

Ministry of Health

Drugs and Devices Division

Drug Submission: Policy Directive

The purpose of this notice is to provide information regarding interim measures to respond to scenarios that may arise due to COVID-19.

Manufacturers are asked to take note of the following:

Effective immediately, the Drugs and Devices Division (DDD) will accept e-mail submissions instead of electronic copies on USB, CD or DVD. This applies to all product submissions (including but not limited to Single Source Drug Product submissions, Multiple Source Drug Product submissions, Valved Holding Chamber submissions, Diabetic Testing Agent submissions, and Nutrition Product submissions).

Please send the submissions to the DDD's email mailbox

DrugSubmissions.MOH@ontario.ca

The submissions must be well organized and indexed/tabbed with description. Manufacturers must not provide submission information in one continuous document. If the submission is too large to be sent by a single e-mail, we will accept the whole submission via multiple e-mails. If you are sending multiple e-mails for one submission, you must clearly identify that the e-mails belong to the same submission and how many total e-mails pertain to that particular submission.

Manufacturers must continue to make submissions to the Drugs and Devices Division to have their products considered by the Executive Officer for listing and funding, in accordance with Ontario Regulation 201/96 under the *Ontario Drug Benefit Act* and Regulation 935 under the *Drug Interchangeability and Dispensing Fee Act*.

For a multiple source drug product to be considered for inclusion in a monthly review cycle for listing in a future Formulary Update, the submission must be received by the monthly submission deadline. Please refer to the [monthly submission deadline](#) date on the ministry website.

Note: In making any submissions to the ministry, manufacturers are to refer to the complete Ontario Guidelines for Drug Submissions and Evaluation together with any updates (i.e., Drug Submissions Policy Directives) for the complete details on requirements and processes.

It is the manufacturer's responsibility to monitor changes made to the Guidelines from time to time.