The Secretary
Therapeutic Goods Committee
Therapeutic Goods Administration
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Email: standards@tga.gov.au

Dear Secretary

CHC Submission: Review of Schedule 1 to Therapeutic Goods Order No. 80 *Child-Resistant Packaging Requirements for Medicines* (TGO 80)

Thank you for the opportunity for the complementary healthcare industry to provide comment on the review of Schedule 1 to the Therapeutic Goods Order No. 80 *Child-Resistant Packaging Requirements for Medicines* (TGO 80) dated 25 August 2009.

Recommendation

The Complementary Healthcare Council (CHC) strongly supports the use of child-resistant packaging for therapeutic goods, including complementary medicines, for the reduction of accidental poisonings in children however believes that all requirements for application of this provision be appropriately justified.

The CHC notes that glucosamine sulfate potassium chloride complex under review by the Therapeutic Goods Committee (TGC) to assess the potential for potassium toxicity. This substance was previously assessed for inclusion into TGO 80 as part of the consultation; it was recommended that glucosamine sulfate potassium chloride complex products should be exempt from the requirement.

Given there has been no reports of any adverse events relating to glucosamine sulfate potassium chloride products (due to potassium overdose), the CHC strongly recommends that this substance remain exempt from the requirements within TGO 80.

Comments

The CHC provides the following information to justify the exemption of glucosamine sulfate potassium chloride complex products from Schedule 1 of TGO 80:

- The lowest probable oral lethal dose for potassium chloride in humans is estimated at 500mg/kg[1]. Therefore, in the case of a 70kg adult, 35g of potassium chloride is required to obtain this level which is equivalent to 141 capsules of a glucosamine sulfate potassium chloride product containing 100mg of glucosamine. The Australian average weight for a 2 year old and 11 year old is 14kg and 40kg respectively. To achieve a lethal dose of potassium, 28 capsules and 80 capsules would need to be consumed respectively. The CHC considers it not practical nor reasonable to assume a 2 year old would be able to consume

[1] Potassium Chloride OECD SIDS (Screening Information Data Sheet) IPSC (International Program on Chemical Safety) INCHEM (Chemical Safety Information from Intergovernmental Organisations).

28 capsules (with a minimum length og 23mm per tablet) of 100mg glucosamine sulfate potassium chloride complex product.

- The target consumers for product containing this substance are those that suffer arthritis or severe joint pain, quite often in the hands, and are often elderly. Placing child-resistant packaging on such products would make it almost impossible for them to open the containers and would deny these consumers access to a product which has proven therapeutic efficacy in alleviating such conditions.

- It should also be noted that many glucosamine sulfate potassium chloride complex products are presented as a two piece hard shell capsule. Such capsules are required to have two levels of tamper evidency on the packaging. The CHC is unaware of any child-resistant closures available in Australia which allow for two levels of tamper evidency.

- By changing the requirements and including glucosamine sulfate potassium chloride complex products in Schedule 1, would have a significant impact on the complementary healthcare industry by limiting the availability of 'bulk' sized products; the CHC is not aware of any child-resistant closures available in Australia to fit larger sized containers i.e. products greater than 180 tablets per container. To add to this, the CHC has been advised that there is also no child resistant closures available to fit plastic jars/containers. As a consequence, all the larger pack sizes (180, 200, 240, 400 tablets), which are almost all in plastic jars, are likely to be forced off the market.

- The CHC also believes there may be confusion and unreasonable alarm amongst consumers as some products containing glucosamine do not contain potassium (glucosamine hydrochloride); these products would not need to comply with the provisions within TGO 80. Consumers may not understand why only certain glucosamine products have child-resistant packaging and may stop using such products.

- The CHC is not aware of any other countries implementing such a requirement on glucosamine sulfate potassium chloride products and raises concern regarding harmonisation.

Including glucosamine sulfate potassium chloride complex products into Schedule 1 of TGO 80 will effectively remove such products from the market, make it inaccessible to many consumers suffering extreme joint pain and creates issues with regard to international harmonisation. The CHC also notes that there has been **no adverse events** reported within the 12 month monitoring period therefore considers there to be **no justification** for changing the requirement.

If you require any further information in relation to the content of this submission, please do not hesitate in contacting me.

Yours sincerely

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Scientific & Technical Manager
23 September 2009