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PRIMARY IMMUNODEFICIENCY DISEASES (PI): ADOPTION OF A EUROPEAN CONSENSUS AIMED AT PROVIDING ENHANCED ACCESS TO IMMUNOGLOBULIN THERAPIES (Ig)

The Council of Europe's newly adopted Resolution on Principles concerning Human Normal Immunoglobulin Therapies for Immunodeficiency and other Diseases (CM/Res(2015)2 adopted by the Committee of Ministers on 15 April 2015 at the 1225th meeting of the Ministers' Deputies) is the first ever pan-European strategy aimed at optimising the treatment and care received by patients with immunodeficiencies and other diseases treated with human normal immunoglobulin.

Primary immunodeficiency diseases (PID) comprise a group of more than 250 rare, chronic disorders in which part of the body's immune system is missing or functions improperly. Increasing awareness of these disorders and improvements in their diagnosis together with the development of secondary immunodeficiencies (related to underlying conditions such as lymphoma, or the use of chemotherapy, etc.), mean that there is now a pressing need for immunoglobulin therapies, especially since the indications of these treatments have been extended to other conditions (e.g. Gillain-Barré syndrome, myasthenia gravis etc.).

The use of immunoglobulin (Ig) preparations for replacement and immunomodulation therapy worldwide has tripled in the past 20 years and represents an ever-increasing cost factor for healthcare organisations. The limited access to the starting material of this essential medicinal product is currently the driving force for human plasma collection.

However, equal access to human normal immunoglobulin therapies is not yet ensured across Europe. Consensus recommendations for the optimal use of Ig in clinical practice, including priority rankings for the most critical indications, were therefore urgently required.

In order to harmonise the treatment and care provided by its member States for patients suffering from these rare disorders, the Council of Europe recommends that the governments of States Parties to the Ph. Eur. Convention take appropriate measures to step up the promotion of the following 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 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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Note for the Editor: Further information is available on the internet site **www.edqm.eu**
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[1]There are now thirty-eight members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union.* There are twenty-seven observers: *Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Brazil, Canada, China, Georgia, Israel, Madagascar, Malaysia, Moldova, Morocco, Republic of Belarus, Republic of Guinea, Republic of Kazakhstan, Republic of Singapore, the Russian Federation, Senegal, South Africa, Syria, Tunisia, United States of America, the Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO)*.

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