



The Secretary
National Drugs and Poisons Schedule Committee
GPO Box 9848
CANBERRA ACT 2601
Email: NDPSC@health.gov.au

Dear Secretary

The Complementary Healthcare Council (CHC) is pleased to provide comment on the Pre-June 2010 Scheduling Meeting Notice.

The CHC advises on its interest in the following proposals listed for consideration and reserves the right to comment further on any proposed scheduling or scheduling changes on the items below, should this be necessary:

1. Foreshadowed Decisions from the Previous Meeting

1.2 Sodium lauryl sulphate -consideration of scheduling, including a proposed new Schedule 6 entry (see item 6.7 of the February 2010 Record of Reasons).

The CHC notes that this substance is used as a lubricant for some gelatin capsules for complementary medicines, at an amount of less than 2%; any scheduling of sodium lauryl sulphate should be above the miniscule amount used in gelatin capsules.

The CHC supports the proposed stated recommendation from the NDPSC Record of Reasons Meeting 58 (February 2010) which proposed:

SODIUM LAURYL SULPHATE **except:**

- a) In wash-off preparations containing 30 percent or less of sodium lauryl sulphate;
- b) In leave-on preparations containing 1 percent or less of sodium lauryl sulphate; or
- c) ***In other preparations containing 2 percent or less of sodium lauryl sulphate.***

5 Other Pharmaceuticals

5.6 Cough and cold medicines - consideration of scheduling, including a proposal resulting from a review by the TGA to reschedule 22 substances used in over-the-counter cough and cold medicines when used in children under 6 years to Schedule 4, when used in children aged 6 to 11 to Schedule 3, and when used in children aged 11 to 12 to Schedule 2.

The CHC notes that the TGA have reviewed selected registered over-the-counter cough and cold medicines. The CHC wishes to point out that any proposed scheduling change for these products should not unintentionally capture complementary cough and cold medicines; there is no identified safety concern in relation to the complementary medicine products and were not included in the review.

5.8 Iodine – consideration of scheduling, including a proposal to exempt from scheduling iodine when used as a prophylaxis under an emergency plan approved by an appropriate authority for radioactive iodine exposure.

The CHC notes that iodine is used in a number of complementary medicines and request further detail as to the proposal for this substance i.e. how will the proposed scheduling for iodine affect current scheduling requirements?

5.11 Magnesium sulfate – consideration for scheduling, including a proposal to amend the scheduling of magnesium sulfate for use in laxation from Schedule 3 to unscheduled by either: exempting from scheduling divided oral preparations containing 15 g or less of magnesium sulfate; or alternatively, to limit the current Schedule 3 entry to magnesium sulfate when in preparations for oral use for bowel cleansing prior to diagnostic, medical or surgical procedures.

The CHC provided comment on this substance in August 2009 (June 2009 Post-meeting outcomes) and recommended that NDPSC consider the entry for magnesium sulfate be amended to include an indication for constipation. The CHC questions the reasoning behind the proposal to change the exemption of scheduling when used in laxation given this substance was considered by the Adverse Drug Reactions Advisory Committee (ADRAC) in 2008; the CHC understands that the original amendment to the entry was addressing this concern.

6.1 Beta-carotene – consideration for scheduling, including a proposal to harmonise with New Zealand through a new Schedule 4 entry with an exemption from scheduling for preparations containing 18 mg or less of beta-carotene.

The CHC notes that a number of listed complementary medicine products in Australia contain 25mg of beta-carotene and the proposed scheduling amendment, if accepted, will capture these products consequently impacting the industry.

If you require any further information please do not hesitate in contacting me further.

Yours Sincerely



Kristy Roberts
Scientific and Technical Manager

26 May 2010