Executive Officer Notice:

Amendments to O. Reg. 201/96 under the *Ontario Drug Benefit Act* and Reg. 935 under the *Drug Interchangeability and Dispensing Fee Act* to modernize submission requirements for "well-established drugs."

March 7, 2024

To modernize the submission requirements for manufacturers of "well-established" brand and generic drug products, the Ontario Government has made amendments to O. Reg. 201/96 under the *Ontario Drug Benefit Act* (ODBA) and Reg. 935 under the *Drug Interchangeability and Dispensing Fee Act* (DIDFA).

Well-established drugs are drug products that are not "new drugs" as defined in the Food and Drug Regulations made under the *Food and Drugs Act* (Canada). In other words, they are drug products containing substances that have been sold in Canada for sufficient time and in sufficient quantity to establish their safety and effectiveness.

Manufacturers of brand and generic drug products are required to make a submission to the ministry to have their products funded under the Ontario Drug Benefit (ODB) program. In the case of generic drug products, the submissions are also used to designate generic drug products as interchangeable with brand and other generic drug products. The requirements for making these submissions are set out in O. Reg. 201/96 made under the ODBA and Reg. 935 made under DIDFA.

Prior to the making of the regulatory amendments described above, Ontario's submission requirements for brand and generic drugs were not fully aligned with Health Canada's requirements for approving well-established drugs for sale in Canada. This misalignment may have prevented manufacturers of certain well-established drugs from having their products funded under the Ontario Drug Benefit (ODB) program and/or designated as interchangeable in Ontario.

The approved regulatory amendments will reduce this burden by ensuring that Ontario's submission requirements are better aligned with Health Canada's requirements for well-established drugs. The amendments will also improve Ontarians' access to publicly funded drugs under the ODB program, including lower cost generic drugs. Timely patient access to drugs will positively impact Ontarians, reducing the burden of illness and overall health care utilization.

The approved regulatory amendments are available at https://www.ontario.ca/laws

Ontario Drug Submission Guidelines

To reflect the regulatory amendments, the Ontario Drug Submission Guidelines for Single Source Drug Products and the Ontario Guidelines for Multiple Source Drug Products have been updated and are available at: https://www.ontario.ca/page/drug-submissions