Ministry of Health and Long Term Care

Ontario Public Drug Programs
Drug Submission – Policy Directive

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 Notice of Compliance for the cross-referenced product [February 14, 2014]

Where a manufacturer’s submission relies on a cross-referenced product, the original (first approved) Notice of Compliance (NOC) issued by Health Canada for the cross-referenced product must be submitted. The supplemental NOC is not accepted as the original NOC even if all the product information is available on the NOC. The submission will be deemed incomplete if the original NOC of the cross-referenced product is not submitted.