MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

DIRECCIÓN DE LA
AGENCIA ESPAÑOLA
DE MEDICAMENTOS Y
PRODUCTOS SANITARIOS

**COMMENTS FROM THE SPANISH AGENCY FOR MEDICINES AND MEDICAL DEVICES ABOUT PUBLIC CONSULTATION PAPER ON THE REVIEW OF THE "VARIATIONS GUIDELINES"**

Please find below the following comment to the proposal for revision of the guideline, March 2012 from the Spanish Medicine Agency and Medical Devices:

*With regard to current variation classification C.I.5. Change in the legal status of a medicinal product for centrally authorised products, we suggest the deletion of the wording "products authorised by centrally procedure" from the heading:*

*The justification for our proposal is due to this variation, is also applicable for national products and taking into account that the revised Variation Regulation will applied to marketing authorisation granted under purely national marketing authorisations, we consider that the scope of the category mentioned should not be limited only for products authorised via centralised procedure.*

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