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9th January 2014

RASML Officer
OTC Medicines Evaluation Section
Office of Medicines Authorisation
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Dear Sir or Madam,

Re: Consultation: Chloramphenicol, propamidine, dibromopropamidine and sulfacetamide for ophthalmic use: proposed advisory statements for medicines.

Thank you for the opportunity to comment on the consultation to include advisory statements for chloramphenicol, propamidine, dibromopropamidine and sulfacetamide in the next update of RASML.

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 supports the proposed advisory statements. Please also see additional comments as shown in the tables below:

Proposed advisory statements for chloramphenicol:

Conditions	Required advisory statements	Comments
In medicines for ophthalmic use	Contact lens wearers should not use this product except on the advice of a doctor or optometrist	ASMI supports the inclusion of this statement. ASMI also requests that sponsors be allowed some flexibility with the way the statement is expressed or worded, for example: <i>"Do not use if you are a contact lens wearer, except on the advice of a doctor or optometrist"</i> should also be allowed so that the statement can be used with the "Do not use" sub-headings commonly used in consumer-focused labelling.
	If your eye infection does not start to improve within 48 hours, seek immediate medical advice	ASMI supports the inclusion of this statement.

	Do not use in children under 2 years of age, except on medical advice	ASMI supports the inclusion of this statement.
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Proposed advisory statements for propamidine, dibromopropamidine, sulfacetamide:

Conditions	Required advisory statements	Comments
In medicines for ophthalmic use	Contact lens wearers should not use this product except on the advice of a doctor or optometrist	ASMI supports the inclusion of this statement. ASMI also requests that sponsors be allowed some flexibility with the way the statement is expressed or worded, for example: <i>“Do not use if you are a contact lens wearer, except on the advice of a doctor or optometrist”</i> should also be allowed so that the statement can be used with the <i>“Do not use”</i> sub-headings commonly used in consumer-focussed labelling.
	If your eye infection does not start to improve within 48 hours, seek immediate medical advice	ASMI supports the inclusion of this statement.

ASMI believes that the proposed advisory statements will contribute to safer use of antibacterial / antimicrobial eye drops by consumers.

We note that RASML allows the wording of statements to be varied provided that the intent of the wording is not changed (RASML September 2008; section 1, p.20). We therefore trust that sponsors will continue to be able to vary the wording of these statements on labelling, in particular so that statements may be used with the appropriate sub-headings used in consumer focussed labelling.

Please contact me should you have any further queries,

Yours sincerely,

