

Pseudoephedrine Rescheduling – Information for Sponsors

The National Drugs and Poisons Schedule Committee (NDPSC), at its June 2005 meeting made the following decision:

DECISION 2005/44 – 23

On the basis of the available information and in the interest of public health and safety, the Committee agreed to reschedule all pseudoephedrine products to S4, with a cut-off to S3 for liquid preparations containing 800 mg pseudoephedrine hydrochloride (or its equivalent) or less per pack or for other preparations containing 720 mg pseudoephedrine hydrochloride (or its equivalent) or less per pack.

Information on the background and reasons for this decision are available at <http://www.tga.gov.au/ndpsc/record/rr200506.pdf>.

The NDPSC at the October 2005 meeting varied the decision to allow for implementation in 2 stages [*DECISION 2005/45-9 (Variation to Decision 2005/44 – 23)*] – refer <http://www.tga.gov.au/ndpsc/record/rr200510.pdf>.

The decisions have the effect of removing all pseudoephedrine-containing medicines from Schedule 2 of the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP), from 1 January 2006. These products will all initially be included Schedule 3.

From 1 April 2006, all liquid preparations containing more than 800 mg of pseudoephedrine and all other preparations containing more than 720 mg of pseudoephedrine will be rescheduled to Schedule 4.

It is a regulatory requirement that all medicines included in Schedules 3 and 4 of the SUSDP have product information (PI) and consumer medicine information (CMI) documents. Given the limited timeframe for implementation of the changes and the numbers of products affected, the TGA has made the following arrangements, in consultation with the Australian Self-Medication Industry (ASMI), to assist sponsors in lodging the necessary documentation.

Lodging applications

The Drug Safety & Evaluation Branch (DSEB) has agreed that the OTC Medicines Section (OTCMS) should evaluate/process applications for all pseudoephedrine-containing products that need to be updated as a result of the scheduling changes coming into effect on 1 April 2006.

Applications should be made using the OTC Products Application Lodgement (OPAL) system, unless the product record contains information flagged as confidential from sponsor, or a specific exemption is obtained from the OTCMS. In these cases, applications may be made using the paper OTC medicines variation form.

PI documents

The TGA and the ASMI have developed core PI documents based on information in standard reference texts and previously evaluated and approved PIs for the following ingredients:

- [Bromhexine](#)
- [Codeine](#)
- [Dextromethorphan](#)
- [Guaiphenesin](#)
- [Ibuprofen](#)
- [Paracetamol](#)
- [Pholcodine](#)
- [Pseudoephedrine](#)
- [Sedating antihistamines](#) – chlorpheniramine maleate, dexchlorpheniramine maleate, diphenhydramine hydrochloride, doxylamine succinate, promethazine hydrochloride and triprolidine hydrochloride

These core PI documents are also available from the ASMI's website (<http://www.asmi.com.au/PseudoephedrineCMIetc.htm>).

Where a product does not have a PI document that has previously been approved by the TGA, sponsors may obtain clearance for the introduction of a PI document by way of notification (change code DPS) provided all of the following conditions are met:

- an assurance that the PI is consistent with the relevant core PI documents (see above);
- an assurance that the PI is consistent with the information on the existing product label;
- copies of the existing label and the proposed PI are submitted with the hard copy application.

The cost of the notification will be \$790.

If any of the above conditions are not met, sponsors must apply for approval of the PI (as would usually be the case) and pay the variation evaluation fee (\$1900) in addition to the application fee (\$790).

CMI documents

The ASMI has developed core CMI documents. These are available from the ASMI web site (www.asmi.com.au).

Where the CMI is NOT supplied as package insert, if:

- the CMI complies with Schedule 13 of the Regulations; and
- the CMI is consistent with either an existing approved PI or a core PI document (see above);

there is no need for notification or prior approval of the proposed CMI. It is the sponsor's responsibility to ensure that all requirements are met. If either of the above criteria is not met, the sponsor must submit an application as outlined below.

Where the CMI is supplied as a package insert (or one of the other criteria above are not met), sponsors may introduce a CMI document by way of notification (change code CPS) where all of the following are provided:

- an assurance that the CMI is consistent with either an approved PI for the product or with a draft PI based on the TGA/ASMI core PI and for which application has been lodged (as above, either separately or together with this application);
- an assurance that the CMI is consistent with the information on the existing label for the product; and
- copies of the existing label, approved or proposed PI and proposed CMI are submitted with the hard copy application.

The cost of the notification will be \$790. If any of the above conditions are not met, the sponsor must apply for approval of the CMI (as would normally be the case) and pay the variation evaluation fee (\$1900) in addition to the application fee (\$790).

How to put together the PI

Start with the 'Template' PI then add in the relevant text from the core PI for each active ingredient and the relevant information as indicated in the template. The text from the core PIs must not be changed.

Enquiries

Enquiries should be made to the OTC Medicines Section (freecall 1800 616 011) or e-mail OTC.medicines@health.gov.au.