FINAL DECISIONS & REASONS FOR DECISIONS BY DELEGATES OF THE SECRETARY TO THE DEPARTMENT OF HEALTH AND AGEING

JUNE 2012

The following delegates' final decisions and reasons relates to matters considered as delegate-only decisions. These matters were not referred to an expert advisory committee.

Notice under subsections 42ZXZS and 42ZCZX of the Therapeutic Goods Regulations 1990 (the Regulations)

A delegate of the Secretary to the Department of Health and Ageing hereby gives notice of delegates' final decisions for amending the Poisons Standard (commonly referred to as the *Standard for the Uniform Scheduling of Medicines and Poisons* – SUSMP) under subsections 42ZCZS and 42ZCZX of the Regulations. This notice also provides the reasons for each decision and the date of effect of the decision.

Matters not referred to an advisory committee

A delegate may decide not to refer a scheduling matter to an expert advisory committee for advice and instead may make a delegate-only decision. When deciding not to refer a matter to an expert advisory committee for advice, the delegate considers the scheduling guidelines as set out in the Scheduling Policy Framework (SPF) accessible at www.tga.gov.au/industry/scheduling-spf.htm.

Implementation

The SUSMP and its amendments are available electronically at the ComLaw website, a link to which can be found at www.tga.gov.au/industry/scheduling-poisons-standard.htm.

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FINAL DECISIONS ON MATTERS NOT REFERRED TO AN EXPERT ADVISORY COMMITTEE

1. EDITORIALS AND ERRATA

1.1 POISONS STANDARD REFERENCE REVIEW

PROPOSAL

To amend the Poisons Standard to include up-to-date references.

BACKGROUND

New editions of, and amendments to, the Poisons Standard (currently entitled the *Standard for the Uniform Scheduling of Medicines and Poisons* [SUSMP]) are legislative instruments and are required to be registered on the Federal Register of Legislative Instruments (FRLI). Section 52D of the *Therapeutic Goods Act 1989* sets out the requirements for validation of the Poisons Standard, including disallowance under the *Legislative Instruments Act 2003*.

References in a legislative instrument must be up-to-date and, in regard to references to quasi-legal publications, must be specific to a particular version before it is registered on FRLI. Wording to the effect "as specified or amended from time to time" is deemed inappropriate for references in a legislative instrument and is to be excluded. This wording is only appropriate for use in an Act, with all subordinate legislation and quasi legal documents (such as the Poisons Standard) to include full titles, and publication dates where available, when referencing.

Following a review of references in the *Poisons Standard 2011* (SUSMP No. 2), the delegates decided to amend a number of entries to include up-to-date references for inclusion in the *Poison Standard 2012* (SUSMP No. 3). These were delegate-only decisions published in the May 2012 *Final Decisions and Reasons for Decisions by Delegates* (http://www.tga.gov.au/industry/scheduling-decisions-1205-final.htm#delegate).

DELEGATES' CONSIDERATION

The delegates noted that subsequent to the publishing of the May 2012 *Final Decisions and Reasons for Decisions by Delegates*, TGA Legal Services proposed three further amendments, principally in the interests of clarity

- Introduction, paragraph 7: the current wording refers to the documents listed as being "Commonwealth legislative instruments". As two of the documents are Acts, the wording in the first line is to be amended to read "The various Commonwealth Acts and instruments which integrate with the SUSMP include";

- Part 1, Interpretation, "Appropriate authority" paragraph (b): the wording "paragraphs 2 to 12 of this Standard" is to be amended to read "paragraphs 2 to 12 in Part 2 of this Standard";

- Appendix C, Clioquinol: for greater consistency with the legislation, this entry is to reference the provisions in the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990* which provide the legislative basis for the schemes known as the Clinical Trial Exemption Scheme (the CTX scheme) and the Clinical Trial Notification Scheme (the CTN scheme).

DELEGATE'S FINAL DECISION

The delegates have made a final decision to further amend the Poisons Standard to include up-to-date references, with the amendments to be included in the *Poisons Standard 2012* (SUSMP No. 3) to be published in June 2012.

Note: the amendments are underlined in the following amended entries.

INTRODUCTION - AMENDMENTS

Paragraph 7 – Amend entry to read:

The various Commonwealth Acts and instruments which integrate with the SUSMP include:

- the *Agricultural and Veterinary Chemicals Code Act 1994*
- the *Agricultural and Veterinary Chemicals Code Regulations 1995*
- the *Therapeutic Goods Act 1989*
- Therapeutic Goods Order 69 – *General requirements for labels for medicines*
- Therapeutic Goods Order 80 – Child-Resistant Packaging Requirements for Medicines
- the Required Advisory Statements for Medicine Labels (RASML)

PART 1, INTERPRETATION

"**Appropriate authority**", paragraph (b) – Amend entry to read:

(b) for the purpose of providing an exemption from all or part of paragraphs 2 to 12 of Part 2 of this Standard by the Australian Pesticides and Veterinary Medicines Authority, the Chief Executive Officer or their delegate;

APPENDIX C - AMENDMENT

CLIOQUINOL- Amend entry to read:

CLIOQUINOL and other halogenated derivatives of 8-hydroxyquinoline for human internal use **except** when being used solely for experimental purposes in humans and where such use:

(a) is in accordance with:

(i) an approval granted under paragraph 19(1)(b) of the Therapeutic Goods Act 1989, including any conditions specified in the notice of approval; and

(ii) any conditions specified in the Therapeutic Goods Regulations 1990 for the purposes of subsection 19(1A) of the Therapeutic Goods Act 1989; and

(iii) any conditions specified in the Therapeutic Goods Regulations 1990 for the purposes of subsection 19(4A) of the Therapeutic Goods Act 1989; or

(b) is in accordance with the requirements of item 3 of Schedule 5A to the Therapeutic Goods Regulations 1990.