18 March 2015

RASML Officer
OTC Medicines Evaluation
Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

Consultation Response - Non-steroidal anti-inflammatory drugs for oral use: proposed additional advisory statements for medicines

ASMI 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. For ASMI’s members please see our website.

ASMI welcome this Required Advisory Statements for Medicine Labels (RASML) consultation on the wording of proposed advisory statements for OTC oral non-steroidal anti-inflammatory drugs (NSAIDs): diclofenac, flurbiprofen, ibuprofen, ketoprofen, mefenamic acid and naproxen, arising from the outcomes of the recent reviews of the cardiovascular safety of NSAIDs and the safety of diclofenac. We note the proposal for their inclusion in the next update to the RASML document. We also note that as we’d anticipated, the outcomes of the review have been extended to the other oral dose substances in the OTC NSAIDs class: flurbiprofen, ketoprofen and mefenamic acid. And we note the proposal of the 12 months allowance for transition previously typical for RASML.

We are pleased the TGA has noted the requests that broad consultation be undertaken with stakeholders on the precise wording for new labelling statements prior to implementation. This is an important learning from previous reviews where we have found that the wording of an imposed statement applied to existing products on the market is subsequently improved after the outcomes of the consultation for inclusion in the RASML – requiring existing products to update their labels twice.

ASMI is supportive of the proposed new advisory statements for:

1. The labels of oral medicines containing flurbiprofen, ibuprofen, ketoprofen, mefenamic acid or naproxen - to the effect that ‘excessive or prolonged use can increase the risk of heart attack or stroke’.

2. The labels of oral medicines containing diclofenac - to the effect that ‘excessive or prolonged use can increase the risk of heart attack, stroke or liver damage’.

However we suggest in the context of the RASML statement entry the use of the term ‘oral medicines’ should be amended to ‘medicines for internal use’. The RASML and the SUSMP include the definition for ‘internal use’ but not a definition for ‘oral use’, ‘oral dose’ or ‘oral medicine’.
“Internal use” means administration:
(a) orally, except for topical effect in the mouth; or
(b) for absorption and the production of a systemic effect;
   (i) by way of a body orifice other than the mouth; or
   (ii) parenterally, other than by application to unbroken skin.

This consistent use of terminology will provide clarity and assist interpretation.

We welcome this pragmatic and balanced approach to achieving a quality use of medicines outcome for these OTC medicines. It recognises the importance of communicating to the consumer at the point of purchase and the need for clear succinct communication in consumer friendly terms. The proposed additional statements are brief. They are directed to all consumers regardless of whether they might carry the cardiovascular risk factors. This is preferable to attempting complex wording statements to call out all the possible risk factors which are often difficult for the consumer to read, understand and to recognise that it is applicable to them. We believe the proposed statements should stand as a strong deterrent to inappropriate use.

Members accept the extension of the outcomes of the review of cardiovascular safety of NSAIDs to the other substances in the OTC NSAIDs class; flurbiprofen, ketoprofen and mefenamic acid.

We note that some of our members already include very similar wording and while there is accommodation of ‘words to the effect’, they have concerns whether the wording will be considered equivalent by an evaluator now and into the future. They would therefore appreciate advice of whether the existing statement ‘Long term continuous use may increase the risk of heart attack or stroke.’ – will equally address the concerns of the review and therefore whether this wording might be included in the RASML as an alternative. This understanding is vital to their planning for compliance. They will otherwise not receive this advice and would need to submit existing labelling to receive a determination on the acceptability of the wording. Advice of acceptability might otherwise be achieved by provision of formal written advice to the sponsor as an outcome of the consultation.

The consultation paper was noted to be silent on the need for the inclusion of the proposed warning statement on paediatric specific products. ASMI would suggest that the same prevalence of CV risk factors in adults is less likely in children under 12 years of age. Children are unlikely to be at risk of taking these medicines for long periods or at higher doses than needed, being supervised by their parents/caregivers. The paediatric medicines are only available in Pharmacy and their sale is typically supervised. A dosing device is typically provided for appropriate measurement of the dose. We therefore suggest that the risk to the paediatric population would be reduced and therefore the inclusion of these statements in the RASML paediatric specific entries might be a cause of unnecessary alarm for parents.

These changes unfortunately are timed just as the majority of our members have completed the labelling update to comply with RASML No.2 of the Medicines Advisory Statement Specification 2014 (MASS 2014). This means they will need to initiate this update as a new change in their systems and will not be able to expedite the timeframe for implementation. Only two of our members are in a position to halt their implementation of the MASS 2014 to allow them to combine the updates as a single change. This of course may require some Section 14 application for exemption for compliance with the MASS 2014 transition timing.

The TGA should allow an adequate transition period for the implementation of the changes. Our members advise a timeframe of 18 months is realistic and even then may require some Section 14 exemption applications to manage slower moving products or products with seasonal dependencies (e.g. Cold and Flu).

ASMI would be willing to assist in providing feedback on any accompanying educational support materials planned to accompany the introduction of these new statements closer to their commencement on pack.
Thank you for this opportunity for consultation of these statements. We hope our comments are constructive and assist in an effective update of the RASML and OTC oral dose NSAID product labelling.