Subject: Comments on the Application for the Addition of Whole Blood and Red Blood Cells to the WHO Model Essential Medicines List and the WHO Model Essential Medicines List for Children

Dear Sir/Madam,

The Malaysian Blood Transfusion Society (MBTS) committee has recently come across the proposal for the addition of Whole Blood and Red Blood Cells to the WHO Model Essential Medicines List and the WHO Model Essential Medicines List for Children.

Transfusion of Whole Blood and Red Blood Cells saves lives and improve outcome for many patients and timely access to blood and blood products is essential for patients requiring transfusion. In Malaysia, blood and blood products are considered as essential therapy and not as medicine. Currently the blood service is not regulated by any authority. Its practices are based on National Standards set by the Ministry of Health (MOH).

Blood services in Malaysia started in the 1950s, based on voluntary non-remunerated blood donation. Since then, the provision of safe and quality blood and blood products through the national blood service has grown under the Ministry of Health of Malaysia. In 2011, there were 627,518 whole blood donations to the MOH Blood Services and 17,068 apheresis donations of plasma and platelets. On average, more than 32,000 kilogram of recovered and apheresis plasma were sent for contract fractionation for the production of FVIII, FIX, IVIG and Albumin. Whole blood, red blood cells and other blood components are provided free of charge for all patients in the public hospitals in Malaysia. Private hospitals pay service charge which is heavily subsidized by the government.
FVIII and FIX are provided free of charge to patients with hemophilia. Similarly, albumin and IVIG are given at no cost for patients requiring these products in public hospitals. The ability for Malaysia to provide access to blood and blood products is due to the commitment and support by MOH, leadership in the field of Transfusion Medicine within the service. Pusat Darah Negara (National Blood Centre) and the network of blood banks, work closely with clinicians and this close working relationship and most importantly the unwavering support from the voluntary non-remunerated blood donors in the country have enable the blood transfusion service to develop to what it is today.

While there are advantages listed in the proposal, MBTS is concerned about the implication of listing whole blood and red cells as medicine in the WHO EML on current national systems since this proposal has not been discussed between ministries of health, the national blood services and national regulatory authorities. Furthermore, as far as we know there is no comprehensive legislation to cover the entire activities carried out by the blood services in Malaysia although it is briefly addressed in the Private Facility Act. We need to fully understand the implication of this move taking into account that there is already a Poison Act (1952) that regulates the pharmaceutical industries.

We urged for dialogues between WHO and member countries as well as representatives from voluntary non-remunerated blood donors associations seeking their opinion and acceptance on this concept given the blood donors are the foundation of safe and quality blood supply for patient access.

The Malaysian Blood Transfusion Society hope our comments will be considered by the WHO Expert Committee during the discussion to include whole blood and red blood cells on the WHO Model Essential Medicines Lists.

Thank you.

Yours sincerely,

[Signature]

President,
Malaysian Blood Transfusion Society

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1. Director General of Health of Malaysia
   Ministry of Health,
   Level 12, Block E7, Complex E,
   Pusat Pentadbiran Kerajaan Persekutuan,
   62590 Putrajaya,
   Malaysia.
2. Director
   National Blood Centre,
   Jalan Tun Razak,
   50400 Kuala Lumpur,
   Malaysia.