European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

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Procedure: 2nd step of the Plasma Master File (PMF) certification procedure for the centrally authorised medicinal products

1. Introduction

2nd step procedure is applicable to all medicinal products for which a PMF is valid, in accordance with the specific requirements laid down in Part III of Annex I to the Directive 2001/83/EC of the European Parliament and of the Council of the Community code relating to medicinal products for human use as amended.

The objective of this document is to give a practical guidance to the MAHs. For additional information, this document should be read in conjunction with the European Commission (EC) Guideline on '2nd step' for PMF and Vaccine Antigen Master File (VAMF) certification[1].

2. Procedure for Marketing Authorisation Holders (MAHs)

The 2nd step notification application form (http://www.emea.europa.eu/htms/human/pmf/info.htm) should be completed and submitted accompanied by the relevant expert statement to the attention of the Central Information Group at EMEA and the Rapporteur of the concerned medicinal product(s).

Additional practical submission details should follow the latest Post-authorisation Guidance on variations. (http://www.emea.europa.eu/htms/human/postguidance/list.htm).

3. EMEA procedure

On arrival of the MAH's notification application, a procedure number is assigned and the documentation validated. After validation, the Rapporteur is contacted in writing by EMEA in order to start the evaluation of the impact of the PMF certification and data package on the finished product.

Within a period of 20 days, the Rapporteur should notify the EMEA of the outcome of the evaluation.

The EMEA will issue an acknowledgement of receipt to the MAH where it establishes whether the notification is valid and if the PMF has been taken into account for the medicinal product.[2]

A copy of this acknowledgement of receipt will be sent to the European Commission by e-mail and letter.

[1] See http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm, volume 2C.

[2] In accordance to the aforementioned EC Guidance, in the majority of cases the changes to the original PMF content of the Marketing Authorisation should not have any impact at the level of the medicinal product(s). Should the new PMF have an impact on the finished product, the MAH will be notified accordingly, and subsequently the MAH should submit the relevant variation to the EMEA in accordance to the Variations Regulation as well as EMEA Post-authorisation Guidance.

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