Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989
Section 10

THERAPEUTIC GOODS ORDER No 81
STANDARDS FOR BLOOD AND BLOOD COMPONENTS

I, ROHAN HAMMETT, delegate of the Minister for Health and Ageing for the purposes of the exercise of the Minister's powers under section 10 of the *Therapeutic Goods Act 1989* and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of that Act, HEREBY:

(1) REVOKE Therapeutic Goods Order No. 74 *Standards for Blood Components* which commenced on 13 January 2006; and
(2) DETERMINE that the matters specified in this Order constitute standards for blood and blood components other than for blood and blood components that are:
    a. collected by a medical practitioner, registered under a law of a State or Territory, or a person under the professional supervision of such a practitioner, in the course of medical treatment and for the purposes of diagnosis of, and testing for, a medical condition; or
    b. manufactured by a medical practitioner, registered under a law of a State or Territory, or a person under the professional supervision of such a practitioner, for therapeutic application to a patient under the practitioner's care; or
    c. manufactured by a blood donation centre for a medical practitioner who is registered under a law of a State or Territory, for therapeutic application to a particular patient under the practitioner's care.

2. Definitions

In this Order:

blood means whole blood collected from a single human donor and processed either for transfusion or further manufacturing.

Blood components means therapeutic components of blood (red cells, white cells, platelets, plasma) that can be prepared by centrifugation, filtration and freezing, but not including haematopoietic progenitor cells.

Haematopoietic progenitor cells means primitive pluripotent haematopoietic cells capable of self-renewal as well as maturation into any of the haematopoietic lineages, including committed and lineage-restricted progenitor cells.

3. Standards and requirements:

(1) Blood and blood components must meet the requirements of the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe document titled "Guide to the preparation, use and quality assurance of blood components", 14th edition, dated 2008, Council of Europe Publishing (the Guide), with the following exceptions:

(a) the reference to tropical areas under the heading 'Tropical Diseases" on page 65 of the Guide should not be taken to include areas within Australia; and

(b) individuals with cancer/malignant disease, or history of such, should not be permanently deferred from donation as specified on page 63 of the Guide.

(2) Blood and blood components must only be manufactured from blood that tests negative for HIV-1 and HCV using nucleic acid amplification technology.

(3) Blood and blood components must not be manufactured from donors who have lived in or visited England, Scotland, Wales, Northern Ireland or the Isle of Man for a cumulative period of six months or more, between 1 January 1980 and 31 December 1996 inclusive.

(4) Blood and blood components must not be manufactured from donors who have received a transfusion or injection of blood or blood products while in England, Scotland, Wales, Northern Island or the Isle of Man from 1 January 1980 onwards.

4. Commencement

This Order commences from the day after the day it is registered on the Federal Register of Legislative Instruments.

Dated this *16th* day of DECEMBER 2008

(Signed by)

Dr Rohan Hammett
Delegate of the Minister for Health and Ageing