

June 4, 2008

Manufacturer Review of Transparency Bulletin

The Ministry of Health and Long-Term Care has now established a process for manufacturers to review the Ministry's transparency bulletins relating to Executive Officer decisions and Committee to Evaluate Drugs (CED) recommendations.

Starting with drug evaluations from the June 2008 CED meeting, the Ministry will be providing the submitting manufacturer an opportunity to review the transparency bulletin pertaining to their own product prior to publication.

On a go-forward basis, the Ministry will endeavour to publish transparency bulletins within two months of the CED recommendation. Hence, transparency bulletins for CED recommendations from the June 2008 meeting will be available sometime in August 2008 for review. The two month period is to allow adequate time for the Ministry and the CED to finalize the meeting minutes and the bulletins.

Once the transparency bulletins have been ratified by the CED and the Ministry, a copy will be sent to the submitting manufacturer for review. Manufacturers will be given five business days to review the bulletin and identify any confidential information (e.g. unpublished data, confidential price) and/or overt errors. Disputes of the CED's findings and recommendations or the submission of new information will not be considered through this process. Comments must be sent to Ontario Public Drug Programs via email by 5:00pm at the end of the fifth business day. (The Ministry contact and email address will be provided to the manufacturer when the bulletin is sent for review.) The Ministry will acknowledge the receipt of any submitted comments; however, there will be no specific response as to whether the manufacturer's comments are accepted. The final version of the bulletin will only be available to the manufacturer when it is publicly posted.