

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Order under Subsection 3(1) - Amendment to the Definition of ‘British Pharmacopoeia’

OUTLINE

The delegate of the Minister for Health and Ageing has, by order, amended the definition of ‘British Pharmacopoeia’ contained in subsection 3(1) of the *Therapeutic Goods Act 1989* (the Act).

On and from 1 July 2006, the definition of British Pharmacopoeia in the Act shall be the British Pharmacopoeia 2005.

BACKGROUND

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (the TGA) is responsible for administering the Act.

Section 14 of the Act requires that medicines, and other therapeutic goods that are not medical devices, which are imported into Australia, supplied for use in Australia or exported from Australia, conform with a standard applicable to the goods. The Act defines ‘standard’ in relation to therapeutic goods, as meaning a standard that is either specified in an order made under section 10 of the Act, or if no such order is applicable to the goods but the goods are the subject of a monograph in the British Pharmacopoeia (in the case of goods for use in humans), then the standard is constituted by the statements in that monograph.

Whilst there are a number of therapeutic goods standards specified in orders made under section 10 of the Act, the British Pharmacopoeia (BP) is the principal (or default) standard applying to medicines and other therapeutic goods that are not medical devices.

Subsection 3(1) of the Act defines ‘British Pharmacopoeia’ as being:

‘the edition of the book of that name, including any additions or amendments, that was in effect for the purposes of the *Therapeutic Goods Act 1966* immediately before the commencement of this section and, if additions or amendments of that book are made after that commencement, or new editions of that book are published after that commencement, includes those additions or amendments, or those new editions, from a day specified by the Minister by order published in the *Gazette*.’

This definition allows the Minister (or his delegate) to determine which edition of the BP will apply. New editions become effective on the date specified by the Minister in the order, with inclusion on the Federal Register of Legislative Instruments satisfying the requirement for gazettal.

Since 1 July 2005, the 2004 edition of the British Pharmacopoeia (British Pharmacopoeia 2004) has had effect in Australia.

The British Pharmacopoeia is published annually, and the 2004 edition now has been superseded by the British Pharmacopoeia 2005.

Adoption under the Act of new editions of the BP is a routine procedure required to allow Australia to maintain consistency with international standards for the quality and safety of therapeutic goods.

Following wide stakeholder consultation, and a recommendation from the Therapeutic Goods Committee (the expert committee established under regulation 34 of the *Therapeutic Goods Regulations 1990* to advise the Minister on matters relating to standards for therapeutic goods), the delegate of the Minister has specified in an order made under subsection 3(1) of the Act that, on and from 1 July 2006, the definition of British Pharmacopoeia in the Act shall be British Pharmacopoeia 2005.

CONSULTATION

Stakeholder consultation on this amendment to the definition of British Pharmacopoeia contained in the Act involved an open invitation for comment on the TGA's website and targeted letters to the following industry associations:

- Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry;
- Australian Dental Industry Association;
- Australian Self Medication Industry Inc.;
- Complementary Healthcare Council of Australia;
- Cosmetic, Toiletry and Fragrance Association of Australia;
- Generic Medicines Industry Association Pty Ltd;
- Medical Industry Association of Australia; and
- Medicines Australia.

No stakeholders raised objections to the adoption of the British Pharmacopoeia 2005.

REGULATION IMPACT STATEMENT

A Regulation Impact Statement has not been prepared as the amendment to the definition of British Pharmacopoeia is of a machinery nature and does not substantially alter existing arrangements under the Act.