Response to the proposal for the inclusion of Whole Blood and Red Blood Cells on the WHO Essential Medicines Lists (EML)

The Thalassaemia International Federation (TIF) was founded in 1986 to establish and protect the rights of patients with thalassaemia, and, by extension today, for other haemoglobin disorders and rare anaemias, for equal access to quality healthcare. Our mission, defined since then is the development and implementation of national programmes for the prevention and control of haemoglobin disorders across the world, utilizing initially and building on the knowledge and experience accumulated from Southern European countries, mainly Cyprus, Greece and Italy; countries, where the problem was recognized as a major public health issue amongst the indigenous population with huge social and economic repercussions, and which was successfully addressed since the early years between 1960 – 1980. We know today that this is not a problem confined to this region (Mediterranean basin) but a problem that occurs widely across the world both as indigenous disease but also as diseases introduced into populations through migration and population movements.

Current available epidemiological data, despite the fact that these estimations may be grossly underestimated and the urgent need to update them, state that:

- Approximately 7% of the global population is a carrier for haemoglobin disorders
- Between 300,000 – 500,000 children are born annually with a severe haemoglobin disorder
- About 80% of affected children are born in middle and low income countries
- About 70% are born with sickle cell and the rest with thalassaemia disorders
- 50 – 80% of children with sickle cell anaemia and 50,000 – 100,000 children with β–thalassaemia major die each year in low and middle income countries (World Bank 2006, report of a joint WHO – March of Dimes meeting 2006)
- A patient with β–thalassaemia major (occurring according to international guidelines) requires regular lifelong blood transfusion and iron chelation
- Between 6,000,000 – 12,000,000 transfusion of whole blood and/or red cells are needed every year to keep alive about 500,000 patients with β–thalassaemia major

The Thalassaemia International Federation (TIF) is a non-profit organization dedicated to improving quality of life and life expectancy for patients with thalassaemia and other haemoglobinopathies. TIF is comprised now of 91 member associations from 47 countries and has been working in official relations with WHO since 1996. Recognizing the public health burden of these diseases, the World Health Assembly (WHA) has formally adopted the following specific resolutions in May
Blood transfusion therapy is the cornerstone and the essential first arm of the medical management of patients with β-thalassaemia major and is also required to ameliorate certain medical complications for patients with other major haemoglobinopathies such as sickle cell disease and patients with milder forms of haemoglobin disorders.

Thus our global patient community constitutes perhaps the largest multiply transfused and lifelong users of whole blood and/or red blood cells (RBCs). In this context our interest in the safety, efficacy, cost-effectiveness and adequacy of blood is immense and the quality of whole blood and red blood cells constitutes a major focus of our activities. Particularly in the context of supporting the development and implementation of national programmes for quality transfusion services and recruitment of blood through voluntary non-remunerated blood donation (VNRBD) practices as recommended through the relevant WHA resolution of 1975 (WHA28.72 - Utilization and supply of human blood and blood products); the EU legislation (Directive 2002/98/EC) and certainly AABB recommendations.

In addition, TIF has been for many years focused attention on the implementation of other key resolutions, directly or indirectly related to blood and blood safety, including WHA56.30 Global health-sector strategy for HIV/AIDS (2003), WHA58.13 Blood Safety: proposal to establish World Blood Donor Day (2005), WHA63.12 Availability, safety, and quality of blood products (2010), The Melbourne Declaration on 100% VNRBD (June 2009) and WHA63.18 Viral Hepatitis (2010), all of which focus amongst others on the relationship of VNRBD and safety of blood and quality transfusion practices and on the rationale that blood is not a medicine and cannot be bought. TIF also provided a statement to the WHO-EB126 (January 2010) on agenda item for ‘Availability, safety, and quality of blood products’, highlighting the need for safe blood systems based on VNRBD as essential public health functions of the governments.

As TIF we do not feel very confident and comfortable, and moreover, have not clearly and fully understood the underlying reason of the proposal for inclusion of Whole Blood and Red Blood Cells on the WHO EML. Particularly because according to the above resolutions it was advocated and agreed that blood as a substance of human origin is excluded from becoming a commodity and the ‘essential’ nature of blood, we believe has been a recognized issue since the early days and thus requires no further underlining. On the other hand, the potential negative effects that this proposal may have on the national efforts for promoting transfusion medicine, blood systems and the VNRBD practices are issues of grave concern to us.

The lessons learned from the HIV and hepatitis epidemics that have occurred through the years and, of course the possibility of new infections occurring in future, have put, and will continue to do so, the safety of blood and blood products for transfusion into jeopardy and constitute a constant threat to our patient community particularly in case Member States choose, as a result of the inclusion of blood in the EML, to become more flexible in the type of sources from which to procure Whole Blood and RBCs. The experience of plasma factors which have been for some time included in the EML with increasing commercial involvement and paid plasma donation, adds greatly to our concerns.

It is thus, important to underscore at this point that the empowerment and education of voluntary non-remunerated blood donors and the community at large to provide on their own free will, without payment at regular interval, has for many years an activity of TIF that supplemented greatly its awareness campaigns for thalassaemia prevention and treatment. The human nature of blood and its description as a gift of life or as a precious act of love have been used by TIF to encourage and promote voluntary non-remunerated practices for many years. A number of position papers of our Federation, and certainly many of our educational activities, focus on the
clear relationship of voluntary non-remunerated donation to the safety of blood and the importance of nationally coordinated transfusion services with national blood policy, plans, legislation and regulation as a means of securing and guaranteeing the safety and adequacy of blood and consequently the quality of treatment for our patients. A significant number of our member national associations globally are actively involved in blood donation campaigns and the development of a voluntary culture occupies indeed a central role in these. It will thus be very difficult for TIF to ‘suddenly’ support such drastic changes.

In conclusion, and although realizing that perhaps there are a few positive points and arguments in AABB proposal, allow us please to express our reservations at this point in time and kindly request for further in-depth analysis and discussion to take place amongst a wider audience focusing attention on the possible short and long term consequences and impact this proposal may have, before actually committing to supporting this proposal.

It is noteworthy that many countries, particularly in Europe have already proceeded to specific legislations on blood following the adoption of specific directives and such a proposal may indeed bring about concerns and confusion to many governments on how to move forward. Perhaps the case of discussing this proposal in the context of the WHA as a principle will be a solution acceptable to all, particularly as governments will need to take decisions on this in the end.