February 21, 2013

Dear Secretary
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

I am writing on behalf of the international Society of Blood Transfusion (ISBT) to comment on the above submission by the AABB. ISBT is a professional society established in 1935 that aims to improve standards of transfusion medicine and science throughout the world by means of education, provision of professional networks and other mechanisms. We are a global society with 1296 members from 101 countries.

The ISBT has a longstanding relationship with the WHO blood transfusion safety teams and actively collaborated as a founding partner around the establishment of World Blood Donor Day (WHA resolution 58.13) and in various consultations including the recent global consultations on self-sufficiency and haemovigilance. This relationship goes back to the development and implementation of WHA Resolution 28.72 in 1975 that promotes the development of national blood services based on voluntary non remunerated blood donation (VNRBD). The ISBT is guided by a Code of Ethics (included after this letter) that was developed to support implementation of WHA 28.72, and which has been endorsed by WHO. The Code aims to define the ethical principles and rules to be observed in the provision of a blood transfusion service. A copy is provided with this submission.

ISBT is supportive of any proposal that will enhance the ability of countries to improve provision of blood transfusion services. Access to sufficient quantities of safe blood is clearly an essential component of any national health service. There is also good evidence that effective regulation using a pharmaceutical model will lead to improved quality and safety. On this basis, we accept that blood might also be considered an essential medicine. We understand and generally support the application by AABB for listing on the Essential Medicines List (EML). However, we are as yet uncertain as to the full impact that a listing might have on WHO member states. We therefore urge the committee to take the time to consider this in detail when making a decision for the reasons outlined below.

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Blood is unusual in that production of the medicine is dependent on the support of the local population. Indeed it might be considered that an effective blood transfusion service comprises a form of social contract, based on the principles of social solidarity, between the BTS provider and the local community. Unlike other forms of medication, blood has a unique attribute in that its source is a donation which gives special meaning to those who give and receive blood. In our opinion the decision whether or not to include blood on the EML must take these unique features into account and should only proceed if the Committee is confident that the listing will not adversely impact on the wider ethical and social contract provisions underpinning effective delivery of a blood transfusion service.

Three elements of the Code of Ethics are particularly relevant. The first relates to the principle that BTS provision should, in all instances, be based on the principle of VNRBD, the second that a profit motive should not be the basis for the establishment and running of a blood service and finally that blood is a public resource and access should not be restricted. We believe these are important elements of an ethically based and socially responsible blood transfusion service and it will be important that the committee is confident that listing blood on the EML will not, in any way, compromise them.

We acknowledge that this submission raises unusual questions for the Committee. In many ways it is unfortunate that the time between the submission and consideration by the Committee is relatively short. This has undoubtedly been a constraint on our ability to effectively canvass the views of our membership. The committee might wish to consider the potential value that a broader and more considered consultation might bring to this very important debate.

Yours Sincerely

Dr Peter Flanagan
President
On behalf of the ISBT Board
A CODE OF ETHICS FOR BLOOD DONATION AND TRANSFUSION

The objective of this code is to define the ethical principles and rules to be observed in the field of Transfusion Medicine.

Blood Centers: donors and donation

1. Blood donation including haematopoietic tissues for transplantation shall, in all circumstances, be voluntary and non-remunerated; no coercion should be brought to bear upon the donor. A donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This would include time off work other than that reasonable needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation.

The donor should provide informed consent to the donation of blood or blood components and to the subsequent (legitimate) use of the blood by the transfusion service.

2. A profit motive should not be the basis for the establishment and running of a blood service.

3. The donor should be advised of the risks connected with the procedure; the donor’s health and safety must be protected. Any procedures relating to the administration to a donor of any substance for increasing the concentration of specific blood components should be in compliance with internationally accepted standards.

Anonymity between donor and recipient must be ensured except in special situations and the confidentiality of donor information assured.

4. The donor should understand the risks to others of donating infected blood and his or her ethical responsibility to the recipient.

5. Blood donation must be based on regularly reviewed medical selection criteria and not entail discrimination of any kind, including gender, race, nationality or religion. Neither donor nor potential recipient has the right to require that any such discrimination be practiced.

7. Blood must be collected under the overall responsibility of a suitably qualified, registered medical practitioner.

8. All matters related to whole blood donation and haemapheresis should be in compliance with appropriately defined and internationally accepted standards.

9. Donors and recipients should be informed if they have been harmed.

10. Blood is a public resource and access should not be restricted.

11. Wastage should be avoided in order to safeguard the interests of all potential recipients and the donor.

Hospitals: patients

12. Patients should be informed of the known risks and benefits of blood transfusion and/or alternative therapies and have the right to accept or refuse the procedure. Any valid advance directive should be respected.

13. In the event that the patient is unable to give prior informed consent, the basis for treatment by transfusion must be in the best interests of the patient.

14. Transfusion therapy must be given under the overall responsibility of a registered medical practitioner.

15. Genuine clinical need should be the only basis for transfusion therapy.

16. There should be no financial incentive to prescribe a blood transfusion.

17. As far as possible the patient should receive only those particular components (cells, plasma, or plasma derivatives) that are clinically appropriate and afford optimal safety.

18. Blood transfusion practices established by national or international health bodies and other agencies competent and authorised to do so should be in compliance with this code of ethics.

The Code has been elaborated with the technical support and adopted by the WHO.
Adopted by General Assembly of ISBT, July 12, 2000
Amended by the General Assembly of ISBT, September 5, 2006