



**CHPNZ**

CONSUMER HEALTHCARE  
PRODUCTS ASSOCIATION NZ

The Secretary,  
Medicines Classification Committee  
Medsafe PO Box 5013  
Wellington 6145

New Zealand  
Sent by email : [committees@moh.govt.nz](mailto:committees@moh.govt.nz)

From:

Consumer Healthcare Products Association Inc.  
P O Box 6473  
Auckland  
New Zealand

Dear Sir/Madam,

Re: [Submission on Item 5.2 of the Agenda of the Medicines Classification Committee – Coroners Recommendations on Paracetamol Pack Sizes and Supply Restrictions](#)

The Consumer Healthcare Product Association (CHPNZ) (formerly the New Zealand Self-Medication Industry Association Inc (NZSMI) is the national trade association representing importers, manufacturers, marketers and distributors of a wide range of products, generally available "over-the-counter" (OTC) and mainly for use in self-medication by New Zealand consumers. NZSMI's mission is to promote better health through responsible self-care. This means ensuring that safe and effective self-care products are readily available to all New Zealanders at a reasonable cost. SMI works to encourage responsible use by consumers and an increasing role for cost-effective self-medication products as part of the broad national health strategy. CHPNZ members account for an estimated 85% of OTC paracetamol sales.

We appreciate this opportunity to provide feedback on this upcoming agenda item

## Current Supply of Paracetamol in New Zealand.

CHPNZ believes it is important to note that close to 80% of the estimated 300 million doses of Paracetamol supplied annually in New Zealand is done so by the prescription pathway. It is the most widely used medicine in New Zealand and is considered by the Medicines Classification Committee to be a safe and effective analgesic when taken at the normal therapeutic dose and is used for the relief of symptoms that can be self-managed by a consumer. However, it is also recognised that paracetamol can cause significant harm if not used in accordance with the directions. For this reason paracetamol has been the subject of a number of reviews and regulatory changes over the decades including pack size restrictions and blister packaging changes aimed at deterring deliberate over-dosing.

New Zealand and Australia, along with Medsafe and the TGA, have worked closely over the last two decades to improve label comprehension and to balance access with safety. When considered globally New Zealand sits about in the middle of regulatory controls around this medicine. Many European countries have more restrictive controls and many countries in the Americas have considerably more liberal supply rules and guidelines.

New Zealand has also acknowledged the technological advantages and risks associated with modified release dose forms of paracetamol and has regulated more stringently in this area of non-prescription supply.

In 2016 Medsafe and the MCC spent considerable time and energy on reviewing the classification of paracetamol. The committee reached the conclusion that the existing supply regulations were the best balance possible. There was a suggestion, as a guideline, that general sales and on-line sales should be restricted but this suggestion was not taken up by the grocery industry as there was a wide range of conflicting views on the measure and the ability to practically implement it. It is CHPNZ's position that the situation has changed in the ensuing years.<sup>[PQ1]</sup>

### Interpretation of the Item:

CHPNZ notes that the Agenda Item gives no detail around the Coroner's recommendations.

Neither the decision of the Chief Coroner Judge D Marshall or the findings of Coroner D P Robinson are included in the item. In the absence of any supporting documentation we have therefore had to assume that the reasoning for this request is based on the findings, and the coroner's interpretation of referenced research documents.

It is also assumed that the coroner has broadly adopted the UK guidelines on the supply restrictions suggested rather than referencing Australian regulatory practices with which New Zealand seeks, where possible, to achieve harmonisation.

There can be no denying that the coroner's report makes tragic reading. Its primary purpose was to establish the cause of death, the circumstances, whether it was suicide and whether it was preventable. While it has done this, it has also raised numerous questions of detail that should have been addressed, or provided to the MCC, given the substantial impact that the adoption of the coroner's recommendations would have, if adopted.

While the coroner states that the subject of the inquest deliberately took an excess quantity of paracetamol his recommendations indicate that restricted supply may have led to a different outcome. CHPNZ does not believe a compelling argument has been presented here.

The coroner's recommendations appear clear in relation to whether it is single active solid dose paracetamol (implicated in overdose cases) being proposed for restriction of access. There is no evidence of overdose with combination paracetamol products (including cold and flu products) or powdered paracetamol products and, as such, these should be excluded from any discussion or decision to restrict access to paracetamol.

The coroner's recommendations are silent on whether paracetamol in combination with other active ingredients should be included in these restrictions. There is no reference to combination products at all and no research or data offered as to where these sit in the misuse and/or poisoning commentary offered in the coroner's report.

It should also be noted that, in paragraph 105 of the coroner's report, the results presented are somewhat selective in that reductions in paracetamol deaths in England and Wales are highlighted but the fact that no change was exhibited in Scotland, has been omitted.

### **Commentary on the Recommendations.**

#### Prescribed limit to be 100 tablets (50g)

As previously noted, the vast bulk of paracetamol taken by New Zealanders is supplied on prescription. While most paracetamol is used for short term acute analgesia it is also prescribed for chronic pain and often in doses reaching two tablets every six hours or 240 per month.

If the coroner's recommendations are to be adopted this would require eight prescriptions over a three month period for a patient on this regime. While this example is at the edge of a continuum it is easy to see that a massive increase in prescription numbers would be inevitable.

This increase is clearly impractical, would impose substantial increases in Pharmac costs and an even greater burden on already taxed prescribing practitioners. There is also a risk that patients will go without appropriate pain relief or seek alternative medication as a result of the lack of access to paracetamol, which may be inappropriate and/or have toxic side-effects.

If the coroner's intent is to reduce misuse solely by restricting access then any supply over his suggested 16 tablets it is inconsistent and prescription quantity should also be a maximum of sixteen. This is clearly not his intent and he has suggested higher numbers in environments where monitoring exists because patient interaction is the key to avoiding unintentional poisoning. Suggestions to improve this situation are discussed later in this submission.

#### Pharmacy Sales limited to 32 Tablets (16g)

It is acknowledged globally that New Zealand has a well distributed network high quality pharmacies with well trained and qualified staff. As a registered pharmacist I have seen a

growing dependence within the community, on Pharmacists to provide impartial, knowledge-based advice. This is a result of consumer information overload from social and other media. Patients need and appreciate a trusted source of advice.

The coroner's recommendations exhibit a misunderstanding of the role the community has attributed to "Pharmacy" per se and do not reflect the public's trust of or access to quality primary care in the form of "pharmacy supply".

The best place for patients to obtain more than two packs of paracetamol is in a pharmacy; whether on prescription or over-the-counter. Pharmacist advice is always at hand and retail shop staff are well trained to ask appropriate questions about medicine purchases[PQ2].

Paracetamol is one of the world's most prolific medicines and is excellent when used well. It is dangerous when not used well. Sales monitoring and advice are helpful in to reducing the risk of misuse and in New Zealand retail pharmacy both are freely available.[PQ3]

The current restriction on pack sizes to 100 (500mg tablets) is appropriate and should not be seen as a "target" for purchase but an upper limit for reasonable access in many situations whether that be a family medicine cabinet or more-than-acute need.

On line pharmacy sales on the other hand may need to be considered separately as there is no pharmacist available to monitor the supply of this medicine to the on line customer.

#### All other Outlets 16 tablets (8g)

CHPNZ members acknowledge the potential for paracetamol to cause serious harm when misused. This misuse is either intentional or unintentional. We are particularly aware of the high incidence of the implication of paracetamol in consumers wishing to self-harm.[PQ4] This is a global concern.

CHPNZ also wishes to comment about "the Elephant in the Room" which is, tragically, that New Zealand has a very high suicide rate for an OECD country. We do not believe the rates of self-poisoning with paracetamol is a function of its availability in non-pharmacy outlets or that this rate will be changed by the adoption of the coroner's recommendations. Access to the means to do self-harm and improving poor mental health is a much bigger campaign and must focus on much wider issues than paracetamol pack sizes. However, as noted by Kumpula (2020) measures to mitigate against excessive stockpiling within the home is an important and practical step that can be supported with consumer and HCP campaigns.

Accidental overdose is a separate issue and one where we believe a change is possible particularly in the area of education around the dangers of stock piling.

It is our contention that paracetamol has become such a ubiquitous household commodity that patients are not always appropriately aware of its real value as an analgesic and its real risks when improperly used. This problem can only be solved by better patient literacy, good packaging and quality labelling. Again, restricting supply to 16 tablets is not the answer.

CHPNZ is heartened to hear that Medsafe is working with the Health Research Council to gain better insights into paracetamol use and ways to improve consumer education. CHPNZ has also been discussing the development and logistics of a patient/consumer education

campaign focussing on analgesics. We have asked to be involved in the Medsafe initiative to ensure maximum and increased effectiveness and to avoid consumer confusion.<sup>[PQ5]</sup>

We note that the 2016 suggested guideline to general sales outlets to voluntarily accept a two pack sales limit was not adopted and we think it is time that this is re-visited. At that time Point-of-Sales systems were not as sophisticated as they are today, the incidence of multi-pack purchasing was poorly traced and the very mechanics of implementing such a guideline was problematic.

Attitudes, data, systems and knowledge have since moved on and CHPNZ will be strongly encouraging all non-pharmacy retail members who market single active solid dose paracetamol products to adopt a pack-sales restriction and will be encouraging all paracetamol suppliers to write to all their GSL customers encouraging them to do likewise. This suggestion would also apply to On-Line sales.

NOTE: The coroner's recommendations do not address sales of combination powdered products containing paracetamol. There is no evidence that these products are involved in overdose cases. This is also reflected in the UK scheduling of paracetamol which allows for 10grams of powdered paracetamol to be available as a general sale medicine vs 8 grams for solid dose single active paracetamol products. The CHPNZ view is that these products should not be included in any decision made to restrict. We do believe that patient education about the potential for excessive dosing, when taking more than one product, is necessary.

## CHPNZ Recommendations to the MCC

On Recommendation (a) Pharmacy Sales;

- that the current maximum pack size limit of 100 is appropriate,
- that there is no benefit to patients, and indeed a potential inconvenience and access issue if the coroner's recommendations are adopted, and
- that suppliers should work with retailers on continuing staff training around the benefits and risks of paracetamol both as a single medication and in combination
- restrict purchase limits for on line pharmacy but explore the opportunity to have a "Pharmacist Signed Off" exemption

On Recommendation (b) All other outlets;

- that a voluntary two-pack transaction limit (2 x 20 tablets) of single active paracetamol tablets/caplets/capsules be adopted for both In-store and On-Line sales;
- that Trade organisations like CHPNZ, Retail NZ and the FGC work with suppliers to encourage general sales outlets to adopt the 2-pack guideline and
- that all parties (along with the Ministry of Health) collaborate to develop and implement a public education plan to highlight the risks and benefits of analgesics and the responsible purchase and use.

- CHPNZ also considered the merits of imposing an under 18 years age restriction on the sale of paracetamol in non-pharmacy outlets and noted a range of opinions based on practicality, enforceability and risk-value

Note: the two pack recommendation follows the UK regulator's (MHRA) guidelines but pack sizes there are 16's – not 20

On Recommendation (c) Prescription supply;

- That the current regulations provide a balance between patient access, cost benefit, safety and both prescriber and pharmacist oversight and do not need to change;
- However, CHPNZ also acknowledges the Kumpula research paper which highlights the need for all health professionals to educate against stock piling and over prescribing
- that Pharmacists and their staff be encouraged to be active and vigilant when processing paracetamol dispensing giving consideration to therapeutic need and the potential for stock piling and;
- that Medicines New Zealand be encouraged to join with all parties in a public education campaign about the risks and benefits of analgesics.

**Thank you.**

CHPNZ appreciates the opportunity to provide input to regulatory decisions like these and is happy to work with both Medsafe and MCC to implement these suggestions.