The Secretary of the 19th Expert Committee on the Selection and Use of Essential Medicines,
Medicine Access and Rational Use
Department of Essential Medicines and Health Products
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27
Switzerland
email: emlsecretariat@who.int

Dear Sir,

This communication is provided by Medsafe (New Zealand Medicines and Medical Devices Safety Authority) in support of an application submitted by AABB to request listing of Whole Blood and Red Blood Cells on the WHO Model List of Essential Medicines.

As in many other jurisdictions, whole blood and red blood cells are considered to be medicines in New Zealand and have been regulated as medicines since the 1980s. As a result, since 1981 the collection, processing, manufacturing and supply of blood and blood products that has been undertaken by different organisations has been subject to local minimum standards enforced under the Medicines Act 1981.

In November 1995, as a result of concerns over the lack of a nationally coordinated approach to maintain the safety and quality of the blood supply in New Zealand, the New Zealand Ministry of Health developed national minimum standards for the collection, processing and quality assurance of blood and medicines derived from human blood and plasma (Minimum Standards). These standards were revised and extended to include bone marrow and haematopoietic stem cells for transplantation in April 1998. The Minimum Standards represent detailed operational practices necessary for blood centres to manufacture blood and blood components safely.

In July, 1998 with the establishment of the New Zealand Blood Service (NZBS) the regulatory oversight of blood and blood products evolved into the pattern seen in other jurisdictions such as Australia and the United States of America.

The NZBS is charged with protecting the safety of blood in New Zealand and following its establishment, responsibility and ownership of the Minimum Standards was transferred from the Ministry of Health to the NZBS. Placing ownership and responsibility for maintaining operating procedures for blood and blood products with the NZBS imposed upon this organisation the same safety, quality and efficacy requirements as the manufacturer of any other medicinal product regulated by the Medicines Act 1981.
Since 1998, Medsafe’s role with respect to blood and blood products has become that of an independent regulator and conformity assessment organisation, applying international standards to the evaluation of the safety, quality and efficacy of blood and licensing of blood collection centres.

In response to this changed role Medsafe adopted the Council of Europe “Guide to the preparation, use and quality assurance of blood products” (CEG) as its base document for audit and licensing purposes of blood and blood products. As you are aware the CEG describes the risks associated with collection, processing and administration of blood and blood products and details minimum standards which must be applied to meet specific identified risks. The Council of Europe document is also a reference document for several of the European Agency for the Evaluation of Medicinal Products (EMEA) notes for guidance including the “Note for guidance on plasma derived medicinal products” (CPMP/BWP/269/95) which is also used by Medsafe in its evaluation of products.

When adopting this standard, Medsafe recognised that adoption of the CEG would potentially increase the safety of blood and blood protect products available to New Zealanders and most certainly would not expose consumers to any increased risks of harm.

Medsafe therefore supports the proposal to list Whole Blood and Red Blood Cells on the WHO Model List of Essential Medicines. I note the concerns raised by some parties to this proposal but the New Zealand experience is that adoption of an external standard, such as the CEG or WHO Assessment Criteria for National Blood Regulatory Systems, has required the regulator (Medsafe) to work collaboratively with the entity responsible for collection, manufacturing and distribution of blood (NZBS) to ensure that the safety of the blood and blood products available to consumers is improved and the supply of quality medicines maintained and developed. The end result of this collaboration is greater access to safer product.

Yours sincerely

Stewart S Jessamine
Group Manager, Medsafe
Ministry of Health