EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 January 2014

Please note that this document is currently under revision. An updated version will be available at the end of February 2014.

Please see Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2) of Regulation (EC) No. 726/2004 Chapter 3.II: XEVPRM User Guidance and Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2), second subparagraph of Regulation (EC) No 726/2004 XEVPRM technical specifications, Chapter 3.I for the latest available information.

Should you have any further questions please contact Art 57 helpdesk (art57@ema.europa.eu)

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union