FINAL DECISION & REASON FOR A DECISION BY A DELEGATE OF THE SECRETARY TO THE DEPARTMENT OF HEALTH AND AGEING

NOVEMBER 2012

The following delegate's final decision and reason on a scheduling matter relates to an application considered as a delegate-only matter, i.e. 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 a delegate's final decision for aending 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 reason for the 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 also available electronically at the ComLaw website, a link to which can be found at www.tga.gov.au/industry/scheduling-poisons-standard.htm.

LORATADINE

SCHEDULING PROPOSAL

The medicines scheduling delegate (the delegate) considered a proposal from the Therapeutic Goods Administration (TGA) to editorially amend the Schedule 2 and Schedule 4 entries for loratadine to correct the intent of the wording in the Schedule entries by including an exemption specifically for divided preparations.

The delegate has made a delegate-only decision to editorially amend the Schedule 2 and Schedule 4 entries for loratadine. The Advisory Committee on Medicines Scheduling (ACMS) was not consulted.

SCHEDULING HISTORY

In May 1992, loratadine was first scheduled by the National Drugs and Poisons Schedule Committee (NDPSC) and included in Schedule 4.

In April 1994, the NDPSC rescheduled loratadine tablets to Schedule 3.

In November 1999, the NDPSC confirmed its decision of February 1999 to reschedule from Schedule 3 to Schedule 2 "loratadine in preparations for oral use" and that the restriction to 'only therapeutically active ingredient' should no longer apply. Loratadine also remained in Schedule 4 except when included in Schedule 2.

In May 2012, the delegate exempted solid dose oral preparations containing 10 mg or less of loratadine in packs containing not more than 5 dosage units for the treatment of seasonal allergic rhinitis (SAR) in adults and children 12 years of age and over.

SCHEDULING CONSIDERATION

The delegate considered the following in regards to this proposal.

- Recent scheduling history

    - Prior to 1 September 2012, loratadine was in Schedule 2 "in [all] preparations for oral use" (including liquid preparations). Loratadine was also included in Schedule 4 except when included in Schedule 2.

    - In May 2012, the delegate decided to amend the Schedule 2 and Schedule 4 entries for loratadine to exempt solid dose oral preparations containing 10 mg or less of loratadine in packs containing not more than 5 dosage units for the treatment of seasonal allergic rhinitis (SAR) in adults and children 12 years of age and over. The implementation date for this decision was 1 September 2012

- Issues raised by TGA:

    - The current Schedule 2 entry "LORATADINE in solid preparations for oral use except in preparations for the treatment of seasonal allergic rhinitis in... " implies that only solid dose oral preparations of loratadine could be in Schedule 2, with all liquid oral preparations inadvertently included in Schedule 4.

    - Loratadine is currently included on the Australian Register of Therapeutic Goods as tablets (including effervescent tablets and chewable tablets), capsules and oral liquids. It is not rational to exempt tablets, but not capsules. Loratadine tablets, capsules and other divided preparations should be exempt from scheduling, including effervescent tablets which should be covered under the SUSMP definition, "divided preparations" as they are only a liquid when added to water and would also presumably be considered to be a 'solid' preparation.

    - Liquid preparations of loratadine are primarily intended for use in children and should not be exempted from scheduling, noting that the scheduling exemption for loratadine only applies to products indicated for use in adults and children 12 years of age and over.

    - The Schedule 2 entry for loratadine should state an exemption specifically for 'divided preparations'. The Schedule 4 entry should include consistent wording, and also refer to 'divided preparations'.

- The original application considered by the February 2012 ACMS meeting to exempt from scheduling loratadine 10 mg in packs of 5 tablets or less (a maximum of 5 days' treatment).
- The advice of the February 2012 ACMS meeting.

DELEGATE'S FINAL DECISION

The delegate has made a delegate-only decision to editorially amend the Schedule 2 and Schedule 4 entries for loratadine to include an exemption specifically for divided preparations.

The implementation date for this decision is 22 November 2012.

The reason for the decision is to correct the intent of the wording in the Schedule entries.

Schedule 2 – Amendment

LORATADINE – Amend entry to read:

LORATADINE in preparations for oral use except in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

(a) in a primary pack containing 5 dosage units or less; and

(b) labelled with a recommended daily dose not exceeding 10 mg of loratadine.

Schedule 4 – Amendment

LORATADINE – Amend entry to read:

LORATADINE except:

(a) when included in Schedule 2; or

(b) in divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

(i) in a primary pack containing 5 dosage units or less; and

(ii) labelled with a recommended daily dose not exceeding 10 mg of loratadine.