Concept of adding blood components to the WHO Model List of Essential Medicines

Dear Sir or Madam,

During the meeting on 18 October 2012, the Blood Regulators Network (BRN) members discussed a proposal to add whole blood and red blood cells to the WHO Model List of Essential Medicines (EML). The BRN members believe that whole blood and red blood cells (RBC) are medicines which satisfy the priority healthcare needs of the population in all countries for treatment of haemorrhage and anaemia, and therefore, listing by WHO of whole blood and RBC as essential medicines will promote global availability of these biological therapeutics.

Swissmedic, Swiss Agency for Therapeutic Products, is the national Swiss supervisory authority for medicines and medical devices and the centre of competence for therapeutic products, providing an important contribution to a high-quality health-care system. We ensure that only high-quality, safe and efficacious therapeutic products are available in Switzerland.

In Switzerland, blood components for transfusion are considered medicinal products and are effectively regulated by the law on therapeutic products and the ordinances referred to by the law. Swissmedic is the competent authority having regulatory oversight and executing the relevant national control functions, such as:

- Issuing establishment licences to institutions involved in the collection, testing, preparation, storage and distribution of blood and blood components for transfusion
- Verification by official initial and regular follow up inspections that all blood establishments comply with applicable principles of GMP/GDP, standards for donor selection and transmissible-disease testing requirements
- Supervision of blood and blood components for transfusion to guarantee that specifications related to quality, safety and efficacy of blood and blood components are met
- Maintaining the mandatory national Haemovigilance system covering all suspected adverse events and reactions related to the collection, preparation and use of blood and blood components for transfusion

Within this legal framework national self-sufficiency through voluntary, non-remunerated donations is maintained in Switzerland. The collection, testing, preparation and distribution of blood and blood components for transfusion by the regional blood establishments is coordinated on a national level.
The experience with the described regulatory and supply system in Switzerland leads us to the conclusion that listing whole blood and RBC to the WHO Model List of Essential Medicines would:

a. Highlight the need for national commitment and thus facilitate the national coordination and oversight of blood for transfusion
b. Promote the availability and the need to improve quality and safety of blood for transfusion
c. Motivate the implementation of national blood programmes and facilitate donor protection and product standards through effective regulation

At the 15th ICDRA, regulators of over 100 countries agreed to recommendations that

a. Member States should take steps to assure the quality, safety and availability of blood for transfusion, including oversight through regulation; and
b. Member States are encouraged to establish lists of essential medicines and to include whole blood and blood components for transfusion on their lists.

In line with these recommendations and based on our considerations and experience explained above, Swissmedic is expressing its strong support to add whole blood and red blood cells to the WHO Model List of Essential Medicines.

Thank you for your consideration of this information in the context of the application.

Your sincerely,

Swissmedic, Swiss Agency for Therapeutic Products
Management Services and Networking Inspectorates
Head of Sector, Head of Division
Member of the Management Board

Petra Dörr

Christian Schärer