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Pharma in brief - Canada

Court upholds Health Canada decision requiring additional information on certain Apotex drugs manufactured in India

Case:	*Apotex Inc v Minister of Health*, 2017 FC 315 (Court File No. T-1915-15)
Drugs:	Varenicline and Sitagliptin
Nature of case:	Judicial review of the decision of the Therapeutic Products Directorate (**TPD**) of Health Canada to require further information on certain drugs manufactured in India for Apotex before issuing an NOC.
Successful party:	Minister of Health
Date of decision:	**March 27, 2017**

Summary

The Federal Court dismissed Apotex's application for judicial review of the Minister of Health's (**Minister's**) decision to require additional information from Apotex as part of its Notice of Compliance (**NOC**) submissions for certain drugs manufactured in India by Apotex affiliates. The additional information was requested to address data integrity concerns.

This is Apotex's third application relating to data integrity concerns with its Indian affiliates. As we reported, Apotex's previous two judicial reviews were granted.

Background

The three decisions that led to Apotex's applications were made by two different groups within Health Canada. The previous two decisions were made by the Health Products and Food Branch Inspectorate (**Inspectorate**), and related to the implementation and maintenance of an import ban on Apotex's API (active pharmaceutical ingredients). This judicial review relates to a Therapeutic Products Directorate of Health Canada (**TPD**) decision not to issue NOCs until more data was provided.

In the previous decisions, Justice Manson held that the import ban was motivated by improper purposes, namely, political pressure, rather than a concern for health and safety. In the third decision, Justice Russell noted that Justice Manson did not find that there were no genuine concerns with data integrity and further found as an objective fact that Apotex acknowledged the concerns and took steps to address them.

The TPD's decision to require further information before issuing NOCs related only to Apotex's submissions that rely on data generated prior to January 2015, data that predates Apotex's corrective action. The TPD asserted that lifting the import ban did not relieve its concerns about data integrity that predated Apotex's corrective actions. Further, the additional information was required pursuant to a general policy the TPD developed that is applicable to any drug for which there were concerns about data integrity and not specific to Apotex or its products.

Apotex initially asserted that 30 drugs were affected by the TPD's decision. However, by the time of the hearing Apotex had already provided the additional data for 28 drugs, 26 of which were approved. Despite Apotex's request for judicial review of the decision as it relates to any drug, the court limited its analysis to the decision as it related to the two drugs for which data had not been submitted: varenicline and sitagliptin.

The court considered whether the TPD's decision was improperly motivated or unreasonable.

The decision was not improperly motivated

The court agreed with Apotex's assertion that the TPD's decision would have been improperly motivated if it was inextricably connected to the import ban or was otherwise improperly motivated.

The court found that the role of the import ban in the decision to require further data was simply a trigger for the TPD, making it aware that it needed to consider data integrity before issuing NOCs. As a result, the TPD put in place a general policy that did just that and applied to all manufacturers equally. Overall, the actions were independent of those of the Inspectorate and justified given the legitimate safety and efficacy concerns.

Apotex had argued that the TPD was given "marching orders" from the Minister to implement "stronger measures" with regard to Apotex's submissions because of the political pressure on the Minister. Apotex pointed to a lack of documentation surrounding certain communications between the TPD and the Inspectorate as a deliberate attempt to shield the decision from scrutiny. The court rejected these accusations as "speculation and a conspiracy theory" with no supporting evidence. Further, the court found that by having approved 26 of the 30 submissions, the TPD was not acting as a regulator trying to uphold an improper ban.

Overall the court found the connection between the decision at issue and the import ban to be "extremely tenuous" and unproven. Rather, the decision was a legitimate action on the part of the TPD to ensure the safety and effectiveness of drugs marketed in Canada.

The decision was reasonable

The court found that Apotex had not established that there were no genuine data concerns prior to January 2015, and that Apotex's own dealings with regulatory authorities demonstrated that the concerns were real. As a result, even if the import ban was what prompted the TPD to take action, the decision was still reasonable.

Further, the court found that although the Inspectorate had given the Indian facilities the all-clear, the TPD could not confirm the reliability of data that predated Apotex's corrective action. In fact Apotex had acknowledged that five other submissions had been affected by data integrity problems. The pre-January 2015 concerns about the data were therefore genuine, and it was not unreasonable for the Minister to require more data to ensure the safety, effectiveness, and quality of the drugs.

Link:

Apotex Inc v Minister of Health, 2017 FC 315

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