Secretary of the Expert Committee on the Selection and Use of Essential Medicines
World Health Organization
Office of the EML Secretariat
Medicine Access and Rational Use (MAR)
Department of Essential Medicines and Health Products
20 Avenue Appia CH-1211 Geneva 27

Oslo and Bergen, 17/2-2013

Re: 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

We are aware of this application of Dec. 14, 2012, from the AABB, ARC, CTS and ISBT. Due to the potential consequences of a decision in favour of this application, we want to make the following comments:

The application correctly points out that transfusion of whole blood and red cells is an essential measure in large parts of somatic medicine, and that the methods of production have become more standardized and better controlled than in the past. Furthermore, the all human beings should have adequate access to haemotherapy when needed as judged by medical indications. The basic argument for the application is that, if blood components and plasma products are considered Essential Medicines, the pressure on governments throughout the world to establish adequate transfusion systems in every country will be much strengthened. Since such systems are lacking in many countries, such an effect seems to be highly desirable.

It is immediately tempting to accept the simple reasoning that having whole blood and red cells in the Essential Medicine List (EML) will improve their availability. Indeed in many WHO publications on essential medicines, it has been highlighted that even for those medicines currently in the WHO EML, their availability in any given country are affected by the complex interplay of several factors and actors.

However, the fact remains that blood and blood products including whole blood and red cells are human derived therapeutic (liquid) tissue. This is so, even though better standardization and control measures have made blood components and plasma products more like standardized medicine. We
reiterate that sales of human organs and tissues are forbidden by international law. Accordingly, as stated by the WHO, the International Red Cross, the Council of Europe and the International Society of Blood Transfusion, all countries should strive for blood and plasma supply based on voluntary non-remunerated blood donors (VNRBD) alone. We also reiterate that VNRB donation started during World War II as an act of solidarity with the fighting soldiers and in support of securing free societies and it has been shown scientifically that social cohesion remains the major factor for recruitment and sustenance of VNRBD.

We are concerned that, if whole blood and red cells are declared as Essential Medicines, there is danger that commercialization of the blood services will be promoted and private companies to use paid donors for the supply of whole blood and red cells to countries with insufficient transfusion systems. Today there is a huge global, commercial market for plasma products which are already listed in the WHO EML, particularly the use of IVIG which is not governed by evidence-based medicine and good clinical judgment, but by market forces. There is a huge overconsumption in some countries, and an underconsumption in the majority of nations due to limited access. Therefore, commercialization does not lead to global justice and adequate equitable access to blood products for all human beings. Instead it is essential to build transfusion systems throughout the world that are based on VNRBD, solidarity and social cohesion as stated by the international organizations mentioned. This is so for reasons of safety as well as protection of human dignity (both in donors as well as in patient) and the added advantage of strong social cohesion that arises from VNRBD.

The points mentioned here have not been considered in the application. We are seriously concerned that a decision in favour of the application by a WHO Expert Committee, which globally gives WHO direction, would have a major negative repercussion, instead of what is aiming. We regard it as is extremely important for the Committee to thoroughly consider the possible negative effects before making a decision. Therefore we strongly urge the WHO EML Expert Committee to postpone the decision and instead initiate an in-depth discussion with all stakeholders including competent organizations on how to avoid such negative effects – and, at the same time, work effectively towards their national goal of achieving national or regional self-sufficiency based on VNRBD, mechanism to increase access, quality and safety to whole blood, red cells and other blood products, as also endorsed by WHA 63.12 on Availability, safety and quality of blood products.

In respect and with kind regards

Yours sincerely

Hans Erik Heier

Tor Hervig

Richard Olaussen