

Petreski, Sonya

From: Wallner, Peter
Sent: Thursday, 4 April 2013 6:01 PM
To: Mackay, Ruth; Ridgway, Nigel; Hutchison, Steve
Cc: Lim, Dixie
Subject: FW: teeth whitening: Recent decision by the poisons and medicines scheduling delegates [DLM=Sensitive]
Attachments: ACCC issues - postscript note (D13-200701).DOCX
Follow Up Flag: Follow up
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Hi All

OCS have sent me some suggested post script words clarifying the Delegates final decision around teeth whiteners. I think it avoids one of our key points - that safety data was not considered by the Delegates in amending the Committee's recommendation. My suggestions in blue – any views?

Post script note of <insert date>: The expression “too restrictive to dental practitioners in the exercise of their professional practice” is not an assessment of the safety of teeth whitening preparations per se but a comment on the scope of the SUSMP to place controls on the advice (activity?) of professional practitioners. The entity administering a chemical substance and the location of use of a chemical substance, whether by a registered practitioner in-clinic or by an individual consumer at home, is not intended to be controlled through the SUSMP. Limitations on the location of use would be applied through the policies of professional practice boards or relevant regulatory authorities (including, but not limited to, the Australian Competition and Consumer Commission).

Peter Wallner

Director | Chemicals & Regulated Products | Product Safety

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From: Neil.Ellis@health.gov.au [mailto:Neil.Ellis@health.gov.au]
Sent: Thursday, 4 April 2013 5:35 PM
To: Wallner, Peter
Subject: teeth whitening: Recent decision by the poisons and medicines scheduling delegates [DLM=Sensitive]

Hi Peter ... as discussed at our meeting the other week, we have had a look at the final decision, in particular the reasons for not including 'in-clinic use', as it appears on our website. I have drafted some wording that could appear as a postscript to the reasons. I haven't yet confirmed the wording with the delegates but thought I would initially get a view from you

see red text in the attached document
appreciate your views

cheers

Neil

Neil Ellis | Director | Chemical Policy and Scheduling Secretariat | Office of Chemical Safety
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Proposed amendment to the public notice on the TGA website to add a post script comment for clarification

Delegate's final decision

The delegates have decided to vary the interim decision.

The delegates have decided that the wording of the interim decision to list the highest strength teeth whitening preparations in Appendix C is to be amended to remove the restriction "for direct in-clinic use". The delegates considered this to be too restrictive to dental practitioners in the exercise of their professional practice* and it did not accurately reflect the advice of the expert advisory committees. This approach was supported by all but one submission received during the consultation on the interim decision, with the exception of a wording change to reflect that the intent was not to limit the way dental practitioners use such products in exercising their professional practice.

The delegates have made a final decision to amend the Standard for the Uniform Scheduling of Medicines and Poisons to:

- include teeth whitening preparations containing more than 18 per cent of carbamide peroxide and more than 6 per cent (20 volume) of hydrogen peroxide in Appendix C; and
- exempt from the new Appendix C entries, teeth whitening preparations containing more than 18 per cent of carbamide peroxide and more than 6 per cent of hydrogen peroxide manufactured for and supplied solely by registered dental practitioners as part of their dental practice.

The delegates have decided that the implementation date for this decision will be 1 May 2013.

*Post script note of <insert date>: The expression "too restrictive to dental practitioners in the exercise of their professional practice" is a comment on the scope of the SUSMP to place controls on the advice of professional practitioners. The location of use of a chemical substance, whether in-clinic or at home, is not intended to be controlled through the SUSMP. Limitations on the location of use would be applied through the policies of professional practice boards or relevant regulatory authorities (including, but not limited to, the Australian Competition and Consumer Commission).