EHC World Hemophilia Day Event 2017

Status of Wildbad Kreuth Recommendations

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edqm European Directorate for the Quality of Medicines & HealthCare

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As a political organisation set up in 1949, the Council of Europe works through intergovernmental cooperation to promote ***democracy and human rights*** *continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states*

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THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEATHCARE
www.edqm.eu

EDQM is a specialised directorate at the Council of Europe

EDQM protects public health by enabling development, supporting implementation, and monitoring the application of ***pharmaceutical quality standards*** *for safe medicines and their safe use.*

Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopeia is legally-binding in 37 *Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.*

LEGAL BASIS FOR EDQM/COE ACTIVITIES

Council of Europe Convention on the elaboration of a European Pharmacopoeia

37 Member States and the European Union
30 observers (countries and organisations)

Secretariat:
European Directorate for the Quality of Medicines and Heath Care (EDQM) / Council of Europe

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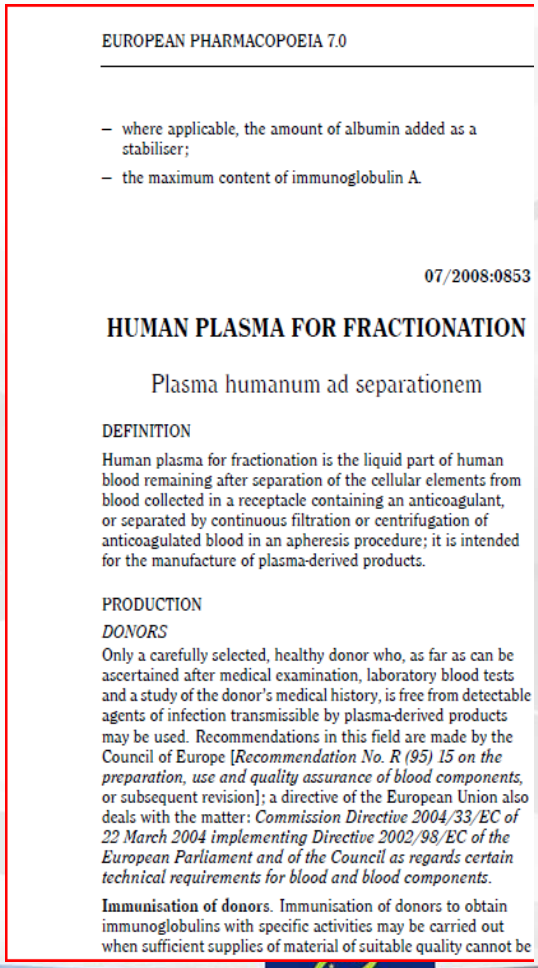
EDQM/COE ACTIVITIES RE WILDBAD KREUTH RECOMMANDATIONS

Experts Group 6B HUMAN BLOOD and BLOOD PRODUCTS

Working methods

Develop pharmaceutical quality standards *that are* ***proposed for adoption by Ph. Eur. Commission (COM)*** *constituted of representatives of member states*

COM decisions by concensus, adoption implies integration in Ph. Eur. and mandatory implementation in all member states (as prescribed by the Convention)



EUROPEAN PHARMACOPOEIA 7.0

– where applicable, the amount of albumin added as a stabiliser;

– the maximum content of immunoglobulin A.

07/2008:0853

HUMAN PLASMA FOR FRACTIONATION

Plasma humanum ad separationem

DEFINITION

Human plasma for fractionation is the liquid part of human blood remaining after separation of the cellular elements from blood collected in a receptacle containing an anticoagulant, or separated by continuous filtration or centrifugation of anticoagulated blood in an apheresis procedure; it is intended for the manufacture of plasma-derived products.

PRODUCTION

DONORS

Only a carefully selected, healthy donor who, as far as can be ascertained after medical examination, laboratory blood tests and a study of the donor's medical history, is free from detectable agents of infection transmissible by plasma-derived products may be used. Recommendations in this field are made by the Council of Europe [*Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components*, or subsequent revision]; a directive of the European Union also deals with the matter: *Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.*

Immunisation of donors. Immunisation of donors to obtain immunoglobulins with specific activities may be carried out when sufficient supplies of material of suitable quality cannot be

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EDQM/COE ACTIVITIES RE WILDBAD KREUTH RECOMMANDATIONS

Blood Transfusion activities

Start 1950th (CoE), as of 2007 a Steering Committee (CD-P-TS) coordinated by EDQM took over

Principles

- *Non-commercialisation of substances of human origin*
- *Voluntary, non-remunerated donations*
- *Protection of the health of recipients and of donors*
- *Quality and safety standards for blood components*
- *Ethical, safety and quality standards for professional practices*
- *Monitor practices, assess epidemiological risks linked to blood and its components*

WORKING METHODS OF THE CD-P-TS (1)

Experts groups, expert studies (guides, state of the art reports, publications)

Research:

- Data collection and analysis
- Enquiries (on regulations, practices, ...)

Scientific symposia

Consensus meetings (eg Wildbad Kreuth) …

Etc…

WORKING METHODS OF THE CD-P-TS (2)

Development of Proposals for legal instruments aimed at being

- *binding :Treaties and Conventions*
- *non binding: Recommendations and Resolutions*

Principles

Develop standards that are proposed for adoption by the Committee of Ministers of the Council of Europe (CM) constitued of representatives of foreign affairs ministries of member and observer states.

CM decisions taken by concensus, adoption implies publication on CoE website and mandatory implementation in all member states

EXAMPLE: WILDBAD KREUTH INITIATIVE

Kreuth II

2008 Questionnaire on clinical use of coagulation factors (and other comp)

24-25 April 2009: 110 experts from 38 countries from academia, blood transfuiosn services, clinicians, control authorities, patients and manufacturers organisations

2010 Consensus recommendations for clottig factor concentrates (and other components) published in Meeting Proceedings.

2011 Berger K, Klein HG, Seitz R, Schramm W, Spieser JM. The Wildbad Kreuth initiative: European current practices and recommendations for optimal use of blood components. Biologicals. 2011 May;39(3):189-93. doi: 10.1016/j.biologicals.2011.03.002. Epub 2011 Apr 23. PubMed PMID: 21524591.

Status: Consensus Recommendations of Wildbad Kreuth II

RESOLUTION CM/RES(2015)3
ON PRINCIPLES CONCERNING HAEMOPHILIA THERAPIES

Kreuth III
2012 Questionnaire on clinical use of coagulation factors
26-27 April 2013: 109 experts from 36 countries from academia, blood transfuiosn services, clinicians, control authorities, patients and manufacturers organisations

2013 Consensus recommendations for clottig factor concentrates (and Igs) published in Meeting Proceedings.

2014 Giangrande P, Seitz R, Behr-Gross ME, Berger K, Hilger A, Klein H, Schramm W, Mannucci PM. Kreuth III: European consensus proposals for treatment of ,haemophilia with coagulation factor concentrates. Haemophilia. **2014 May;**20(3):322-5. doi: 10.1111/hae.12440. PubMed PMID: 24731129.

Status: Consensus Recommendations of Wildbad Kreuth III

RESOLUTION CM/RES(2015)3
ON PRINCIPLES CONCERNING HAEMOPHILIA THERAPIES

CD-P-TS

2014 Draft Consensus recommendations for clotting factor concentrates (and other components) elaborated and Reviewed

2015 : Proposal for Consensus recommendations for clotting factor concentrates (and other components) finalised

Committe of Ministers of the Council of Europe

Proposal of CD-P-TS adopted on 15 April 2015
Publication on CoE website Résolution
CM/Res(2015)3 sur les principes gouvernant les traitements de l'hémophilie
CM/Res(2015)3 on principles concerning haemophilia therapies

Status: Recommendations of Committee of Ministers of Council of Europe

Consequence : Member states need to implement prescriptions of Res (2015)3

CONCLUSION

Through the CD-P-TS and the Ph. Eur.

the EDQM /Council of Europe

develops and updates standards for labile blood components and for plasma derived medicinal products thus creating a complete set of technical guidelines which are extensively used in Europe and beyond