24 July 2014
EMA/412937/2014
Human Medicines Evaluation Division

Agenda for Meeting on Plasma Master File (PMF) Epidemiology - 18-19 November 2014

1. Introduction

The guideline on epidemiological data on blood transmissible infections (EMA/CHMP/BWP/548524/2008) outlines the scientific data requirements for epidemiological data on blood transmissible infections to be included in applications for Plasma Master File certification submitted to the EMA.

Applicants for Plasma Master File (PMF) certification are required to include epidemiological data on the viral epidemiology for each blood/plasma centre listed in the PMF application.

The requirement to collect epidemiological data on blood transmissible infections is intended to obtain information on the infection risk in a specific donor population and is thus an essential part of the measures taken to ensure an adequate selection of donors of blood and plasma. The purpose of collecting these data is to characterise the donor population with respect to infection risk, to allow trend analyses to be undertaken over periods of time, and to allow comparison of risks between donor populations of individual collection centres. This is one of the measures to ensure that donations do not come from donors with a high probability of being infected with blood transmissible agents.

The goal is final product safety and this is based on complementary approaches to assure virus safety (e.g. donor selection/donation testing, and virus reduction by the production process).

The first revision of this guideline came into effect in 2011, and it was recognised at that time that a further revision may be needed based on the experience of data submission and evaluation.

A PMF epidemiology expert group meeting took place in December 2013 to look at experience with the guideline and a further epidemiology meeting with industry is now scheduled to take place in November 2014.

As a result of the meeting in December 2013, a concept paper is being published for public consultation and the consultation period has been aligned to allow stakeholders to provide their comments after the November meeting. The concept paper provides further background on the topics to be discussed in this meeting.

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2. Purpose of the workshop

The purpose of this workshop is to look at the experience of PMF data submission and evaluation and to look into the issues identified during the PMF EMA experts meeting in December 2013, in particular:

- Approaches to monitor trends and to establish acceptable ranges for epidemiological data.

- Residual risk calculation - HBsAg adjustment factor, window periods used in calculations.

- Extension of the trend analysis period to more than 3 years now that data is available over longer periods in the format required by the guideline.

- The usefulness of both graphical representations of trends and statistical significance approaches for trend analysis for organisations/countries

- Approaches to identify trends on a centre basis

- Criteria for acceptance of new centres in terms of epidemiological data.

3. Time and location of the workshop

18 November (approx. start time 9.30pm) to 19 November 2013 (approx. finish time 1pm for meeting with Industry), Room to be announced at the European Medicines Agency.

Please note:

From 1 August 2014 our new address will be:

30 Churchill Place | Canary Wharf | London E14 5EU | United Kingdom

4. Organisation of the meeting

EMA (Correspondence to jose.childs@ema.europa.eu)

5. Steering committee

M. Nuebling, Chair of Epidemiology core group

J. Dodt, Chair of PMF Drafting group

G. Silvester, EMA

S. Domingo, EMA

J. Childs, EMA

6. Participants

PMF coordinators/assessors/drafting group

PMF Epidemiology drafting group

EDQM

EC

PPTA

IPFA

PMF holders of PMF Certification

An Adobe Connect link to listen to the workshop will also be possible.

7. Structure of workshop

Meeting with Industry followed by closed session with regulators/EDQM/EC

Closed Session

In the light of the information presented in the workshop, the closed session will discuss the points identified under the purpose of the workshop (point 2 above).

1. General introduction and objective of the meeting
2. Examples on PMF epidemiology data reporting experience from Industry *(Alert limits/Residual Risk/Trend analysis).*
3. Draft Revision of IQPP standards – update
4. Main Topic discussion:

    4.1. Alert limits

    4.2. Residual Risk, including HBsAg adjustment factor and window period (WP) calculations.

    4.3 Trend Analysis.

    4.4 New centres.
5. Close of meeting
6. Closed session with regulators/EDQM/EC