COMMITTEE OF MINISTERS
COMITÉ DES MINISTRES

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Resolution CM/Res(2015)3
on principles concerning haemophilia therapies

(Adopted by the Committee of Ministers on 15 April 2015
at the 1225th meeting of the Ministers' Deputies)

The Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50);[1]

Considering that the aim of the Council of Europe is to achieve greater unity between its member States and that this aim may be pursued, *inter alia*, through common action in the health field;

Having regard to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (ETS No. 164), and in particular to Article 3, Chapter I – General provisions – of the Convention;

Recalling Recommendations Rec(80)5 concerning blood products for the treatment of haemophiliacs, Rec(86)6 on guidelines for the preparation, quality control and use of fresh frozen plasma (FFP), Rec(90)9 on plasma products and European self-sufficiency and Rec(93)4 concerning clinical trials involving the use of components and fractionated products derived from human blood or plasma;

Having regard to Recommendation Rec(95)15 on the preparation, use and quality assurance of blood components and its appendix, the "Guide to the preparation, use and quality assurance of blood components" (17th Edition 2013);

Having regard to Recommendation Rec(2002)11 on the hospital's and clinician's role in the optimal use of blood and blood products;

Taking into account the recommendations of the European symposium on optimal use of clotting factors and immunoglobulins, organised under the auspices of the European Committee on Blood Transfusion (CD-P-TS) of the Council of Europe (26-27 April 2013, Wildbad Kreuth, Germany);[2,3]

Considering that great variability in patient care and availability of the different coagulation factor concentrates persists across member States and that the differences in per capita use of coagulation factor VIII are particularly striking;

Considering that, in addition to available plasma-derived and recombinant coagulation factors, several new and innovative products are in different stages of development;

Considering that haemophilia therapies (and in some cases adequate doses of coagulation factors) are not equally accessible across Europe, and that, as a result, some patients are experiencing significant harm and reduced life expectancy;

Taking into account the fact that, in light of the experience acquired in the implementation of its recommendations set out in the appendix to the present resolution, that appendix may be updated by the European Committee on Blood Transfusion (Partial Agreement) (CD-P-TS) of the Council of Europe five years after its adoption, or sooner if new developments, insights or data so require,

Recommends that the governments of States Parties to the Convention take appropriate measures to step up the promotion of the principles contained in the appendix to this resolution.

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[1] Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine and United Kingdom.

[2] Optimal use of clotting factors and immunoglobulins, European symposium proceedings, 26-27 April 2013, Wildbad Kreuth Germany, available on http://www.edqm.eu/en/proceedings-international-conference-83.html

3 Giangrande P., Seitz R., Behr-Gross M.-E., Berger K., Hilger A., Klein, H., Schramm W. and Mannucci P. M., Kreuth III: European consensus proposals for treatment of haemophilia with coagulation factor concentrates, Haemophilia (2014), 20, 322–325; doi: 10.1111/hae.12440.

Appendix to Resolution CM/Res(2015)3

Principles

1. To optimise the organisation of haemophilia care, a system should be established in each member State to allow the implementation of a multidisciplinary approach for the treatment and care of patients (for example by setting up an advisory body including representatives of the relevant clinicians, national haemophilia bodies, patients' organisations, the health ministry, the paying authority, blood establishments and the regulatory authorities or by setting up centres of excellence);

2. In each member State, the coagulation factor VIII utilisation level should be at least 3 International Units (I.U.) per capita;

3. Decisions on whether to use a new or an alternative product should be based on evidence of safety and effectiveness and not solely on cost;

4. The evidence of the effectiveness of different treatment regimes should be strengthened. Prophylaxis is currently recognised as the optimum therapy for children with severe haemophilia. Ongoing prophylaxis for adults should be provided, when required based on a clinical decision by the clinician in consultation with the patient;

5. Prophylactic treatment with bypassing agents should be offered to haemophiliac children who have developed inhibitors and in whom immune tolerance induction therapy has failed or was unsuitable;

6. Single coagulation factor concentrates should be used as therapy wherever possible in patients with rare bleeding disorders.