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

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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE

(CHMP)

CONCEPT PAPER ON the revision of the GUIDELINE ON EPIDEMIOLOGICAL DATA ON BLOOD TRANSMISSIBLE INFECTIONS (EMEA/CPMP/BWP/125/04)

AGREED BY BIOLOGICS WORKING PARTY	November 2008
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	20 November 2008[1]
END OF CONSULTATION (DEADLINE FOR COMMENTS)	28 February 2009[2]

The proposed guideline will replace guideline / NfG Reference EMEA/CPMP/BWP/125/04

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KEYWORDS	PMF, epidemiology, first time tested donors, repeat tested donors, prevalence, incidence, residual risk.

[1] Last day of relevant CxMP meeting
[2] Last day of the month concerned

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1. INTRODUCTION

Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use introduces the concept of the PMF. Part III, section 1.1 of Annex I lays down specific requirements related to PMF and states that "For medicinal products derived from human blood or plasma and by derogation from the provisions of Module 3, the dossier requirements mentioned in "Information related to the starting and raw materials", for starting materials made of human blood/plasma may be replaced by a PMF certified in accordance with this Part.

In light of the experience with the use of the Guideline on Epidemiological data (published in Jan. 2005 http://www.emea.europa.eu/pdfs/human/bwp/012504en.pdf), a group of experts was assigned to critically look at the:

- 2006 submitted epidemiological Plasma Master File (PMF) data, in conjunction with the CHMP Epidemiological guideline,
- 2006 and 2007 PMF evaluation reports for the relevant PMF

Feed back on this work has been provided to the PMF Drafting Group, to BWP/CHMP and a revision of the guideline is recommended.
As part of this exercise, it is also planned that the individual analysis of the PMF's epidemiological data will be communicated to the individual PMF Holders and also a more general outcome can be the basis for a subsequent PMF Epidemiological meeting with Industry to be scheduled in 2009.

2. PROBLEM STATEMENT

The Epidemiological expert group assigned by the CHMP/BWP has undertaken an extensive critical analysis of the data in the PMF dossiers and, based on this current experience, a revision to the guideline will benefit and improve the PMF dossiers with better submission of data and consistency across evaluations.

3. DISCUSSION (ON THE PROBLEM STATEMENT)

The conclusions on the experience gathered through this critical analysis on the epidemiological data in the PMF dossiers are a good basis for a revision of the Guideline to set out agreed principles, and additional guidance so as to ensure consistency in the submission and reporting of PMF epidemiological data.

4. RECOMMENDATION

The Biologics Working Party/Committee for Medicinal Products for Human Use recommends revising the guideline on Epidemiological Data on Blood Transmissible Infections (EMEA/CPMP/BWP/125/04).

The scope of the revision will be to provide additional guidance to PMF holders on:
- Submission of Epidemiological data
- Reporting and critical analysis of Epidemiological data (e.g. identification and reporting of trends)
- Elements to be considered for calculation of residual risk estimations

5. PROPOSED TIMETABLE

Release of the revision of the guideline for consultation in 2Q2009
Deadline for comments 30th September 2009
Discussion in BWP 3Q2009
Expected date for adoption by the Committee December 2009.

6. RESOURCE REQUIREMENTS FOR PREPARATION

Resources include:
- Three meetings/teleconferences with the Epidemiological group
- Discussion with the PMF Drafting Group
- 2-3 BWP plenary meeting
- Written consultation with CHMP in two rounds prior and after public consultation.

7. IMPACT ASSESSMENT (ANTICIPATED)

The revision will contribute to the harmonised understanding of the PMF data submission and reporting to the EMEA for the PMF initial certification and subsequent annual updates. This will be of benefit to both PMF stakeholders and PMF coordinators/assessors.

8. INTERESTED PARTIES

Appropriate consultation is foreseen of the BWP, PMF Drafting Group, PMF Coordinators/ Assessors and PMF Epidemiological Drafting Group.
Interested external parties include Plasma fractionation industry, pharmaceutical industry scientists and other regulatory bodies.

9. REFERENCES TO LITERATURE, GUIDELINES ETC

http://www.emea.europa.eu/pdfs/human/bwp/012504en.pdf