

# Ontario Public Drug Programs Drug Submission-Policy Directive

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In accordance with Part VII of the Drug Submission Guidelines, the Ministry is publishing this policy directive regarding the drug submission review process.

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

Manufacturers are asked to take note of the following submission requirement(s):

- Submission requirement for the number of hard copies for Multiple Source Submissions and for Single Source Submissions [August 12, 2015]

## For Multiple Source Submissions

The manufacturer must submit one (1) full hard copy and one (1) electronic copy for each submission. One (1) full hard copy and one (1) electronic copy are also required for any material responding to any deficiency from the Ministry's NDSS or CED recommendations letters. For the electronic copy, the Ministry will accept CDs and DVDs only.

The electronic copy:

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

A Submission will be deemed incomplete if these requirements are not met. All submissions must be delivered by either mail, courier services or in person by the manufacturer by 3:30p.m. on the Submission Deadline for Receipt date.

## For Single Source Submissions

The manufacturer must submit one (1) full hard copy and two (2) electronic copies for each submission. One (1) full hard copy and two (2) electronic copies are also required for any material responding to any deficiency from the Ministry's NDSS or CED recommendations letters. For electronic copies, the Ministry will accept CDs and DVDs only.

The electronic copy:

- The documents must be provided in MS Word or PDF format that is unlocked, searchable and printable.
- Users must have the ability to extract information or combine documents.
- For the Pharmacoeconomic Information, a model (or a spreadsheet) that is unlocked (or executable) must be provided. The user should be able to specify inputs, view calculations, and run various analyses.

A Submission will be deemed incomplete if these requirements are not met.