## <u>Dicolofenac Sodium and Misoprostol Delayed-Release Tablets</u>

Type of Posting: Notice of Intent to Revise

Posting Date: 28-Jul-2017

Targeted Official Date: Interim Revision Announcement 01-Mar-2018

**Expert Committee:** Chemical Medicines Monographs 3

In accordance with section 7.04 (c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the USP Chemical Medicines Monographs 3 Expert Committee intends to revise the Dicolofenac Sodium and Misoprostol Delayed-Release Tablets monograph.

The purpose of this revision is to update the Organic Impurities test as follows to accommodate products approved by FDA:

- Widen the specifications for B-type misoprostol from NMT 0.5% to NMT 0.7% and for A-type misoprostol from NMT 1.0% to NMT to 3.5%.
- Add limit for total misoprostol related impurities of NMT 6.2%
- Add limit for total diclofenac related impurities of NMT 1.0%.
- Delete the total impurities limit of NMT 3.0% for combined misoprostol and diclofenac impurities.

It is anticipated that the revision will be published as a Proposed Interim Revision Announcement in PF 43(5) [Sept. 1, 2017] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on November 30, 2017

Should you have any questions, please contact Andrea Carney, Associate Scientific Liaison to the USP Chemical Medicines Monographs 3 Expert Committee (301–816–8155 or <a href="mailto:afc@usp.org">afc@usp.org</a>).