



March, 2006

Notifications to the EMEA/CHMP in the Mutual Recognition /Decentralised Procedures (MRP/DCP)

The following notifications should be made to the EMEA by the Marketing Authorisation Holder:

In the event of arbitration to CHMP for applications for marketing authorisation in the mutual recognition or decentralised procedure, the EMEA should receive the full dossier as set out in the Article 29 (5) of Directive 2001/83/EC, as amended.

In the event of arbitration to CHMP for applications for variation to marketing authorisations in the mutual recognition or decentralised procedure, the EMEA should receive the dossier for the respective variation application.

Any MRP/DCP related documentation other than the above mentioned should **not** be sent to the EMEA.

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