

## Policy Directive

New biosimilar products and their new indications approved by Health Canada will not require a routine review by the Committee to Evaluate Drugs (CED) or the Ontario Steering Committee for Cancer Drugs (OSCCD), the ministry's expert drug advisory committees for non-cancer and cancer drugs respectively.

This will improve efficiencies and better align with national processes for the funding consideration of biosimilar products, including the pan-Canadian Pharmaceutical Alliance and the Canadian Agency for Drugs and Technologies in Health (CADTH).

On a case-by-case basis, the Ontario Public Drug Programs (OPDP) may seek advice from the provincial drug expert reviewers as needed.

Manufacturers must continue to make complete submissions to the OPDP to have their biosimilar products considered by the Executive Officer for listing and funding, in accordance with Ontario Regulation 201/96 under the *Ontario Drug Benefit Act* and the policy requirements outlined in the Ontario Guidelines for Drug Submission and Evaluation.

It is the responsibility of manufacturers to monitor clarifications of, or changes to, the Guidelines through the Ministry's website.