December 11, 2012

The Secretary of the 19th Expert Committee on Selection and Use of Essential Medicines, Medicine Access and Rational Use
Department of Essential Medicines and Health Products
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27, Switzerland
email: emlsecretariat@who.int

Dear Sir,

The WHO Blood Regulators Network (BRN) was established in 2006 as a forum comprised of leading international regulatory authorities responsible for blood, blood products and associated substances and medical devices including in vitro diagnostics. The network focuses on scientific assessment of current and emerging threats to blood safety and availability and provides global leadership in the advancement of blood product regulation. Its conclusions and recommendations are communicated to the WHO Expert Committee on Biological Standardization (ECBS). Current members of the BRN include US Food and Drug Administration; Health Canada, Canada; Agence Nationale de Sécurité du Médicament et des Produits de Santé, France; Paul-Ehrlich-Institut, Germany; Ministry of Health, Labour and Welfare, Japan; Swissmedic, Switzerland; and Therapeutic Goods Administration, Australia. WHO serves as the Secretariat of the BRN. I am sending you this letter in my capacity as current Chairman of the BRN.

The concept of adding blood components to the WHO Model List of Essential Medicines was discussed at the 63rd meeting of the ECBS in October 2012. At their meeting on 18 October 2012, which was held during the ECBS, the BRN members expressed universal support for an initiative to establish Whole Blood and Red Blood Cells on the WHO Model List of Essential Medicines (EML). While mindful of concerns regarding commercialization, the BRN members believe that listing by WHO of Whole Blood and Red Blood Cells as essential medicines will promote global availability of these biological therapeutics as products that meet internationally recognized standards for their quality and safety, including oversight through effective regulation. This position also was endorsed by the ECBS.

The BRN members presently are aware that AABB (formerly the American Association of Blood Banks and one of the largest and oldest professional societies in blood banking and transfusion medicine) has submitted an application requesting that WHO add Whole Blood and Red Blood Cells to the EML. We write to you today to express our support for this application.

The BRN members believe that Whole Blood and Red Blood Cells are medicines which satisfy the priority healthcare needs of the population in all countries for treatment of hemorrhage and anemia. This is especially important in developing world countries where deaths are common due to bleeding from trauma and at labour and where there is high childhood mortality due to anemia from malaria and certain hemoglobinopathies. Furthermore, listing Whole Blood and Red Blood Cells would: a) raise the visibility of blood components and the need for national commitment and oversight to improve blood quality and safety; b) promote the global availability of safe blood for transfusion, which is an unmet need with tragic consequences in many Member States; and c) protect donors and patients by strengthened donor protections and product standards. The initiative to list Whole Blood and Red Blood Cells on the EML concurrently supports implementation of both resolution WHA63.12 (2010) and the WHO Millennium
The BRN members anticipate that there may be resistance to listing of blood and blood components on the EML on the grounds that blood components are provided as medical services rather than as products. Additionally, concerns may be expressed that listing of blood and components as medicines could have undesired effects of product commercialization that could undermine efforts at national self-sufficiency through voluntary non-remunerated donation and also promote exploitation of blood donors. However, decades of experience in many countries has established that assuring the quality, safety and availability of blood for transfusion requires a coordinated national program under which donor protections and product standards are assured through effective regulation, which includes Good Manufacturing Practices. Past experiences with tainted blood further emphasize the need to consider blood components as essential medicines subject to product quality standards. While differences exist between blood components and pharmaceutical medicines in general, these differences do not negate their overarching commonalities. These include raw material qualification (i.e. through donor selection and testing), defined processing methods and conditions (e.g. aseptic collection, closed system manipulation, etc.), in-process quarantines and unit release (i.e. unit by unit suitability determinations), quality controls (e.g. temperature monitoring, visual inspections), labeling (e.g. for identity, content, expiration dating and intended use), traceability through labeling and record keeping, and administration on physician order or prescription. This general view was strongly endorsed at the 15th ICDRA by regulators of over 100 countries who agreed to recommendations that “Consistent with WHA 63.12 (2010) Member States should take steps to assure the quality, safety and availability of blood for transfusion, including oversight through regulation; and “Member States are encouraged to establish lists of essential medicines and to include whole blood and blood components for transfusion on their lists.”

We ask you to take these perspectives under consideration in your review of the AABB application.

Very truly yours,

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c.c. Mr Kees de Joncheere, Director, Department of Essential Medicines and Health Products, WHO (dejoncheerec@who.int)