NSW poisons Information Centre
the children's hospital at Westmead

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TGA Medicines Labelling Review

The NSW Poisons Information Centre (NSW PIC) is the largest Australian Poisons Information Centre with main coverage of New South Wales, Tasmania and the Australian Capital Territory; and after-hours coverage of the rest of Australia. Approximately 105,000 calls are handled per year, which is almost half of the nations calls. The Poisons Information Centre is a 24-hour service providing advice on the management of suspected and known poisonings and an after-hours drug information service.

There has been a limited amount of research done from Australian Poisons Information Centres in recent times on medication errors[1-7] and adverse medicine events[8-12]. There is however, great potential for PICs to increase their participation in research and pharmacovigilance activities. The NSW PIC received 13,542 calls relating to medication errors (12% in or referred to hospital and 3% at or referred to GPs) and 11696 requests for drug information in 2013. Many of these calls originate from confusion in the packaging and labelling of products, particularly consumer product misidentification and errors in reading the dosage. Paracetamol is the most common product involved in calls to the centre, with 7243 calls received in 2013.

NSW PIC supports the changes proposed in Option 3 of the consultation document, with the adoption of TGO79 to improve the safe use of medicines by reducing the risk of medication errors by consumers and health workers. Suggested improvements are outlined below:

1. The importance of prominence of the active ingredient compared to the brand name – the active ingredient should be equal or greater prominence compared with the brand name. Consumer confusion is common with the expanding use and range of generics on offer and brand switching is relatively common[13] and consumer identification of active ingredient is well below 100%.
2. Look-alike and sound-alike packaging and labelling needs to be addressed, as these are a common source of error in misidentification of products, as is evidenced by calls to PIC's. This includes the usage of prefixes (e.g. APO) before product names where the product is referred to as the prefix rather than the drug name. This issue is highlighted by brand extension ('umbrella branding') which results in consumer and health worker confusion.
3. Setup of pre- and post-implementation evaluation of changes made to monitor the impacts and suggest potential further improvements which can be made in packaging and labelling. Pharmacovigilance systems for monitoring medication errors could be improved as routine analysis of data on medication errors collected by services such as Poisons Information Centre's is not currently conducted.
4. Proprietary dosing devices, such as syringes have been the result of confusion and dosing errors, as is evidenced by the products Infacol and Children's Panadol – these

devices differ compared with regular syringes and so cause consumer confusion. Pre-market assessment and post-market surveillance is necessary.

5. Improved clarity in the expression of dosages in labelling where decimal points are used – 10-fold dosing errors occur with a range of products.
6. The medicine name should be displayed on a single line and the label design should be such to accommodate this.
7. The introduction of mandatory warnings and design changes to the packaging of methotrexate tablets to indicate weekly dosing is vital to ensure that consumer safety. NSW PIC has been consulted on six cases of patient's who had mistakenly been taking daily dosing for the year 2014 to date.
8. Establishment of a medicines labelling and packaging advisory committee is supported.
9. Improved legibility of the batch and expiry on products is supported.

If you would like to discuss the contents of NSWPIC's submission or require further information, please do not hesitate to contact Jared Brown (jared.brown@health.nsw.gov.au or 02 9845 3969).

Yours sincerely,

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