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

SEPTEMBER 2012

The following delegates' final decisions and reasons on scheduling matters relate to applications considered as delegate-only decisions. These applications 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 application to an expert advisory committee for advice and instead may make a delegate-only decision. When deciding not to refer an application 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 ADVISORY COMMITTEE

1. CHEMICALS

1.1 CARBIMAZOLE

SCHEDULING PROPOSAL

The Office of Chemical Safety (OCS) has evaluated the data provided in support of an application for the approval of a new veterinary medicine product, namely carbimazole for the treatment of feline hyperthyroidism.

The OCS recommended that carbimazole be included in Schedule 4. The applicant was provided a copy of the evaluation report and agreed with the proposed schedule listing.

The delegate considered this application and made a delegate-only decision. The Advisory Committee on Chemicals Scheduling (ACCS) was not consulted.

SCHEDULING STATUS

Carbimazole is listed in Schedule 4[1].

SCHEDULING HISTORY

Carbimazole was last considered by the Poisons Schedule Sub-Committee in 1966.

DELEGATE'S CONSIDERATION

The delegate considered the following in regards to this proposal:

- OCS evaluation report (not publicly available);
- section 52E of the *Therapeutic Goods Act 1989*;
- scheduling factors[2]; and
- other relevant information.

DELEGATE'S FINAL DECISION

[1] For human therapeutic use.
[2] Scheduling Policy Framework for Medicines and Chemicals http://www.tga.gov.au/industry/scheduling-spf.htm

The delegate has made a delegate-only decision that the existing Schedule 4 carbimazole prescription-only medicine entry remains appropriate for animal therapeutic use in addition to human therapeutic use.

The delegate decided that the relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* include (b) the purposes for which a substance is to be used and the extent of use of a substance and (c) toxicity.

The decision that the entry for carbimazole remains appropriate included the following reasons:

- The toxicological profile of this class of anti-thyroid drugs is well established, including its long-term use in human therapeutics.
- Carbimazole is already included in Schedule 4 on account of its human therapeutic use.
- Its proposed use in the treatment of primary hyperthyroidism in cats requires diagnosis and management by a veterinarian. Therefore, its current scheduling as a prescription-only medicine in Schedule 4 remains appropriate, covering both the human and animal clinical uses.
- There is no need to consider any more restrictive scheduling.
- The principal toxicological risks to humans when administering the veterinary product will be adequately managed via the listed warning statements and safety directions, and by advice from the prescribing veterinarian.
- The OCS technical report did not include a recommendation that the product label include the cautionary statement – FOR ANIMAL TREATMENT ONLY[3]. This should be standard practice for a veterinary Schedule 4 medicine.

1.2 AMINOCYCLOPYRACHLOR

SCHEDULING PROPOSAL

The Office of Chemical Safety (OCS) has evaluated the data provided in support of an application for the approval of a new herbicide namely aminocyclopyrachlor. The OCS recommended that aminocyclopyrachlor be included in Schedule 5.

The applicant was provided a copy of the evaluation report and agreed with the proposed schedule listing.

The delegate considered this proposal and made a delegate-only decision. The Advisory Committee on Chemicals Scheduling (ACCS) was not consulted.

SCHEDULING STATUS

[3] PART 2 LABELS AND CONTAINERS, 7. (1) (i) (page 14) – Standards for the Uniform Scheduling of Medicines and Poisons.

Aminocyclopyrachlor is not specifically scheduled.

SCHEDULING CONSIDERATION

The delegate considered the following in regards to this application:

- the OCS Evaluation Report (not publicly available);
- section 52E of the *Therapeutic Goods Act 1989*; and
- scheduling factors for inclusion in Schedule 5[4].

DELEGATE'S FINAL DECISION

The delegate has made a delegate-only decision to include aminocyclopyrachlor in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons.

The implementation date for this decision is 1 January 2013.

The delegate decided that the relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* include (c) toxicity.

The decision to include aminocyclopyrachlor in Schedule 5 included the following reasons:

- The toxicological profile of this auxin-type herbicide is well characterised in the OCS evaluation report.
- The slight eye irritancy potential (but not skin irritancy) and the low potential for acute or chronic toxicity for aminocyclopyrachlor are consistent with the Scheduling Policy Framework's (SPF) criteria for listing in Schedule 5, driven primarily by the evidence of slight eye irritancy.
- It is inappropriate to consider a possible scheduling cut-off to exempt status at this time in the absence of information on a proposed product.
- The weight-of-evidence in the OCS evaluation of the astrocytomas seen in the 2-year rat study, and the skeletal malformation found at high doses in pregnant rabbits. The findings were not of sufficient toxicological significance to impact scheduling consideration.
- While there are no impurities of toxicological concern associated with technical grade aminocyclopyrachlor, an environmental degradation product may be more toxic than the parent molecule. This metabolite does not appear to contribute significantly to the toxicity of administered aminocyclopyrachlor, since it was not generally found in the

[4] Scheduling Policy Framework for Medicines and Chemicals http://www.tga.gov.au/industry/scheduling-spf.htm

metabolite/toxicokinetic studies in rats. While the formation of the environmental residue may be of more significance in determining the ADI and potential worker exposure to crop and environmental residues, it is not an issue for consideration in poison scheduling.

- The United States Environmental Protection Authority is reviewing the registration of aminocyclopyrachlor in the United States. However, this appears to relate to its effects on non-target trees, and this too is not an issue for consideration in poison scheduling.
- Aminocyclopyrachlor has low acute and chronic toxicity, with some evidence of minor eye irritancy potential. Its toxicity profile is consistent with the Scheduling Policy Framework's criteria for listing in Schedule 5.

SCHEDULE ENTRY

Schedule 5 – New Entry

AMINOCYCLOPYRACHLOR.