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Question & Answer N. 61/2008

Informed consent application

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QUESTION

Does the existing guidance allow an informed consent application to be made in a country which was a Concerned Member State in the Mutual Recognition Procedure involving the originator, where the proposed Marketing Authorisation Holder is independent of the originator MAH?

ANSWER

It is allowed to submit an informed consent application in a country that was CMS in an MRP for the product that will be referred to. However, it shall be noted that an informed consent application to a generic product should not be possible as the requirements laid down in Article 13c of Directive 2001/82/EC (as amended) could not be met.