Dutasteride

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Expert Committee: Chemical Medicines Monographs 5

In accordance with section 7.04 (c) of the Rules and Procedures of the 2015-2020 Council of Experts, this is to provide notice that the Chemical Medicines Monographs 5 Expert Committee intends to revise the Dutasteride monograph to change the relative response factor of dihydrodutasteride from 0.38 to 1.0 to accommodate a drug substance from another FDA approved manufacturer.

The proposed revision will replace the Interim Revision Announcement (IRA) for Dutasteride published in *Pharmacopeial Forum* (PF) 41(5) [Sep.–Oct. 2015], which becomes official on March 1, 2016.

Should you have any questions, please contact Mary P. Koleck, Ph.D., Scientific Liaison (301-230-7420 or mpk@usp.org).