

## EXPLANATORY STATEMENT

**Subject: THERAPEUTIC GOODS (EXEMPTING MONOGRAPHS IN PHARMACOPOEIAS) DETERMINATION NO. 1 OF 2011**

*Section 3C(1), Therapeutic Goods Act 1989*

### OUTLINE

Therapeutic Goods (Exempting monographs in pharmacopoeias) Determination No. 1 of 2011 (the Determination) is a Determination made by the delegate of the Minister for Health and Ageing under section 3C(1) of the *Therapeutic Goods Act 1989* (the Act).

The Determination determines that specified monographs in the United States Pharmacopoeia-National Formulary are exempt for the purposes of paragraph (d) of the definition of “standard” in subsection 3(1) of the Act.

The Determination commenced on the day after the day it was registered on 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.

Section 3C of the Act authorises the Minister, or the Minister's delegate, to determine that specified monographs in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopoeia-National Formulary are exempt for the purposes of paragraph (b), (c) or (d) respectively of the definition of “standard” in subsection 3(1).

The effect of the Determination is that the specified monographs in the United States Pharmacopoeia-National Formulary do not constitute a “standard”.

### CONSULTATION

A draft Determination (then described as an Order) was made available by the TGA for public consultation in September 2009. It was published on the TGA Internet site and key stakeholders were informed. There were two responses.

The draft Determination was considered and endorsed by the Therapeutic Goods Committee (the TGC) at its 36<sup>th</sup> meeting. The TGC is the committee established by the Therapeutic Goods Regulations 1990 to advise the Minister on matters relating to standards for therapeutic goods.

The registered version of the Determination is not materially different to the consultation draft.

### REGULATION IMPACT STATEMENT

The Office of Best Practice Regulation has agreed that no Regulation Impact Statement is necessary for the Determination (OBPR reference number 11770).

## REFERENCED DOCUMENTS

Information on the documents referred to in the Determination or this Explanatory Statement follows.

- The current definition of the *United States Pharmacopeia – National Formulary* is the 34<sup>th</sup> -29<sup>th</sup> edition, inclusive of the First Supplement. It contains more than 4500 monographs with specifications for identity, strength, quality, purity, packaging, and labelling for substances and dosage forms. The United States Pharmacopeia – National Formulary is published by The United States Pharmacopeial Convention. It is available for purchase in print, CD and online.
- The meeting outcomes of the TGC's 36<sup>th</sup> meeting referred to in this Explanatory Statement may be viewed and downloaded from the TGA Internet site.