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Pre-authorisation Evaluation of Medicines for Human Use

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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

CONCEPT PAPER ON REVISION OF CORE SPC FOR HUMAN PLASMA FIBRINOGEN PRODUCTS

AGREED BY THE BLOOD PRODUCTS WORKING PARTY (BPWP)	25 November 2005
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	15 December 2005
END OF CONSULTATION (DEADLINE FOR COMMENTS)	31 March 2006

This Guideline on the core SPC will replace the core SPC contained in the European Commission Medicinal Products Derived from Human Blood or Plasma, Core Summaries of Product Characteristics dated 1992.

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1. INTRODUCTION

The current core SPC for Human Plasma Fibrinogen Products has been in operation since 1992. As the medical knowledge and treatment regimens for the products covered by the core SPC as well as the regulatory experience from the marketing authorisation applications and viral safety issues have been developing during the past decades, a review of the core SPC appears appropriate.

2. PROBLEM STATEMENT

According to a recent survey performed by the BPWP, there are several fibrinogen products authorised within the EU. The aim of the revision of the core SPC is to clarify the effective and safe use of fibrinogen products.

3. DISCUSSION

Congenital afibrinogenemia, dysfibrinogenemia and hypofibrinogenemia are extremely rare. Bleeding tendency in dysfibrinogenemia and hypofibrinogenemia is generally low, but can be considerable after surgery. Congenital afibrinogenemia is associated with severe bleeding tendency. Acquired fibrinogen deficiency followed by increased consumption or impaired synthesis of fibrinogen is also rare. In the defibrination syndrome the consumption of fibrinogen is increased secondary to increased intravascular coagulation and hyperfibrinolysis.

As there is a risk of thrombosis when patients, with either congenital or acquired deficiency, are treated with human plasma fibrinogen, the replacement therapy must be considered carefully and monitoring and replacement of other coagulation factor may be necessary. Acquired deficiency of fibrinogen is usually observed in complex clinical situations with severe disturbance of the overall haemostatic system. Fibrinogen treatment has a limited but important role in the management of these clinical situations which needs to be adequately reflected in the core SPC. Thus, the current core SPC needs to be revisited to ensure the proper use of the fibrinogen products. It will also be updated in accordance with the relevant regulatory and scientific guidelines.

4. RECOMMENDATION

The Blood Products Working Party recommends revising the core SPC for Human Plasma Fibrinogen Products. As examples it is proposed to review the following sections in the core SPC taking the recently revised regulatory guidelines into account: methods of potency determination and activity, wording of the indications, posology, contraindications, special warnings and precautions for use, pregnancy and lactation, and undesirable effects. The revised core SPC will apply to already authorised products as well as new products.

5. PROPOSED TIMETABLE

It is anticipated that the draft revision of the core SPC for Human Plasma Fibrinogen Products will be available for final discussion at the Blood Products Working Party in 2006 for release for consultation and finalisation in 2007.

6. RESOURCE REQUIREMENTS FOR PREPARATION

There will be a Rapporteur and a Co-Rapporteur involved in the preparation of the revised core SPC. The draft will be discussed during the meetings of the BPWP.

7. IMPACT ASSESSMENT (ANTICIPATED)

The revised core SPC will reflect the increasing medical knowledge and current clinical practice. The document will provide standards for industry and knowledge about the safe and effective use of the human plasma fibrinogen products for physicians and patients. The resource implications for the revision are justified.

8. INTERESTED PARTIES

Interested parties with specific interest in this topic will be consulted during the revision of the core SPC, including IPFA, PPTA and ISTH. PhVWP will also be consulted prior to the release of the draft guideline.

9. REFERENCES TO LITERATURE, GUIDELINES ETC

Guideline on the Warning of Transmissible Agents in SPCs and Package Leaflets for Plasma-Derived Medicinal Products (CPMP/BPWG/BWP/561/03)

A Guideline on Summary of Product Characteristics

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