



7 April 2010  
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## Dossier requirements for Post-Authorisation Submissions in the Centralised Procedure

**EMA\*:** 1 Electronic copy of the complete application on DVD or CD-ROM + 1 original, signed cover letter (cc PTL with no additional copy needed).

Application / Submission Type	Dossier Requirements for (Co-)Rapporteur <sup>#</sup> and CHMP Members <sup>**</sup> Electronic copy (DVD or CD Rom)
Type IA/IB variation	Rapporteur: 2 electronic copies Other CHMP members: o eCTD: 1 electronic copy
Type II variation Renewal USR FUM/SO Annual Re-Assessment	(Co)-Rapporteur: 2 electronic copies Other CHMP members: 1 electronic copy  Please note the following exceptions: Germany (Dr Enzmann or Dr Broich) require 3 electronic copies
Transfer Art 61(3) Notification Art 46 Paediatric study	Rapporteur: 2 electronic copies Other CHMP members: 1 electronic copy
Extension	As for initial MA applications - see EMEA website: <a href="http://www.emea.europa.eu/htms/human/presub/q23-2.htm">http://www.emea.europa.eu/htms/human/presub/q23-2.htm</a>
PSUR	For submission and delivery requirements - See EMEA website: <a href="http://www.emea.europa.eu/pdfs/human/phv/12997608en.pdf">http://www.emea.europa.eu/pdfs/human/phv/12997608en.pdf</a>

\* The same requirements apply to submission of 'Responses'.

# For Sweden, one electronic copy on CD/DVD(s) in total is sufficient.

**Dossier delivery** addresses for CHMP members:

<http://www.emea.europa.eu/htms/human/presub/dossierrequirements.pdf>



For the **EMA policy** on paperless submissions and eCTD implementation in the Centralised Procedure, please refer to:

<http://www.emea.europa.eu/pdfs/human/regaffair/57245908en.pdf>

<http://www.emea.europa.eu/pdfs/human/regaffair/56336607en.pdf>