Policy Directive

The Drugs and Devices Division is working to improve efficiencies and to reduce burden on manufacturers for drug submission requirements.

The purpose of this notice is to provide information regarding changes to the Ontario Guidelines for Drug Submission and Evaluation (Guidelines) to assist manufacturers in making submissions to the Drugs and Devices Division.

Manufacturers are asked to take note of the following:

- Effective July 1st, 2019, the ministry will no longer require drug manufacturers to provide a full printed copy of their submission.
- The Drugs and Devices Division will accept one electronic copy of the submission for 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.)

For electronic submissions, the Ministry will accept CDs, DVDs or USB keys, and they must fulfill the following requirements:

- The documents must be provided in MS Word, Excel or PDF format that is unlocked, searchable and printable.
- Users must have the ability to extract information or combine documents.

Manufacturers may wish to password protect any electronic submissions (i.e. CD, DVD or USB key) made to the Ministry. Please send the password needed to access the files to the email DrugSubmissions.MOH@ontario.ca ahead of the arrival of the electronic drug submission to the Drugs and Devices Division.

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

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