

## Resolution CM/Res(2015)2

### on principles concerning human normal immunoglobulin therapies for immunodeficiency and other diseases

(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);<sup>1</sup>

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*, by the adoption of 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(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 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;

Having regard to Recommendation Rec(96)11 on documentation and record-keeping to guarantee the traceability of blood and blood products, especially in hospitals;

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);<sup>2,3</sup>

Considering that the demand for plasma-derived medicinal products has continuously increased in the past 20 years; however, the consumption per capita varies greatly from country to country;

Considering that the demand for human normal immunoglobulin preparations will keep increasing mainly due to new indications and emerging markets;

Considering that availability of human normal immunoglobulin therapies (and in some cases adequate doses of immunoglobulin) are not equitable across Europe, and that some patients are experiencing significant harm and reduced life expectancy because of this;

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) five years after its adoption or sooner if new developments, insights or data so require,

Recommends that 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.

<sup>1</sup> 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.

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

<sup>3</sup> Sewell WC, Kerr J, Behr-Gross ME, Peter HH: European consensus proposal for immunoglobulin therapies, *Eur J Immunol.* 2014 Jun 28; doi: 10.1002/eji.201444700.

*Appendix to Resolution CM/Res(2015)2*

**Principles**

1. To acknowledge the status of “essential medicine” granted to human normal immunoglobulin by the World Health Organisation (WHO) and to ensure that all patients in need have access to this medicine in quantities sufficient to be clinically effective;
2. To adopt a suitable process, e.g. evidence-based human normal immunoglobulin demand management, in European countries to ensure adequate supplies for all patients in need, and to implement a strategy to assure supplies for obligate users<sup>4</sup> for times of immunoglobulin shortages;
3. To make available to patients all recognised routes of human normal immunoglobulin administration;
4. To take into account that human normal immunoglobulin therapeutic products differ from one another in terms of production processes, which might have an impact on specifications and clinical performance;
5. To expand the basis of Health Technology Assessment (HTA) of human normal immunoglobulin therapies (e.g. to evaluate general and brand-specific efficacy of different immunoglobulin preparations for off-label uses) by considering disease-specific patient registries;
6. To promote research on the use of human normal immunoglobulin in the treatment of secondary immunodeficiencies;
7. To ensure pharmacovigilance for adverse reactions and adverse events associated with the therapeutical use of human normal immunoglobulin.

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<sup>4</sup> See “Guideline on core Summary of Product Characteristics (SmPC) for human normal immunoglobulin for intravenous administration (IVIg)”, Committee for Medicinal Products for Human Use (CHMP), EMA/CHMP/BPWP/94038/2007, revision currently ongoing.