Final Amendments to the PMPRB Regulations Announced

August 09, 2019

Today, the federal government announced the final draft of the *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements*) (the *Regulations*). The *Patented Medicines Regulations*[1]provide companies with patented medicines, the amended Patented Medicines Prices Review Board (the Board or the PMPRB) reporting requirements. These amendments have been anticipated since the consultation period on the draft published in the *Canada Gazette,* Part I ended in February 2018. The *Regulations* are expected to publish in the *Canada Gazette*, Part II (the CGII) on August 21, 2019.

For all medicines, the basket of comparator countries has been amended.[2] The United States and Switzerland have been removed, while Australia, Belgium, Japan, Netherlands, Norway, and Spain have been added. France, Germany, Italy, Sweden, and the United Kingdom remain in the basket. Notably, the price used for comparison from these countries is still the ex-factory price.

In addition, for all medicines, the calculations of “average price” and “net revenue” that require reporting have changed.[3] For both calculations, the patentee will be required to report the actual price or revenue obtained, taking into account any adjustments, reimbursements, or reductions including as a result of free goods, free services, gifts or other benefits of a like nature. According to the regulatory impact analysis statement (RIAS), this information will be considered privileged under s. 87 of the *Patent Act*.

Reporting requirements will be reduced for patented veterinary medicines, generic medicines, and over the counter (OTC) medicines (with the exception of drugs found in Schedule D to the *Food and Drugs Act*). Patentees will only be required to report price, sales, identity information and information on the new regulatory factors when requested by the Board. This has expanded the reduced requirements for OTC medicines to include controlled substances and radiopharmaceuticals, however, biologics listed on Schedule D will still be required to report.

For medicines assigned their drug identification number (DIN) on or after the day these *Regulations* are published in the CGII, the following additional requirements will apply and be considered as other factors in determining whether the medicine is sold at an excessive price.[4]

a) The medicine's pharmacoeconomic value in Canada[5]

If a cost-utility analysis prepared by a publically funded Canadian organization shows that the cost of the medicine, when pro-rated for use over a 12-month period, is greater than or equal to 50 per cent of the GDP per capita in Canada at the time the analysis is published, patentees will be required to provide that analysis to the Board. This requirement applies to an analysis in which the outcomes are expressed as the cost per quality-adjusted life year for each indication that is the subject of the analysis. Furthermore, if any information is redacted from the public version of the analysis, the patentee is required to provide that redacted information to the Board. This information will be due 30 days after the day the medicine is first offered for sale in Canada, or 30 days after it is first published, if publication is after the date of first sale.

b) The size of the market for the medicine in Canada[6]

The patentee will be required to provide to the Board the estimated maximum use of the medicine in Canada as measured by the total quantity of the medicine expected to be sold in final dosage form and the period of time used for this estimate. This will be required within 30 days of the date the medicine is first offered for sale in Canada. Updates to this estimate will be required within 30 days of any Notice of Compliance (NOC) approving a new or modified therapeutic use of the medicine.

c) The GDP in Canada and the GDP per capita in Canada

No additional criteria are set out explaining this factor. The patentee will not need to report on this information, as it can be obtained from Statistics Canada.

The PMPRB will have to amend its guidelines in order to reflect these amendments. It was announced at a media briefing on August 9, 2019, that draft guidelines are expected to be published early in the fall with the goal of a final product in February 2020 — although these are not firm deadlines. If this is the case, it will give companies time to review the guidelines and prepare for compliance as of the coming into force of the *Regulations*.

The *Regulations* will come into force on July 1, 2020.

[1] SOR/94-688 as amended.

[2] Amended Schedule to section 4(1)(f)(iii).

[3] Amended sections 4(4)(a) and (b).

[4] New section 4.4

[5] New section 4.1

[6] New section 4.2

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