Queensland Injury Surveillance Unit

Mater Hospital
Lvl 1 Whitty Building
Raymond Terrace
South Brisbane, Qld 4101

20th August, 2012

Dear Sir/ Madam,

Re: TGA Medicine Labelling and Packaging Review

I would like to take the opportunity to comment, not on the proposed scope of changes currently under consideration, but on the 'outside of scope' issues raised within the labelling and packaging review document; **in particular the review of TGA 80 Child Resistant Packaging for Medicines.**

I am an emergency paediatrician, director of the Queensland Injury Surveillance Unit (QISU) and a member of the Standards Australia committee for child resistant packaging: HE-016. As such, I have experience in assessing and treating children following poisoning incidents, collating and analysing injury data and designing systems for poisoning prevention.

I have been advocating for improvements in the functionality of child resistant packaging for some years and would like to highlight some of the failings of the current packaging systems for urgent consideration.

Non-reclosable child resistant packaging (Blister packs)

In 2008, QISU together with the Queensland Poisons Information Centre, co-produced an injury bulletin addressing the issue of toddler medicinal poisoning, with a focus on **solid poisoning and packaging**.

The bulletin can be found at: http://www.qisu.org.au/ModCoreFilesUploaded/Bulletin_10189.pdf

This **solid poisoning** data has demonstrated that **for the majority of toxic medicinal exposures amongst toddlers, the medicine was accessed from a blister pack (79%)** as opposed to a bottle with simple cap, bottle with child resistant cap (CR), dosette box or multi-dose pharmacy pack.

Following considerable lobbying from child safety advocates, the new Australian Standard for child resistant non-reclosable packaging (blister packs) for pharmaceuticals was developed by the HE-016 committee and **published in June 2010**.

It is now more than 2 years since this standard was published, and I have been attempting to follow the progress of its potential implementation by the TGA with little success.

Research by the Consumer Product Safety Committee (CPSC) has shown that toddlers, given unlimited access to tablets in standard blister packs, are able to unpack up to 85 tablets in 5 minutes, so the risk is clear. There are manufacturers ready with post-production solutions, such as individual adhesive covers for blister packaging, so a solution is at hand. Yet my most recent response from the TGA was that the implementation of this standard required further review and a regulatory impact assessment and that **it 'was not inevitable that this standard would be implemented',** indicating to me that expediency may prevail over child safety.

Reclosable Child Resistant Packaging

My experience from treating children in the emergency department is that consumer and health professional awareness of the scheduling, performance limitations and failures associated with child resistant caps (CRCs) is poor:

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1. CRCs are commonly incorrectly referred to as 'child-proof caps', and consumers are surprised to hear that the caps still pass testing if 20% of tested toddlers can access the contents.

2. The presence or absence of a CRC on a pharmaceutical product does not align with the potential toxicity of the contents. For example, CRCs are present on many paediatric preparations where the risk of toxicity following exposure is very low (such as many penicillin based antibiotic syrups), and not present on other products where the risk is high (such as 200 ml containers of eucalyptus oil). Therefore, consumers cannot rely on the regulatory discretion of the TGA (under the current working order 80) nor the packaging selection of the company to guide their risk management strategies.

3. Many parents believe that the CRC is activated when they close the cap and hear/ feel a click. However, this click is not an indication that the CRC mechanism has engaged and many caps require an additional rotation to the point where no more rotation is felt in order to activate the CRC. Some caps require downward pressure both to close and activate the CRC as well as to unlock and open it. **Therefore, the functionality and engagement of the CRC mechanism is not apparent to the consumer.**

4. CRC testing is completed prior to the manufacturing process. Unless the company has a post-production quality assurance process, **CRC functionality is not assessed during the lifetime of the production of that product**. This is not required under Australian law.

In the context of my HE-016 committee work, I have advocated for a defined point of closure for reclosable child resistant packaging (point 3) and a post production quality assurance process. The risk associated with a lack of post production quality assurance is evidenced by the following:

In April 2012, I raised a product safety alert with the TGA following an ingestion incident where a 6 year old autistic boy accessed Lithium tablets. The container in question (when assessed by me in the emergency department) had a CRC that did not engage. Despite the fact that I had raised a complaint with the TGA and with the sponsor company in question, several phone calls were required to obtain any response

My understanding of the investigation process following my complaints is that, despite the sponsor company admitting to having had 3 other similar complaints in 4 years, that this did not represent a sufficient signal to warrant any further action, either by the company or by the TGA.

Consumers are generally not aware of the functionality, nor failings of CRC mechanisms, and therefore reports to the TGA in the event of CRC failure are likely to be few. My investigations through local pharmacies revealed that CRC failure was prevalent amongst other similar Lithium containers. The company, having reviewed their retained batches, also admitted that the cap did not reliably engage, but reiterated that their sponsored product complied with all of the necessary requirements. Whilst I acknowledged that this was probably so, **the fact remains, that the product in the market place did not function as intended.**

Therefore, a company that sponsors the importation and sale of a potentially toxic medication, when informed that their product has a non-functioning CRC, rather than initiating a product assessment and (if required) recall, cites the overseas pre-production testing and certification of CRC compliance to demonstrate that they have met their Australian consumer safety obligations.

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To date, I have been able to identify 14 cases of children 6 years or under who have ingested Lithium tablets in the last few years: 8 in one jurisdiction (2007-2012), 5 in another (2009-2012) and another single case in April, 2012. One jurisdiction is still to report. Of these, 8 cases have been Lithium provided by the company in question. Mechanism of access to medication is not routinely recorded by the four Australian Poisons Information Centres. In some instances, it is not known. In many situations, call volumes and clinical priorities take precedence over additional data collection. It is clear that brand details and mechanism of access to poisons would better inform pharmaceutical safety regulators, however, there appears to be little regulator interest in supporting poisons centres to collect this data.

In contrast to this , I am pleased to see that, according to the current TGA alert, male urinal bottles are to be checked for sharp edges by 'health professionals', following an incident where a male patient sustained lacerations when using this product. I wonder whether this information has been passed to the relevant 'health professionals' in question, as this is a role almost exclusively performed by nursing staff who are unlikely to subscribe to email alerts from the TGA. Similarly, one would hope that the manufacturer in question now has a quality assurance system to ensure the future safety of male members.

Sarcasm aside, it is time that the issue of child resistant packaging received some logical consideration, closely followed by appropriate action.

I call on the TGA to reconvene the packaging and labelling committee to review the 'out of scope' issue of child resistant packaging for pharmaceuticals. This would require the following:

- Analysis of pharmaceutical agents available on the Australian market with the potential to cause significant toxicity to young children if exposed
- Review and updating of working order 80 (current requirements for child resistant packaging of pharmaceuticals) based on the above analysis
- Establish a system to regularly update working order 80 based on market availability of product and exposure data
- Review of effectiveness of current quality assurance mechanisms for child resistant packaging
- Review of effectiveness of reporting and investigation mechanisms following failure of child resistant packaging

Yours sincerely,

Dr Ruth Barker

Emergency Paediatrician, Mater Children Hospital

Director, Queensland Injury Surveillance Unit