PROCEDURAL NOTE CONCERNING

THE GUIDELINE ON THE OPERATION OF THE PROCEDURES LAID DOWN IN CHAPTERS II, III, AND IV OF COMMISSION REGULATION (EC) 1234/2008 OFCONCERNING THE EXAMINATION OF VARIATIONS TO THE TERMS OF MARKETING AUTHORISATIONS FOR MEDICINAL PRODUCTS FOR HUMAN USE AND VETERINARY MEDICINAL PRODUCTS

Section 2.3.5 of the *Guideline on the operation of the procedures laid down in Chapters II, III and IV of Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products* provides that major variations of Type II that do not require a Commission decision amending the relevant marketing authorisation may be implemented after the marketing authorisation holder has been informed by the Commission.

As from 1 May 2011, the task of informing marketing authorisation holders that these variations may be implemented is delegated to the European Medicines Agency.