COMMITTEE OF MINISTERS
COMITÉ DES MINISTRES

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

MINISTERS' DEPUTIES Resolutions CM/Res(2017)43 13 December 2017

Resolution CM/Res(2017)43
on principles concerning haemophilia therapies (replacing Resolution CM/Res(2015)3)

(Adopted by the Committee of Ministers on 13 December 2017
at the 1302bis 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: Convention on Human Rights and Biomedicine (ETS No. 164), and in particular to Article 3 (Chapter I – General provisions) of this 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* (19th edition, 2017);

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 platelets, organised under the auspices of the European Committee on Blood Transfusion (Partial Agreement) (CD-P-TS) of the Council of Europe (6-7 May 2016, Freising, 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;

[1] States concerned: 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, Republic of Moldova, 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 platelets", European symposium proceedings, 6-7 May 2016, Freising (Germany), available at https://register.edqm.eu/freepub.
[3] Giangrande P. L. F., Peyvandi F., O'Mahony B., Behr-Gross M.-E., Hilger A., Schramm W. and Mannucci P.M., "Kreuth IV: European consensus proposals for treatment of haemophilia with coagulation factor concentrates", *Haemophilia* (2017) May; 23(3): 370-375. DOI: 10.1111/hae.13211.

Recommends that the governments of States Parties to the convention take appropriate measures for the care and treatment of haemophiliacs according to the principles contained in the appendix to this resolution;

Adopts the following revised Resolution CM/Res(2017)43 on principles concerning haemophilia therapies, which shall replace Resolution CM/Res(2015)3, adopted on 15 April 2015, on the same subject matter, and invites member States to use it as a practical tool to improve the quality of care and the treatment of haemophilia;

Invites the governments of the member States to ensure that the revised resolution is widely translated and disseminated among all authorities responsible for haemophilia therapies;

Agrees that in light of the experience acquired in the implementation of its recommendations set out in the appendix to the present resolution, this appendix may be updated by the CD-P-TS of the Council of Europe five years after its adoption, or sooner if new developments, insights or data so require.

Appendix to Resolution CM/Res(2017)43

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 Ministry of Health, the paying authority, blood establishments and the regulatory authorities, or by setting up centres of excellence).

2. Hospitals providing clinical care for people with haemophilia and related disorders are strongly recommended to seek formal designation as either European Haemophilia Comprehensive Care Centres or European Haemophilia Treatment Centres (access to comprehensive care and replacement therapy should be equitable in all parts of a country).

3. There should be agreed national guidelines or protocols on management of the ageing patient with haemophilia. Treatment centres are encouraged to include an appropriate general physician in the comprehensive care team.

4. In each member State, the annual coagulation factor VIII utilisation level should be at least 4 International Units (I.U.) per capita of general population (data expressed as I.U. per severe haemophilia patient should also be collected in parallel in future).

5. The minimum annual consumption of factor IX concentrate in a country should be 0.5 I.U. per capita of general population.

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

7. Treatment with extended half-life factors should be individualised and protection against bleeding should be improved by increasing trough levels.

8. 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 a clinical decision by the clinician, in consultation with the patient, so requires.

9. People with inhibitors should have access to immune tolerance.

10. People with inhibitors should also have access to elective surgery at a specialist centre with relevant experience.

11. 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 is unsuitable.

12. There is increasing evidence that the incidence of inhibitors amongst previously untreated patients varies between products. Steps should be taken to understand and minimise this risk (patients, or their parents, should be involved in discussions related to product choice).

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

14. Treatment for hepatitis C with direct-acting antiviral agents should be provided to all people with haemophilia on a high-priority basis.

15. Genotype analysis should be offered to all patients with severe haemophilia. Patients should be free to decide whether or not to take up this possibility. Genetic counselling of the affected person, when given, should encompass the recommendation that genetic relatives of the affected person be advised to seek genetic counselling.

16. National or regional tenders for factor concentrates are encouraged and should always include both haemophilia clinicians and national haemophilia patient representatives.

17. Outcome data including health-related quality of life should be collected with appropriate study design, for example annualised bleed rates, mortality, joint score and time off from education or employment.