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Federal Court ruling exposes difficulty of reversing Health Canada scientific decisions

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In this Update

- The Federal Court of Canada recently upheld Health Canada's denial of approval of a generic hormone replacement product (progesterone) submitted by Apotex.
- The Court's ruling in *Apotex Inc v Canada (Health)* offers guidance regarding the level of procedural fairness that Health Canada must provide when making scientific decisions pertaining to a product's safety and efficacy.
- *Apotex* also provides useful insight for future drug applicants facing points of scientific disagreement with Health Canada reviewers regarding the appointment of an external review panel, the circulation of a draft decision before a hearing, *ex parte* review of evidence, and time taken before seeking judicial review.
- Key takeaway from the ruling: On matters of disputed science, applicants should put their best foot forward from the outset and present well-supported scientific advocacy submissions that address the current state of applicable science clearly, honestly and persuasively.

On February 1, 2017, the Federal Court of Canada upheld Health Canada's denial of approval of a generic hormone replacement product (progesterone) submitted by Apotex. The judgment, issued by Justice Phelan in *Apotex Inc v Canada (Health)*, 2017 FC 127, offers guidance regarding the level of procedural fairness that Health Canada must provide when making scientific decisions pertaining to a product's safety and efficacy. This ruling should convince drug applicants of the importance of preparing well-supported scientific advocacy submissions for Health Canada's consideration at the earliest opportunity to prevent prejudgment of drug applications on the basis of disputed science.

Health Canada's review of Apotex's progesterone product

Despite able efforts, Apotex was unsuccessful in overturning Health Canada's decision to deny approval of its progesterone product. Health Canada expressed concerns about the high amount of a non-medicinal ingredient (sodium lauryl sulfate, SLS) in Apotex's product. Apotex attempted to squarely address the issue in its drug submission, including noting that the FDA had previously approved products with even higher levels of SLS. Health Canada nevertheless denied Apotex's product.

Apotex requested reconsideration, and Health Canada established an internal scientific panel to review the issue. Apotex's product was again denied. The panel agreed with aspects of Apotex's scientific arguments but elected to take a conservative approach. Apotex challenged the procedural fairness of the panel's decision on judicial review.

Federal Court finds no breach of procedural fairness

Justice Phelan was reluctant to interfere with the panel's scientific findings, noting that its review exercise was detailed, technical and based on expert knowledge. His analysis of the matter provides useful insight for future drug applicants facing points of scientific disagreement with Health Canada reviewers:

- **Formation of an external panel:** Often in disputed matters, drug applicants seek formation of an external review panel out of concern that Health Canada personnel will be unlikely to change their minds. In this case, the Court found that Apotex had no legitimate expectation for the appointment of an external review panel. Rather, Apotex's legitimate expectation was to an independent and impartial panel in accordance with Health Canada guidelines. The Court found that the panel met these requirements.
- **Drafting of a preliminary decision:** The Court found that the Chair of the panel did not create a reasonable apprehension of bias by circulating a draft memorandum in advance of the panel meeting. Whether such a draft establishes a reasonable apprehension of bias depends on how far it has gone toward "being cast in stone." The Court found that, despite the draft decision, the panel had kept an open mind.
- ***Ex parte* review of evidence:** Although the panel did its own research and raised new studies at the hearing, the Court held that Apotex was not deprived of its right to be heard. Apotex had the ability to review the same research and could have sought an additional opportunity to address any new evidence.
- **Time for seeking judicial review:** Although Apotex waited to judicially review Health Canada's decision until after the reconsideration, the Court permitted Apotex's application to proceed. The Court did not penalize Apotex for electing to first seek reconsideration, noting that Apotex clearly expressed its continuing intention to dispute the matter and that Health Canada faced no prejudice in fact.

Takeaway: Put your best foot forward on Day One

Although health product regulatory agencies around the world apply very similar standards, they often reach different conclusions about the same product. These divergences are particularly common in areas of disputed or cutting-edge science and can have enormous consequences on drug applicants. The review of Apotex's progesterone product shows how difficult it can be to reverse a Health Canada scientific decision even when other regulators have reached a different conclusion.

What is the takeaway then?

On matters of disputed science, applicants should put their best foot forward from the outset, presenting scientific advocacy submissions, possibly supported by expert evidence, that address the current state of applicable science clearly, honestly and persuasively. To avoid being at the mercy of the regulator, applicants should avail themselves of reasonable

opportunities to address contentious matters with their reviewers before the reviewers have formed their views.

External counsel can provide valuable assistance in preparing scientific advocacy briefs to accompany regulatory submissions for business-critical products. If you need help advocating before Health Canada on matters of scientific dispute, contact Nathaniel Lipkus for assistance at 416.862.6787 or nlipkus@osler.com.