

Biosimilars Review Process & pCPA Negotiations Update

Biosimilar Review Process Updates

The Canadian Agency for Drugs and Technologies in Health (CADTH) has made the decision to no longer review biosimilars*.

The process for Québec's Institut national d'excellence en santé et en services sociaux (INESSS) remains unmodified for biosimilars. As such, listing and coverage of biosimilars by the Québec public drug plan will continue to be contingent on the availability of the INESSS recommendation.

**In rare circumstances, however, when additional information is required to inform a biosimilars negotiation, the pCPA may seek CADTH's expertise.*

Initiating pCPA Negotiations

The pan-Canadian Pharmaceutical Alliance (pCPA) indicated within the [Biologics Policy Directions & pCPA Negotiations](#) that negotiations for biosimilars can begin in parallel with the HTA process. The absence of CADTH review of biosimilars will not impact when pCPA negotiations may be initiated.

Negotiation Process Steps

1. Up to 6 months before obtaining a Health Canada Notice of Compliance (NOC) for a biosimilar, a manufacturer may submit a [Manufacturer Notification of Intent to Negotiate a Biosimilar](#) form to info@pcpacorp.ca to begin pCPA's negotiation process.

The pCPA, on behalf of all pCPA jurisdictions, is the initial point of contact for biosimilar manufacturers for negotiation purposes.

The pCPA will contact the biosimilar manufacturer after receiving a completed form to discuss negotiation expectations.

2. Upon obtaining an NOC for a biosimilar, the pCPA will advise manufacturer to make their submission to the pCPA jurisdictions.

Note: Inclusion in jurisdictional Product Listing Agreements is dependent on successful completion of all mandatory review processes and listing requirements, including jurisdictional submission requirements.



More information

Further details pertaining to pCPA Negotiations can be found in the [Brand Process Guidelines](#) and the accompanying FAQs.

For more information or queries please contact the pCPA at info@pcpacorp.ca.