

## Pharma in brief - Canada

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

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#### 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 NEWSletter – February 2017, Volume 21, Issue 1](#)

[Compendium of Policies, Guidelines and Procedures – Updated February 2017](#)

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