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RASML Officer
Office of Scientific Evaluation
Therapeutic Goods Administration
PO Box 100
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Submitted via upload facility

Dear Sir / Madam,

Consultation: Proposed additional advisory statements for medicines containing benzocaine for topical oral use (except lozenges)

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. Further information about ASMI and ASMI members is available on our website (www.asmi.com.au).

ASMI values this opportunity to provide comment on the proposed warning statement for medicines for topical oral use that contain benzocaine.

ASMI Comment:

ASMI supports the TGA's proposed entry No. 4 and required statement (shown in red), contraindicating use of these products in children under the age of 2.

Column 1 - Substance	Column 2 - Conditions	Column 3 – Required statement
Benzocaine (Entry 4 of 4)	In preparations for topical oral use except lozenges	Do not give to children under 2 years of age

There are no benzocaine containing infant teething products on the ARTG, so the risk of these products being selected by consumers for use in this age group is very low. ASMI believes that the above statement is an appropriate warning statement for the labelling of benzocaine containing products for topical oral use.

ASMI hope that this feedback is constructive. Please contact me if you have any further queries.

Yours sincerely

[Redacted signature]