

EXPLANATORY STATEMENT

**Subject: THERAPEUTIC GOODS (THINGS THAT ARE NOT BIOLOGICALS)
DETERMINATION NO. 1 OF 2011**

Section 32A(3), Therapeutic Goods Act 1989

OUTLINE

Therapeutic Goods (Things that are not Biologicals) Determination No. 1 of 2011 (the Determination) is a Determination made by the delegate of the Secretary of the Department of Health and Ageing under subsection 32A(3) of the *Therapeutic Goods Act 1989* (the Act).

The Determination declares that the things specified in the instrument are not, for the purposes of the Act, biologicals.

The Determination commenced on the day it was registered in 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.

A number of new provisions have been added to the *Therapeutic Goods Act 1989* (the Act) and the Therapeutic Goods Regulations to establish and implement a new regulatory framework for biologicals. The new regulatory scheme commenced on 31 May 2011.

Section 32A of the Act includes a definition of *biological* for the purposes of the Act.

Subsection 32A(3) empowers the Secretary to declare by legislative instrument that a specified thing is not a biological for the purposes of the Act.

The scope of the biologicals framework, as recommended by the Australian Health Minister's Council (AHMC) in 2006, was to include some human cell and tissue therapy products. The current definition of biological in the Act is broad and includes any therapeutic product containing cells or tissues of human origin. This was done to allow additional cell and tissue therapy products to be included in the framework, if appropriate, over time.

This Determination will ensure the scope of the products regulated in the biologicals framework is consistent with the AHMC recommendation by declaring some products, that are otherwise captured in the definition of biological but are already regulated by the Act as medicines or medical devices, are not biologicals.

The products to be included in this Determination to ensure the scope of the biologicals framework is consistent with the AHMC recommendations are:

- a. blood, blood components and haematopoietic progenitor cells used for haematopoietic reconstitution – these have been deferred from inclusion in the biologicals framework

and, pending further consultation, will continue to be regulated as medicines under the Act;

- b. *in vitro* diagnostic devices, which for example may contain human plasma – these were not within the agreed scope of the framework and will continue to be regulated as medical devices;
- c. diagnostic samples which are not for use as a therapeutic good in an individual; and
- d. biological medicines, such as vaccines and plasma derived products – these will continue to be regulated as medicines for the purposes of the Act.

CONSULTATION

The scope and details of the biologicals framework as recommended by AHMC were consulted with the Australian public in 2004, 2006 and 2007. The Determination was developed in accordance with these recommendations. In addition, presentations to key organisations in the cell and tissue sector in 2009, 2010 and 2011 have described the products proposed to be included and those proposed not to be included in the biologicals framework, and the mechanisms, including this Determination, to achieve that outcome.

REGULATION IMPACT STATEMENT

The *Regulatory Impact Statement for the Regulation of Human Cellular and Tissue Therapy Products (Biologicals)* (ORR ID 5066 February 2009) addressed the coverage of the biologicals framework and how it would be implemented. Under the Determination there will be no change in the regulatory status of the products included in the Determination. As a result there will be no increase in compliance costs as these products are already regulated as medicines or medical devices.