column 'K', entitled 'Exception Required', will automatically populate with 'No' and there is no need to fill in any other cell that lies to the right of column 'J' on the same row.
 - Repeat Steps 1 to 4 for each DIN you wish to submit a price confirmation for
 - If your submitted list price is different than the green 'Target MALP' see Step 5 below



Figure 7: Entering a manufacturers pricing response

5) If your confirmed list price is higher or lower than the green 'Target MALP', enter the confirmed list price into column 'J' within the blue section (the column entitled 'Pricing Response'). Make sure your price confirmation is rounded to the nearest \$0.0001;

If Your Confirmed List Price is Higher than Target MALP:

 For every DIN that has a price confirmation that is higher than the Target MALP, the value in column 'K', entitled 'Exception Required', will automatically populate with 'Yes', except in situations where a new row is added (please see section below on 'How to Deal with Multiple DINs in a Single LCA Category') . You will then be prompted to answer the questions in the corresponding cells in the blue section within columns 'L', 'M', 'N', and 'O'.

- In column 'L', respond appropriately with either 'Yes' or 'No'.
- In column 'M', respond appropriately with either 'Yes' or 'No'.
- In column 'N', respond appropriately with either 'Yes' or 'No'.
- Should your response to **Question 3** in column 'N' be a 'YES', please provide in column 'O' a detailed breakdown of the costs attributed to:
 - i. cost for each raw material separately, including that of the active pharmaceutical ingredient,
 - ii. cost of manufacturing (excluding costs of raw materials),
 - iii. cost of distribution (including direct distribution fees paid to distributors but excluding all rebates/professional allowances), and
 - iv. other reasons (if applicable, please specify what "other" costs represent). Rebates/professional allowances must be excluded from all costs provided herein.

Costs must be stated in one unit of measure consistent for all costs requested in this question (e.g. cost per tablet or cost per production run of 100,000 tablets). Additional evidence to support exception request may be required. (Field will only accept 10,000 characters).

• Should your response to **Question 3** in column 'N' be 'No', please leave the corresponding cell in column 'O' blank.

If Your Confirmed List Price is Lower than Target MALP:

• For every DIN that has a price confirmation that is lower than the 'Target MALP', do **not** fill in any other cell that lies to the right of column 'J' on the same row. The value in column 'K', entitled 'Exception Required', will **automatically** populate with 'No'.

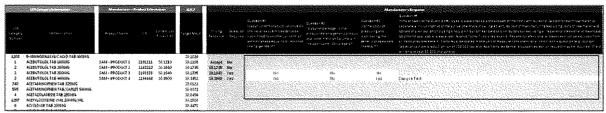


Figure 8: Submitting answers to questions when submitting a list price greater than the Target MALP

Note: Please be concise in your remarks. See below for some suggested remarks:

- Distribution and/or raw material costs for this product have risen significantly over the past few years.
- Production requires specialized and segregated facilities devoted exclusively to this drug. This specialization results in additional costs.

How to Deal With Multiple DINs in a Single LCA Category

Should the manufacturer have two or more DINs belonging to a single LCA category, you will have to duplicate the horizontal row containing the particular LCA category. See Figure 9 below to see how it should be created.

Note: The 'Exception Required' field in column 'K', will **not** automatically populate and you will need to fill all relevant responses manually and as appropriate.

	ECA Category Information	Manufacturer's P	redisct Enternation	n	MALP
LCA Category Number	LCA Description	Product Name	DIN	Current List Price in BC	Target MALP
1208	5-AMINOSALICYLIC ACID TAB 400MG				\$0.1820
1	ACEBUTOLOL TAB 100MG	SAM - PRODUCT 1	2191111	\$0.1210	\$0.1156
[2	ACEBUTOLOL TAB 200MG	SAM - PRODUCT 2	2192222	\$0.1940	\$0.1735
<u> </u>	ACEBUTOLOL TAB 200MG	SAM - PRODUCT 3	2193333	50.1940	\$0.1735
3	ACEBUTOLOL TAB 400MG	SAM - PRODUCT 4	2194444	\$0.4500	\$0.3452
740	ACETAMINOPHEN TAB 325MG				\$0.0121

Figure 9: A duplicate row for ACEBUTOLOL TAB 200MG has been created (as highlighted in red)

Section 3.4: MALP Calculation Information

In response to requests from some manufacturers, we have prepared additional information to show how the Target MALP for the LCA Category has been determined. As noted in the cover letter of December 16, 2011, the MALP for a generic drug is generally calculated as a percentage of the manufacturer's list price for a brand drug in the same LCA Category. However, where there is no brand drug price available within an LCA category, the Province has had to apply other methodologies to determine the Target MALP.

Column 'Q' notes the rationale upon which the MALP for the corresponding LCA Category is based. Where the MALP has been based on a brand drug's price (whether that brand is still actively sold or not), that brand drug is identified in column 'R' by its DIN. Similarly, where the MALP has been based on generic pricing, column 'R' will identify the Reference DIN of the generic drug. Where more than one drug (whether brand or generic) could have been used to arrive at the same MALP, only one of those drugs' DINs will be listed in Column 'R'. Column 'S' provides the corresponding name of the Reference Product used.

Column 'T' identifies the Reference Price that the Target MALP for the LCA Category has been based on, using the rationale in column 'Q'.

Section 3.5: How Information Will Be Extracted from the Workbook

All information submitted through the Workbook will be extracted by an automated process. Therefore, it is important that the sheets remain in their original formatting. This will ensure proper data integrity. For example, the automated program will expect DINs to appear in a specific column. Given that the sheets are not protected, manufacturers need to take extra care to ensure that the Workbook they submit is of the same formatting as when they received the

Workbook from the Province. The Province will accept price submissions only if they are inputted into the Workbook in the required formatting.

Due to the automated extraction process of the submitted Workbooks, manufacturers will also be required to ensure that they adhere to the inputting requirements in the table below. The following columns listed are of particular importance and should be handled with care.

Workbooks not meeting the minimum standard formatting requirements will be rejected by the automated process.

Column	Data	Description
E	DIN (Manufacturer's DIN)	DINs are to be stored as text without any leading zeros
Α	LCA Category Number	Numeric value of the LCA category.
	Pricing Response	Options: 1. The word 'Accept' or; 2. The submitted list price (if value is higher or lower than the Target MALP) –rounded to the nearest \$0.0001; or 3. Blank Cell. This indicates that your company is not seeking a listing for the corresponding drug on the PharmaCare formulary.
	Question 1: Is your current product list price OR the list price submitted (or to be submitted) to another jurisdiction within Canada equal to or less than the Target MALP?	Options: 1. Blank Cell – leave this blank if the product meets or is less than the Target MALP; otherwise 2. Enter 'Yes' or 'No'
M	Question 2: To your knowledge, is the product the only generic product available in British Columbia in the applicable LCA category?	Options: 1. Blank Cell – leave this blank if the product meets or is less than the Target MALP; otherwise 2. Enter 'Yes' or 'No'
N	Question 3: Do the costs of producing and distributing the generic drug exceed the MALP?	Options: 1. Blank Cell — leave this blank if the product meets or is less than the Target MALP; otherwise 2. Enter 'Yes' or 'No'
0	Question 4: Provide breakdown of costs	If you answered 'Yes' to Question 3, please provide further explanation as outlined in Question 4.

Table 3: Required data and its location in the Submission Sheet

Section 4: Useful Excel Tricks

Adjusting the Size of the Text Entry Box

You can adjust the size of the 'text entry box' if you wish to view more of the words that have been inputted into a cell. This can be done by clicking and dragging the very bottom of the text entry box. By default you can only see a single line.



Figure 10: Where to click to expand the text entry box

Page 22 redacted for the following reason:
Not Responsive

Not Responsive

From: Newman, Sakya HLTH:EX

Sent: Wednesday, February 15, 2012 5:56 PM

To: Guillen, Emy HLTH:EX

Subject: Meeting request from TEVA Canada

Hi Emy,

Liliana Polcari from TEVA Canada is requesting 15 minutes with Mitch to discuss 2 items:

1. Not Responsive

2. 2012 launch of generic Oxycodone

She called this afternoon and I told her I was forwarding the request to Mitch. Her contact info is:

Phone 416-940-6426 Cell 416-301-5632

Email <u>liliana.polcari@tevacanada.com</u>

Thanks,

Sakya Newman, BA, PGD

Administrative Assistant
Pharmanet | Business Management and Supplier Relations | Pharmaceutical Services
Ministry of Health | 3-2, 1515 Blanshard St. | Victoria BC V8W 3C8

Sakya.Newman@gov.bc.ca ρ 250 952-2218 | f 250 952-2790

From: PSD BMSRS - Generic Submissions HLTH:EX Sent: Thursday, February 16, 2012 6:24 PM

To: Lun, Eric HLTH:EX; Moneo, Mitch HLTH:EX; Nakagawa, Bob HLTH:EX; Taylor,

Suzanne C HLTH:EX; Walsh, Sara M HLTH:EX; Bethel, John HLTH:EX; Pop, Sorin HLTH:EX; Wilmer, Brett D HLTH:EX; Hosick, David HLTH:EX; Fazlagic, Tijana HLTH:EX; Moneo, Mitch HLTH:EX; Campbell, Diane E HLTH:EX; Capelli, John HLTH:EX; Munro, Deborah HLTH:EX; Healey, Susan HLTH:EX; Chong, Elaine HLTH:EX; Therrien, Darlene HLTH:EX; 'XT:Vasseur, Melissa SSBC:IN'; Arenson,

Darlene H HLTH:EX; Hardy, Jillian HLTH:EX; Yamaguchi, Jesse HLTH:EX; Voggenreiter, Christine HLTH:EX; Day, Patrick HLTH:EX; de Boer, Cheryl

HLTH:EX; wendy.parker@hibc.gov.bc.ca

Cc: Guillen, Emy HLTH:EX; Shin, Sophia HLTH:EX; Kwok, Jess HLTH:EX; Tan,

Dominic HLTH:EX; Ghouse, Ray HLTH:EX

Subject: FW: Important Message from BC Ministry of Health - Identification of

Potential Inconsistencies

Importance: High

Hi

Please see below for the communication sent today to manufacturers regarding the upcoming generic pricing period.

Best,

BMSRS

From: PSD BMSRS - Generic Submissions HLTH:EX Sent: Thursday, February 16, 2012 6:19 PM To: PSD BMSRS - Generic Submissions HLTH:EX

Subject: Important Message from BC Ministry of Health - Identification of Potential Inconsistencies

Importance: High

IMPORTANT COMMUNICATION FROM THE BRITISH COLUMBIA MINISTRY OF HEALTH –

PHARMACEUTICAL SERVICES DIVISION CONCERNING THE IMPLEMENTATION OF THE APRIL 2012 GENERIC PRICING PERIOD

The Pharmaceutical Services Division (PSD) thanks all manufacturers that submitted a signed List Price Proposal Agreement and a completed Price Confirmation Workbook (Exhibit A to the List Price Proposal Agreement).

As referenced in earlier communications, PSD shall confirm by February 28, 2012 which generic products shall be eligible for PharmaCare reimbursement from April 2, 2012 through to March 31, 2013 (the

Pricing Period), as well as the maximum reimbursement prices that shall apply. PSD has started reviewing manufacturer price confirmations and is in the process of finalizing the list of eligible generic drugs and the maximum reimbursement prices.

As part of PSD's process for finalizing such lists, we attach below a spreadsheet that sets out those drugs which remain under consideration for PharmaCare reimbursement during the Pricing Period, as well as the maximum reimbursement limits being considered for each of those drugs. PSD is disseminating this spreadsheet in order to provide manufacturers with an opportunity to notify PSD of any items in the spreadsheet that are **inconsistent with the data submitted** by them in their respective Price Confirmation Workbooks. Any such notification, in order to be considered prior to the publication of the next LCA documents, must be received in an email sent to generic.submissions@gov.bc.ca no later than **5:00pm Pacific Daylight Standard Time on Tuesday, February 21, 2012**, and must:

- 1) bear the subject heading "Notification Concerning Spreadsheet of February 16, 2012",
- 2) clearly identify the specific LCA category number, DIN and name of the relevant product,
- 3) clearly state why the information in the spreadsheet is inconsistent with the price confirmation submitted by the manufacturer in their Price Confirmation Workbook, and
- 4) clearly state how the spreadsheet should be amended so as to accurately reflect the price confirmation submitted by the manufacturer in their Price Confirmation Workbook.

Manufacturers are strongly encouraged to carefully review the data in the attached spreadsheet and to provide notifications promptly so as to avoid any erroneous information being published in the eventual LCA documents that may affect the eligibility of their products and applicable maximum reimbursement prices.

Manufacturers should note that the information in the attached spreadsheet is still subject to change, as PSD has yet to finalize which generic products will be eligible during the Pricing Period, as well what the maximum reimbursement limits will be. Therefore, the attached spreadsheet does **not** constitute confirmation of which products will be eligible for PharmaCare reimbursement during the Pricing Period nor does it constitute confirmation of the maximum reimbursement prices that will apply during the Pricing Period. Such confirmations will be provided by February 28, 2012.

As set out in the December 16, 2011 letter, the Province retains sole discretion to take whatever action it deems appropriate to address situations where within an LCA category, no manufacturer commits to sell a generic product at or below a MALP or where the Province has concerns relating to the sufficiency of supply offered by those manufacturers confirming prices that meet or fall below a MALP. One of the possibilities is that some generic products listed in the attached spreadsheet may be accorded Full Benefit status on a provisional basis only.

While changes to PharmaCare reimbursement limits for eligible generic drugs will not be implemented until April 2, 2012, please note that where the list price submitted for a generic drug in accordance with this process represents a change to the current list price, the new list price must take effect in British Columbia no later than March 2, 2012.

Generic products that are accorded a provisional Full Benefit status may potentially not remain eligible for PharmaCare reimbursement throughout the entirety of the Pricing Period. PSD will have the discretion to delist these products at any time prior to the end of the Pricing Period. PSD shall confirm by February 28, 2012 which products will be accorded Full Benefit status on a provisional basis only.

In the attached spreadsheet, brand and generic products are listed in their respective LCA categories. Only those generic products accorded Full Benefit status shall be eligible for PharmaCare reimbursement on April 2, 2012. Generic products enjoying Full Benefit status shall be reimbursed up to the maximum price (shown as "Max Price", or Column J in the attached spreadsheet). Subject to finalization of the upcoming LCA documents, generic products not listed in the attached spreadsheet will be ineligible for PharmaCare reimbursement during the Pricing Period.

Brand products may be accorded Full Benefit or Partial Benefit status. Those that are a Full Benefit shall be reimbursed up to the maximum price, while those that are Partial Benefit will be reimbursed up to the LCA price (Column K in the attached spreadsheet).

Manufacturers are also advised that, as in the past, maximum prices, LCA prices, and PharmaCare reimbursement in general remain subject to eligibility criteria, as well as other reimbursement limiting measures, such as those of PharmaCare's programs (i.e. Reference Drug Program and Special Authority program), plan rules, policies, pricing exceptions, and reimbursement practices.

Please forward any questions that you may have regarding the above to generic.submissions@gov.bc.ca.

Regards, PSD

Draft LCA readsheet For Man From: PSD BMSRS - Generic Submissions HLTH:EX

Sent: Tuesday, February 28, 2012 11:10 AM

To: Lun, Eric HLTH:EX; Moneo, Mitch HLTH:EX; Nakagawa, Bob HLTH:EX; Taylor,

Suzanne C HLTH:EX; Walsh, Sara M HLTH:EX; Bethel, John HLTH:EX; Pop, Sorin HLTH:EX; Wilmer, Brett D HLTH:EX; Hosick, David HLTH:EX; Fazlagic, Tijana HLTH:EX; Moneo, Mitch HLTH:EX; Campbell, Diane E HLTH:EX; Capelli, John HLTH:EX; Munro, Deborah HLTH:EX; Healey, Susan HLTH:EX; Chong, Elaine HLTH:EX; Therrien, Darlene HLTH:EX; 'XT:Vasseur, Melissa SSBC:IN'; Arenson,

Darlene H HLTH:EX; Hardy, Jillian HLTH:EX; Yamaguchi, Jesse HLTH:EX; Voggenreiter, Christine HLTH:EX; Day, Patrick HLTH:EX; de Boer, Cheryl

HLTH:EX

Cc: Tan, Dominic HLTH:EX; Kwok, Jess HLTH:EX; Shin, Sophia HLTH:EX; Guillen,

Emy HLTH:EX

Subject: FW: IMPORTANT COMMUNICATION FROM THE BRITISH COLUMBIA MINISTRY

OF HEALTH - PHARMACEUTICAL SERVICES DIVISION - FINAL LCA AND

REMOVAL SPREADSHEETS

Importance: High

Hi all,

Please see below for the communication which went out today to all manufacturers who participated in the April 2012 price confirmation process as well as generic associations. The email contains the final LCA and Removal Spreadsheet which will be posted on to PharmaCare website by tomorrow, Feb 29, 2012.

Regards,

BMSRS

From: PSD BMSRS - Generic Submissions HLTH:EX **Sent:** Tuesday, February 28, 2012 11:03 AM **To:** PSD BMSRS - Generic Submissions HLTH:EX

Subject: IMPORTANT COMMUNICATION FROM THE BRITISH COLUMBIA MINISTRY OF HEALTH -

PHARMACEUTICAL SERVICES DIVISION - FINAL LCA AND REMOVAL SPREADSHEETS

Importance: High

IMPORTANT COMMUNICATION FROM THE BRITISH COLUMBIA MINISTRY OF HEALTH –

PHARMACEUTICAL SERVICES DIVISION CONCERNING THE IMPLEMENTATION OF THE APRIL 2012 GENERIC PRICING PERIOD

Further to various communications sent to manufacturers since December 16, 2011, this email communication provides two attached files. The first attached file ("LCA Spreadsheet for April 2012") lists the drugs that will be included within the Low Cost Alternative (LCA) program as of April 2, 2012. The second attached file ("Removal Spreadsheet for April 2012") sets out the drugs that will be removed from the PharmaCare Formulary, and thus become ineligible for PharmaCare reimbursement, as of April 2, 2012. The two attached files are further described in subsequent sections below.

1) LCA Spreadsheet for April 2012

On February 16, 2012, Pharmaceutical Services Division (PSD) distributed to manufacturers of generic drugs a draft spreadsheet that set out those drugs which remained under consideration for PharmaCare reimbursement for the upcoming Reimbursement Period (April 2, 2012 to March 31, 2013), as well as the applicable maximum reimbursement limits being considered for each of those drugs. PSD distributed the spreadsheet in order to provide generic manufacturers with an opportunity to notify PSD of any items in the spreadsheet that were inconsistent with the data submitted by them in their respective Price Confirmation Workbooks (deadline for those workbooks was January 13, 2012). We thank those manufacturers that submitted such notifications.

PSD undertook to confirm by February 28, 2012 which generic products would be eligible for PharmaCare reimbursement for the Reimbursement Period, as well as the maximum reimbursement prices that would apply to them. The first attached file bearing the file name "LCA Spreadsheet for April 2012" provides such confirmation. Please note that since the draft spreadsheet sent out on February 16, 2012, the attached LCA Spreadsheet for April 2012 may contain updated information which may impact your respective products. Therefore, we encourage you to review this attached LCA Spreadsheet for April 2012 and ensure to take note of any such changes.

As contemplated in the February 16, 2012 communication, some generic products listed in the attached LCA Spreadsheet for April 2012 are accorded Full Benefit status on a provisional basis only (identified by an "X" in the column entitled "PROV"). Generic products that are accorded a

provisional Full Benefit status may potentially not remain eligible for PharmaCare reimbursement throughout the entirety of the Reimbursement Period. PSD will have the discretion to delist these products at any time prior to the end of the Reimbursement Period.

In the attached LCA Spreadsheet for April 2012, brand and generic products are listed in their respective LCA categories. Only those generic products accorded Full Benefit status under the LCA program shall be eligible for PharmaCare reimbursement effective April 2, 2012. Generic products enjoying Full Benefit status (indicated by an "F" or a "P*" in the column entitled "Full/Partial LCA Benefit") under the LCA program shall be reimbursed up to the maximum price, unless subject to a Reference Price under the Reference Drug Program. The maximum price is equal to the manufacturer list price plus, in general, an 8% mark-up (5% for certain drugs subject to the Reduced Mark-up for High Cost Drugs policy). Generic products not listed in the attached LCA Spreadsheet for April 2012 will be ineligible for PharmaCare reimbursement during the Reimbursement Period.

Brand products may be accorded Full Benefit or Partial Benefit status. Partial Benefit status under the LCA program is indicated by a "P" in the column entitled "Full/Partial LCA Benefit". Those that are a Full Benefit shall be reimbursed up to the maximum price (unless subject to a Reference Price under the Reference Drug Program), while those that are Partial Benefit will be reimbursed up to the LCA price (shown in the column entitled "LCA Price", where applicable).

Manufacturers are again advised that, as in the past, maximum prices, LCA prices and PharmaCare reimbursement in general, remain subject to eligibility criteria, as well as other reimbursement limiting measures, such as those of PharmaCare's programs (i.e. Reference Drug Program and Special Authority program), plan rules, policies, pricing exceptions and reimbursement practices.

We strongly urge manufacturers to, based on the data in the LCA Spreadsheet for April 2012, communicate and take note of the reimbursement limits and list prices applicable to their drugs. Should they notice any data that is inconsistent with the Price Confirmation Workbooks they submitted along with their List Price Proposal Agreement (deadline for such submission was January 13, 2012), they should notify PSD immediately, at geov.bc.ca with an email bearing the subject heading "LCA Spreadsheet for April 2012 Concern".

Please note the following headings for the columns in the attached spreadsheet.

LCA CATEGORY NO.: The Low Cost Alternative (LCA) category number, as assigned by PSD.

DIN: The Drug Identification Number (DIN) assigned to each of the products by the Health Protection Branch of Health Canada.

CHEMICAL NAME: The chemical name for each drug.

DRUG NAME: The product name associated with a specific manufacturer's version of a drug.

MAN: The manufacturer code assigned by Health Canada. While this information is from sources believed to be accurate, it is important to note that the accuracy of these manufacturer codes and names cannot be guaranteed.

FULL/PARTIAL LCA BENEFIT: This column indicates whether or not a product will be automatically and fully covered by PharmaCare.

- "F" indicates that the product is a "Full Benefit" and will be fully covered by PharmaCare, subject to the Maximum Pricing Policy.
- "P" indicates that the product is a "Partial Benefit" and coverage is limited according to LCA or RDP pricing policy.
- "P*" identifies a product that will be recognized as a full benefit if a Special Authority has been granted for exemption to the RDP.

PLAN B ONLY: An "X" in this column indicates that the product is a benefit for Plan B patients only. These drugs are subject to LCA or RDP rules.

RDP: This column identifies a drug that is subject to the rules of the RDP. Claims for drugs that are designated as "**RDP**" will be reduced to the RDP price. The RDP price is determined by the cost of the reference drug. "**REF**" refers to the reference drug(s) in the category. If this column is blank, the drug is not included in the RDP.

SA: This column identifies a drug that is a **LIMITED COVERAGE DRUG** covered only with an approved Special Authority. Claims for "SA" drugs adjudicate to zero unless a Special Authority has been granted and entered on PharmaNet before the prescription is filled. All valid claims for an "SA" drug adjudicate according to LCA Program rules.

MAX PRICE: The price entered in PharmaNet as the maximum price that PharmaCare will reimburse for the drug. When there is a price in both the MAX PRICE and LCA PRICE column, claims adjudicate to the lower of the two prices. Please note that if a product is an RDP product it will be adjudicated at the lesser of the MAX PRICE, LCA PRICE or RDP PRICE.

LCA PRICE: This is the Low Cost Alternative price for each drug. If this column is blank, the drug is not subject to the LCA price for that category.

PROV: An "X" in this column indicates that the generic drug has been accorded Full Benefit status on a provisional basis only.

As communicated in the December 16, 2011 letter to manufacturers, and further to an update in the December 23, 2011 Question and Answers document, starting April 2, 2012, PSD will no longer accept for review a new generic drug product submission for a generic drug in an existing LCA category, where all existing Full Benefit products are priced at or below the MALP, except in situations where the generic drug product's Notice of Compliance (NOC) was obtained after the price confirmation submission deadline. Manufacturers will have an opportunity to be considered for coverage during the next pricing period. However, PSD will continue to review a new generic drug product submission for a generic drug in an existing LCA category, where the list price submitted is below the list price of an existing Full Benefit drug that did not meet the MALP for the LCA category.

Where the NOC was available prior to the submission and where the manufacturer confirmed pricing for the generic product in the Price Confirmation Workbook, such products will not be eligible for PharmaCare coverage until the supply date is formally confirmed to PSD.

2) Drugs to be Removed from the PharmaCare Formulary

The second attached file bearing the file name "Removal Spreadsheet for April 2012" lists out the drugs that will be removed from the PharmaCare formulary, and thus made ineligible for PharmaCare reimbursement, effective April 2, 2012. These drugs will be removed for reasons that include, without limitation, the following:

- A price confirmation for the drug was not submitted by the manufacturer in accordance with the process and timeframes set out in earlier communications
- A price confirmation was submitted for the drug by the manufacturer that did not meet the MALP eventually established for the LCA Category
- Discontinuation of the drug by the manufacturer

We strongly encourage all manufacturers to review the data in the Removal Spreadsheet for April 2012 to satisfy themselves that such spreadsheet does not contain any drug that should not be removed. Column headings in the spreadsheet have the same meaning as those in the LCA Spreadsheet for April 2012, as described above in this communication. Should any drug not belonging in this spreadsheet be found, the manufacturer should immediately notify PSD at generic.submissions@gov.bc.ca with an email bearing the subject heading "Removal Spreadsheet for April 2012 Concern", so as to prevent any removal that would be inconsistent with the process outlined by PSD in this and other prior communications. Such notification must clearly state the LCA Category number, the DIN of the drug, and the reason why the removal would be inconsistent.

These documents will also be available on the PharmaCare website by February 29, 2012.

Should you any other questions concerning the above, please email them to us at generic.submissions@gov.bc.ca.

Regards,

PSD





LCA Spreadsheet Removal for April 2012... readsheet for April

Pages 33 through 79 redacted for the following reasons:

LCA (Low Cost Alternative) Master Spreadsheet (effective April 2, 2012)

LCA Category no.	IN Chemical Name	Drug Name	MAN	Full / Partial Pian B Only LCA Benefit	RDP	SA Man	Max Price LCA Price		PROV
1286	392472 OXYCODONE HCL SUPP.RECT 20MG	SUPEUDOL 20	12027	4		:33	53.0996		×
923 923 923	443948 OXYCODONE HCI TAB 10MG 2240131 OXYCODONE HCI TAB 10MG 2319985 OXYCODONE HCI TAB 10MG	SUPEUBOL 10 OXY.IR PMS-OXYCODONE	12027 7054 3550	a a u.		***	\$0.2048 \$0.4169 \$0.1638	\$0.1638 \$0.1638	×
1043 1043 1043	2240132 OXYCODONE HCI. TAB 20MG 2262983 OXYCODONE HCI. TAB 20MG 2319993 OXYCODONE HCI. TAB 20MG	OXY.IR SUPEUDOL PMS-OXYCODONE	7054 12027 3550	ک ۵. ند		***	\$0.7247 \$0.3556 \$0.2845	\$0.2845 \$0.2845	×
922 922 922	789739 OXYCODONE HCL TAB SMG 2231934 OXYCODONE HCL TAB SMG 2319977 OXYCODONE HCL TAB SMG	SUPEUDOL 5 ONY.IR PMS-OXYCODONE	12027 7054 3550	a a w		***	\$0.1390 \$0.2830 \$0.1112	\$0.1112 \$0.1112	×
431 431 431 431 431	1916475 DXYCODONE/ACET TAB 5/325MG 608186 DXYCODONE/ACET TAB 5/325MG 1910548 DXYCODONE/ACET TAB 5/325MG 2307889 DXYCODONE/ACET TAB 5/325MG 2246282 DXYCODONE/ACET TAB 5/325MG 2361361 DXYCODONE/ACET TAB 5/325MG	PERCOCET RATIO-OXYCOCET RATIO-OXYCOCET SANDOZ OXYCODONE/ACETAMINOPHEN APO-OXYCODONE/ACET OXYCODONE/ACET OXYCODONE/ACET OXYCODONE/ACET	3798 10402 3798 12027 3636 14236	<u>скяст</u>		* * * * * *	\$0.8321 \$0.1388 \$0.1388 \$0.1388 \$0.1388 \$0.1388	\$0,1388	× ×××
				•					

Not Responsive