**EXPLANATORY STATEMENT**

***Therapeutic Goods Act 1989***

**Order under Subsection 3(1) - Amendment to the Definition of 'British Pharmacopoeia'**

## OUTLINE

This Order is an order under subsection 3(1) of the Therapeutic Goods Act 1989 (the Act) for the purpose of the definition of "British Pharmacopoeia". The purpose of this Order is to amend the definition of "British Pharmacopoeia" under subsection 3(1) of the Act.

The delegate of the Minister for Health and Ageing has, under this Order, specified that on and from 1 June 2009, the relevant edition for the purposes of the definition of "British Pharmacopoeia" under subsection 3(1) of the Act shall be the British Pharmacopoeia 2009.

## BACKGROUND

This Order is a legislative instrument for the purposes of the Legislative Instruments Act 2003 and is subject to the registration, tabling, disallowance and other requirements under that Act.

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.

Sections 14 and 14A of the Act require that therapeutic goods which are imported into Australia, supplied for use in Australia or exported from Australia, conform with a standard applicable to the goods, unless the Secretary or her delegate consents to the importation, supply or exportation of those goods that do not conform with the applicable standard. The Act currently 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 currently 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 authorises the Minister (or her delegate) to determine which edition of the British Pharmacopoeia will apply. New editions referred to in an order become effective on the day after the order is included on the Federal Register of Legislative Instruments, or such later date as the Minister specifies.

The British Pharmacopoeia is published annually and, since 1 July 2008, the 2008 edition of the British Pharmacopoeia (British Pharmacopoeia 2008) has had effect in Australia. However the 2008 edition now has been superseded by the British Pharmacopoeia 2009.

Adoption under the Act of new editions of the British Pharmacopoeia is a routine procedure required to allow Australia to maintain consistency with international standards for the quality and safety of therapeutic goods. The use of an international standard benefits industry in their import and export activities. Adoption of the new edition of the British Pharmacopoeia will also benefit patients and consumers, as the new edition provides authoritative standards for a greater number of substances and medicines, and incremental improvements in defining the quality of other medicines.

This order also ensures that the most recent edition of the British Pharmacopoeia is in effect at commencement of the proposed multi-default pharmacopoeia arrangements provided for in the *Therapeutic Goods Amendment (Medical Devices and Other Measures) Bill 2008*, which will adopt the most recent editions of the European Pharmacopoeia and the United States Pharmacopeia-National Formulary as additional default standards under the Act.

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 June 2009, the edition of the British Pharmacopoeia defined in the Act shall be British Pharmacopoeia 2009.

## CONSULTATION

Stakeholder consultation on the proposal that the edition of the British Pharmacopoeia in force under the Act become British Pharmacopoeia 2009 involved publication of a notice on the TGA's website inviting comment on the proposal and targeted letters to the following industry associations:

- Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry;
- AusBiotech;
- Australian Dental Industry Association;
- Australian Red Cross Blood Service ;
- Australian Self Medication Industry Inc.;
- Complementary Healthcare Council of Australia;
- Generic Medicines Industry Association Pty Ltd;
- Medical Technology Association of Australia; and
- Medicines Australia.

A period of four weeks was allowed for responses.

Only two responses were received – one from an industry association, and one from a sponsor of prescription medicines. Both responses advised that there was no objection to the proposal that edition of the British Pharmacopoeia in force under the definition of British Pharmacopoeia set out in subsection 3(1) of the *Therapeutic Goods Act 1989* become British Pharmacopoeia 2009 with effect 1 June 2009.

Responses to the consultation were considered by the Therapeutic Goods Committee in March 2009, with the Therapeutic Goods Committee recommending that the proposal, that the edition of the British Pharmacopoeia in force under the Act become British Pharmacopoeia 2009 with effect 1 June 2009, proceed.

## REGULATION IMPACT

A preliminary assessment of compliance costs was undertaken in accordance with the requirements of the Office of Best Practice Regulation.

This preliminary assessment led to the conclusion that the changes are machinery in nature, involving technical changes which will not have an appreciable impact on business and would not substantially alter existing arrangements under the Act.

Consultation with industry stakeholders identified no significant obstacles or compliance costs associated with the proposal. However stakeholders who encounter difficulties complying with the requirements of a specific monograph of the British Pharmacopoeia can apply to the TGA for consent for the non-compliance to the applicable standard under sections 14 and 14A of the Act. This application for consent will be considered on a case-by-case basis.

As the impact of the proposal would be minimal, the Business Cost Calculator has not been used to estimate full compliance costs, nor is a Regulation Impact Statement considered necessary.

## INFORMATION ABOUT THE BRITISH PHARMACOPOEIA

The British Pharmacopoeia 2009 is a collection of approximately 3000 monographs for pharmaceutical substances and medicinal products for human use. The monographs specify requirements for identification, solubility, uniformity, assay (strength), sterility, impurities, and other parameters. There are monographs for active ingredients, excipients (inert substances that are necessary to manufacture the product), formulated preparations (e.g. tablets, injections, ointments), traditional herbal medicinal products, homoeopathic medicines, blood products, vaccines and radiopharmaceuticals. The associated test methods and infrared reference spectra are also included in the British Pharmacopoeia.

The British Pharmacopoeia is generally considered to be an essential reference for anyone concerned with the quality of medicines, including the pharmaceutical and chemical industries, quality control personnel, analysts and academics.

The British Pharmacopoeia is produced by the British Pharmacopoeia Commission Secretariat, part of the Medicines and Healthcare products Regulatory Agency (MHRA) of

the United Kingdom (UK). It is available as a hard copy edition, CD-ROM and online and can be purchased from The Stationery Office of the UK (http://www.tsoshop.co.uk/bookstore.asp).

The following documents referred to in this Explanatory Statement may be viewed and obtained from the following locations:

1. the Act may be viewed and downloaded from the website ComLaw (www.comlaw.gov.au), a link to which is on the TGA's website (www.tga.gov.au);
2. information on the British Pharmacopoeia is available on the website of the British Pharmacopoeia Commission (http://www.pharmacopoeia.co.uk).
3. the recommendation made by the Therapeutic Goods Committee in March 2009 concerning British Pharmacopoeia 2009 may be viewed and downloaded from the TGA's website.
4. The *Therapeutic Goods Amendment (Medical Devices and Other Measures) Bill 2008* may be accessed from the website of the Parliament of Australia at http://www.aph.gov.au.