Ken Harvey: The risks from vague medicine labels

TWO cases of salicylate intoxication caused by infant teething gels containing choline salicylate were reported last month in MJA InSight, following publication of “Lessons from Practice” in the MJA.

The authors noted that dosing this gel directly from the tube is potentially inaccurate, increasing the risk of it causing chronic toxicity. They also recommended that a warning label should be added to these products.

In fact, the Therapeutic Goods Administration (TGA) is currently conducting a consultation on “Required Advisory Statements for Medicine Labels (RASML)”. This includes proposals for new labelling for all non-prescription medicines containing choline salicylate. Unfortunately, this information is buried on page 36 of a 49-page document and so, not surprisingly, I initially missed the relevance of this RASML consultation to the MJA article.

The RASML review has invited comment from five industry associations; two pharmacy organisations and one consumer group — but NO medical or public health organisations. This omission is despite the fact that it has been health professionals who have reported Australian and New Zealand cases of salicylate intoxication caused by infant teething gels.

When I bought a pack of teething gel containing salicylate last week, the directions and warnings on the pack were covered by a pharmacy label (see image). This seems to regularly happen in pharmacies.

However, directions and warnings were printed on the tube and stated: “Directions: Wash your hands, apply enough Bonjela gel to cover the tip of your index finger, rub well into the affected area every 3 hours when necessary. Warnings: Do not apply more than once every 3 hours. Do not exceed the stated dose. Not suitable for babies under 4 months. If symptoms persist seek medical or dental advice.”

The new warning proposed by RASML states: “Do not exceed the recommended dose. Excessive or prolonged use can be harmful”.

Both the old “stated dose” and the proposed “recommended dose” label warnings are ambiguous and unhelpful.

What is the recommended dose? For example, the “dose” obtained by covering the tip of my index finger would be at least double that obtained from my wife’s finger. And with the proposed labelling, what does “excessive” and/or “prolonged” use mean?

Given that no duration of treatment is mentioned on either the old or the proposed label it’s understandable that the parents of the two children mentioned in the recent MJA article kept using choline salicylate teething gels for several months. It is also likely that other parents may do this regardless of the benign additional warning proposed for the label.

In order to prevent future cases of salicylate intoxication from teething gels containing choline salicylate, shouldn’t both the dose and the duration of use for these products be better defined?

Asking these specific questions would be more likely to produce an informed response for the TGA RASML consultation, especially if a medical professional organisation were included to provide input.

A number of submissions to the TGA Transparency Review, which was announced at the end of last year, have suggested that the TGA proactively initiate debate on such matters using online and web resources for health professionals, such as MJA InSight, and online consumer forums.

Ironically, in 2009, the UK the Medicines and Healthcare Products Regulatory Agency advised that teething gels containing salicylate salts were no longer indicated in children under 16 years of age. As a result, the sponsor of Bonjela reformulated the UK product eliminating choline salicylate.

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That approach certainly eliminates debate over labelling subtleties!

Dr Ken Harvey is an adjunct senior lecturer at the School of Public Health, La Trobe University, and the CHOICE consumer representative on the TGA Transparency Review Panel.

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Dear RASML Document Manager/OTC Medicines,

The MJA Insight article (and associated comments) "The risks from vague medicine labels" is relevant to your review.

See:

Please acknowledge receipt of this material as a submission.

Cheers

Ken

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