VALUE IN HEALTH ▮ (2017) ▮▮▮–▮▮▮

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/jval

Market Exclusivity Time for Top Selling Originator Drugs in Canada: A Cohort Study

*Joel Lexchin, MSc, MD**

School of Health Policy and Management, York University, Toronto, Ontario, Canada

ABSTRACT

Objectives: This study looks at market exclusivity time for the top selling originator drugs in Canada. Total sales for drugs without competition were also calculated. **Methods:** A list of the top selling originator drugs by dollar sales from 2009 to 2015 inclusive, except for 2010, was compiled along with their annual sales. Health Canada databases were used to extract the following information: generic name, date of Notice of Compliance (NOC, date of marketing authorization), whether the product was a small molecule drug or a biologic, and date of NOC for a generic or biosimilar. Market exclusivity time was calculated in days for drugs. **Results:** A total of 121 drugs were identified. There were 96 small molecule drugs (63 with a generic competitor and 33 with no generic competitor) and 25 biologics (none with a biosimilar competitor). The 63 drugs with a competitor had a mean market exclusivity time of 4478 days (12.3 years) (95% CI 4159–4798). The 58 drugs without competition had total annual sales of Can$8.59 billion and were on the market for a median of 5357 days (14.7 years) (interquartile range 3291–6679) as of January 31, 2017. **Conclusions:** Top selling originator drugs in Canada have a considerably longer period of market exclusivity than the 8 to 10 years that the research-based pharmaceutical industry claims.

Keywords: biologics, Canada, generics, market exclusivity, originator, therapeutic groups.

Introduction

The pharmaceutical industry claims that adequate market exclusivity is important to generate the needed revenue to invest in research and development (R&D) for future products. Market exclusivity is the time between when the originator product first appears on the market and when it encounters competition from either a generic (for small molecules) or a biosimilar (for biologics). Innovative Medicines Canada, the body representing the research-based industry in Canada, claims that market exclusivity in Canada is 8 to 10 years [1] and needs to be brought up to international standards [2].

In the United States, market exclusivity for new drugs is 12.4 to 12.5 years [3,4]. However, the equivalent period in Canada may be different for a number of reasons. Almost 50% of new drugs go through the priority review process (180 days vs. 300 days for a standard review) in the United States [5], whereas in Canada it is only half that number [6]. Drug reviews by the Food and Drug Administration are, on average, 46 days faster than those by Health Canada [7] and finally, the United States, but not Canada, has provisions for patent term restoration that compensates for the time spent in the regulatory review process [2].

From the point of view of generating R&D revenue, the most important group of drugs for pharmaceutical companies should be the ones that have the largest dollar sales volume. Conversely, large sales should attract generic producers interested in capturing part of a lucrative market. The purpose of this study was to examine the market exclusivity time for the top selling originator, that is, brand name, products in Canada. Secondarily, the study investigates 1) the likelihood that small molecule drugs and biologics will face competition, 2) the total annual sales for drugs without competition, 3) whether the percentage of biologics in a therapeutic group affects the number of drugs with competitors, and 4) whether market exclusivity time varies by therapeutic group.

Methods

This study adopted the methodology used by Kesselheim et al. [4] to examine the issue of market exclusivity time in the United States. Two sources for top selling drugs in Canada were available. For 2009, 2011, and 2012, the Web site of the Canadian Healthcare Network had lists of the top 100 products [8–10]. (Data for 2010 were not available.) Lists of the 50 top selling drugs for the period 2013 to 2015 came from the 2014-2016 annual reports from IMS|Brogan [11–13]. From each of these six lists, the names and dollar sales of originator drugs were extracted. Nondrug

* *Address correspondence to*: Joel Lexchin, School of Health Policy and Management, York University, 4700 Keele Street, Toronto, Ontario, Canada M3J 1P3.

E-mail: jlexchin@yorku.ca.

1098-3015$36.00 – see front matter

http://dx.doi.org/10.1016/j.jval.2017.05.004

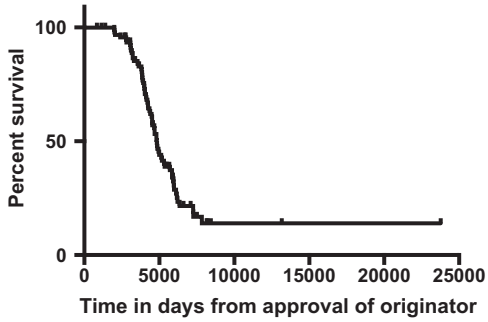

Figure 1 – Likelihood of competition for originator.

products such as diabetic reagent strips were excluded. If an originator drug was listed in more than one formulation, then each formulation was included. The lists were combined and duplicates excluded.

The names of each of the originator drugs were entered into the Notice of Compliance (NOC) database maintained by Health Canada (https://health-products.canada.ca/noc-ac/index-eng.jsp). An NOC is the authorization from Health Canada to market a drug. From the database, the following information was extracted: generic name, manufacturer, the NOC date, whether the drug was a small molecule or biologic, and date of NOC for a generic or biosimilar. In the seven cases in which the first generic approved was made by either a subsidiary of the company marketing the originator or through a formal agreement with that company, that is, an authorized generic, the NOC for the first generic from an independent company was used. In order for a product to be considered a competitor to the originator, the NOC database had to specifically list the originator as the reference product and the formulation of the drug had to be the same as that of the originator. When information was missing from the NOC database, it was supplemented by data from the Drug Product Database (https://health-products.canada.ca/dpd-bdpp/index-eng.jsp), which contains product-specific information on drugs approved for use in Canada.

The time between the NOC for the originator product and a generic or biosimilar was computed in days. For purposes of this study, the time between the NOC for the originator and the NOC for a competitor was taken as the market exclusivity time. A Kaplan-Meier survival curve, that is, time to event curves, was calculated for the period from approval of the originator until approval of the first generic or biosimilar. A Kaplan-Meier analysis accounts for the fact that drugs were on the market for variable periods of time and therefore, some drugs were more likely to have a generic or biosimilar competitor by the end of the study period (January 31, 2017). Dollar sales for drugs without competition at the end of the study period were summed on the basis of the most recent year that the drug was listed as one of the top selling products and converted to 2017 dollars using the Bank of Canada inflation calculator (http://www.bankofcanada.ca/rates/related/inflation-calculator/).

Products were put into first-level Anatomic Therapeutic Chemical groups [14] and a linear regression equation was used to determine whether the percentage of biologics in the group was associated with the number of drugs with competitors in the group. Average market exclusivity times for drugs with competition in the different groups were compared using one-way analysis of variance.

All the data were publicly available and therefore ethics approval was not required. All analyses were done with Prism 7.0 (GraphPad Software, La Jolla, CA, http://www.graphpad.com) and $P < 0.05$ was considered statistically significant.

Results

There were 122 originator drugs in total that were identified. One was eliminated from analysis because there was no information about it in either the NOC or Drug Product Databases, leaving 121 products. One product was available in five different formulations and two were available in two formulations. (For a list of all drugs, see Appendix 1 in Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2017.05.004.) Yearly sales of these products as a percentage of sales of all prescription drugs are presented in Table 1.

There were 96 small molecule drugs (63 with a generic competitor and 33 with no generic competitor) and 25 biologics (none with a biosimilar competitor). The 63 drugs with a competitor had a mean market exclusivity time of 4478 days (12.3 years) (95% CI 4159– 4798). Figure 1 shows the likelihood of competition for an originator after its approval. There was no statistically significant difference in the time of market exclusivity for the 58 drugs with a competitor that had undergone a standard review (4487 days; 95% CI 4146–4828) and the 5 drugs with a competitor with a priority review (4378 days; 95% CI 3182–5574) ($P = 0.8555$, unpaired t test).

By the end of the study period (January 31, 2017), the 58 drugs without a competitor had been available for a median of 5357 days (14.7 years) (interquartile range 3291– 6679) (data not normally distributed). These drugs had total annual sales of Can$8.59 billion in 2017 dollars (see Appendix 2 in Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2017.05.004). One small molecule drug (Premarin) was available for 23,773 days (65.1 years) and another (Epipen) for 13,180 days (36.1 years) without competition.

The percentage of products with competition varied considerably among therapeutic groups from a high of 94% for the 18 drugs in the cardiovascular system group to 24% in the antineoplastic and immunomodulating agents group. The percentage of biologics in the therapeutic groups did not affect the number of products with competition ($P = .0738$, linear regression) (Table 2). There was a statistically significant difference in average market exclusivity times in the therapeutic groups ($P = 0.0349$, one-way analysis of variance).

Discussion

For this subset of top selling originator drugs, market exclusivity averaged 12.3 years. Drugs without competition were marketed for a median 14.7 years and had total annual sales of $8.59 billion.

Table 1 – Percentage of total dollar sales accounted for by brand name products, 2009, 2011, 2012, 2013–2015.

Year	Percentage of dollar sales	Number of brand name products out of top selling 100 products (2009, 2011, 2012) and top selling 50 products (2013–2015)
2009	44.9	80
2011	39.0	73
2012	49.7	76
2013	32.7	46
2014	32.9	47
2015	33.5	46