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13. Pharmaceutical Market in Canada: a Brief Treatise

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13.1 Introduction

Canada is the largest country in North America in area and the second largest in the world. It is classified as a federal parliamentary democracy/constitutional monarchy having Queen Elizabeth II of the United Kingdom as its head of state. With a population of nearly 37 million, it is the 38th largest country and has the 10th largest Gross Domestic Product (GDP) of 1.5 trillion dollars (U.S.). Canada has the fourth highest per capita expenditure on pharmaceuticals [1].

The purpose of this chapter is to discuss the Canadian pharmaceutical market. First, this chapter will discuss the overall healthcare system in Canada. Then, a more specific description of the Canadian Drug Market will follow. Next, there will be an account of the drug approval process and prescription drug pricing. The Chapter will conclude with a brief treatise of the prescription drug promotion in Canada.

13.2 Canadian Healthcare System

Canada's publicly funded healthcare system was enacted by the Canadian Health Act of 1984 and is informally known as Medicare. Under established federal guidelines, the healthcare system is locally administered by ten provincial and three territorial governments. Therefore, there are thirteen different health insurance plans across the country rather than just one national plan. All Canadian citizens are entitled to reasonable access to preventive care and medically necessary medical treatments from physicians with no out-of-pocket expense [2]. They are also entitled to hospital services, dental surgery, and other medical services with few exceptions regardless of personal income or medical history.

Canada is the only country in the world that has universal health care, but no universal drug coverage. As a result, Canadian patented drug prices are among the highest in the world. Provinces and Territories have established programs of varying comprehen-

siveness for senior patients (those over 65) and the poor. Around two-thirds of Canadians pay for and have private health insurance to cover items exempted from public reimbursement, such as prescription drugs [2].

13.3 Canadian Drug Market

Most of the Canadian health expenditures (60%) are paid to hospitals, physicians, and pharmaceuticals. Drugs are the second largest component of overall healthcare costs, accounting for 16% of the total. Overall sales of pharmaceutical are now about $25 billion (in Canadian dollars). Canada is the 10th largest pharmaceutical market place in the world and accounts for 2% of the worldwide market. Branded products make-up 77% of the overall sales (in dollars) and generic drugs comprise 66% of the total prescription volume with 87.5% of the sales taking place in community pharmacies. Private prescription drug insurance and individuals account for 58% of all drug expenditures with the federal, provincial, and territorial governments paying for 42% [3]. The annual pharmaceutical manufacturing production domestically was approximately $9.8 billion. Over 50% of all Canadian pharmaceutical production is exported, with the United States being the largest importer. Over two-thirds of the Canadian drug market is imported, mostly from the United States and secondarily from the European Union [3]. Four of the provinces, Alberta, British Columbia, Ontario, and Québec, account for nearly 85% of all expenditures on drugs. Canadian pharmaceutical manufacturers are concentrated in the country's three largest metropolitan areas of Vancouver, Montreal, and Toronto [3].

13.4 Drug Approval Process

Canada has its own unique regulatory approval procedures for prescription drugs, which includes multiple phases and involves several federal government agencies [4]. Pharmaceutical products cannot be sold in Canada until they have successfully navigated the drug review and approval process. The Health Products and Food Branch (HPFB) of Health Canada assesses the safety and efficacy of drug products as well as their quality parameters. HPFB is the federal agency that is responsible for the regulation and evaluation of diagnostic and therapeutic products sold in Canada. In procedures similar to the United States Food and Drug Administration's assessment of a New Drug Application, Health Canada reviews a drug for its quality, safety, and efficacy profiles [5]. The process includes:

- Evaluating the results of submitted preclinical and clinical studies;
- Reviewing manufacturing and production details and guidelines for Good Manufacturing Practices;
- Revising packaging and labeling;

- Examining efficacy and safety claims; and
- Assessing all information pertinent to the drug.

Regulatory approval is granted in the form of a Notice of Compliance (NOC). On average, it takes approximately 12 years from the initial laboratory work.

Once a NOC is issued for a product, the next step is a review by the Patented Medicine Prices Review Board (PMPRB). A manufacturer can establish a price for its drug as it is launched. If the product is patented, however, the amount charged to patients must be within the range fixed by the PMPRB. If the launch price exceeds the limits set, PMPRB has options to reign in the manufacturer's price [6]. It is the PMPRB's function to protect Canadians by safeguarding them from excessive prices on patented medicines. Thirty-seven New Active Substances were approved in 2016 [7] and 37 in 2015 [8].

The final step in the new drug review process is the Common Drug Review performed by the Canadian Agency for Drugs and Technologies in Health. These health technology assessments evaluate the cost-effectiveness and clinical efficacy of new drugs in order to make a recommendation as to whether the drug should be publicly funded [7].

Canadian regulation of pharmaceutical products continues even after a drug is being sold to the public. Manufacturers are accountable for monitoring the safety and quality of their products under the Canadian Food and Drugs Act. They must report all new data collected on serious side effects, including product failures to work as indicated [9].

13.5 Prescription Drug Pricing

Even with the PMPRB review process, Canadian's pay the third highest prices in the world for patented medicines. Among the 35 member countries of the Organization for Economic Co-operation and Development, only citizens of Mexico and the United States pay more. There are millions of self-employed Canadians who do not have workplace drug coverage.

It is estimated that one in ten Canadians (about 3.6 million people) cannot afford their prescription drugs. Additionally, all payers in Canada are struggling with the dramatic increase in the number of high-cost new drugs on the market [10].

13.6 Prescription Drug Promotion

Pharmaceutical promotion in Canada has many similarities to those undertaken in the United States [5]. One key difference is that Canada does not permit direct-to-consumer advertising (DTCA) of prescription drugs. While Canada is a very large country in area, nearly 90% of the population lives within 100 miles of the border with the U.S. There is a significant broadcast, cable, and print media "bleeding" of DTCA across the Canadian border.

As a result, over 50% of Canadians believe that DTCA is legal in Canada. This spillover effect mitigates the Canadian government's efforts to protect Canadians from these ads. It also provides an opportunity for pro-DTCA forces to criticize Canadian restrictions as ineffective. DTCA from the United States are not pre-cleared by the U. S. FDA, so these unregulated commercials reach Canadians through cable television. The primary objections to DTCA revolve around harm and costs. Many DTCAs promote products with health warnings that are severe and several of the products have been removed from the market for causing health problems. There appears to be a direct correlation between volumes of costly TV ads and drug costs [11].

13.7 In Summary

Unimaginable, worldwide influences are causing significant disruption to the healthcare systems. As with other pharmaceutical markets, the Canadian marketplace is undergoing rapid and remarkable changes. The high prices of new biologic products are putting tremendous pressure on both the public and private system of financing prescription drugs.

In Canada, as well as elsewhere, high drug prices are an emotional, volatile, and political issue. Solutions to this situation are yet to be found and could pose a hurdle to market access. Canada has a complex health system, which has variances from Province to Province (and territory to territory). These differences could possibly create barriers to market access as well.

13.8 References

1. Oyedele A. One chart shows how much Americans are spending on drugs compared to the rest of the world. Business Insiders. November 4, 2015. Available at http://www.businessinsider.com/pharmaceutical-spending-by-country-2015-11 (last accessed October 2017)
2. Government of Canada. Canada's Health Care System. Available at https://www.canada.ca/en/health-canada/services/canada-health-care-system.html (last accessed October 2017)
3. Government of Canada. Pharmaceutical Industry Profile. Available at http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html (last accessed October 2017)
4. Government of Canada. How Drugs Are Reviewed in Canada. Available at https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/drugs-reviewed-canada.html (last accessed October 2017)
5. Bleidt BA. Pharmaceutical Market in the U.S.: A Brief Treatise. In Kockaya G, Wertheimer A (Eds). Pharmaceutical Market Access in Developed Market. Turin: SEEd Medical Publishers, 2018

6. Government of Canada. Patented Medicine Prices Review Board. Available at http://www.pmprb-cepmb.gc.ca/home (last accessed October 2017)
7. Health Canada. New Drug Authorizations: 2016 Highlights. Available at https://www.canada.ca/content/dam/hc-sc/documents/services/publications/drugs-health-products/health-canada-new-drug-authorizations-2016-highlights-eng.pdf (last accessed October 2017)
8. Health Canada. New Drug Authorizations: 2015 Highlights. https://www.canada.ca/content/dam/canada/health-canada/migration/healthy-canadians/publications/drugs-products-medicaments-produits/2015-highlights-faitssaillants/alt/2015-highlights-faitssaillants-eng.pdf (last accessed October 2017)
9. Health Canada. Health Products and Food Branch. Access to Therapeutic Products: The Regulatory Process in Canada. Available at http://publications.gc.ca/collections/collection_2007/hc-sc/H164-9-2006E.pdf (last accessed October 2017)
10. Government of Canada. Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations. Available at https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-regulations-patented-medicine-document/con1-eng.pdf (last accessed October 2017)
11. Chow EC. Direct-to-Consumer Advertising of Pharmaceuticals on Television: A Charter Challenge. *Canadian Journal of Law and Technology* 2011; 9: 73-91