EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

London, 20 February 2014
EMA/CHMP/BWP/66813/204
Human Medicines Evaluation Division
PMF Certificate no: EMEA/H/PMF/000009/05/AU/013/G

EMA Plasma Master File (PMF) CERTIFICATE of compliance with Community legislation

This certificate is valid together with its Evaluation report and Annexes.

After positive evaluation of the information provided on the PMF:

The Agency certifies that the PMF (EMEA/H/PMF/000009/05/AU/013/G) submitted for certification is considered to be in accordance with the specific requirements as laid down in Part III, section 1.1 of Annex I to the Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, as amended.

PMF Certificate Holder	[redacted]
Period of Epidemiological data collection	01 January - 31 December 2012[1]
List of Products	As annexed
List of Centres	As annexed
Specific conditions of Certificate	none
Next PMF annual update start date[2]	October 2014

This certificate shall be valid throughout the European Community.

The PMF dossier shall be updated and re-certified on an annual basis[3] or after any significant modification of the dossier. The existing certificate remains valid until the evaluation of the re-certification is determined.

Failure to comply with these provisions will render this certificate void.

Signed:

Enrica Alteri
Head of Human Medicines Evaluation Division

Issued by the EMA on 20 February 2014

[1] This period refers to collection of data for the initial certificate, or, where applicable, for the most recent PMF annual update.
[2] For submission deadline please look on EMA Website, Plasma Master File, submission dates
[3] The application for this re-certification of the PMF shall be submitted at the agreed "birth date" of the PMF and yearly thereafter.

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