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COMMITTEE OF HUMAN MEDICINAL PRODUCTS (CHMP)

CONCEPT PAPER ON THE NEED TO UPDATE THE CHMP POSITION STATEMENT ON CJD AND PLASMA-DERIVED AND URINE-DERIVED MEDICINAL PRODUCTS (EMEA/CPMP/BWP/2879/02 REV. 1)

AGREED BY THE BIOLOGICS WORKING PARTY	June 2009
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	23 July 2009
END OF CONSULTATION (DEADLINE FOR COMMENTS)	31 October 2009

The proposed document will replace the CHMP Position Statement on Creutzfeld-Jakob Disease and Plasma-derived and Urine-derived Medicinal Products (EMEA/CPMP/BWP/2879/02 rev 1)

Comments should be provided using this template to alberto.ganan@emea.europa.eu

KEYWORDS	*Creutzfeldt-Jakob disease, vCJD, plasma-derived medicinal products, urine-derived medicinal products, prion infectivity reduction*

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1. INTRODUCTION

The last revision of the "CHMP position statement on CJD and plasma-derived and urine-derived medicinal products" (EMEA/CHMP/BWP/2879/02/rev.1) was published in June 2004.

The document is the current EMEA/CHMP guidance on CJD and vCJD and plasma-derived and urine-derived medicinal products. It includes recommendations for these products based on the knowledge on CJD and vCJD epidemiology, human tissue distribution of infectivity/abnormal prion protein and infectivity in blood.

2. PROBLEM STATEMENT

The current position statement dates from 2004. Additional information has been accrued in this field since 2004 including the finding of four cases of vCJD infection associated with blood transfusion of non-leucodepleted red blood cells.[1,2] TSE infectivity has also been detected in urine in some animal models[3,4,5,6] in the clinical phase of the disease.

The CHMP opinion and recommendations reflected in the position statement were based on the knowledge on CJD and vCJD at the time of publishing. The progress in the field during the subsequent years reinforces the need to update the content of the document and to review the recommendations for these products.

The current position statement covers plasma-derived medicinal products and urine-derived medicinal products. Currently, there is no specific guidance on CJD and vCJD and advanced therapy medicinal products based on human tissues.

3. DISCUSSION

The position statement needs to include the latest epidemiological data and to reflect any new findings regarding the distribution of infectivity/abnormal prion protein in human tissues and the risk of infectivity and transmissibility of vCJD by plasma-derived and urine-derived medicinal products.

The position statement should revise some of the statements, which were uncertain in June 2004 but where further evidence has now accumulated (e.g. the presence of vCJD infectivity in human blood). It should also take into account the outcome of the ongoing investigations following the detection of abnormal prion protein in the spleen of a haemophiliac patient who received a plasma-derived medicinal product from a donor that later developed vCJD.[7]

Manufacturers of plasma-derived and urine-derived medicinal products were required to estimate the potential of their specific manufacturing processes to reduce infectivity and provide this information to the relevant Competent Authorities. Based on the experience in the evaluation of these data, the recommendations should be re-discussed and revised if necessary.

The main conclusions of the two meetings regarding CJD risk and plasma-derived and urine-derived medicinal products held at EMEA in 2005 and 2007 respectively should also be incorporated in the current revision. Additionally, there is a need to update some of the references to the additional relevant EMEA guidance published (e.g. the guidance on the Investigation of Manufacturing Processes for Plasma-Derived Medicinal Products with Regard to vCJD Risk).

Furthermore, the updated position statement should also consider possible future situations which may have an impact on the risk assessment of plasma-derived medicinal products (e.g. the availability of a possible screening test for vCJD in blood donations).

The vCJD risk of medicinal products based on human cells and tissues will also be considered for discussion. A decision on whether the guidance and recommendations of the Position Statement should also cover these products will be discussed during the revision.

4. RECOMMENDATION

As already announced in the Biologics Working Party (BWP) work programme, an update of the CHMP position statement on CJD and plasma-derived and urine-derived medicinal products is recommended.

5. PROPOSED TIMETABLE

The appointment of the drafting group members and chairperson took place during the June BWP meeting. The updated CHMP Position Statement is intended to be adopted in 2010 following a 3 months' public consultation.

6. RESOURCE REQUIREMENTS FOR PREPARATION

A dedicated drafting group will be involved in the preparation of the revision of the CHMP position statement. Initially, the drafting group will meet by teleconference or virtual meeting system. Meetings at the EMEA involving the drafting group members and some co-opted members for specific topics may be needed at a later stage. A meeting with interested parties may be needed.

7. IMPACT ASSESSMENT (ANTICIPATED)

The updated position statement will have an impact on the recommended measures for human plasma-derived and urine-derived medicinal products.

8. INTERESTED PARTIES

Other EMEA Committees and Working Parties (including the Committee on Advanced Therapies (CAT), the Working Parties on Blood Products (BPWP), Cell-Based Products (CPWP) and on Gene Therapy Products (GTWP)) will be involved during the preparation. There will be liaison with the European Commission (DG Sanco) and ECDC. Internationally, there will be liaison with the WHO and with regulatory authorities in other regions. Interested parties with specific interest in this topic will be consulted, including EHC, EPPIC, IPFA and PPTA.[*]

9. REFERENCES

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7. UK Health protection Agency website:
http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1195733818681?p=1225960597236

[*] EHC: European Haemophilia Consortium
EPPIC: European Patients Primary Immunodeficiency Collaboration
IPFA: International Plasma Fractionation Association
PPTA: Plasma Protein Therapeutics Association