



10 January 2014

Comments by the Pharmacy Guild of Australia on Proposed advisory statements for medicines – Chloramphenicol, Propamidine, Dibromopropamidine and Sulfacetamide

Background

The Pharmacy Guild of Australia welcomes the opportunity to comment on the proposed advisory statements for chloramphenicol, propamidine, dibromopropamidine and sulfacetamide prepared by the Therapeutic Goods Administration (TGA).

Pharmacy assistants must complete appropriate training regarding Schedule 2 and Schedule 3 medicines as part of the Quality Care Pharmacy Program (QCPP) accreditation and since April 2010, refresher training for pharmacy assistants, focused on appropriately applying Pharmacy Medicines and Pharmacist Only Medicines professional supply protocols, has been required for QCPP re-accreditation.

Pharmacists are experienced in triaging patients and referring for further medical support when required. The availability of professional support materials for pharmacists assists in maintaining and improving this competency.

While advisory statements provide an additional risk management option to ensure consumers have access to important information about the safe and appropriate use of a medicine, they do not replace interaction with, and counselling from a pharmacist.

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Proposals

Proposed advisory statements for chloramphenicol, propamidine, dibromopropamidine and sulfacetamide:

Table 1: Proposed advisory statements for chloramphenicol

Conditions	Required advisory statement(s)
In medicines for ophthalmic use	<i>Contact lens wearers should not use this product except on the advice of a doctor or optometrist</i>
	<i>If your eye infection does not start to improve within 48 hours, seek immediate medical advice</i>
	<i>Do not use in children under 2 years of age except on medical advice</i>

Table 2: Proposed advisory statements for propamidine

Conditions	Required advisory statement(s)
In medicines for ophthalmic use	<i>Contact lens wearers should not use this product except on the advice of a doctor or optometrist</i>
	<i>If your eye infection does not start to improve within 48 hours, seek immediate medical advice</i>

Table 3: Proposed advisory statements for dibromopropamidine

Conditions	Required advisory statement(s)
In medicines for ophthalmic use	<i>Contact lens wearers should not use this product except on the advice of a doctor or optometrist</i>
	<i>If your eye infection does not start to improve within 48 hours, seek immediate medical advice</i>

Table 4: Proposed advisory statements for sulfacetamide

Conditions	Required advisory statement(s)
In medicines for ophthalmic use	<i>Contact lens wearers should not use this product except on the advice of a doctor or optometrist</i>
	<i>If your eye infection does not start to improve within 48 hours, seek immediate medical advice</i>

Comments

Chloramphenicol

Since chloramphenicol is a Schedule 3 medicine, pharmacists assess the safety and appropriateness of non-prescription supply and counsel as appropriate.

The Guild supports the inclusion of the three advisory statements proposed by the TGA. A minor variation the Guild suggests to the advisory statement is removing “start to” from the second proposed statement.

Current wording of statement: *If your eye infection does not **start to** improve within 48 hours, seek immediate medical advice*

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Proposed alternate wording: *If your eye infection does not improve within 48 hours, seek immediate medical advice*

The phrase “start to” is effectively redundant and does not provide any additional information to the patient.

The proposed alternate wording is more concise and is consistent with the precautionary wording recommended in UK’s electronic Medicines Compendium ⁱ It may also reduce the likelihood patients with more serious eye conditions will delay seeking medical treatment.

In addition, the Guild proposes the addition of the following statement

- *Do not use for more than 5 days in total except on medical advice*

As chloramphenicol is an antibiotic, the prolonged use of the product may occasionally result in overgrowth of non-susceptible organisms, including fungi.ⁱⁱ

In addition, chloramphenicol is absorbed systemically from the eye and toxicity has been reported following chronic exposure.ⁱⁱⁱ Bone marrow hypoplasia, including aplastic anaemia and death, has been reported following topical use of chloramphenicol. As such, the Guild feels it is important including this advisory statement.

Propamidine

The Guild supports the inclusion of the two advisory statements proposed by the TGA. As mentioned above, the Guild believes the second statement should be amended to remove the words “start to”.

Dibromopropamidine

The Guild supports the inclusion of the two advisory statements proposed by the TGA. As mentioned above, the Guild believes the second statement should be amended to remove the words “start to”.

Sulfacetamide

The Guild supports the inclusion of the two advisory statements proposed by the TGA. As mentioned above, the Guild believes the second statement should be amended to remove the words “start to”.

ⁱ <http://www.medicines.org.uk/emc/medicine/25612/SPC>

ⁱⁱ [IBID](#)

ⁱⁱⁱ [IBID](#)