EXPLANATORY STATEMENT

Subject: *Section 10, Therapeutic Goods Act 1989*

THERAPEUTIC GOODS ORDER NO. 81 – STANDARDS FOR BLOOD AND BLOOD COMPONENTS

OUTLINE

Therapeutic Goods Order No. 81 *Standards for Blood and Blood Components* (TGO 81) is an Order made by the delegate of the Minister for Health and Ageing under section 10 of the *Therapeutic Goods Act 1989* (the Act).

TGO 81 revokes Therapeutic Goods Order No. 74 *Standards for Blood Components* (TGO 74), and determines that the matters specified in the instrument constitute the standards applying to blood and blood components. Subject to certain exceptions, TGO 81 determines that the standards are based on the updated edition of a key reference document that prescribes the minimum standards to be met by blood and blood components in Australia and specifies manufacturing requirements for blood and blood components. This key reference document is the 14th edition of the Council of Europe document titled "Guide to the preparation, use and quality assurance of blood components", published by the Council of Europe Publishing.

TGO 81 commences on the day after it was registered on the Federal Register of Legislative Instruments.

BACKGROUND

The Act provides for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods for use in humans. The Therapeutic Goods Administration (TGA) is responsible for administering the Act.

Section 10 of the Act authorises the Minister, or the Minister's delegate, to determine standards for therapeutic goods, or to amend or revoke existing standards, after consultation with the Therapeutic Goods Committee, a committee established by the *Therapeutic Goods Regulations 1990* (the Regulations) to advise the Minister on matters relating to standards.

TGO 74, which commenced on 13 January 2006, established the applicable minimum standards in Australia for blood and blood components. Specifically, TGO 74 required that blood and blood components (other than specifically excepted blood and blood components) must meet the requirements of the 11th edition of the Council of Europe document titled "Guide to the preparation, use and quality assurance of blood components", Council of Europe Publishing (the Guide), dated January 2005. TGO 74 also required that blood and blood components only be manufactured from blood that tests negative for HIV-1 and HCV using nucleic acid amplification technology (NAT).

Under TGO 74, the 11th edition of the Guide represented the minimum standard to be met by blood and blood components. The Guide is updated annually and Australia, through the TGA's observer status on the European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS), contributes to the maintenance and ongoing development of the Guide. Adoption of TGO 81 to reflect the current edition of the Guide, being the 14th edition

of that document, is essential to maintaining Australia's currency in the field of blood and blood components. This includes plasma, which can be collected for the purpose of fractionation and manufacture of plasma-derived products.

TGO 81 revokes the existing TGO 74 and determines the standards applying to blood and blood components be, subject to certain exceptions, be based on the updated edition of the Guide referenced in TGO 74 from the 11th edition to the 14th edition. The definitions set out in section 2 of TGO 81 are consistent with the definitions set out in the 14th edition of the Guide.

TGO 81 also provides that there are two exceptions to the application of the 14th edition of the Guide, those being that:

- the reference to tropical areas under the heading 'Tropical Diseases" on page 65 of that document should not be taken to include areas within Australia, and
- individuals with cancer/malignant disease, or history of such, should not be permanently deferred from donation, as specified on page 63 of that document.

TGO 81 also incorporates requirements that blood must not be manufactured:

- from donors who have resided in the United Kingdom for a cumulative period of six months or more between 1980 and 1996 inclusive; or
- from donors who have received a transfusion of blood or blood products in the United Kingdom from 1980 onwards.

These donor deferral requirements maintain current practice within Australia and also reflect public announcements by Australian Health Ministers and the Federal Minister for Health and Ageing.

TGO 81 incorporates the requirement that plasma collected for the purpose of fractionation and manufacture of plasma-derived products must be manufactured only from blood and donors that test negative for HIV-1 and HCV using NAT. While this has been standard practice for plasma for fractionation collected in Australia since August 2000, TGO 74 did not specify the requirement that plasma for fractionation must test negative for HIV-1 using NAT. Inclusion of this requirement in a Therapeutic Goods Order formalises current practice.

The most significant change in the 14th edition of the Guide is an increase in the maximum volume of plasma allowed to be collected by plasmapheresis annually from 15 to 25 litres per donor.

Under paragraph 6(d)(i) of the *Legislative Instruments Act 2003* (LIA), an instrument is a legislative instrument if it is declared to be a disallowable instrument under legislation in force before the commencement of the LIA. On the basis of paragraph 6(d)(i) of the LIA and section 12 of the Act, TGO 81 is a legislative instrument and it is subject to tabling and disallowance in the Parliament under sections 38 and 42 of the LIA.

Copies of the 14th edition of the Guide may be ordered from the website for the European Directorate for the Quality of Medicines and HealthCare (www.edqm.eu).

REGULATION IMPACT STATEMENT

The assessment prepared using the Preliminary Assessment Form of the Office of Best Practice Regulation indicates that a Regulatory Impact Statement is not required in relation to this instrument as the amendments effected by the instrument would not have a significant impact (direct or indirect) on business and would not restrict competition.

The adoption of TGO 81 has been supported by the Therapeutic Goods Committee established under the Regulations and the Regulatory Practice Committee of the TGA.

The Australian Red Cross Blood Service (ARCBS) has been consulted and is fully supportive of the adoption of TGO 81 and the 14th edition of the Guide.