

**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE****Excessive Pricing in Pharmaceutical Markets – Note by Canada****28 November 2018**

This document reproduces a written contribution from Canada submitted for Item 9 of the 130th OECD Competition Committee meeting on 27-28 November 2018.

More documents related to this discussion can be found at
www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm

Please contact Mr. Antonio Capobianco if you have any questions about this document
[E-mail: Antonio.Capobianco@oecd.org]

JT03438761

Canada

1. Introduction

1. In Canada, constraining the cost of pharmaceuticals is an ongoing concern. In 2017, pharmaceuticals made up 16.4% of total health expenditures and are the fastest growing of the three largest health spending categories (the others being hospitals and physician services).¹ Among OECD countries, Canada has the fifth highest expenditure on retail pharmaceuticals per capita.²

2. Healthcare is a matter of provincial jurisdiction in Canada.³ A national healthcare system, however, was created through federal legislation that provided funding to provinces that implemented a publicly administered healthcare system with universal coverage. The most recent iteration of this legislation is the *Canada Health Act* (CHA).⁴ With the exception of pharmaceuticals administered in hospitals, the CHA does not address reimbursement for pharmaceuticals. About one-third of Canadians have drug coverage through a publicly funded program while two-thirds have private coverage.⁵ The rising cost of pharmaceuticals in Canada has led to a renewed debate over whether to implement a national pharmacare plan.⁶

3. Currently, Canada relies primarily on two avenues to constrain excessive pharmaceutical pricing: (i) federal and provincial government policies directed at controlling pharmaceutical prices; and (ii) the Competition Bureau's (Bureau's) advocacy and enforcement work aimed at encouraging price competition in pharmaceutical markets.

¹ Canadian Institute of Health Information, *National Health Expenditure Trends, 1975 to 2017* (Ottawa: Canadian Institute for Health Information, 2017), at 4, online: CIHI <<https://www.cihi.ca/sites/default/files/document/nhex2017-trends-report-en.pdf>>.

² Organisation for Economic Co-operation and Development, *Health at a Glance 2017: OECD Indicators* (Paris: OECD, 2017), at 187, online: OECD <https://read.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2017_health_glance-2017-en#page1>.

³ Joel Lexchin, "Drug Pricing in Canada" in Zaheer-Ud-Din Babar, ed., *Pharmaceutical Prices in the 21st Century* (Cham, CH: Springer, 2015), 25 at 26.

⁴ *Canada Health Act*, R.S.C., 1985, c. C-6.

⁵ Valérie Paris & Annalisa Belloni, *Value in Pharmaceutical Pricing – Country Profile: Canada* (Paris: OECD, 2014), at 3, online: OECD <<https://www.oecd.org/health/Value-in-Pharmaceutical-Pricing-Canada.pdf>>.

⁶ See e.g. Health Canada, *Towards Implementation of National Pharmacare: Discussion Paper* (Ottawa: Health Canada, 2018), online: Health Canada <https://www.canada.ca/content/dam/hc-sc/documents/corporate/publications/council_on_pharmacare_EN.PDF>.

2. Government Policies

2.1. Patented Medicine Prices Review Board (PMPRB)

4. The PMPRB is an independent, quasi-judicial body established by Parliament in 1987 through amendments to the *Patent Act*⁷. The PMPRB's mandate is to protect the interests of Canadian consumers by ensuring that the prices of patented medicines sold in Canada are not excessive. The PMPRB is also responsible for reporting on trends in pharmaceutical sales and pricing for all medicines and for reporting research and development spending by patentees.⁸

5. The PMPRB's approval is not required before a patented medicine may be sold in Canada. Instead, PMPRB staff review the prices of the first sale of a patented medicine at arm's-length by the patentee. The PMPRB has no authority over non-patented medicines, nor over the prices of patented medicines beyond the factory-gate "ex-factory" price, such as prices charged by wholesalers or retailers or pharmacists' professional fees.

6. PMPRB staff is responsible for the review and investigation of the prices of patented medicines and is administratively separate from the PMPRB's members, who are responsible for adjudication. If PMPRB staff identifies a potential instance of excessive pricing, the PMPRB can hold public hearings and order price reductions or the offset of excess revenues earned by the patentee.

7. The PMPRB does not explicitly consider market power as it relates to patented medicines. Rather, subsection 85(1) of the *Patent Act* stipulates the factors the PMPRB must consider when determining whether a patented medicine has been sold at an excessive price in any market in Canada. These factors are:

- The prices at which the medicine has been sold in the relevant market;
- The prices at which other medicines in the same therapeutic class have been sold in the relevant market;
- The prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
- Changes in the Consumer Price Index (CPI); and
- Such other factors as may be specified in regulations.⁹

8. Pursuant to section 96 of the *Patent Act*, the PMPRB publicly consults on and publishes non-binding Guidelines that operationalize these factors in tests to establish non-excessive price ceilings for patented medicines. Under the PMPRB's current Guidelines, PMPRB staff assesses new patented medicines for their level of therapeutic benefit relative to existing therapies and calculates a price ceiling based on:

⁷ *Patent Act*, R.S.C., 1985, c. P-4, ss. 79-103.

⁸ Patented Medicine Prices Review Board, *Mandate and Jurisdiction*, online: PMPRB <<http://www.pmprb-cepmb.gc.ca/about-us/mandate-and-jurisdiction>>.

⁹ *Patent Act*, R.S.C., 1985, c. P-4, ss. 85(1).

- The medicine’s median international price within a schedule of seven comparator countries specified in regulations;¹⁰
 - The medicine’s highest-priced comparator in its domestic therapeutic class; or
 - Some combination of the two.
9. After entering the market, a medicine’s average transaction price can increase in keeping with CPI but never to the point of becoming higher than in all other comparator countries.¹¹
10. When a patented medicine’s average transaction price appears to exceed its ceiling, PMPRB staff will commence an investigation.¹² An investigation could result in:
- The closure of the investigation where PMPRB staff determines the price does not appear to be excessive;
 - A Voluntary Compliance Undertaking, whereby the patentee agrees to reduce the price and to offset excess revenues through a payment or additional price reduction; or
 - A public hearing to determine whether the price is excessive.
11. In 2017, patentees agreed to pay back \$35 Million in excess revenues to the Government of Canada through Voluntary Compliance Undertakings submitted to the PMPRB.¹³
12. In December 2017, the Government of Canada pre-published proposed amendments to the *Patented Medicines Regulations* intended to modernize the PMPRB’s regulatory framework and provide it with more relevant and effective tools to protect Canadians from excessive prices for patented medicines.¹⁴ These amendments include three additional economics-based regulatory factors that will allow the PMPRB to consider cost-effectiveness, budget impact and national wealth in determining whether a price is excessive and an updated schedule of 12 countries¹⁵ to be used for international price comparisons that is more aligned with median OECD prices. While finalized regulations remain to be published, the PMPRB is currently consulting stakeholders on a potential

¹⁰ France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States. *Patented Medicines Regulations* SOR/94-688.

¹¹ Patented Medicine Prices Review Board, *Compendium of Policies, Guidelines and Procedures* (Ottawa: PMPRB, February 2017), at 45-47, online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Compendium_Feb_2017_EN.pdf>.

¹² *Ibid.* at 49.

¹³ Patented Medicine Prices Review Board, *Patented Medicine Prices Review Board: Annual Report 2017* (Ottawa: PMPRB, 2018), at B, online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Publications/Annual%20Reports/2018/2017_Annual_Report_Final_EN.pdf>.

¹⁴ *Regulations Amending the Patented Medicines Regulations*, C. Gaz. 2018. I. 4497.

¹⁵ Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden and the United Kingdom.

framework that would implement these new proposed regulatory factors in advance of developing revised Guidelines for public consultation.¹⁶

2.2. Pan-Canadian Pharmaceutical Alliance (pCPA)

13. An intergovernmental initiative that has influenced pharmaceutical pricing in Canada is the pCPA. The pCPA was established by the provinces and territories in 2010 to achieve greater value for publicly funded drug programs and patients through the use of combined negotiating power of participating jurisdictions. The pCPA's mandate is to enhance patient access to clinically relevant and cost-effective drug treatment options. It serves this mandate by conducting collective, expert-informed negotiations for drugs with pharmaceutical manufacturers. The pCPA is a collaborative effort including participation of all the public drug plans in Canada and is supported by a centralized office that was established in 2015. The stated goals of the pCPA are to:

- Increase access to clinically effective and cost effective drug treatment options;
- Improve consistency of decisions among participating jurisdictions;
- Achieve consistent and lower drug costs for participating jurisdictions; and
- Reduce duplication of effort and improve use of resources.

14. The pCPA thus provides provinces and territories with a means to leverage their collective bargaining power to obtain lower prices from manufacturers. The pCPA has estimated that its efforts have resulted in \$1.98 billion a year in combined jurisdictional savings as of April 1, 2018.

15. The negotiation process typically involves the following steps.¹⁷ First, once the Common Drug Review, pan-Canadian Oncology Drug Review or Institut national d'excellence en santé et en services sociaux issues a recommendation for a product,¹⁸ the pCPA will decide whether to initiate joint negotiations and if so, establish common objectives. A pCPA jurisdiction may decide not to participate in a particular negotiation; in such cases, the jurisdiction commits to not negotiating individually with pharmaceutical

¹⁶ Patented Medicine Prices Review Board, *Steering Committee on Modernization of Price Review Process Guidelines*, online: PMPRB <<http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1378&lang=en>>.

¹⁷ Pan-Canadian Pharmaceutical Alliance, *Scope of pan-Canadian Pharmaceutical Alliance*, online: Council of the Federation <http://canadaspremiers.ca/wp-content/uploads/2013/12/scope_of_pcpa_process_dec_2014.pdf>. For further detail, see pan-Canadian Pharmaceutical Alliance, *pCPA Brand Process Guidelines* (N.p.: pCPA, May 2018), online: PDCI <<http://www.pdci.ca/wp-content/uploads/2018/06/Part-1-pCPA-Brand-Process-Guidelines-final-2.pdf>>.

¹⁸ The Common Drug Review provides listing recommendations for new drugs to federal, provincial and territorial plans excluding Quebec, which has its own agency, the Institut national d'excellence en santé et en services sociaux. Similarly, the pan-Canadian Oncology Drug Review provides recommendations for cancer drugs for all provinces and territories excluding Quebec. The Common Drug Review and pan-Canadian Oncology Drug Review operate as part of the Canadian Agency for Drugs and Technology in Health, which was created by federal and provincial governments to, among other things, provide decision-makers with evidence-based assessments of drugs and medical technologies.

manufacturers for the product. Second, if the pCPA decides to initiate negotiations, then a jurisdiction is selected to lead the negotiations on behalf of pCPA and the manufacturer is notified which other jurisdictions are being represented. Third, if the participating jurisdictions and the manufacturer come to an agreement, the lead jurisdiction and the manufacturer will sign a Letter of Intent that contains material financial and clinical terms (e.g., confidential net pricing via rebates).¹⁹ Lastly, each participating jurisdiction will then use the Letter of Intent to enter into a jurisdiction-specific product listing agreement (not a separate or further negotiation) with the manufacturer.

16. As of August 31, 2018, the pCPA has completed 235 joint negotiations covering branded pharmaceutical products.²⁰ The pCPA has also concluded joint negotiations covering generic products. As of April 1, 2018, pCPA negotiations have resulted in 70 of the most commonly prescribed generic products in Canada being priced at either 10% or 18% of the equivalent branded product.²¹

3. Competition Advocacy and Enforcement

17. The *Competition Act*²² does not contain a prohibition against excessive pricing. Consequently, the Bureau's advocacy and enforcement work focuses on protecting the competitive process rather than enforcing a particular market outcome. In other words, the Bureau's work targets the disease (lack of competition) rather than the symptom (excessive prices). This approach ensures that the Bureau is not required to engage in price regulation, which is at odds with traditional Canadian competition law principles. As the description of the PMPRB demonstrates, price regulation of pharmaceuticals is a complex process that differs substantially from traditional competition enforcement.

18. The following section illuminates when the Bureau can potentially intervene during the life cycle of a pharmaceutical product to facilitate greater price competition. The subsequent sections then provide examples of the Bureau's work in the pharmaceutical industry. As these sections reveal, many competition issues arise from the regulatory framework governing pharmaceuticals.

3.1. The Pharmaceutical Life Cycle and Competition Enforcement

19. Research and Development (R&D): Bringing a pharmaceutical product to market may require a manufacturer to undertake costly and risky R&D. Manufacturers may want to collaborate in order to share these costs and risks or to join complementary technology and resources to facilitate bringing the product to market quicker. R&D agreements,

¹⁹ Pan-Canadian Pharmaceutical Alliance, *LOI Template* (N.p.: pCPA, May 2018), online: PDCI <<http://www.pdci.ca/wp-content/uploads/2018/06/Part-3-LOI-Template.pdf>>.

²⁰ Pan-Canadian Pharmaceutical Alliance, *Pan-Canadian Pharmaceutical Alliance: Completed Negotiations*, online: Council of the Federation <http://www.canadaspremiers.ca/wp-content/uploads/2018/09/PCPA_completed_negotiations_August31_2018.pdf>.

²¹ Ministry of Health and Long-Term Care, "Statement by Minister of Health and Long-Term Care" (29 January 2018), online: Ministry of Health and Long-Term Care <https://news.ontario.ca/mohltc/en/2018/01/statement-by-minister-of-health-and-long-term-care.html?utm_source=ondemand&utm_medium=email&utm_campaign=p>.

²² *Competition Act*, R.S.C. 1985, c. C-34.

however, may reduce competition by removing the incentive for a manufacturer to develop its own product. In assessing whether a pharmaceutical R&D agreement may violate s. 90.1 of the *Competition Act*, the civil provision prohibiting anticompetitive agreements, the Bureau generally considers:

- Whether the agreement is between competitors;
- Whether the agreement is limited to R&D or also contains provisions regarding the joint exploitation of products;
- Whether the parties hold market power in the relevant market;
- Whether the restrictions on competition are reasonably necessary for achieving the objective of the R&D agreement; and
- Whether any anti-competitive effects are offset and outweighed by the efficiencies generated through the R&D agreement.²³

20. Commercialization: As part of an agreement to jointly develop a pharmaceutical product, manufacturers may decide to jointly commercialize the product as well. Similar to R&D agreements, joint commercialization agreements may have efficiencies, such as the sharing of costs, risks and know-how. Nevertheless, commercialization agreements may reduce price competition where the manufacturers agree on the price of the product or the territories where each manufacturer will sell the product. In determining whether a pharmaceutical commercialization agreement violates s. 90.1, the Bureau would examine:

- Whether the agreement is between competitors;
- Whether the parties to the agreement hold market power;
- Whether the agreement deals with competitively significant terms of trade, such as price;
- Whether the parties are able to commercialize products outside the scope of the agreement or otherwise retain the ability to compete independently;
- Whether the commercialization agreement requires or provides opportunities for the disclosure of competitively sensitive information between the participants; and
- Whether any anti-competitive effects are offset and outweighed by the efficiencies generated through the commercialization agreement.²⁴

21. Production: Once a pharmaceutical product is granted the necessary regulatory approvals, manufacturers may decide to engage in joint production. Although joint production may provide for cost efficiencies, such as through economies of scale or scope, in some instances it may also result in anticompetitive effects. For example, joint production may result in supracompetitive prices if it significantly reduces competition in the supply of the product. In assessing whether pharmaceutical production agreements violate s. 90.1, the Bureau generally considers:

²³ Competition Bureau, *Competitor Collaboration Guidelines* (Gatineau, QC: Competition Bureau, 2009), at 29-30, online: Competition Bureau <[http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/Competitor-Collaboration-Guidelines-e-2009-12-22.pdf/\\$FILE/Competitor-Collaboration-Guidelines-e-2009-12-22.pdf](http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/Competitor-Collaboration-Guidelines-e-2009-12-22.pdf/$FILE/Competitor-Collaboration-Guidelines-e-2009-12-22.pdf)>.

²⁴ *Ibid.* at 24-26.

- Whether the joint production agreement is between parties that are actual or potential competitors;
- Whether the joint production agreement contains provisions that limit output of a relevant product, fix prices or otherwise restrict competition on competitively significant matters;
- Whether the joint production agreement otherwise reduces the incentive or ability of the parties to compete independently;
- Whether the parties to the agreement have market power or will likely have market power (either in the upstream or downstream markets); and
- Whether any anti-competitive effects are offset and outweighed by the efficiencies generated through the joint production agreement.²⁵

22. Pre-Generic Entry: When the patent for a branded pharmaceutical product approaches the date of expiry, a manufacturer may engage in various anticompetitive practices to inhibit the entry of generic competitors in order to preserve its market power. For example, a branded manufacturer could engage in a “hard product switch” by ceasing to sell a product with an expiring patent in order to switch patients onto a similar product with longer patent or data protection.²⁶ The hard product switch could deter generic entry because generic substitution could occur for the former product but not the latter. This practice would be assessed under s. 79 of the *Competition Act*, which covers abuses of dominance. Another example of an anticompetitive practice would be when a branded manufacturer pays a potential generic entrant to delay entry under the guise of settling patent litigation.²⁷ This practice has the effect of the branded manufacturer and the potential generic entrant sharing the supracompetitive profits resulting from the delay of price competition between them. In addition to potentially violating ss. 79 and 90.1, in very limited circumstances the practice could violate s. 45, the criminal cartel provisions, such as when the settlement prevents entry beyond patent expiry, restricts competition for products not subject to patent litigation or if the settling parties know the patent is invalid or not infringed.

23. Post-Generic Entry: Even after the entry of generic competitors, a branded manufacturer may be able to exploit its advantages as an incumbent to engage in anticompetitive practices that inhibit the expansion of generics. For example, with the monopoly profits it earned during the period it had patent protection, a branded manufacturer could deter a generic competitor from gaining a foothold in the market by engaging in predatory pricing. Alternatively, a branded manufacturer could leverage its installed base of existing patients, which for medical reasons are unlikely to switch to a generic, to deter competition for new patients. It could do this by offering rebates to insurers on its installed base of existing patients in return for them agreeing not to steer new patients

²⁵ *Ibid.* at 31-33.

²⁶ Competition Bureau, *Intellectual Property Enforcement Guidelines* (Gatineau, QC: Competition Bureau, 2016), at 37-39, online: Competition Bureau <[http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/cb-IPEG-e.pdf/\\$file/cb-IPEG-e.pdf](http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/cb-IPEG-e.pdf/$file/cb-IPEG-e.pdf)>.

²⁷ *Ibid.* at 42-52.

to lower cost generics. Among other provisions, these practices would be assessed under s. 79 to determine whether they are abuses of dominance.

3.2. Alcon Canada²⁸

24. A notable example of the Bureau's enforcement activities in the pharmaceutical industry is the investigation into Alcon's practices relating to Patanol. In September 1997, Alcon obtained approval from Health Canada to market Patanol, which had two separate patents covering its medicinal ingredient and formulation. The patent covering Patanol's medicinal ingredient expired on November 21, 2012, while the one covering its formulation expired on May 3, 2016. Alcon began supplying Patanol in Canada in February 1998.

25. In January 2011, Alcon was granted approval from Health Canada to market Pataday and began doing so in April 2011. Pataday has the same active ingredient as Patanol but with a stronger formulation. Patent protection on Pataday expires in 2022.

26. When Pataday and Patanol were initially on the market simultaneously, Pataday had lower sales compared to Patanol. In July 2012, Alcon suspended the supply of Patanol in Canada so physicians were no longer able to prescribe it. As a result, physicians began prescribing Pataday, which in the vast majority of cases replaced the sales of Patanol.

27. In February 2010, Apotex sought Health Canada approval to market a generic version of Patanol. Under Canadian regulations, this triggered patent litigation between Apotex and Alcon and resulted in a 24-month stay of Health Canada's approval of Apotex's application. Apotex only challenged the patent pertaining to Patanol's formulation as it decided to just wait for the patent covering the medicinal ingredient to expire on November 21, 2012. On April 13, 2012, Alcon and Apotex settled their patent litigation. Apotex subsequently obtained Health Canada approval for its generic version of Patanol on November 22, 2012.

28. The Bureau commenced an inquiry in November 2012 because of concerns that Alcon's conduct would inhibit the entry of a generic version of Patanol. Alcon's conduct could have harmed consumers by forcing them to pay for the higher priced Pataday over a generic version of Patanol. Subsequent to the Bureau commencing an inquiry, Alcon resumed supplying Patanol in January 2013. By May 2013, Patanol sales were back in line with its sales prior to Alcon's conduct. Generics were able to enter the market and capture significant market share from Alcon. Consequently, the Bureau discontinued its inquiry in May 2014 after observing that competition had been restored to the market.

3.3. Teva/Allergen²⁹

29. Another way the Bureau protects price competition in pharmaceutical markets is through its review of mergers. A notable example is the Bureau's review of Teva's

²⁸ Competition Bureau, Position Statement, "Competition Bureau statement regarding the inquiry into alleged anti-competitive conduct by Alcon Canada Inc." (13 May 2014), online: Competition Bureau <<http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03686.html>>.

²⁹ Competition Bureau, Position Statement, "Competition Bureau statement regarding Teva's acquisition of Allergan's generic pharmaceuticals business" (18 April 2016), online: Competition Bureau <<http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/04065.html>>. In addition to Teva/Allergen, the Bureau has reviewed several other notable pharmaceutical mergers, including GlaxoSmithKline/Novartis <<http://www.competitionbureau.gc.ca/eic/site/cb->

acquisition of Allergan's generic pharmaceutical business, which was announced on July 27, 2015. The Bureau assessed whether the transaction was likely to substantially lessen competition in markets where both parties were suppliers. In situations where the parties had products in development, the Bureau considered whether the transaction was likely to substantially prevent future competition.

30. Consistent with its approach in other reviews involving generic drugs, the Bureau generally found that the parties' products to be within the same relevant product market where they contain the same molecule or active ingredient and are supplied in the same format. The Bureau found that the relevant geographic market was no broader than Canada since there are significant regulatory barriers that limit the entry of pharmaceutical products from outside of Canada.

31. For each relevant market, the Bureau considered whether there was effective remaining competition. This analysis consisted primarily of identifying remaining suppliers of equivalent generics to the parties and any likely future generic suppliers. The Bureau also considered whether the branded drug remained in the market following the entry of generics, as well as the brand's market share relative to the generics. When assessing potential future suppliers, the Bureau considered factors such as the likelihood, timeliness and effectiveness of entry.

32. The Bureau identified two products where the transaction would substantially lessen or prevent competition: tobramycin inhalation solution and buprenorphine/naloxone tablets.

33. Tobramycin inhalation solution is used for the management of cystic fibrosis in patients with certain chronic pulmonary infections. Teva launched a generic version of this product in early 2016 while Allergan was also developing the product at the time of the transaction. The Bureau had identified one other potential generic supplier but nevertheless concluded that there would not be a sufficient number of future suppliers. Tobramycin is also available in other formats, including ophthalmic solution, ophthalmic ointment and injection. The Bureau found that the inhalation solution represented a distinct product market. Healthcare professionals often decide on the most suitable drug format for a particular patient. Further, generics are generally priced with reference to the historical branded drug price in the same format and dosage strength. Accordingly, the Bureau concluded that the transaction would likely result in a substantial prevention of competition in the supply of tobramycin inhalation solution.

34. Buprenorphine/naloxone is a tablet used for substitution treatment in adult opioid drug dependence. Teva is a supplier of a generic version of this drug, in addition to one other generic supplier. Allergan was also developing the drug. Consequently, the Bureau concluded that the transaction would likely result in a substantial prevention of competition in the supply of buprenorphine/naloxone tablets.

35. In order to resolve the Bureau's competition concerns, Teva entered into a registered consent agreement with the Bureau. The agreement required Teva to divest either

bc.nsf/eng/03874.html>, Pfizer/Hospira <<http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03979.html>>, Teva/Ratiopharm <<http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03271.html>>, Merck/Schering-Plough <<http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03146.html>> and Pfizer/ Wyeth <<http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03141.html>>.

of the parties' Canadian assets relating to tobramycin inhalation solution and buprenorphine/naloxone tablets.

3.4. Canadian Generic Drug Sector Study³⁰

36. The Bureau has also conducted advocacy work relating to pharmaceuticals. On September 28, 2006, the Bureau announced that it would be undertaking a study of the generic drug sector. The Bureau initiated this project in response to several studies that found the price of prescription generics to be high in Canada compared to other countries.

37. In conducting the study, the Bureau relied on publicly available information, data purchased from data providers and information obtained from market participants in interviews and contacts conducted over January to April 2007.

38. On October 29, 2007, the Bureau released the study's results. The study found that although strong competition exists in the supply of many generics, the benefits of this competition was not reaching Canadian consumers in the form of lower prices. To compete for space on pharmacy shelves, generic manufacturers offered rebates or other payments to pharmacies in most provinces. These rebates or payments on average accounted for 40% of the price invoiced to pharmacies. In most provinces, however, pharmacies had limited incentive to pass on these savings. To ensure that savings from generic competition would be better passed on to Canadian consumers, the study provided several recommendations, including:

- Providing manufacturers with incentives to compete to be listed on plan formularies;
- Using competitive tendering processes to determine the products that can be dispensed by pharmacies;
- Monitoring of the net price paid by pharmacies for generic drugs to ensure the price paid by plans reflects competitive prices; and
- An increased role for private plans in obtaining lower prices for their customers.

39. On November 25, 2008, the Bureau released a follow-up report.³¹ In the report, the Bureau suggested additional ways in which private and public insurers can obtain greater savings from competition between generic manufacturers. For private insurers, suggestions included:

- Developing preferred pharmacy networks;
- Promoting greater use of mail-order pharmacies; and
- Providing patients with incentives to seek lower prices.

³⁰ Competition Bureau, *Canadian Generic Drug Sector Study* (Gatineau, QC: Competition Bureau, 2007), online: Competition Bureau <[http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/Competition%20Bureau%20Generic%20Drug%20Sector%20Study.pdf/\\$FILE/Competition%20Bureau%20Generic%20Drug%20Sector%20Study.pdf](http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/Competition%20Bureau%20Generic%20Drug%20Sector%20Study.pdf/$FILE/Competition%20Bureau%20Generic%20Drug%20Sector%20Study.pdf)>.

³¹ Competition Bureau, *Benefiting from Generic Drug Competition in Canada: The Way Forward* (Gatineau, QC: Competition Bureau, 2008), online: Competition Bureau <[http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/GenDrugStudy-Report-081125-fin-e.pdf/\\$FILE/GenDrugStudy-Report-081125-fin-e.pdf](http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/GenDrugStudy-Report-081125-fin-e.pdf/$FILE/GenDrugStudy-Report-081125-fin-e.pdf)>.

40. The Bureau suggested that public insurers should, among other things:
- Introduce measures for reimbursing pharmacies for the true cost of their drugs;
 - Reimburse pharmacy services such as dispensing and patient counselling separately from drug costs;
 - Remove unnecessary restrictions to pharmacy competition; and
 - Coordinate generic pricing and reimbursement policies to ensure that they promote and sustain effective generic drug competition.

4. Conclusion

41. As the Bureau's enforcement and advocacy experience demonstrates, competition in the pharmaceutical industry is intertwined with the regulatory framework that governs the industry. As a result, facilitating greater price competition between pharmaceutical manufacturers may require regulatory solutions to complement competition enforcement. Possible solutions include reducing regulatory barriers to entry for generics and ensuring that manufacturers cannot manipulate the regulatory process to deter price competition.