NORTON ROSE FULBRIGHT

Pharma in brief - Canada

PMPRB switches to complaint-based process for patented generic drug price review

---

Summary

In its February 2017 newsletter, the Patented Medicine Prices Review Board (the **PMPRB** or the **Board**) announced its intention to move patented generic drug price reviews to a complaint-based process, similar to the provisions for over-the-counter drug products and veterinary medicines. This means that Form 1 (medicine identification) will continue to be required for patented generic drugs, but Form 2 (identity and prices of medicine) will only be submitted on request.

Key points

What qualifies as a "patented generic drug"? The PMPRB has stipulated that the new policy is limited to those patented generic drugs approved for sale on the basis of: (1) a comparison to a Canadian reference product or otherwise approved by way of Abbreviated New Drug Submission (ANDS); (2) having been declared interchangeable to a Canadian reference product by a provincial/territorial formulary; or (3) being licensed versions of an existing brand reference product (e.g., drug approved by cross-referenced New Drug Submission). The drug in question must of course fall within a patent for an "invention pertaining to a medicine" sold by a "patentee" as defined in the *Patent Act*.

When will the Board investigate the price of a patented generic drug? The Board will initiate an investigation into the price of a patented generic drug if all of the following conditions are met: (1) a substantiated complaint has been received in respect of the patented generic drug; (2) the patentee of the patented generic drug is the only company in Canada selling a generic version of the drug in Canada; and (3) the patented generic drug is not the subject of a pricing agreement with the pan-Canadian Pharmaceutical Alliance, to which it is compliant.

What is the Board's rationale for the new policy? The Board regularly reviews existing policies to reduce the regulatory burden where possible. The Board's opinion is that "[f]rom the point of view of risk of abuse of market power, the PMPRB recognizes that patented generic drugs represent a potentially lower-risk category of patented medicines, and therefore a lower priority for PMPRB regulatory investigation."

When will the new policy be implemented? The new policy applies as of the July 1 to December 31, 2016, reporting period.

Links:

PMPRB *NEW*Sletter – February 2017, Volume 21, Issue 1

Compendium of Policies, Guidelines and Procedures – Updated February 2017

For more information, please contact your IP/Life sciences or healthcare practice professional at Norton Rose Fulbright Canada LLP.

For a complete list of our IP team, click here. For a complete list of our Life sciences and healthcare team, click here.