

JOINT INTERIM EXPERT ADVISORY COMMITTEE ON STANDARDS

Questions and Answers on Draft Managing Director's Order on Child-Resistant Packaging

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Who were the Members of the TGC’s specialist Subcommittee on Child-Resistant Packaging?

A Chairperson who is a Member of the Therapeutic Goods Committee	A/Professor Loraine Holley Associate Professor, Faculty of Science, University of Technology, Sydney
A Member with expertise in child-resistant packaging technologies	Mr John Staton Technical Consultancy Services Pty Ltd Rockdale NSW
Two Members with expertise in the packaging of medicines, one each from Australia and New Zealand	<ul style="list-style-type: none"> • Mr Stewart Jackson Packaging Development Manager GlaxoSmithKline Consumer Healthcare Australia • Mr Philip Morrish General Manager, Quality Healthcare Manufacturing Group New Zealand
Two Members with expertise in poisons information, one each from Australia and New Zealand	<ul style="list-style-type: none"> • Dr Ron Somers Injury Surveillance and Control Unit Epidemiology Branch SA Department of Human Services • Dr Wayne Temple Director, National Poisons Centre New Zealand
A physician with knowledge of poisons	A/Professor Henry Kilham Deputy Medical Director NSW Poisons Information Centre Head of Academic and General Medicine at the Children’s Hospital at Westmead and A/Professor in the Discipline of Paediatrics and Child Health, University of Sydney.
A Member with expertise in the consumer use of medicines	Ms Alison Marcus
Joint Interim Expert Advisory Committee on Standards representative (corresponding member)	A/Professor Nick Holford Department of Pharmacology and Clinical Pharmacology, University of Auckland

What were the Terms of Reference of the Subcommittee?

Under its Terms of Reference (TOR), the Subcommittee was to:

- Define the criteria that determine which substances require child-resistant packaging;
- Develop a consolidated list of substances for which child-resistant packaging is considered necessary taking account of those substances currently required to have child-resistant or safety packaging in Australia and/or New Zealand and applying the criteria determined above to other potentially hazardous therapeutic products;
- Review national and international Standards for child-resistant packaging and/or safety packaging and recommend those Standards that might be suitable for adoption;
- Consider issues related to the child-resistant packaging of therapeutic products that are of concern to injury prevention agencies and health departments, including the performance of blister packaging as a child-resistant barrier; and
- Develop a draft order on child-resistant packaging for review by the JIEACS and subsequent release by that Committee for stakeholder consultation in Australia and New Zealand.

On what basis have substances been included in the First Schedule?

The criteria and principles intended for use in determining which substances require CRP are stated in the 'Introduction' to the draft Order.

Preparation of the First Schedule took into account a gap analysis of current Australian and New Zealand requirements, submissions made to the Subcommittee by health departments and injury prevention agencies, information from Poisons Information Centres in Australia and the NZ National Poisons Centre, and knowledge and experience of Subcommittee Members.

The Subcommittee recognised the need to include all substances with high toxicity, even if only present in products with infrequent use, and also the fact that instances of accidental poisoning can occur with discontinued products that remain in household medicine cupboards.

A conservative approach was taken in the development of the First Schedule, and hence the Subcommittee requested that stakeholders be invited to submit evidence to support exclusion of specific substances if this is believed to be justified.

Why are class entries used in the First Schedule?

The use of class entries to specify substances for which CRP is required has the advantage of there being an automatic requirement for CRP for new drugs within the specified class, with no lag time. It provides clarity to industry on packaging expectations and to the regulator early in the application / evaluation process.

How are class entries named?

Consistency is sought in the naming of classes through use of terminology from the World Health Organization Anatomical Therapeutic Chemical (ATC) classification system.

What do class entries include?

Class entries include all substances within the class whether named or not. However, as classes may include substances with dissimilar toxicity, specific substances can be excluded from a class entry by exception.

Because discontinued products may be present in some homes, and substances currently exempt from requirements due to dose form or presentation may be marketed in new dose forms or presentations in the future, each class entry includes for reference purposes as complete a list as possible of substances within that class.

What if my product contains a substance listed under a specific class, but is indicated for another use?

Requirements for CRP are independent of indication. Therefore, any substance named in the First Schedule under a specific class is required to have CRP (unless a general exception exists for the dose form, particular presentation or circumstances) even if licensed for an indication not consistent with the class under which the substance has been named.

If a substance is included in the First Schedule, is CRP required for all pack sizes?

Yes. The intent of the guideline on toxicity is that, if a substance is marketed in any pack size that meets the criteria, then every pack size of that substance requires CRP. Only with rare exception does the Order differentiate between products containing the same substance on the basis of pack size.

If a substance is included in the First Schedule, is CRP required for all dosage forms and presentations?

No. The draft Order includes (Clause 3) a number of general exceptions to CRP requirements. These exceptions are based on the assessment that some dose forms, presentations or circumstances of use result in a reduced risk of accidental ingestion of the product by children, or there being minimal availability of the product to children. For example, dose forms such as injections, products not at their final stage of manufacture and products only used in hospitals or nursing homes would all have minimal availability to children.

To accommodate dispensing practice in NZ (which often involves decanting from bulk containers), general exceptions have been included for bulk packs of both liquid preparations and solid dosage units provided these are for dispensing purposes only and not for retail sale.

Will the First Schedule be updated over time?

Yes. A proactive approach to the identification of substances which may present a hazard to children, and which therefore warrant CRP, is considered essential. It is therefore intended that the expert advisory committee on standards will review, on an annual basis, the need for new substances to be packaged with CRP, and any new information relevant to the potential hazard presented by existing substances.

What sort of CRP can be used?

The selection of appropriate CRP rests entirely with the product licence holder and should take into account normal packaging considerations such as stability and maintenance of product quality.

If reclosable CRP is used, it must comply in all respects with at least one of the national or international Standards nominated under Clause 6(1) of the draft Order and the product licence holder must hold evidence that establishes this. The selected CRP must also comply with all of the general requirements specified in Clause 5.

If non-reclosable CRP such as blister or foil strip packaging is used, the packaging must comply with the requirements of Clause 7 of the draft Order as well as the general requirements specified in Clause 5.

What is the status of CRP previously approved by the Agencies or complying with superseded editions of Standards?

Under the ANZTPA, reclosable CRP previously approved on the basis of compliance with superseded editions of Standards will no longer be accepted because of the concern that such packaging may not perform as well as packaging meeting the requirements of contemporary Standards.

Therefore during the transition period for obtaining an ANZTPA product licence, product licence holders using such CRP will need to either obtain evidence of certification against the current editions of Standards or move to packaging systems for which such certification exists.

Where a new edition of a Standard differs only in relation to one of the panel tests (for example, the adult panel test) then conduct of only that one panel test is required and the results of the alternate panel test (ie the child panel test) undertaken in accordance with the previous edition of the Standard would remain valid.

Does every combination of closure and container need to be tested?

No. In many cases, where testing in accordance with a Standard has been conducted on one combination of container and closure, the nominated Standard permits extrapolation of the results to a range of container and/or closure sizes. The ANZTPA will accept extrapolation within the parameters set by the nominated Standards. It is intended that further guidance on this matter will be issued by the Authority in due course.

Is non-reclosable CRP such as blister or strip packaging required to comply with any specified Standards?

Non-reclosable packaging used to meet CRP requirements must comply with the requirements given in Clause 7 of the draft Order. There is no requirement at present for it to comply with any particular Standard(s) for non-reclosable CRP that involves child and adult panel tests. However, product licence holders should consider the need for improvements in non-reclosable packaging in order to enhance its child-resistant properties, and note that mandatory compliance with available national or international Standards for non-reclosable CRP will be considered in the future. Product licence holders are therefore encouraged to move voluntarily towards achieving compliance with these Standards.