Pharmaceutical Economics

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Abstract: Canada and the European Commission conducted a joint study in 2008 on the economic impacts of the agreement's proposed reductions in trade barriers between Canada and the EU, finding substantial annual gains to both economies (European Commission & Canada, 2008). However, that study did not address CETA"s pharmaceutical IP provisions. The present analysis addresses this gap. Pharmaceutical costs are a pressing issue in Canada. Healthcare costs are rising as Canada's population ages, and pharmaceuticals comprise a significant and growing percentage of these costs. A recent report indicates that the drug sector will be the second largest component of Canadian healthcare spending in 2010 – ahead of physicians – at more than $31 billion. (All dollar values in this paper are in Canadian currency.) Sales of patented drugs were approximately $13 billion in 2009. Canadian public drug plans have been at the forefront of efforts to control drug spending, with the creation of the Common Drug Review, with the use of special reimbursement mechanisms such as reference pricing, and with various efforts to control prescribing volume. Most recently, several provinces have set lower regulated or negotiated prices for generic drugs, leading to system-wide generic price reductions of as much as 50 percent (in the case of Ontario and Quebec), yielding annual savings in the hundreds of millions of dollars. Specific consideration of the impact of the agreement's intellectual property provisions on the pharmaceutical market is therefore warranted.

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1. Introduction

The study examines the impact of the changes on Canada's pharmaceutical market – consumers, payers, and industry. While there will be costs and benefits to various parties, we find that the provisions proposed by the EU will create substantial costs for payers – including the provinces – matched by increased revenues for brand name pharmaceutical manufacturers, which are primarily based outside of Canada.

2. The Status of the CETA Negotiations

The launch of negotiations toward CETA was announced at the Canada-EU Summit on May 6, 2009. To our knowledge, there have been no formal negotiations regarding the pharmaceutical-related IP provisions since the EU first made proposals in the first round. The leaked text on which this analysis is predicated represents the EU negotiating position and is not necessarily the basis for a final agreement.

3. Data Exclusivity

Canadian law protects innovative drugs for a period of eight years from generic competition through the protection of innovator data. The idea is that, during this period, the Minister of Health cannot grant a market authorization to a product that would directly or indirectly rely on the clinical trials sponsored by the firm that obtained the regulatory approval. There is also a six-month extension granted for innovative products that have been the subject of clinical testing in pediatric populations. Data exclusivity in Canada is currently restricted only to certain drugs meeting specific criteria, and does not apply to new uses for existing drugs. The policy motivation for data exclusivity is that clinical testing is extremely expensive – approximately half the total cost of developing a new drug and bringing it to the point of approval – but such testing is generally not covered by patents. Thus, in the case where patents are for some reason inadequate to protect the product"s exclusivity for a reasonable period of time, data exclusivity may still provide a motivation to a firm to invest in the clinical trials required to bring the product to the point of approval. The combination of these three types of exclusivity protections is specifically tailored to the pharmaceutical industry"s unique structure, in which extensive bench science is followed by lengthy and very costly clinical trials, and in which generic firms are able to obtain substantial market share upon being listed on provincial formularies. There have been frequent adjustments to the system in Canada over the course of many years, evidently made to ensure that Canada is an attractive place to invest in R&D, that it fulfills its international obligations under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and under the North American Free Trade Agreement (NAFTA), and that the exclusivity rights are consistent with a financially sustainable health-care system.

Thus, if the average exclusivity period is extended by 3.46 years (as estimated above), the increase in annual cost to payers would be approximately $2.8 billion per year,

4. calculated as follows

Total Annual Brand Sales	$13.3 billion
x % Sales Going Generic	x 0.1
Annual Brand Sales Losing Exclusivity	$1.33 billion
x 61% Price Discount	x 0.61
Annual Loss from 1 Year Entry Delay	$811 million
x Number of Years Delay	x 3.46
Total Annual CETA Delay	$2.8 billion

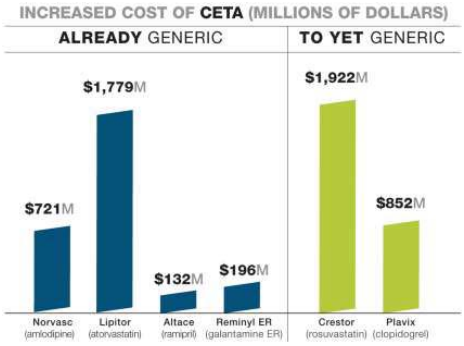
This calculation can of course be adjusted. If there were fewer new drugs with exclusivity in the future, the financial impact of extensions would be smaller. If the average price after the end of exclusivity were relatively higher or lower, that would reduce or increase the impact on payers. The estimate also depends on the average extension to exclusivity periods: the longer the extension, the greater the additional cost.

an approximate decomposition showing how these costs would be allocated between the public and private sectors in the different provinces. The public sector includes both provincial and federal government expenditures; while the private sector includes private insurance and out-of-pocket payments by patients. We have assumed, for the purpose of this analysis, that the average price following generic entry falls by 61%. The allocation of costs across provinces is based on CIHI's analysis of expenditures on prescription drugs in Canada, and the methodology is described in Appendix II.

PROVINCE	PUBLIC ($M)	PRIVATE ($M)	TOTAL ($M)
Alberta	96.1	118.7	214.8
British Columbia	101.2	151.9	253.0
Manitoba	38.0	43.1	81.1
New Brunswick	18.4	34.7	53.1
Newfoundland and Labrador	13.2	20.5	33.6
Northwest Territories	1.3	0.9	2.2
Nova Scotia	30.0	38.9	68.9
Nunavut	0.9	0.6	1.4
Ontario	551.2	671.9	1223.1
Prince Edward Island	3.4	5.3	8.8
Quebec	412.2	372.5	784.6
Saskatchewan	40.3	33.2	73.5
Yukon	1.1	0.8	1.9
Total	1300.9	1499.1	2800.0

5. Methodology

Data was obtained from IMS Brogan on the unit volumes and drug plan spending(excluding pharmacy dispensing fees but including wholesale and retail markups) of all oral solid dosage forms of these molecules for private and public drug plans, province, and quarter over the period 2001 quarter 1 to 2010 quarter 3. Data were available for shorter time periods for several public plans, including Manitoba (data available to 2010q1), as well as BC, Alberta, Saskatchewan, New Brunswick, Newfoundland and the federal Non-Insured Health Benefit (NIHB) program (data available to 2010q2). The IMS Brogan data are intended to be representative of both public and private plans in each of the provinces.



6. Results

The following tables show estimates of the additional cost to payers of the proposed IP changes, by province, for each of the molecules. The exclusivity provisions are separated into patent term extension (PTE), extended data exclusivity (EDE), and right to appeal (RTA). The column ALL shows the additional cost to payers if all three proposed policies are implemented. In brief, the aggregated extra cost associated with extended exclusivities on the six selected molecules is calculated to be approximately $5.6 billion.

TABLE 6.1 COSTS OF EU PROPOSALS IN CETA FOR ALBERTA, SIX SELECTED MOLECULES, IN MILLIONS OF DOLLARS

	PATENT TERM EXTENSION (PTE)	EXTENDED DATA EXCLUSIVITY (EDE)	RIGHT TO APPEAL (RTA)	ALL
Norvasc (amlodipine)	60.4	0	0	60.4
Lipitor (atorvastatin)	137.2	0	0	137.2
Plavix (clopidogrel)	60.9	0	0	60.9
Reminyl ER (galantamine ER)	0	10.6	11.7	11.7
Altace (ramipril)	11	0	11	11
Crestor (rosuvastatin)	145.3	41.2	27.6	145.3

TABLE 6.2 COSTS OF EU PROPOSALS IN CETA FOR BRITISH COLUMBIA, SIX SELECTED MOLECULES, IN MILLIONS OF DOLLARS

	PATENT TERM EXTENSION (PTE)	EXTENDED DATA EXCLUSIVITY (EDE)	RIGHT TO APPEAL (RTA)	ALL
Norvasc (amlodipine)	37.4	0	0	37.4
Lipitor (atorvastatin)	142.2	0	0	142.2
Plavix (clopidogrel)	80.2	0	0	80.2
Reminyl ER (galantamine ER)	0	11.7	12.9	12.9
Altace (ramipril)	19.1	0	19.1	19.1
Crestor (rosuvastatin)	152.3	43.2	28.9	152.3

TABLE 6.3 COSTS OF EU PROPOSALS IN CETA FOR MANITOBA, SIX SELECTED MOLECULES, IN MILLIONS OF DOLLARS

	PATENT TERM EXTENSION (PTE)	EXTENDED DATA EXCLUSIVITY (EDE)	RIGHT TO APPEAL (RTA)	ALL
Norvasc (amlodipine)	23.1	0	0	23.1
Lipitor (atorvastatin)	59.1	0	0	59.1
Plavix (clopidogrel)	44.7	0	0	44.7
Reminyl ER (galantamine ER)	0	1.7	1.9	1.9
Altace (ramipril)	3.8	0	3.8	3.8
Crestor (rosuvastatin)	53.1	15.1	10.1	53.1

TABLE 6.4 COSTS OF EU PROPOSALS IN CETA FOR NIHB, SIX SELECTED MOLECULES, IN MILLIONS OF DOLLARS

NIHB	PATENT TERM EXTENSION (PTE)	EXTENDED DATA EXCLUSIVITY (EDE)	RIGHT TO APPEAL (RTA)	ALL
Norvasc (amlodipine)	6.2	0	0	6.2
Lipitor (atorvastatin)	17.4	0	0	17.4
Plavix (clopidogrel)	8.1	0	0	8.1
Reminyl ER (galantamine ER)	0	0.1	0.1	0.1
Altace (ramipril)	2	0	2	2
Crestor (rosuvastatin)	12.4	3.5	2.4	12.4

The Non-Insured Health Benefits (NIHB) Program provides, to registered Indians and recognized Inuit, a limited range of medically necessary health-related goods and services which supplement benefits provided through private insurance plans, provincial/territorial health and social programs.

TABLE 6.5 COSTS OF EU PROPOSALS IN CETA FOR NEW BRUNSWICK, SIX SELECTED MOLECULES, IN MILLIONS OF DOLLARS

	PATENT TERM EXTENSION (PTE)	EXTENDED DATA EXCLUSIVITY (EDE)	RIGHT TO APPEAL (RTA)	ALL
Norvasc (amlodipine)	8.4	0	0	8.4
Lipitor (atorvastatin)	27.1	0	0	27.1
Plavix (clopidogrel)	16	0	0	16
Reminyl ER (galantamine ER)	0	3.6	4	4
Altace (ramipril)	3.5	0	3.5	3.5
Crestor (rosuvastatin)	42.9	12.2	8.2	42.9

TABLE 6.6 COSTS OF EU PROPOSALS IN CETA FOR NEWFOUNDLAND AND LABRADOR, SIX SELECTED MOLECULES, IN MILLIONS OF DOLLARS

	PATENT TERM EXTENSION (PTE)	EXTENDED DATA EXCLUSIVITY (EDE)	RIGHT TO APPEAL (RTA)	ALL
Norvasc (amlodipine)	3.1	0	0	3.1
Lipitor (atorvastatin)	18.9	0	0	18.9
Plavix (clopidogrel)	11.5	0	0	11.5
Reminyl ER (galantamine ER)	0	1.3	1.5	1.5
Altace (ramipril)	1.5	0	1.5	1.5
Crestor (rosuvastatin)	44.5	12.6	8.5	44.5

TABLE 6.7 COSTS OF EU PROPOSALS IN CETA FOR NOVA SCOTIA, SIX SELECTED MOLECULES, IN MILLIONS OF DOLLARS

	PATENT TERM EXTENSION (PTE)	EXTENDED DATA EXCLUSIVITY (EDE)	RIGHT TO APPEAL (RTA)	ALL
Norvasc (amlodipine)	13.3	0	0	13.3
Lipitor (atorvastatin)	29.4	0	0	29.4
Plavix (clopidogrel)	17.5	0	0	17.5
Reminyl ER (galantamine ER)	0	4.3	4.7	4.7
Altace (ramipril)	3.2	0	3.2	3.2
Crestor (rosuvastatin)	55.7	15.8	10.6	55.7

TABLE 6.8 COSTS OF EU PROPOSALS IN CETA FOR ONTARIO, SIX SELECTED MOLECULES, IN MILLIONS OF DOLLARS

	PATENT TERM EXTENSION (PTE)	EXTENDED DATA EXCLUSIVITY (EDE)	RIGHT TO APPEAL (RTA)	ALL
Norvasc (amlodipine)	332.3	0	0	332.3
Lipitor (atorvastatin)	719.5	0	0	719.5
Plavix (clopidogrel)	351.7	0	0	351.7
Reminyl ER (galantamine ER)	0	113.5	125.5	125.5
Altace (ramipril)	60.1	0	60.1	60.1
Crestor (rosuvastatin)	827.8	234.8	157.3	827.8

TABLE 6.9 COSTS OF EU PROPOSALS IN CETA FOR PEI, SIX SELECTED MOLECULES, IN MILLIONS OF DOLLARS

	PATENT TERM EXTENSION (PTE)	EXTENDED DATA EXCLUSIVITY (EDE)	RIGHT TO APPEAL (RTA)	ALL
Norvasc (amlodipine)	1.1	0	0	1.1
Lipitor (atorvastatin)	2.2	0	0	2.2
Plavix (clopidogrel)	1.9	0	0	1.9
Reminyl ER (galantamine ER)	0	0.3	0.3	0.3
Altace (ramipril)	0.3	0	0.3	0.3
Crestor (rosuvastatin)	4.1	1.2	0.8	4.1

"Note: IMS-Brogan excludes data on the public plan for PEI."

TABLE 6.10 COSTS OF EU PROPOSALS IN CETA FOR QUEBEC, SIX SELECTED MOLECULES, IN MILLIONS OF DOLLARS

	PATENT TERM EXTENSION (PTE)	EXTENDED DATA EXCLUSIVITY (EDE)	RIGHT TO APPEAL (RTA)	ALL
Norvasc (amlodipine)	216.8	0	0	216.8
Lipitor (atorvastatin)	584.2	0	0	584.2
Plavix (clopidogrel)	235.3	0	0	235.3
Reminyl ER (galantamine ER)	0	28.4	31.4	31.4
Altace (ramipril)	23.4	0	23.4	23.4
Crestor (rosuvastatin)	524.3	148.8	99.7	524.3

TABLE 6.11 COSTS OF EU PROPOSALS IN CETA FOR SASKATCHEWAN, SIX SELECTED MOLECULES, IN MILLIONS OF DOLLARS

	PATENT TERM EXTENSION (PTE)	EXTENDED DATA EXCLUSIVITY (EDE)	RIGHT TO APPEAL (RTA)	ALL
Norvasc (amlodipine)	18.7	0	0	18.7
Lipitor (atorvastatin)	41.3	0	0	41.3
Plavix (clopidogrel)	23.9	0	0	23.9
Reminyl ER (galantamine ER)	0	1.8	2	2
Altace (ramipril)	3.8	0	3.8	3.8
Crestor (rosuvastatin)	59.8	17	11.4	59.8

References

1. HUMIRA (Adalimumab) Compound patent 1,341,082 expires on Aug. 8, 2017 Delay until approval was over 10 years PTE is 5 yrs – maximum allowed under CETA Extension of 082 Patent leads to exclusivity expiry of Aug. 8, 2022
2. HERCEPTIN (Trastuzumab) Compound patent 2,243,459 expires on Feb. 10, 2017 Delay until approval was 7 yrs, 7 mo, 14 days
3. PTE is 2 years, 7 months, 14 days Extension of 459 Patent leads to exclusivity expiry of Sep. 24, 2019
4. RITUXAN (Rituximab) Compound patent 1,336,826 expires on Aug. 29, 2012 Delay until approval was over 10 years PTE is 5 years – maximum allowed under CETA Extension of 825 Patent leads to exclusivity expiry of Aug. 29, 2017
5. AVASTIN (Bevacizumab) Compound patent 2,145,985 expires on Oct. 28, 2012
6. AVANDAMET (Rosiglitazone/Metformin)* Since 452 Patent not asserted against this product, we assume very conservatively that a PTE for the 452 Patent would not be sought.

1/15/2013