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Council of Europe adopts an official Resolution on Principles of Immunoglobulin Therapies for Immunodeficiency and Other Diseases

On 15th of April the Council of Europe adopted an official Resolution CM/Res(2015)2 on Principles regarding Immunoglobulin Therapies for Immunodeficiency and Other Diseases taking the Wildbad Kreuth III recommendations into account.

Mrs Jose Drabwell, IPOPI President, stated: "We are delighted that with this Resolution the Council of Europe has formally recognised vital recommendations concerning immunoglobulin therapies and their use in different indications including Primary Immunodeficiencies (PIDs)". Mrs Drabwell added: "The fact the resolution has come out just in time for the World Primary Immunodeficiency Week (WPIW) to be held from 22 to 29 April 2015 will further raise awareness about the essential nature of immunoglobulin therapies and their importance in the treatment of patients living with primary immunodeficiencies".

The 7 principles that the Council of Europe has adopted are the following:

1. Acknowledgement of the status of "essential medicine" granted to human normal immunoglobulin by the World Health Assembly (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.

Background on the Wildbad Kreuth III Meeting: In 2013 IPOPI attended the High Level Wildbad Kreuth III meeting (Germany) organised by the European Directorate for the Quality of Medicines and Healthcare (EDQM, an organisation part of the Council of Europe) and attended by 36 Council of Europe states, regulatory agencies and patient representatives including Mrs Jose Drabwell, IPOPI President and Prof Helen Chapel, Professor of Clinical Immunology at University of Oxford and IPOPI Honorary Vice President.
In this meeting, recommendations concerning immunoglobulin therapies for primary immunodeficiency (PID) were adopted and afterwards published in the scientific journal European Journal of Immunology.

Background on the Council of Europe: The Council of Europe is an international organisation promoting cooperation amongst European countries in different areas such as human rights, democratic development, the rule of law and cultural cooperation. The Council of Europe also works in the area of health and more specifically, in the area of blood and organ donation and control of medicines including immunoglobulins.
The Council of Europe has 47 members: 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.

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