Dear Sir and Madame,

We are writing this letter to show our intention on the adding Whole Blood and Red Blood Cells to the WHO Model List of Essential Medicines (EML), in the capacity as regulatory authority of blood and blood products of Japan.

In Japan, blood and blood products for transfusion are categorized "drug" and regulated by the Pharmaceutical Affairs Law and in further more safety by Securing a Stable Supply of Safe Blood Products etc Law. Ministry of Health, Labour and Welfare (MHLW) is the authority having regulatory oversight and executing the relevant national control functions with relevant national institute such as National Institute of Infectious Diseases.

Within the legal framework national self-sufficiency through voluntary, non-remunerated donations is maintained in Japan. The collection, testing, preparation and distribution of blood and blood products for transfusion by the Japan Red Cross blood establishments solely is coordinated on a national level.

At the 15th ICDRA, regulators of over 100 countries 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".

In line with these recommendations and from our experience with the regulatory
and supply system in Japan, we support adding Whole Blood and Red Blood Cells to the WHO EML and are convinced that it can promote equitable access to indispensable therapeutic products.

Sincerely yours,

Masami Kato, MD  
Director,  
Blood and Blood Products Division

Naoyuki Yasuda  
International Planning Director,  
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(Member of WHO BRN)