Marketing Before Patenting: Implications for Price Controls in Canada

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Background

Drugs that are marketed before being patented do not have their prices regulated by the Patented Medicine Prices Review Board (PMPRB). This study was undertaken to determine how many drugs are marketed before being patented, the time period between marketing and patenting and the excess revenue, if any, earned before prices are regulated.

Methods

Annual reports of the PMPRB between 2000 and 2008 were hand searched for all medications that were marketed before being patented and which of these medications were excessively priced. Databases listing the dates when drugs were approved for marketing and when patents were received were searched.

Results

Thirty-three drugs were marketed before being patented and may have been outside PMPRB jurisdiction between 54 and 2707 days. Three products earned excess revenue of $9,289,687.63.

Discussion

Although only 3 of 33 drugs were overpriced the fact that prices can go unregulated for up to 7.4 years is potentially troublesome. If companies are charging excessive prices then the additional payments they receive may limit the ability of provincial formularies to list additional drugs.

Introduction

The Patented Medicine Prices Review Board (PMPRB) is a federal agency created in 1987 with a mandate to ensure that prices charged by pharmaceutical companies holding patents on medicines sold in Canada are not excessive. The Board exercises this authority by subjecting each new patented medicine that is marketed to a series of pricing tests to determine whether or not the introductory price exceeds the price allowed under the Board's regulations.[1]

Each year a number of drugs are marketed before they receive a Canadian patent and therefore are not subject to the Board's authority. Once a patent of any sort is granted the PMPRB reviews the drug's price from the time it was initially marketed. If the price during the period between marketing and patenting is found to be excessive the PMPRB can order the company to repay the excess revenue to the federal government.

This study was undertaken to determine how many drugs are marketed before they receive a patent, the time period between marketing and patenting and the excess revenue, if any, earned by companies.

Methods

The annual reports of the PMPRB between 2000 and 2008 were hand searched for all New Active Substances (NAS) that were marketed before being patented. For each drug the following information was extracted: year the drug came under PMPRB jurisdiction, generic name, brand name and manufacturer.

If introductory drug prices are thought to be excessive companies may be required to repay any excessive revenues through either a Voluntary Compliance Undertaking (VCUs) or a formal order from the PMPRB. VCUs and orders are documented in PMPRB reports and were recorded for each included drug.

Databases listing when drugs received their marketing authorization (Notice of Compliance, NOC) (http://205.193.93.51/NocWeb/nocqrye.jsp) and when patents were applied for and granted (http://www.patentregister.ca/) were searched. The period between the NOC and the first patent was calculated in days. This period represents the maximum amount of time that a drug could have been marketed without a patent. The time in days between patent application and receipt was also computed.

The Ontario Drug Benefit Formularies issued between December 1, 1994 and June 27, 2008 were hand searched to determine which of the drugs were listed on the formulary.

Results

Between 2000 and 2008 there were a total of 192 NAS that came under the jurisdiction of the PMPRB and 42 of these (22%) were reported by the PMPRB as being marketed before they had received a patent. Nine of the 42 were excluded from analysis for the following reasons: the product was not listed in the patent register, there was a contradiction between when the PMPRB reported it had jurisdiction and when the patent register listed the first patent was granted, the date when the patent register reported that

the patent was granted was before the NOC date in the NOC database.

Table 1 gives all of the drugs included along with the dates when they received a NOC and a first patent. Drugs were potentially being marketed between 54 and 2707 days before they came under PMPRB jurisdiction. The time between patent application and receipt ranged from 1531 to 7096 days. (Data not shown.) Three products exceeded the maximum introductory price and the total excess revenue for these was $9,289,687.63. The PMPRB is still investigating if the price of one product is excessive. Twelve of the 33 drugs were listed on the Ontario Drug Benefit Formulary including 1 with an excessive price. Five had received a patent by the time that they were listed.

Discussion

More than 1 in 5 NAS marketed between 2000 and 2008 were initially being sold before they received a patent. One drug was potentially marketed for 2707 days (over 7.4 years) before it received a patent. The total excess revenue for 3 drugs was $9.2 million.

It is unclear why these drugs were marketed before they had a patent. One possibility is that there was an undue delay between when the patent was applied for and when it was granted. The average time between the 2 dates was almost 10 years.

Although only 3 of 33 (9%) drugs were found to be overpriced the fact that prices can go unregulated for up to 7.4 years is potentially troublesome. If companies are charging excessive prices then the additional revenue paid to the company may limit the ability of

provincial formularies to list additional drugs. Even though the excess revenue is eventually recovered it is paid to the federal government not the provincial governments that funded the drug through their drug benefit schemes. Similarly, people who paid out of pocket and private insurance plans do not recover their excess payments. Excessive prices may also stop provincial formularies from listing useful drugs. In the case of the drugs in this study the Ontario government paid out relatively little extra money due to excessive prices as it only listed 1 of the 3 drugs that were overpriced.

Drugs marketed after they have received a patent may also be priced excessively but in these cases the Board's authority starts as soon as the drug is being sold and therefore excessive prices will be recognized and reduced much earlier.

References

1. Annual report 2008. Ottawa: Patented Medicine Prices Review Board; 2009.