



THE PAEDIATRIC SOCIETY OF NEW ZEALAND

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Medsafe
New Zealand Medicines and Medical Devices Safety Authority
PO Box 5013
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Dear Sir/Madam

On behalf of the Pharmacist and Therapeutics Special Interest Group of the Paediatric Society, we are writing to show our concern over the submission for reclassification of both liquid paracetamol and ibuprofen to general sales.

We have concern around the lack of professional advice available in supermarkets when children are ill, particularly with pain and fever. We also have concerns about the access to accurate measuring devices with the potential for inaccurate dosing. Although the bottles have proposed recommended age dosing and bottle sizes, in a supermarket environment there are no controls to check these or to ask questions to flag serious cases that should be referred for medical assessment. There are also no checks around the number of bottles purchased. The interaction between supermarket staff and caregivers in relation to sale of paracetamol is purely transactional.

A report with data from the USA National Electronic Injury Surveillance System – Co-operative Adverse Drug Event Surveillance database from 2004-2009, concluded that it was necessary to 'better inform parents and caregivers about the correct paracetamol dosing and administration to infants and toddlers' and to 'more clearly/strongly inform adolescents and other acetaminophen (paracetamol) users about recommended dosing amounts and maximum daily dosages'¹.

Another FDA adverse event reporting system database search in 2010 identified 630 reports of adverse events with acetaminophen (paracetamol) with 94 of these relating to oral paracetamol in paediatric patients. The greatest number of fatal cases was in children in the age range 6 months to less than 2 years and the 2-13 year age group.¹

Our concerns are for a number of reasons:

- This proposal has been submitted by Pharmaceutical Solutions in consultation with the New Zealand Retailers Association (on behalf of Grocery Retailers). It is not being submitted primarily for reasons of increased well-being for our paediatric population.
- There is a consumer perception that paracetamol and ibuprofen are safe medicines for everyday use. In one survey from a local population in 2007(unpublished), data collected from 84 respondents with children ranging from 0-7years showed reasons given for using paracetamol included: to help a restless child with sleep, prior to travel, the child was grizzly and prior to vaccinations.

- There is concern that although the proposed packaging contains wording to seek medical input if symptoms persist after 48 hours, there is no good evidence to show that this will happen.
- One of the proposed indications is to use paracetamol for symptoms associated with vaccinations. Paracetamol is not indicated prior to vaccinations as some vaccines have a lower antibody response when paracetamol is given.
- Although paracetamol is widely used, it does have risks which are often poorly understood by parents and caregivers. By allowing liquid paracetamol and ibuprofen to be available from supermarkets, the message is that these are safe medicines for children. In the correct dose and for the correct diagnoses they have benefit, but in some cases with diagnosis by a caregiver, these medicines can be misused and a delay in diagnosis may occur. Incorrect dosing may lead to unintended toxicity or inadequate symptomatic improvement.²
- In New Zealand, there have been documented cases of liver failure in children after inadvertent overdose of paracetamol. This highlights the need for increased caregiver education around administration which will not occur via supermarket sales.
- There are also cases of documented acute kidney injury in dehydrated children taking ibuprofen.³ There is concern that caregivers will not be adequately advised of this risk in the information on the packaging.
- We have increasing populations of migrant families and those with English as their second language. If liquid medicines are available without good advice, the risk to children is greater.
- Reclassification to general sale contradicts recent efforts by health professionals to reduce overuse eg the suggestion to doctors⁴ and a submission to PHARMAC⁵ about prescribing smaller volumes.
- Patient information leaflets that reinforce safe behaviours around paracetamol use have been specifically developed for community pharmacies to use when educating caregivers face-to-face with first-language versions currently under development to address issues relating to low literacy⁶
- Currently paracetamol dispensed via prescription is labelled with a weight chart and community pharmacy staff advise customers about this when prescriptions are collected. This initiative by pharmacists has increased safety when bottles of paracetamol are shared amongst family members.
- The leaflets available from Waitemata District Health Board <http://www.saferx.co.nz/paracetamol-for-children-patient-guide.pdf> are used widely in WDHB and across New Zealand to increase awareness of dosing and safety. These are promoted by pharmacies and aim to increase safety. They would not be promoted by staff in supermarkets.
- Anecdotal evidence of a person requesting Losec® for 12 weeks old babies at a pharmacy without prescription, raises concerns that if this had been available in a supermarket, it would have been given to these babies without medical advice. If this is what the public think of medicines available OTC, paracetamol has a very real risk of being used inappropriately.

These important approaches to improve education of caregivers around dosing of paracetamol, would be obviously undermined by the re-classification of paracetamol to general sale because it removes the opportunity for doctors, pharmacists, nurses and other health workers to support caregivers to use paracetamol and ibuprofen safely.

The proposal is based on access to these medicines and not for increased wellbeing or safety reasons. Although the submission states that supermarkets are open for longer than pharmacies, in most centres that have supermarkets open longer hours, they also have after-hours pharmacies and medical centres.

The current availability is from pharmacies. The proposal benefit therefore would be to have these products available after hours (evenings and some weekend days) only. We do not consider the benefit of access to liquid paracetamol and ibuprofen after usual pharmacy hours to outweigh the risk of lack of advice around diagnosis of conditions and dosing of these medicines.

Conclusion

We oppose any moves that remove the current safeguards around access to liquid paracetamol and ibuprofen.

We would encourage the committee to base their decision on the safety concerns to our paediatric population and justify whether increased access to these liquid medicines confers benefit over risk to our vulnerable children who are not making the decision to self-dispense.

Yours faithfully

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Chairperson
Pharmacist and Therapeutics SIG
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Endorsed by

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References

1. <https://www.documentcloud.org/documents/793895-2011-pediatric-fda-background.html#document/p217/a120902>
2. Sui Fai L et al. *Acetaminophen and ibuprofen dosing by parents*, Pediatric Emergency Care Vol16 No 6 394-397
3. Misurac J et al. *Non-steroidal Anti-inflammatory Drugs are an Important Cause of Acute Kidney Injury in Children* J Pediatr 2013 1-4
4. <http://www.saferx.co.nz/paracetamol-for-children.pdf>
5. PSNZ Submission to PHARMAC around quantity of liquid paracetamol available, 2011 (on PSNZ website)
6. <http://www.saferx.co.nz/paracetamol-for-children-patient-guide.pdf>