



Welcome

This newsletter is to provide an update on the progress in implementing a new regulatory framework for human cellular and tissue based therapy products, also known as biologicals.

Currently biologicals are either exempted from regulation, or aspects of regulation, by the TGA or are regulated as medicines or devices. A new framework is being implemented to regulate these goods.

An overview of the history of the development of the framework is given below. Future newsletters will focus on details of the new framework and its implementation.

History

A framework to regulate biologicals was first proposed during the development of the now postponed joint Australia New Zealand Therapeutic Products Agency (ANZTPA). This reflected the global shift toward separate regulation of these goods. During this time significant consultation was undertaken to ensure development of a framework that appropriately recognises the nature of these products and the environment in which they are made available.

Following the postponement of ANZTPA in July 2007, the Government agreed in 2008 to move forward with a number of improvements identified during the development of ANZTPA in an Australian-only context. This included the implementation of the biologicals framework by the TGA through the *Therapeutic Goods Act 1989*.

Further consultations were undertaken with industry and other interested parties in July and August 2008 as part of the broader regulatory reform program. These face-to-face consultations were convened at Parliament House. In addition to overarching information on the regulatory reform program a number of sector-specific sessions were held, including a medical device session that included discussion of the biologicals framework.

Legislation is currently being developed to implement the framework as consulted upon under the *Therapeutic Goods Act 1989*. Further information on progress of the legislation will be provided in future editions of this newsletter.

The biologicals framework will address a number issues identified with the current regulatory arrangement for these products as medicines and devices. Principally, the framework will address the following:

- the need to minimise infectious disease risk associated with the use of these products/therapies;
- the desirability of international harmonisation of regulatory requirements;
- the need for greater flexibility to respond to changes in technology; and
- the desirability of adopting a risk-based approach to regulation reflecting the differing risk profiles of each biological product.

Further information on the development of the framework including the consultation sessions is available on the TGA website at the following address: <http://www.tga.gov.au/regreform/index.htm>

Updates and Progress on the Biologicals Framework

Legislation

A bill, the Therapeutic Goods Amendment (2009 Measures No 3) Bill 2009, is currently being drafted. As foreshadowed in a speech to Parliament by the Parliamentary Secretary for Health, the Hon Mark Butler, MP, the bill will include amendments to give effect to a new regulatory framework for biologicals.

The bill is expected to be introduced in to Parliament in the Spring 2009 sittings, which begins on 11 August 2009. Contingent upon Parliamentary approval of the bill the new framework for biologicals will begin in 2010 with transition arrangements provided for over a subsequent three year period as agreed by Commonwealth, state and territory health ministers in 2006.

Further details of the regulatory arrangements for biologicals will be set out in regulations and other instruments made under the bill once this is enacted. A series of consultation papers are planned for release for consideration and comment by industry and other interested parties to inform the regulations and instruments, a list of some of these is below.

Product standards and Codes of Good Manufacturing Practice (GMP)

In anticipation of the enactment of the bill giving effect to the new biologicals framework, the TGA has started work on a number of instruments and other documents enabled by the bill that will provide the detail for the framework, including product standards and Codes of GMP.

As an initial step in developing these, the TGA is currently considering the interaction between the proposed draft Biological Standards and the Codes of GMP to ensure that these will operate together as intended. In particular, focus is currently being given to the Infectious Disease Standard and Codes of GMP that would be applied to biologicals.

It is expected that a consultation paper will be released shortly for consideration and comment by interested parties on the proposed draft standards and Codes of GMP to be applied to biologicals. Further details are provided below under 'Future Events'.

Future Events

Conferences/Meetings

Representatives of the TGA will be presenting at the following conferences:

- Australian Bone Marrow Donor Registry – 13 -14 August 2009;
- NSW BMT Network Scientific Forum – 4 September 2009; and
- International Society for Cellular Therapy – 17 October 2009.

Consultation papers

Consultation papers for consideration and comment by interested parties to be released in the coming months include:

- Consultation paper on the potential inclusion of haematopoietic progenitor cells into the biologicals framework;
- Consultation paper on proposed draft product standards and Codes of GMP for biologicals

Further information

If you have any queries or would like further information please contact the TGA by email at: bloodandtissues@tga.gov.au or by phone on: 1800 678 799