

## EXPLANATORY STATEMENT

**Subject: THERAPEUTIC GOODS ORDER NO. 76 “REVOCATION OF THERAPEUTIC GOODS ORDERS”**

### *Section 10, Therapeutic Goods Act 1989*

#### OUTLINE

Therapeutic Goods Order No. 76 “Revocation of Therapeutic Goods Orders” (TGO 76) is an Order made by the delegate of the Minister for Health and Ageing under section 10 of the *Therapeutic Goods Act 1989* (the Act).

This Order revokes the following Therapeutic Goods Orders, which are obsolete and/or no longer relevant to the Therapeutic Goods Administration's (TGA) area of regulation:

- Therapeutic Goods Order No. 8 “Standards adopted from the British Pharmaceutical Codex 1973” (TGO 8) made on 25 March 1982;
- Therapeutic Goods Order No. 9 “Standard for Brucella abortus Rose-Bengal Antigen” (TGO 9) made on 4 December 1983;
- Therapeutic Goods Order No. 10 “Standard for Brucella abortus Milk Ring Test Antigen” (TGO 10) made on 4 December 1983;
- Therapeutic Goods Order No. 12 “Standard for Sterility of Intramammary Injections” (TGO 12) made on 4 December 1983;
- Therapeutic Goods Order No. 21 “General Standard for Live Avian Viral Vaccines” (TGO 21) made on 5 February 1986;
- Therapeutic Goods Order No. 25 “Standard for Hydrocortisone Acetate Eye Ointments and Ear Ointments” (TGO 25) made on 10 April 1986;
- Therapeutic Goods Order No. 29 “Standards for Ethanol” (TGO 29) made on 10 April 1986;
- Therapeutic Goods Order No. 30 “Standards Adopted from The British Pharmacopoeia (Veterinary) 1985, The British Pharmacopoeia (Veterinary) 1977, and The British Veterinary Codex 1965, Supplement 1970” (TGO 30) made on 26 May 1987;
- Therapeutic Goods Order No. 45 “Amendments of the Schedule to TGO8: “Standards adopted from the British Pharmaceutical Codex 1973”” (TGO 45) made on 29 October 1993; and
- Therapeutic Goods Order No. 47 “Barium Lime” (TGO 47) made on 24 January 1994.

TGO 76 commenced on the day after 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 the therapeutic goods. The Therapeutic Goods Administration (TGA) is responsible for administering the Act.

Section 10 of the Act provides the Minister, or the Minister's delegate, with the power to determine standards for therapeutic goods, or to amend or revoke existing standards, after consultation with the Therapeutic Goods Committee (TGC), a committee established by the *Therapeutic Goods Regulations 1990* to advise the Minister on standards.

TGO 76, revoking a number of TGOs, has resulted from a process undertaken by the TGC to review all existing TGOs for relevance under current regulatory arrangements, and to determine if the orders, some of which are over 20 years old, continue to reflect contemporary standards for therapeutic goods. Specific explanation of the reasons for the revocations is outlined in the following paragraphs.

**Revocation of TGO 8 “Standards adopted from the British Pharmaceutical Codex 1973” and TGO 45 ‘Amendments of the Schedule to TGO8: “Standards adopted from the British Pharmaceutical Codex 1973” ’**

TGO 8 specified that the monographs given in the British Pharmaceutical Codex 1973 (BPC73) for a number of ingredients and formulations constituted the standards for those products. The original intention of TGO 8 was to retain BPC73 monographs from the former *Therapeutic Goods Act 1966* until these ingredients and formulations were included in the British Pharmacopoeia (BP). The amendments to TGO 8 made by TGO 45 deleted names of monographs which had been adopted into the BP by 1991. No further amendments were made to TGO 8.

In its review, the TGC recognised that many BPC73 monographs adopted through TGO 8 related to products that were outdated, no longer available, and/or no longer clinically relevant. Also, as monographs for a number of other ingredients and formulations listed in TGO 8 had appeared in the BP, the need to retain TGO 8 had further diminished.

Consultation subsequently undertaken with stakeholders confirmed the conclusion that the monographs of the BPC73 referred to in TGO 8 (as amended by TGO 45) were of little relevance to contemporary therapeutic goods. As stakeholders raised no objections to the proposed revocation of TGO 8 (as amended by TGO 45), the TGC recommended that revocation of these Orders proceed.

TGO 76 revoked TGO 8 and TGO 45.

**Revocation of TGO 9 “Standard for *Brucella abortus* Rose-Bengal Antigen”; TGO 10 “Standard for *Brucella abortus* Milk Ring Test Antigen”; TGO 12 “Standard for Sterility of Intramammary Injections”; TGO 21 “General Standard for Live Avian Viral Vaccines”; and TGO 30 “Standards Adopted from The British Pharmacopoeia (Veterinary) 1985, The British Pharmacopoeia (Veterinary) 1977, and The British Veterinary Codex 1965, Supplement 1970”**

TGOs 9, 10, 12, 21 and 30 related to products for veterinary use rather than human use. Such products are now regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The TGOs therefore were no longer applicable to the TGA's area of regulation

Advice provided by the APVMA to the TGA confirmed that there was no need for retention of TGOs 12, 21 or 30 as alternative regulatory arrangements are in place. The need for TGOs 9 and 10 had ceased as the production of the Rose Bengal Antigen and Milk Ring Test

Antigen had stopped when brucellosis was eradicated in Australia and the mass screening of cattle herds using these reagents stopped.

The TGOs were therefore considered to be redundant. There were no objections from stakeholders to the TGC's recommendation for revocation.

TGO 76 revoked TGOs 9, 10, 12, 21 and 30.

### **Revocation of TGO 25 “Standard for Hydrocortisone Acetate Eye Ointments and Ear Ointments”**

TGO 25 provided a monograph for eye and ear ointments containing hydrocortisone acetate as the only therapeutically active substance. This monograph included specifications and test methods that did not reflect those of contemporary pharmacopoeias and referred to other Orders that had been revoked.

Investigation of the continued relevance of TGO 25 revealed that the current British Pharmacopoeia includes general monographs for these types of preparations that would provide a suitable regulatory standard upon revocation of TGO 25. There were no issues with the quality of the only product potentially affected by the revocation, and neither the sponsor of that product nor the relevant industry organisations had any objections to the proposed revocation of TGO 25. On this basis, the TGC recommended that this Order be revoked.

TGO 76 revoked TGO 25.

### **Revocation of TGO 29 “Standards for Ethanol”**

TGO 29, made in 1986, specified different standards for ethanol when prepared by a fermentation process and when prepared by a synthetic process. The standards specified came from different editions of the British Pharmacopoeia (BP), with ethanol produced by fermentation being required to comply with the 1973 edition, and ethanol produced by a synthetic process being required to comply with the 1980 edition. The reason for retaining the 1973 standard for ethanol produced by fermentation was to accommodate local manufacturers of ethanol who could not meet the more stringent limits of the 1980 BP monograph.

The effect of TGO 29 had been to fix the 1973 BP monograph as the standard for 95% ethanol produced by a fermentation process, and the 1980 BP monograph as the standard for 96% ethanol produced by a synthetic process, despite the monographs of the BP further advancing over time.

Review of TGO 29 and the production capability of Australian distilleries resulted in the TGC reaching the conclusion that there was no longer any need for an Australian specific standard for ethanol. The major Australian distilleries producing ethanol for the pharmaceutical market could now meet the requirements of the current edition of the BP, impurity levels were significantly reduced, adopting the standard of the current BP would be moving to best practice and this would assist sponsors supplying goods for export.

Based on these findings, the TGC recommended that TGO 29 should be revoked, with a 12 month transition period to allow sponsors and/or distilleries to make any necessary changes. This suggested transition period elapsed some time ago and the delegate of the Minister for Health and Ageing has acted to revoke TGO 29 through TGO 76.

### **Revocation of TGO 47 “Barium Lime”**

TGO 47, which determined that the standard for barium lime was the monograph entitled ‘Barium Hydroxide Lime’ in the United States Pharmacopoeia, had been made in 1994 to remedy the absence of a monograph for barium lime in the British Pharmacopoeia and specifically to control the particle size of the substance for public health reasons.

The need for retention of TGO 47 was questioned during the review of current TGOs undertaken by the TGC, as it was believed that the use of barium lime had been discontinued for safety reasons and products were no longer available in Australia. Barium lime had been used as a carbon dioxide absorbent in anaesthesia equipment. It was subsequently confirmed that barium lime was no longer used in anaesthetic equipment for safety reasons, and barium lime did not appear to have any other recognised therapeutic uses. As there were no products on the Australian Register of Therapeutic Goods with barium lime as an ingredient, it was concluded that an Order stipulating its quality and performance was unnecessary.

TGO 76 revoked TGO 47.

### **REGULATION IMPACT STATEMENT**

Consultation with relevant stakeholders was undertaken throughout the TGC’s review process and stakeholder responses were taken into consideration by the committee in formulating its recommendations. No significant objections or issues were raised by stakeholders in any of the consultations.

Preliminary assessment of compliance costs associated with each of the Orders revoked has been undertaken in accordance with Best Practice Regulation requirements. The preliminary assessments led to the conclusion that the revocations would have a nil or minimal impact on business, and would not restrict competition. As the impact would be nil or minimal, a Regulation Impact Statement was not necessary.