



5 May 2014

ASMI Response - TGA OTC Cough medicines for oral use Proposed advisory statements for medicines

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI appreciates the opportunity to respond to the consultation paper on the proposed advisory statements for OTC cough medicines for oral use.

TGA proposed warning statement – “If [coughing/symptoms] persist or worsen(s), consult your doctor or pharmacist.

ASMI supports the inclusion of a statement on labelling that advises consumers to seek advice from their doctor or pharmacist if their symptoms persist or worsen.

Although there is some variation on the exact wording of the warning statements, most sponsors currently have a similarly worded statement on labelling, i.e. words to the effect of:

“If symptoms persist, consult your healthcare practitioner”, or

“If symptoms persist, consult your doctor or pharmacist”, or

“If symptoms persist, seek advice from a health care practitioner”, which is currently RASML statement no. 77.

“If cough persists, see your doctor or pharmacist”

Despite the considerable variation in the exact wording of the existing warning statements, ASMI notes that there is no evidence showing that the variety of existing, differently worded warning statements has resulted in any safety concerns and consumers generally intuitively know that they should seek medical advice if their condition does not improve. OTC cough medicines are indicated for “temporary relief” of coughs, which in itself conveys the message that these products should not be used for persistent symptoms or conditions of long duration. As the consultation states, the RASML proposal has resulted from the draft OTC Monograph for Pholcodine (rather than any demonstrated safety concerns), and is being extended to the various other cough active ingredients in order to achieve consistency.

ASMI understands that the TGA has previously stated in letters to sponsors following the review of cough and cold products for children, that the terms “health care practitioner” or “health professional” are not substitutes for “doctor or pharmacist”, and ASMI does not object to this wording. However, it could be argued that the statement “If cough/symptoms persist” is actually a stricter warning than “If cough/symptoms persist or worsen”. A worsening cough may also be considered synonymous with, or a subset of a persistent cough, so ASMI believes sponsors should be given the option to use an alternative statement such as:

“If [coughing/symptoms] [persist/persist or worsen] consult your doctor or pharmacist”

ASMI does not believe that this alternatively worded statement will have any impact on consumer safety. Since the statement may already be in use by most sponsors on existing labelling, it could in some cases

mean that existing labelling statements would be compliant and that no regulatory action would be needed as a result of this RASML consultation for these sponsors.

Transitional arrangements

ASMI requests a 2 year transitional period, or alternatively allow these changes to be introduced together with the proposed updates to the Therapeutic Goods Order for labelling & packaging, as cough and cold products have recently had label changes following the TGA's review of cough & cold medicines in children during 2012. This will mean that sponsors could make one set of labelling changes rather than two. Sponsors will incur significant costs by requiring an additional two rounds of labelling changes resulting from this consultation together with changes to the TGO 69.

Some sponsors market many different OTC cough medicine brands, in a number of pack sizes. These sponsors in particular will incur additional, unexpected costs as a result of labelling changes following any changes to RASML.

Conclusion

ASMI appreciates the opportunity to comment on this consultation paper, and supports the requirement for labelling of OTC cough medicines to include a statement advising consumers to seek medical or pharmacist advice if their condition persists.

ASMI proposes a slight variation in wording, which would result in most sponsors' labelling of cough medicines being compliant and not require specific labelling changes as a result of this RASML proposal. In the event that labelling changes are needed, ASMI requests that a two year transition be allowed, or that the changes may be made with the TGO 69 review, in order to avoid multiple labelling changes to products which have only recently had labelling updates as a result of the TGA's review of cough and cold medicines in children.