Dextromethorphan Hydrobromide

Type of Posting: Notice of Intent to Revise

Posting Date: 28–Feb–2014; updated 29–Apr–2016*; updated 01–Dec–2016**

Targeted Official Date: Mar–01–2017, Revision Bulletin

Expert Committee: Chemical Medicines Monographs 6

Reason for Revision: Safety

In accordance with section 7.04(c) of the 2015–2020 Rules and Procedures of the Council of Experts, this communication is to provide notice that the Chemical Medicines Monographs 6 Expert Committee intends to revise the Dextromethorphan Hydrobromide monograph.

This monograph does not currently possess a procedure for determining the controlled substance, levomethorphan (an enantiomer). This is a major safety concern, because recently, levomethorphan was found at toxic levels in the drug formulation and resulted in many deaths globally. The purpose of this revision is to introduce a procedure to quantitatively monitor levomethorphan in Dextromethorphan Hydrobromide.

The revision including the procedure to monitor levomethorphan was initially published as a Revision Bulletin on May 27, 2016 with a delayed official date of January 1, 2017, pursuant to section 7.02 of the Rules and Procedures of the Council of Experts. A revised Revision Bulletin is anticipated to be published on January 27, 2017 to modify the official date of the revision to March 1, 2017.

Should you have questions, please contact Clydewyn M. Anthony, Ph.D, Senior Scientific Liaison (301-816-8139 or cma@usp.org).

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* The notice was updated on April 29, 2016 to change the proposed revision vehicle for this revision to a Revision Bulletin. The posting date was updated to May 27, 2016 with an official date of January 1, 2017.

** The notice was updated on December 01, 2016 to indicate that the Expert Committee intends to change the official date of the revision from January 1, 2017 to March 1, 2017, because of a delay in the availability of the reference standard.