

VOLUNTARY COMPLIANCE UNDERTAKING
OF
GLAXOSMITHKLINE INC.
TO
THE PATENTED MEDICINE PRICES REVIEW
BOARD

1.0 Background

- 1.1. GlaxoSmithKline Inc. ("GSK") has, *sua sponte*, conducted a comprehensive and extensive audit of its patent portfolio to determine compliance with sections 79 to 103 of the *Patent Act*, the *Patented Medicines Regulations* made thereunder and the *Compendium of Policies, Guidelines and Procedures* of the Patented Medicine Prices Review Board (the "Guidelines" and the "PMPRB", respectively).
- 1.2. The results of GSK's voluntary audit have disclosed a number of instances of inadvertent non-compliance in reporting and pricing, including in respect of some products which have been discontinued or are otherwise not actively marketed. These instances of inadvertent non-compliance include drug products that have never been reported to the PMPRB and drug products that, while once-reported, ceased to be reported to the PMPRB.
- 1.3. The reporting non-compliance has been rectified to the satisfaction of the PMPRB. The purpose of this Voluntary Compliance Undertaking ("VCU") is to remedy the pricing non-compliance to the satisfaction of the PMPRB.

2.0 Affected Products

- 2.1. The products in respect of which filing non-compliance was found, identified by brand and drug identification number, are set out on Schedule "A" attached hereto (individually, a "Product" and, collectively, the "Products").
- 2.2. GSK is the patentee of the Products as that term is defined in subsection 79(1) of the *Patent Act* and for purposes of the PMPRB.

3.0 Position of Patentee

- 3.1. This VCU constitutes no admission by GSK that the prices of the Products are or were excessive for purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking

VCUs represent a compromise between the PMPRB and the patentee as a result of negotiations between the parties in view of the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.

- 4.1 In order to comply with the Guidelines to the satisfaction of the PMPRB, GSK undertakes as follows:
- 4.1.1 to offset cumulative excess revenues received by GSK in respect of the Products as of December 31, 2016, by making a payment to Her Majesty the Queen in right of Canada in the amount of \$31,000,000.00 within 90 days of the notification of the acceptance of this VCU.
 - 4.1.2 to agree that the 2017 N-NEAPs for the Products that continued to be sold in 2016 are as set out on Schedule "B";
 - 4.1.3 subject to subsection 4.1.4, to reduce the N-ATPs of the Products in 2017 to the 2017 N-NEAPs referred to in subsection 4.1.2 and set out on Schedule "B";
 - 4.1.4 to the degree that GSK is unable to comply with subsection 4.1.3 in respect of any given Product due to the existence of reasonable timing and volume constraints, to offset any additional excess revenues received by GSK in respect of the Products from January 1, 2017 to December 31, 2017, as calculated by PMPRB Staff, within 30 days of the filing of the July to December 2017 price and sales data; and
 - 4.1.5 to ensure that the price of any given Product remains within the Guidelines in all future periods in which such given Product is under the PMPRB's jurisdiction.

GlaxoSmithKline Inc.

Signature: Original signed by

Name:

PAUL LIRETTO

Position:

PRESIDENT CANADA

Date:

FEB 8th 2017

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Schedule A to Voluntary Compliance Undertaking

Product List

<u>DIN</u>	<u>Brand Name</u>
02192691	3TC 10 MG/ML
02192683	3TC 150 MG
02247825	3TC 300 MG
02240835	ADVAIR DISKUS 50/100
02240836	ADVAIR DISKUS 50/250
02240837	ADVAIR DISKUS 50/500
02245126	ADVAIR HFA 25/125
02245127	ADVAIR HFA 25/250
02336650	AREPANRIX H1N1
02401886	AREPANRIX H5N1
02298589	AVAMYS
02248440	AVANDAMET 2/1000
02247086	AVANDAMET 2/500
02248441	AVANDAMET 4/1000
02247087	AVANDAMET 4/500
02241112	AVANDIA 2 MG
02241113	AVANDIA 4 MG
02241114	AVANDIA 8 MG
02370050	BENLYSTA 120 MG
02370069	BENLYSTA 400 MG
00370568	BENOXYL LOTION 10%
00187585	BENOXYL LOTION 20%
02247600	BOOSTRIX
02312557	BOOSTRIX POLIO
02408872	BREO ELLIPTA 100/25
02212277	CEFTIN TABLETS 250 MG
02212285	CEFTIN TABLETS 500 MG
02299844	CESENTRI 150 MG
02299852	CESENTRI 300 MG
02342227	CERVARIX
02242970	CLINDASOL
02243050	CLINDETS
02382822	CLINDOXYL ADV GEL
02243158	CLINDOXYL GEL
00068756	COACTIFED EXPECTORANT SYRUP
00068594	COACTIFED SYRUP
00068608	COACTIFED TABLETS

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02239213	COMBIVIR
02025736	CORTISPORIN EYE/EAR SUSPENSION
01912828	CORTISPORIN LIQUID OTIC SOLUTION
00666246	CORTISPORIN OINTMENT
02089912	CUTIVATE CREAM
02192284	CYCLOCORT CREAM
02192276	CYCLOCORT LOTION
02192268	CYCLOCORT OINTMENT
00192597	EMO CORT CREAM 1%
00595799	EMO CORT CREAM 2.5%
00192600	EMO CORT LOTION 1%
00595802	EMO CORT LOTION 2.5%
00641154	EMO CORT SOLUTION 2.5%
00666130	EMPRACET-30
01919431	ENGERIX-B
02296454	ENGERIX-B PEDIATRIC
02034506	ERY SOL
02213672	FLONASE
02237245	FLOVENT DISKUS 100 MCG
02237246	FLOVENT DISKUS 250 MCG
02237247	FLOVENT DISKUS 500 MCG
02237244	FLOVENT DISKUS 50 MCG
02244292	FLOVENT HFA 125 MCG
02244293	FLOVENT HFA 250 MCG
02244291	FLOVENT HFA 50 MCG
01914510	FLUVIRAL
02015986	FLUVIRAL
02420686	FLUVIRAL
02187078	HAVRIX 1440
02231056	HAVRIX 720 JUNIOR
02239193	HEPTOVIR 100 MG
02239194	HEPTOVIR 5 MG/ML
02239200	HIBERIX
02253852	INFANRIX HEXA
02257122	INFANRIX IPV/HIB
02241284	INFANRIX-IPV
02337258	INFLUENZA A H1N1
02269341	KIVEXA
02366924	LUXIQ
00587826	NERISONE CREAM
00587818	NERISONE OILY CREAM

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00587834	NERISONE OINTMENT
02344408	OLUX-E
00527661	PANOXYL BAR 10%
00263699	PANOXYL GEL 10%
00373036	PANOXYL GEL 20%
02027887	PAXIL 10 MG
01940481	PAXIL 20 MG
01940473	PAXIL 30 MG
02248503	PAXIL CR 12.5 MG
02248504	PAXIL CR 25 MG
00804541	PREVEX B
00804533	PREVEX HC
02239208	PRIORIX
02297884	PRIORIX TETRA
02232565	REQUIP 0.25 MG
02232567	REQUIP 1 MG
02232568	REQUIP 2 MG
02232569	REQUIP 5 MG
02238348	RESCRIPTOR
02008688	RETISOL-A 0.01%
02008718	RETISOL-A 0.05%
02008696	RETISOL-A 0.25%
02008726	RETISOL-A FORTE 0.1%
01902660	RETROVIR TABLETS 100 MG
01902644	RETROVIR IV 10 MG/ML
01902652	RETROVIR SYRUP 10 MG/ML
02300591	ROTARIX
02214261	SEREVENT DISKHALER 50 MCG
02231129	SEREVENT DISKUS 50 MCG
02019825	SOLUGEL
02247228	STIEPROX SHAMPOO
00657204	STIEVA-A CREAM 0.01%
00578576	STIEVA-A CREAM 0.025%
00518182	STIEVA-A CREAM 0.05%
00662348	STIEVA-A CREAM 0.1%
00587966	STIEVA-A GEL 0.025%
00641863	STIEVA-A GEL 0.05%
00578568	STIEVA-A SOLUTION 0.03%
01945262	STIEVAMYCIN FORTE
02015994	STIEVAMYCIN MILD
01905112	STIEVAMYCIN REGULAR

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02320541	SYNFLORIX
02430932	TRIUMEQ
02244757	TRIZIVIR
02230578	TWINRIX
02237548	TWINRIX JUNIOR
02242727	TYPHERIX
00503134	UREMOL HC CREAM 1%/10%
00560022	UREMOL HC LOTION 1%/10%
02241047	VARILRIX
02213443	VENTOLIN IM INJECTION
02213451	VENTOLIN IV INFUSION
02213400	VENTOLIN NEBULES 1.25 MG
02022125	VENTOLIN NEBULES 1.25 MG
02213419	VENTOLIN NEBULES 2.5 MG
01945203	VENTOLIN NEBULES 5 MG
02213427	VENTOLIN NEBULES 5 MG
02212390	VENTOLIN ORAL LIQUID
02213486	VENTOLIN RESPIRATOR SOLUTION
02348489	VERDESO
02240358	ZIAGEN 20 MG/ML
02240357	ZIAGEN 300 MG
02213567	ZOFRAN TABLET 4 MG
02213575	ZOFRAN TABLET 8 MG
02213745	ZOFRAN INJECTION
02229639	ZOFRAN ORAL SOLUTION
00634506	ZOVIRAX TABLET
00886157	ZOVIRAX SUSPENSION

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Schedule B to Voluntary Compliance Undertaking

2017 NEAPs for drug products with 2016 sales that had never been reported to the PMPRB and drug product that, while once-reported, ceased to be reported

DIN	Brand Name	2017 N-NEAP
02312557	BOOSTRIX POLIO	\$10.5296
02212277	CEFTIN TABLETS 250 MG	\$1.3323
02212285	CEFTIN TABLETS 500 MG	\$2.1496
02243050	CLINDETS	\$0.5635
00068594	COACTIFED SYRUP	\$0.0713
02192284	CYCLOCORT CREAM	\$0.2530
02192276	CYCLOCORT LOTION	\$0.2635
02192268	CYCLOCORT OINTMENT	\$0.2530
00192597	EMO CORT CREAM 1%	\$0.1448
00595799	EMO CORT CREAM 2.5%	\$0.2104
00192600	EMO CORT LOTION 1%	\$0.1469
00595802	EMO CORT LOTION 2.5%	\$0.2134
02213672	FLONASE	\$0.1979
02420686	FLUVIRAL	\$6.3765
02239200	HIBERIX	\$20.5791
02241284	INFANRIX-IPV	\$15.7758
00587818	NERISONE OILY CREAM	\$0.3107
00804541	PREVEX B	\$0.2106
00804533	PREVEX HC	\$0.1571
02232565	REQUIP 0.25 MG	\$0.2249
02232567	REQUIP 1 MG	\$0.6386
02232568	REQUIP 2 MG	\$0.9770
02232569	REQUIP 5 MG	\$1.5817
02247228	STIEPROX SHAMPOO	\$0.1010
00657204	STIEVA-A CREAM 0.01%	\$0.3069
00578576	STIEVA-A CREAM 0.025%	\$0.3050
00518182	STIEVA-A CREAM 0.05%	\$0.2143
02242727	TYPHERIX	\$21.0601
02241047	VARILRIX	\$32.4826
02213451	VENTOLIN IV INFUSION	\$0.9330
02213419	VENTOLIN NEBULES 2.5 MG	\$0.2336
02213427	VENTOLIN NEBULES 5 MG	\$0.2716
02213486	VENTOLIN RESPIRATOR SOLUTION	\$0.2393
00886157	ZOVIRAX SUSPENSION	\$0.2236

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