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RCPA
The Royal College of Pathologists of Australasia

10 March 2010

Blood and Tissues Unit
Therapeutic Goods Administration

Biologicals_consultation@tga.gov.au

Re: TGA Public Consultation – Standards and Code of GMP

Thank you for clarifying the issue. The College notes your response and supports the proposed changes to the ID Standard provided it is updated to include the current exemption for blood and blood components specified in Therapeutic Goods Order No 81, thus (in particular please note Clause b. and c.):

"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."

Yours sincerely,

Dr Debra Graves
Chief Executive Officer