From: Jacinta Patel
To: committee@health.govt.nz
Subject: Comments on pholcodine reclassification
Date: 29/10/2020 9:11 am

Kind regards,

Jacinta

Jacinta Patel | Advisor Science (Secretary for the MAAC and the MCC) | Medsafe | Ministry of Health | (04) 819 6860 |

MEDSAFE

From: paul lau <paullau77@yah oo.co.nz>
Sent: Monday, 12 October 2020 9:54 am
To: committee@health.govt.nz
Subject: Comments on pholcodine reclassification

Medicines Classification Committee

Comments on Submissions Cover Sheet

Meeting	27 October 2020
Agenda item	Re-classify Pholcodine
Name	[redacted]
Occupation and / or Company or Organisation	
Contact phone number and email address	

1. I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*	☑ Yes ☐ No
2. I would like my name to be removed from all documents prior to publication and for my name not to be included within the list of submissions on the Medsafe website.	☑ Yes ☐ No
3. If answered yes to point 2, to have my name removed from all documents prior to publication. I have provided a copy of my submission with my name removed along with my original submission.	☑ Yes ☐ N/A

Pholcodine has a lot less interaction than dextromethopan as cough suppressant. If the classification changed, it will be a lot harder for patient to access pholcodine.

Attached copy of submission

From: [redacted]
To:
Subject:
Date:
Attachments:

To whom it may concern,
I would like to express my opposition to the rescheduling of Pholcodine from Pharmacy ONLY to Pharmacist ONLY classification. The MCC's recommendation relates to an unsubstantiated link between pholcodine and a rare form of anaphylaxis to neuromuscular blocking agents (NMBAs) during anaesthesia. In my lifetime I have sold Pholcodine as a cough suppressant agent for over 30 years and find the claims hard to fathom. The reclassification of Dextromethorphan due to its abuse potential we accept (despite the fact that here again the few ruin the ability of the many to access effective symptom relievers) but Pholcodine has been sold for many many years safely. It seems hard to believe that there has been an underlying risk over this long period. If so I wonder why evidence has not emerged earlier.
Our armoury against cold and flu symptoms is declining which is a real shame for those who suffer from these symptoms. We seem to run on a culture of knee-jerk reaction. The reclassification of Pseudoephedrine has NOT limited the spread of the "P" epidemic as container loads of the raw ingredients continue to make it through our custom systems to feed the habits it does. The loser here has been the public who have lost access to an incredible decongestant for which Phenylephrine holds no candle.
Please show us the pragmatic evidence before knee jerk reactions are made - that whatever is argued - will as a result of reclassification reduce the availability of this effective cough suppressant to the average kiwi.
Kind regards
Lynette

Lynette O'Brien
UNICHEM PAPATOETOE
63 St George St
Papatoetoe 2025
Ph (09) 278-7613
Fax (09) 278-7615

From: [redacted]
To:
Subject:
Date:

Hi Committee

Please re-consider my objection as a comment for discussion regarding Item 5.1.1 of the 65th meeting of the MCC.

[redacted]

Re Pholcodeine Reclassification.

Pholcodeine has been in common and extensive use to the community for minor ailments for 60 years. Pholcodeine access is valuable to a community where it is now socially unacceptable to cough and the physiological stress the risk of coughing brings.

It is not neccessary to restrict access to the community for an unproven interaction with neuro muscular blocking agents in surgical procedures. The acceptable process is to have a drug check which should be a standard procedure before starting surgical procedures

Regards

Karen Rich

Crofton Downs Pharmacy
Ph: 04 479 1977
124 Churchill Drive
Crofton Downs
Wellington 6035

Karen Rich

Crofton Downs Pharmacy
Ph: 04 479 1977
124 Churchill Drive
Crofton Downs
Wellington 6035

From: [redacted]
To:
Subject:
Date:
Attachments:

To whom it may concern,
Please find attached the cover sheet, along with the submission below,
Many thanks
Claire Way
(pharmacist)

Submission regarding the up-scheduling of pholcodine to be Pharmacist Only Medicine

We believe that pholcodine should NOT be reclassified to pharmacist only due to the following points:

1. It is one of the last cough suppressants available over the counter in New Zealand and to restrict the ability of people to purchase it over the counter is restricting to the many people in New Zealand who would benefit from using the medicine. The response seems to be 'overly restrictive' and heavily weighted towards the very few people who may experience some form of side effects from the medicine.
2. It doesn't have problems with addiction which means it has limited potential for abuse.
3. We are worried that reclassifying such products excessively will mean that suppliers of these products may not choose to produce them in response to the usual flow on effect of reduced demand from consumers. It may mean they eventually they are not supplied to the NZ market and we lose the ability for consumers and pharmacies to have choice in what they use to treat their minor ailments such as dry cough.
4. We feel that the evidence of harm is weak (particularly between anaphylaxis and NMBAs) according to the paper compiled by MARC as there have been so few reported cases since 1969 and the proposed change would not be effective at managing the risk.
5. We feel that the 'lack of demonstrated efficacy' for pholcodine is likely to be due to the age of the medicine. It has been available for such a long time and due to studies having small sample sizes, poor patient selection and not being adequately controlled it makes it difficult to make this statement with certainty.

Thank you for reading this submission

From: [redacted]
To:
Subject:
Date:
Attachments:

Please consider my objection below as a comment for discussion regarding item 5.1.1 of the 65th meeting of the MCC in regards to the reclassification of Pholcodine to a Pharmacist Only Medeicine
Kind Regards,
Vicki Douglas

Vicki Douglas
Director
Unichem Kerikeri Pharmacy
64 Kerikeri Rd
Kerikeri
P 09 4077144
F 09 4071216
E vicki@unichemkerikeri.co.nz
Unichem
Kerikeri Pharmacy

From: Vicki Douglas
Sent: Monday, 31 August 2020 9:15 AM
To: committees@moh.govt.nz
Subject: Pholcodine as a Pharmacist Only Medicine

Good morning
I would like to raise an objection to the reclassification of Pholcodine to a Pharmacist Only Medicine.
Our retail staff are well trained in identifying the right medicine for the right patient, which includes questioning around what medications patients are taking.
I believe this decision is based on insufficient evidence around the link between Pholcodine and neuromuscular blocking agents.
Taking pharmacists away from other work with patients to improve outcomes is counter-productive in this instance.
Kind regards
Vicki Douglas

Vicki Douglas
Director

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F 09 4071216
E vicki@unichemkerikeri.co.nz

Unichem
Kerikeri Pharmacy

care · advice

From: [redacted]
To:
Cc:
Subject:
Date:
Attachments:

To Whom It May Concern,

I would like you to consider my objection as a comment for discussion regarding Item 5.1.1 of the 65th meeting of the MCC.

I am writing to you to ask you to keep the classification status of pholcodine as pharmacy only.

It would seem that there is a gradual erosion of medicines classified as "pharmacy only" which I do not understand as surely you can appreciate the training and oversight that is provided in a pharmacy situation. Patients are asked a series of questions to determine the medicine's appropriateness and supervision by the pharmacist is provided especially when certain conditions present themselves. Many other medicines with highly concerning safety profiles such as ibuprofen have been released from "pharmacy only" to "general sale" of which really are a concern. Whereas the reclassification of this medicine to "pharmacist only" status would seem completely unwarranted.

Furthermore, the reclassification of medicines is expected where there is a clear and demonstrable shift in the body of scientific evidence over time. However, in this instance, there is no proven link to cross-reactive anaphylaxis with NMBAs and therefore insufficient data to support any change of classification of pholcodine.

Please accept that medicines classified as "pharmacy only" are the correct option for many medicines. To reiterate, while pholcodine should not be reclassified to pharmacist only, neither should ibuprofen be classified as general sale. "Pharmacy only" is a genuine option that provides patients with credible oversight of the sale.

Yours Sincerely,

Tania Adams
pharmacist

21 October 2020

The Secretary
Medicines Classification Committee
Medsafe
P.O. Box 5013
WELLINGTON 6145

Sent by email: committees@moh.govt.nz and committees@health.govt.nz

Re: Public Comment - Agenda for the 65th Meeting of the Medicines Classification Committee

Item 5.1.1: Reclassification of pholcodine – objection to the proposed recommendation that pholcodine be reclassified from a pharmacy medicine to a restricted medicine

iNova Pharmaceuticals (iNova) does not support the proposal to reclassify pholcodine to restricted medicine status.

iNova welcomes the decision to refer to proposed reclassification of pholcodine back to the Medicines Classification Committee (MCC) for further review and consideration. As has been noted in several previous communications, iNova strongly contends that pholcodine is a safe and efficacious ingredient for which patient access in a pharmacy environment is appropriate.

iNova would like to take this opportunity to reiterate the key arguments for the current classification status of pholcodine and against the previous recommendation made by the MCC. For ease of reference these have been provided briefly below and overleaf under related headings:

Safety and Efficacy of Pholcodine

- iNova acknowledges the limited availability of studies examining the efficacy of pholcodine. This is to be anticipated given the 'grandfathered' nature of pholcodine and its long history of use. However, patients continue to return to pholcodine-containing products when suffering from a dry cough, which strongly advocates for their efficacy, as acute cough is an obvious and irritating symptom and a person can quickly ascertain following self-medication whether their cough improves or not. [1]

- The safety argument mounted against the pharmacy-only availability of pholcodine, even in the documents submitted to the Committee for review by the MARC, have been acknowledged to be hypothetical, being based primarily on a range of small studies conducted by a single research group in the European Union between 2005 and 2011. [1]

- The very limited literature regarding the potential for allergic cross-reactivity between pholcodine and Neuromuscular Blocking Agents (NMBAs) used in anaesthetic procedures has been recognised, even by the MARC, as suggestive, not conclusive. Additionally,

whilst there have been many reviews of the pre-existing studies, there have been relatively little new data published since 2011). The limited new data have not clarified the issue, instead additional confounding factors have been added e.g. patients showing cross-reactivity to NMBAs who have not been exposed to pholcodine or showing potential cross-reactivity following exposure to common household and/or occupational products. [1]

Previous Health Authority Reviews of Pholcodine

The safety and efficacy of pholcodine have been extensively reviewed by various Health Authorities (including Medsafe) over the last 10 years and they have uniformly concluded that the benefit: risk balance for pholcodine is appropriate:

- The EMA published a thorough assessment for pholcodine in 2012. This document undertook a full review of the safety and efficacy of pholcodine, whilst considering the available evidence for the 'Pholcodine Hypothesis'. The conclusions of this study were as follows:

  ..the evidence in support of an association between pholcodine and NMBA-related anaphylaxis is circumstantial, not entirely consistent and does not support the conclusion that there is a significant risk of cross-sensitisation to NMBAs and subsequent development of anaphylaxis during surgery.[2]

- The MCC also undertook a review of pholcodine classification at the 61st meeting of the MCC in November 2018. At this meeting, the MCC reviewed the potential for abuse of pholcodine by the general public, and issues relating to the 'pholcodine hypothesis'. The MCC concluded that pholcodine has limited potential for abuse. Furthermore, a rare but fatal association with anaphylaxis and neuromuscular blockers and pholcodine was discussed by the Committee, but the evidence for this was considered limited by the Committee. The Committee concluded that there were minimal safety concerns around pholcodine and that the current classification was appropriate. [3]

It should be noted that no new compelling data has been published regarding the 'Pholcodine Hypothesis' since the MCC review of pholcodine in 2018.

Issues with the Pholcodine Review and Recommendation at the 64th Meeting of the MCC

- The published minutes of the meeting do not refer to any new safety concerns. Pholcodine is not the subject of abuse, drug dependence or misuse. The adverse event profile is well known and there are no new safety issues reported – as indicated in the minutes of the 61st Meeting of the MCC. It therefore seems inconsistent that the MCC has recommended reclassification of pholcodine in the absence of any new supporting evidence of emerging safety concerns relating to NMBA anaphylaxis. The MCC acknowledge themselves:

  "....The change in classification may not mitigate the risk of anaphylaxis under anaesthetic, as the sensitisation may occur from exposure to a number of substances…."

  and

  "....the connection with neuromuscular blocking agents is not clear due to other environmental factors" [4]

- The MCC has stated that the reclassification decision was made to offer the chance of reducing volumes of pholcodine supplied. As outlined previously, there is no evidence that pholcodine-containing products have been supplied inappropriately or are over-used. Furthermore, the classification of medicines is intended to provide appropriate oversight based on the risks of a substance or the conditions for which it is used - the classification of a medicine is not a tool for managing sales volumes.

- The NZ Pharmacy Guild propose that the recommendation to reclassify pholcodine to a restricted medicine will place an unnecessary burden on the pharmacist to replace a process that is already managed appropriately in a pharmacy. Additionally, they concur that the current measures and controls in place in community pharmacy are sufficient to effectively manage the unnecessary sale and supply of medicines containing pholcodine. [5]

- The MCC minutes qualitatively comment that anaphylaxis is rare, and neuromuscular blocking agent anaphylaxis is rarer again, but do not provide that important context, which enables risk: benefit to be appropriately determined. Quantification of the risks reveals that they are very small:
    - The preamble to the 2012-2014 ANZCA report states: "Anaesthesia in Australia and New Zealand has never been safer for our patients."
    - Of the 22 deaths reported in the 2012-2014 ANZCA report, there were seven deaths (32%) from anaphylaxis due to drugs administered by the anaesthetist, six (27%) involved pulmonary aspiration, six (27%) involved cardiac arrest and two (9%) each for stroke and airway related deaths. The results suggest *there is no significant difference in the frequency of death by anaphylaxis compared to pulmonary aspiration or cardiac arrest*.
    - Given the 11.40 million individual episodes of anaesthesia care referred to in the ANZCA report, seven deaths attributed to anaphylaxis is very small; furthermore, four of these deaths were in obese patients and one had cardiac disease. These results provide no indication of the role pholcodine may have had in contributing to the anaphylaxis deaths.
    - When considering the overall safety of anaesthesia and the incidence of anaphylaxis, it becomes apparent that any contribution pholcodine may have to the outcome is circumstantial or speculative. The high degree of safety already associated with anaesthesia and the very rare occurrence of anaphylaxis during anaesthesia strongly suggest that further limiting the availability of pholcodine is unlikely to have any significant impact on anaesthesia outcomes. [5]

- Beyond noting that "anaphylaxis is rare and NMBA anaphylaxis is rarer again", the MCC minutes give no indication that they have considered the extremely rare occurrence of these anaphylactic events within the context of the surgical setting, and the potential contribution of pholcodine in this context. No evidence was presented that pholcodine consumption contributed to any of these NMBA anaphylaxis outcomes. [5]

- The meeting minutes and associated documents indicate that there was a lack of balance when considering the eight submissions made to the MCC. Seven of the submissions made to the MCC opposed a change in scheduling compared to a single submission supporting the proposed change from ANZCA (Australian and New Zealand College of Anaesthetists). [5]

- The meeting record does not indicate that there was any discussion on alternative actions to re-classification of pholcodine. If the safety risk is indeed solely the possibility of a sensitizing reaction with neuro-muscular blockers, education on this could be achieved by the use of amended datasheets for NMBAs highlighting the theoretical risks and reminding physicians to take comprehensive patient histories prior to surgical procedures. [5]

- Review of the MCC meeting appears to demonstrate that there are insufficient grounds for the Recommendation made. There have been no new data to suggest a shift in the well-established safety profile of pholcodine. The pholcodine hypothesis, upon which this reclassification is largely justified, continues to be uncertain; the causality unproven as other environmental factors have also been implicated in such reactions. [5]

- iNova notes that a total of 72 Objections were submitted to Medsafe regarding the proposal to reclassify pholcodine. Whilst only five of these met the stringent standards required to be considered further by the MCC, this is a large number of Objections and is considered to be representative of the level of opposition to the proposed change in New Zealand. [6]

On the basis of the information summarised above, iNova conclude that there is no justification to reclassify pholcodine and request the MCC to revoke their initial decision and retain the current classification entry for pholcodine as Pharmacy Only Medicine.

Please note, iNova reserve all of our rights and remedies in relation to this matter.

References

1. Comments on the Agenda for the 64th Meeting of the Medicines Classification Committee. https://www.medsafe.govt.nz/profs/class/Agendas/Agen64/MCC64_CommentsonAgendaItems.pdf (Accessed 15th October 2020)
2. Assessment Report for Pholcodine Containing Medicinal Products. https://www.ema.europa.eu/en/documents/referral/pholcodine-article-31-referral-assessment-report_en.pdf (Accessed 15th October 2020)
3. Minutes of the 61st Meeting of the Medicines Classification Committee. https://www.medsafe.govt.nz/profs/class/Minutes/2016-2020/mccMin2Nov2018.htm (Accessed 15th October 2020)
4. Minutes of the 64th Meeting of the Medicines Classification Committee. https://www.medsafe.govt.nz/profs/class/Minutes/2016-2020/mccMin09July2020.htm (Accessed 15th October 2020)
5. Objections to Recommendations Made at the 64th Meeting. https://www.medsafe.govt.nz/profs/class/Agendas/Agen65/CollatedObjections.pdf (Accessed 15th October 2020).
6. Medsafe has completed its review of Objections from the 64th Medicines Classification Committee to reclassify pholcodine https://www.medsafe.govt.nz/publications/media/2020/Reclassifypholcodine.asp (Accessed 15th October 2020).

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23rd October 2020

Medicines Classification Committee (MCC) Secretary
Medsafe
133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand

Sent via email to: committees@moh.govt.nz

Dear Secretary,

Re: Public Comment on Agenda for the 65th Meeting of The Medicines Classification Committee

Agenda item 5.2: Paracetamol – recommendation received from the coroner

First and foremost, GlaxoSmithKline Consumer Healthcare (GSK) are deeply sorry to learn about the death [redacted]

Following this tragic case, the investigating Coroner has made recommendations to reduce pack sizes and restrict current access to paracetamol in New Zealand. Whilst this proposal draws upon the measures adopted in 1998 in the United Kingdom (UK), the available information from that and other international markets does not provide conclusive evidence that such an approach will result in any meaningful impact on reducing incidence of intentional paracetamol overdose.

As a market leader in paracetamol-containing medicines, GSK acknowledges the importance of balancing the benefits of appropriate access to paracetamol for immediate therapeutic need alongside effective safety measures. Given intentional paracetamol self-poisoning is often impulsive in nature,[1,2] mitigating the accumulation of excessive stock in the home needs to be the key area of focus.

Based on the available evidence, the current scheduling of paracetamol in New Zealand remains appropriate. However, to support the responsible use of this medicine, the following measures are proposed and are considered to provide a greater opportunity for a sustained and positive impact. This approach has been informed by a review of international experience and literature/data and draws upon current New Zealand specific data, which has been the subject of recent publications:

1. Retain the current scheduling of paracetamol in New Zealand.
2. Implement a two-pack purchase limit for all paracetamol-containing products outside of the pharmacy environment (including all online sales in addition to supermarkets and other general retail outlets).
3. Industry support for healthcare professional educational activities to increase awareness of the risks of accumulation of agents, such as paracetamol, and the need to assess clinical requirements of their patients to determine suitable prescribing and dispensing quantities.
4. A Government-initiated Public Health Campaign aimed at educating consumers against stock piling of medicines.

Introduction

Paracetamol has been widely available as an over-the-counter analgesic in many countries for over 55 years and is sold both as a single active and in combination with other active ingredients. Most notably, Panadol has been marketed in New Zealand since 1969. The efficacy and safety profile of paracetamol at the 1000 mg single and 4000 mg maximum daily dose level is well-characterised (when used as directed).

Labelling serves an important role in supporting responsible use with clear and prominent identification of the presence of paracetamol displayed on front of pack, warnings against co-administration of medicines containing paracetamol and the dangers of excessive consumption. Furthermore, all pack sizes of all GSK paracetamol-containing products are supplied across all channels of New Zealand with a detailed Consumer Medicine Information (CMI) leaflet inside the pack outlining detailed warning and advisory information for the patient.

Paracetamol is the leading pharmaceutical agent responsible for calls to the National Poisons Centre in New Zealand. It is known to be used in cases of intentional overdoses and is the most common drug taken in overdose leading to hospital presentation and admission.[3,4]

The guidelines[25] for the management of paracetamol overdose in Australia and New Zealand are well established and updated periodically. Following the 2015 revision to the ANZ guidelines, an expert panel, including the Poisons Information Centres of Australia and New Zealand were appointed to update an evidence-based guidance that led to the publication of the updated guidelines in 2020. The authors in this latest revision note that optimal management of most patients with paracetamol overdose is usually straightforward. One of the key changes in this latest revision is management guidance for patients consuming very large or massive dose of paracetamol and multiple and staggered paracetamol ingestion.

Intentional self-poisoning is often an impulsive decision,[1,2] where ease of access to substances readily available in the home plays a key role in the agent chosen. Given availability of medicines in the home can facilitate intentional self-poisoning, unnecessary accumulation of large stocks should be avoided.

Current New Zealand Situation

Appropriate access to therapeutic paracetamol needs to be balanced with preventing unnecessary accumulation of paracetamol stocks in households. A New Zealand publication[5] noted efforts to reduce residual stock in the home is an important initiative that needs to be informed by evidence about current household stocks and how they were obtained. This recent study found that a significant proportion of New Zealanders:

- have large quantities of paracetamol stockpiled in their homes; and
- the main source of large paracetamol stock (78.2%) was obtained via prescription

Based on the study sample, the authors estimated that a third of all New Zealand households had 30 g or more of prescribed paracetamol present. This was not considered surprising to the authors given the large quantities of low-cost paracetamol available via prescription dispensing under the current PHARMAC funding arrangements (NZD 5.00 for up to 720 units of 500 mg tablets in one prescription dispensing, corresponding to 90 days' treatment and 360 g of paracetamol in total).

The significance of prescribed paracetamol on current incidence levels of paracetamol self-poisonings in New Zealand was confirmed in a separate study,[6] which investigated the specific substances used in intentional self-poisoning and the sources from which they are obtained. The study found a high prevalence of paracetamol and ibuprofen being used in self-poisoning which may be obtained both without and by prescription, but participants mostly indicated it was by prescription.

A recent study in New Zealand[5] concluded that prescribers and pharmacists need to be aware of the risks of accumulation of agents such as paracetamol and assess the therapeutic needs of their patients to determine how much is needed when prescribing and dispensing. The authors suggest that public initiatives, such as "Dispose of Unwanted Medication Properly" should be regularly undertaken to encourage people to return unused or expired medicines to pharmacies for safe disposal. This would assist in reducing inappropriate access such as use in intentional self-poisoning, or accidental paediatric exposures. In addition, the authors advocate that a current policy priority should be to focus on limiting prescription paracetamol, so that people have what they need, but avoid build-up of large stocks.

Review of Evidence of Pack Size Restriction Measures

Excessive stock in the home has also been recognised in other markets as a key contributing risk factor to intentional overdose and is irrespective of scheduling.[7,8] Internationally, Health Authorities have employed several mechanisms to mitigate against this including pack size restrictions, however there is no consensus that this measure has had a sustained positive impact.

Determining the effectiveness of pack size restrictions on paracetamol overdose is challenging due to limited available information and is further confounded and made complex by other important factors such as additional regulatory restrictions (i.e. channel and age restrictions) and environmental factors influencing suicide rates (i.e. the economy).

The literature provides some beneficial effects of pack size restriction in some markets, notably Ireland and Denmark.[9-13] However, the publications describing the situation in Denmark indicate that reduction of intentional overdose cannot be fully attributed to pack size restriction measures and could be explained, at least partly, by other factors such as: spill-over effects through increased awareness regarding safe storage of household medication or prevention policies and socio-demographic changes, which are a potential source of confounding. The authors highlighted that a causal link to pack size reductions could not be inferred.

In 1998, the UK introduced pack size restrictions with the stated aim of limiting availability and reducing residual stocks in the home.[14] Being one of the first countries to do so, there has been significant analysis of the impact of these measures within this market.

In some studies,[7,15-16] evidence in favour of the pack size restriction in some UK countries has been reported although this was not observed in Scotland.[17] Other studies have presented inconclusive data regarding success of legislation in reducing incidence of paracetamol related overdose.[18-21] The effectiveness of these measures has been questioned with OTC pack size reductions in the UK having not reduced deaths from paracetamol exposure.[20]

Findings from a recent study,[22] in a European wide evaluation, found that despite pack size restrictions having been implemented, the Poisons Information Centres in the UK and Ireland still had particularly high frequencies of paracetamol-related enquires (16%) compared to the other participating countries. Similarly, another study[23] concludes that paracetamol overdose remains a major problem in the UK with the observed high frequency of self-poisoning with paracetamol in England. While the authors suggest that the further restrictions on access to paracetamol in the UK should be considered, the results of this study rather indicate that reduced paracetamol pack size, is in itself, insufficient.

[redacted]

Proposal

The available literature [redacted] provides no conclusive evidence that reducing pack size will have any significant impact on reducing incidence of intentional paracetamol overdose. As a result, GSK's response to the subject consultation is predicated on a multifaceted and industry-aligned approach, informed by the available evidence as described above. Such an approach is aligned to the well-established New Zealand advertising and promotion code/guidelines as summarised in TAPS Guideline #6: Guideline on the use of 'Multi-Buy' offers in Pharmacy that state advertisements must not encourage or be likely to encourage or persuade consumers to purchase or use inappropriate or excessive quantities of a medicine, and that pharmacists only promote or sell quantities appropriate to the clinical needs of the patient.

1. Retain the current scheduling of paracetamol in New Zealand

In 2016, the Medicines Classification Committee concluded that they were satisfied that overall, the benefit of access outweighed the risks and that the classification of paracetamol was appropriate. GSK are not aware of any new evidence in this area that would require the Committee to reconsider the classification of paracetamol pack sizes currently available in New Zealand. Data from other markets has demonstrated that pack size restriction measures in isolation are insufficient to address the issues of intentional paracetamol overdose.

The availability of paracetamol in New Zealand has recently become more restrictive. In 2019, the Committee recommended to change the classification of modified-release paracetamol to a restricted medicine so that it may only be purchased following consultation with a pharmacist. This recommendation was in response to the potential difficulties of managing overdose of the modified release formulation of paracetamol.

2. Support a two-pack purchase limit outside of pharmacy

Supermarkets offer conveniently accessible options for consumers whilst pharmacies handle prescription requirements and non-prescribed, larger pack size supplies.

Availability of paracetamol as a general sales medicine provides New Zealand consumers with access and convenience to an effective pain relief medicine outside the opening hours of pharmacies. Current restrictions applied to non-pharmacy (general) paracetamol sales is a maximum pack size 20 x 500mg (10g) which is equivalent to 2½ days dosage for a single person and consumers shopping for a whole family may need to purchase more than one pack to meet their household's legitimate needs.

GSK is supportive of a two-pack purchase limit for any paracetamol-containing product when purchased in an environment devoid of physical presence of pharmacist/pharmacy assistant oversight. This would apply to both grocery and online environments.

Whilst the maximum allowable pack size for paracetamol outside of pharmacy in the UK is 16 tablets, there is a two-pack purchase limit which equates to 32 tablets/capsules equivalent to 16 g. Thus, GSK supports a similar two-pack purchase limit, albeit which equates to 20g, as this reflects the current maximum allowable pack size for paracetamol outside of pharmacy in New Zealand being 20 500mg tablets.

Recently updated paracetamol overdose guidelines in Australia and New Zealand do not differentiate between treatment protocols for ingestion of 16 g versus 20 g, as heightened management protocol comes into effect at ingested doses of 30g & over.[24] Thus, a two-pack limit for New Zealand would align with the UK approach in all practicalities for access outside of pharmacy.

The proposed purchase limits (see Table 1) seek only to support the implementation of suitable purchase controls that provide a reasonable balance between meeting a customer's immediate need for pain relief while helping minimise stockpiling and accidental or impulsive overdose. Doing so also enables the consumer to purchase from multiple categories, either for themselves or for their family. For example, a single ingredient analgesic for headache and a combination cold & flu paracetamol-containing product for self-limiting cold & flu symptoms.

Table 1: Proposed purchase limits for any paracetamol-containing product in New Zealand.

	Physical Stores "Bricks & Mortar"	**Online "E-commerce"**
Non-Pharmacy Retailer "GSL"	Don't sell more than **two packs** in any **one transaction** (each pack containing ≤ 20 tablets)	Don't sell more than **two packs** in any **one transaction** (each pack containing ≤ 20 tablets)
Pharmacy Retailer	No purchase limits (i.e. up to the pharmacist/pharmacy assistant to decide)	Don't sell more than **two packs** in any **one transaction** (each pack containing ≤ 20 tablets), *and* **Prescription *and/or* pharmacist conversation** required for any online pharmacy purchases not meeting the immediately preceding criteria

GSK will continue to strongly encourage retailers in New Zealand to support a two-pack purchase limit across all paracetamol-containing products.

3. Implement a health care professional awareness/education programme

Pharmacists must abide by the Pharmacy Council New Zealand Code of Ethics 2018 which requires that a pharmacist promotes the safe, judicious and efficacious use of medicines, and prevents the supply of unnecessary and/or excessive quantities of medicines, or any product which may cause harm.

GSK acknowledges the professionalism and training of pharmacists and pharmacy assistants in New Zealand and will support initiatives for activities to provide continuing education and support the profession in meeting their responsibilities in assessing therapeutic need being aware of risks of accumulation, particularly large quantities available via PHARMAC.

PHARMAC legislation allows a patient to receive up to 720 tablets (3 months' supply) at any one time via this mechanism. The volume of solid dose paracetamol dispensed to the public via the PHARMAC scheme accounted for ~ 78% of the total paracetamol volume in 2019 on a per tablet basis.[5] Therefore, if the goal of this consultation is to reduce residual stock in the home and ease of access to paracetamol in the community, PHARMAC-funded dispensed products cannot be overlooked.

Furthermore, PHARMAC-funded products are not required to be dispensed in labelling that includes all the warning and advisory statements New Zealand regulations mandate for equivalent OTC paracetamol products. The lack of consistency in label warnings between OTC and prescription paracetamol was noted by the US FDA in 2011.[25]

The impact of access to funded prescription paracetamol has been observed in Sweden where it is available in large counts (up to 100g) and is reimbursed whereas OTC paracetamol is restricted to 10g but is not reimbursed. A study[8] has noted this has led to a shift from equal sales of OTC and prescription in 2000 to prescription supply accounting for 77% of all sales in Sweden (which is a similar level of prescription supply as is currently the case in New Zealand). In parallel to this shift from OTC to prescription, Sweden has seen a fourfold increase in paracetamol poisonings since 2000.[8] This implies that large quantities of paracetamol in the home increases the risk of intentional overdose, regardless of the scheduling of the paracetamol.

Drawing upon the recommendations made by a study[5] specific to New Zealand, it is important that prescribers and pharmacists be reminded of the risks of accumulation of agents such as paracetamol and assess the therapeutic needs of their patients to determine how much is needed when prescribing and dispensing.

4. Support a Government-led public education campaign

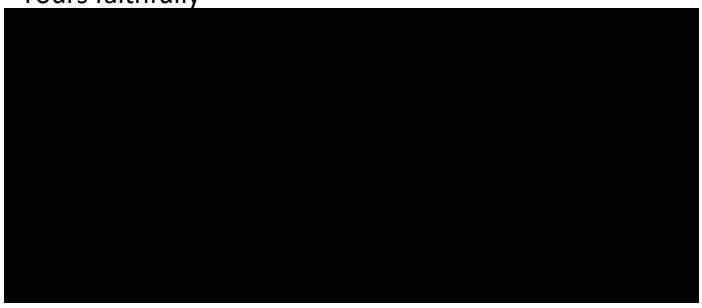
A study[5] recommended that public initiatives, such as "Dispose of Unwanted Medication Properly" should be regularly undertaken in New Zealand to encourage people to return unused or expired medicines for pharmacies for safe disposal. This would assist in reducing inappropriate access such as use in intentional self-poisoning, or accidental paediatric exposures.

A holistic Government-led initiative drawing upon broad principles of Quality Use of Medicines is suggested. It is important that unintended consequences of inadvertently promoting paracetamol as an option for self-poisoning to vulnerable individuals be avoided. Such a campaign would provide multiple benefits particularly in the current climate where pantry stocking was reported during the COVID-19 pandemic and supports responsible use of medicines in the community.

Conclusion

GSK acknowledges previous concerns raised by the Committee in relation to the sale of paracetamol in New Zealand grocery environment. GSK are of the view that no change in scheduling of paracetamol access is warranted but support mechanisms to meaningfully help mitigate against excessive consumer purchase and stockpiling at home beyond reasonable amounts such as general sales and online purchase limits. However, such measures can only reach true effect in the presence of both a health care professional awareness/education programme in conjunction with a Government-led public education campaign. In addition to these suggested measures, as the world's largest consumer healthcare company, GSK is currently undertaking a significant piece of work at a global level to execute a consumer-focussed educational programme targeting responsible use of medicines. Paracetamol will be a key priority for this project and Australia/New Zealand, as a significant paracetamol market within GSK internationally, will be prioritised in the scope of these activations.

Yours faithfully



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14 October 2020

Jacinta Patel
The Secretariat
Medicines Classification Committee
Medsafe
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Wellington 6011

Dear Jacinta

The Medsafe pharmacovigilance team and the Chair of the Paracetamol Overdose Prevention Group (a working group of the Medicines Adverse Reactions Committee) would like to comment on agenda item 5.2 of the 65th meeting of the Medicines Classification Committee, relating to the coroner's recommendations on the sale of paracetamol.

Firstly, we wish to express our sympathy for the family and friends of Alannah Spankie and to thank the coroner for his recommendations arising from this case. We have been under taking a number of activities to try an improve the safe use of paracetamol arising from cases of overdose in children. We would like to take this opportunity to pass on feedback received during a recent consultation on paracetamol labelling. These comments were largely from health care professionals, about safety issues relevant to the classification of paracetamol. The extensive scope of comments received highlight that multiple approaches are needed in concert to promote safe use of paracetamol.

Background

At the December 2018 Medicines Adverse Reactions Committee (MARC) meeting, the MARC discussed a serious case report of acute liver failure in a young patient due to a suspected overdose of paracetamol. The MARC noted that they had discussed similar case reports in the past, indicating an ongoing issue. The Poisons Centre confirmed that they had also received calls reporting paracetamol dosing errors.

After the MARC meeting discussion, a working group was set up and a number of recommendations were made with the aim of improving the safe use of paracetamol. One of the recommendations was to check the labelling for non-prescription paracetamol products. Medsafe conducted a consultation that was open from November 2019 until January 2020, with the aim of gathering views on the appropriateness of the required label statements for products containing paracetamol.

Medsafe received 72 responses to the consultation. Of these, 59 were from health care professionals and their representative bodies, 10 were from industry, and three were classified as 'other'. There were many comments outside the context of the consultation. Some of these comments related to the classification of paracetamol and we have provided an overview of these in this letter.

Pack sizes of tablets

Many comments received stated that the wide availability of large pack sizes of paracetamol creates the perception that paracetamol is a benign medicine and undermines safety messages. Other comments stated that this availability may contribute to intentional overdose.

These comments supported reducing general sale and pharmacy maximum pack sizes to 12 tablets (6 grams of paracetamol) and 32 tablets (16 g of paracetamol), respectively. Similar limits could be considered for other dose forms such as powder sachets.

Repacking by pharmacists

Some comments pointed out that if paracetamol products are repacked by pharmacists, important administration and safety information on the manufacturer's original packaging is lost. While this is standard practice in the context of supply by prescription, repacking is inappropriate in the context of over-the-counter sale, and this should be prohibited by the classification statement. This was felt to be particularly pertinent to liquid paracetamol (see below).

The comments supported changing the classification statement for all over-the-counter classifications to include 'when sold in the manufacturer's original pack'.

Liquid paracetamol

Some submissions expressed concerns around quantities of paracetamol liquid supplied. The classification for liquid paracetamol does not include a pack size limit for over-the-counter sale.

The comments supported limiting the pack size of paracetamol liquid in the classification statement. A maximum pack size of 200 mL of paracetamol liquid would be appropriate.

The comments supported the mandatory provision of dosing devices with paracetamol liquid. One solution suggested was to amend the Pharmacy Only classification for the liquid form to state 'in liquid form when supplied with a dose measuring device' or similar.

Repacking of paracetamol liquid by pharmacists for over-the-counter sale was considered inappropriate for the reasons stated earlier in this letter. The comments also highlighted that a single pack of paracetamol liquid is often used for dosing multiple children and dosing of the liquid is more complex than tablets. Access to the dosing table and safety information on the manufacturer's original pack is therefore considered very important.

The comments also highlighted that availability of two strengths of paracetamol liquid is confusing for consumers and a common source of dosing errors. The misconception that a certain

flavour correlates to a certain strength was also noted. These topics are outside of the scope of the medicine classification, but highlight the importance of informative medicine labels in promoting safe use of paracetamol.

Sale of multiple packs

Concerns were voiced in many comments about sale of multiple packs of paracetamol in a single transaction, especially through the use of discounting and dump bins. This also contributes to public perception of paracetamol as a benign medicine.

While restricting the number of packs sold is not within the scope of the classification statement, it is noted that Principle 1 of the Pharmacy Council Code of Ethics 2018 states, 'A pharmacist promotes the safe, judicious and efficacious use of medicines, and prevents the supply of unnecessary and/or excessive quantities of medicines, or any product which may cause harm'. The Pharmacy Council Advertising Guidelines echo this and also set out expectations around promotion of medicines.

Pharmacists should be reminded of these ethical obligations as they relate to the sale of paracetamol.

We also note the recent statement from Countdown that they will no longer be selling multiple packs in their supermarkets and we would encourage other retail sales groups to follow suit.

Yours sincerely

[redacted]

Susan Kenyon
Manager, Clinical Risk Management
Medsafe

[redacted]

Associate Professor David Reith
Chair of the Paracetamol Overdose Prevention Group

UNIVERSITY of OTAGO
Te Whare Wānanga o Otāgo
NEW ZEALAND

23 October 2020

Medicines Classification Committee
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Agenda for the 65th meeting of the Medicines Classification Committee: 5.2 Paracetamol – recommendation received from the coroner

Dear Sir/Madam,

The purpose of this letter is to provide information to the Committee regarding paracetamol exposures/poisonings reported to the National Poisons Centre (NPC) as context for the discussion of agenda item 5.2 paracetamol recommendation received from the coroner.

As the only poisons centre in New Zealand, the NPC provides a 24/7 nationwide service to the public and healthcare professionals with comprehensive risk assessment, clinical management guidelines, and specialist physician advice for poisonings. The mission of NPC includes optimising care for poisoned patients and promoting public health.

Paracetamol is the single most common substance about which enquiries are made to NPC, and also the most commonly viewed substance on the NPC's TOXINZ Poisons Information Database by healthcare providers working at District Health Boards.[1] Paracetamol is also the most common single substance involved in cases of intentional self-poisoning based on a review of New Zealand national registry data.[2] Intentional self-poisoning is a significant public health problem that is often an impulsive act by those individuals who harm themselves – reaching for whatever substance is near at hand during the act. A recent study found nearly 87% of New Zealand households had at least one paracetamol product present with a median dose of 24 grams per household, and 53% of households had 30 grams or more paracetamol present.[3] Guidelines for the management of paracetamol poisoning in New Zealand and Australia identify 30 grams of paracetamol as a massive dose warranting special consideration during treatment, including use of higher doses of the antidote n-acetylcysteine.[4] Recently, NPC medical toxicologists have anecdotally noted an increase of massive ingestions being reported in consultations with treating clinicians across New Zealand.

The NPC exposures database was investigated to determine whether this anecdotally perceived increase in massive paracetamol exposures has a corresponding increase in actual cases. To do this, contacts to the NPC between 10 August 2016 and 12 October 2020 were examined (this starting date chosen as it was the first date using the current NPC system). To be relevant to the coroner's recommendations being presently considered by the committee, only tablet/capsule exposures were included in the analysis. Also, only paracetamol exposures where NPC advised medical assessment were included. The chart below shows a trend of increasing massive (30 grams or more) paracetamol exposures since 2016, and also an increasing trend in overall paracetamol exposures

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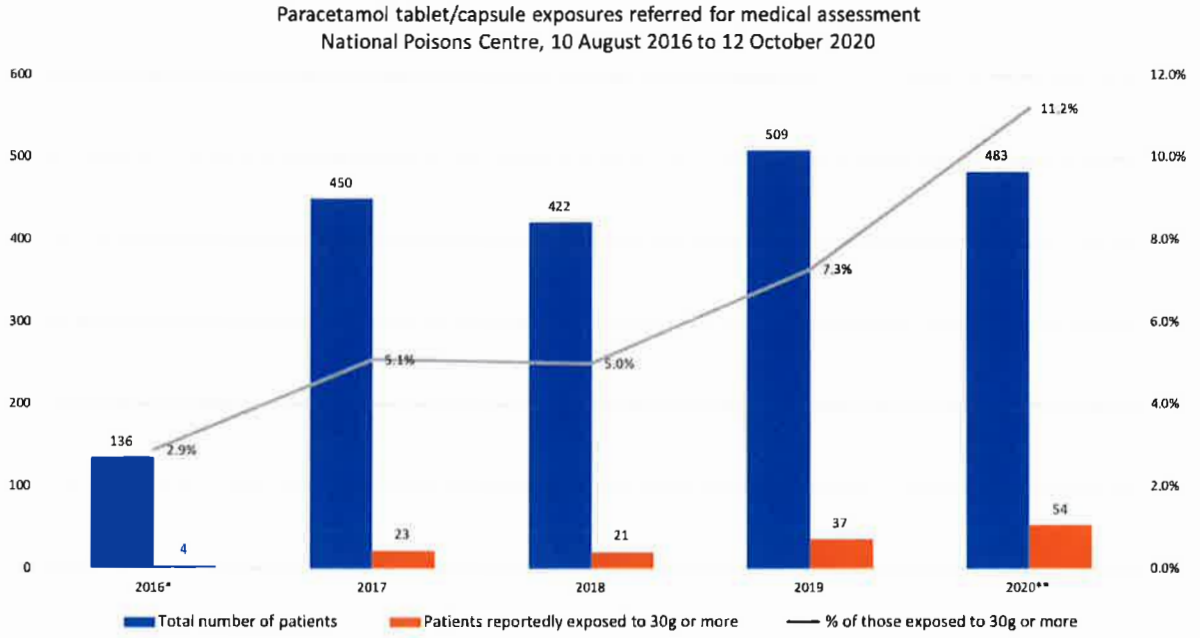
requiring medical assessment. Over the final five months of 2016 there were 4 exposures involving 30 grams or more (2.9% of all paracetamol exposures requiring medical assessment), whereas in 2020, up to 12 October, there have been 54 such exposures (11.2% of all paracetamol exposures requiring medical assessment). For the entire period, there have been 139 exposures involving 30 grams or more, and 126 (91%) of these were noted to involve intentional self-poisoning.



There are a few limitations to these findings that should be noted:

- Ultimately, data captured by NPC is only a portion of the total amount of paracetamol exposures occurring in the country. Reporting bias is present in poisons centre data as it is at an individual's discretion whether to contact NPC. There are members of the community who will be unaware of NPC's service, and not all healthcare providers will seek consultation from NPC when managing patients for paracetamol poisoning.
- Substances and amounts involved in exposures are documented as reported by the caller (healthcare professional or member of the public), NPC is unable to independently verify the information.
- Cases where the exposure dose was not known have not been included even if high paracetamol blood levels (when available) indicated a potentially significant dose.

It is also important to note that NPC does not have information about the sources of paracetamol involved in these exposures – whether it was acquired from a retail outlet or pharmacy, or whether it was prescribed or over the counter cannot be determined.

Contacts to the NPC are a reflection of exposures occurring in the New Zealand community. While it may simply be due to increased contacts to the NPC, this data suggests that paracetamol exposures requiring medical assessment, and massive paracetamol overdoses, are likely occurring with increasing frequency over time. There are several possible contributing reasons for this trend. How the availability of paracetamol impacts these data is open for speculation, however a reasonable hypothesis would be that limiting availability could limit opportunities for impulsive intentional self-poisonings with large amounts of paracetamol.

Please feel free to contact me directly at adam@poisons.co.nz with any questions or if there is any additional information I can provide.

Sincerely,

[redacted]

Adam Pomerleau, MD, FAACT, FACEM
Director and Medical Toxicologist
National Poisons Centre

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MEDICINES CLASSIFICATION COMMITTEE AGENDA FOR THE 65TH MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE TO BE HELD IN WELLINGTON ON 27 OCTOBER 2020

Comments on agenda item 5.2 Paracetamol- recommendation received from the coroner

Dear Committee members,

[redacted] welcomes the opportunity to comment on agenda item 5.2, a recommendation by the coroner to the Committee proposing the implementation of restrictions on the quantities of paracetamol available for purchase in New Zealand. Specifically, the coroner has recommended the following restrictions;

(a) Pharmacy sales: 16 g per transaction (i.e. 32 x 500 mg tablets)

(b) All other outlets 8 g per transaction (i.e. 16 x 500 mg tablets)

(c) A maximum of 50 g (i.e. 100 x 500 mg tablets) by prescription.

[redacted] is a proactive member of the NZ selfcare industry, with a key role in helping to support the health and well-being of all New Zealanders through self-care education, promoting quality use of medicines, and delivering safe and effective medicines that are appropriately available in a self-care environment.

Whilst the submission made to MCC is lacking in detail, the concerns related to single active solid dose paracetamol overdose (intentional and unintentional) and associated toxicity have been known for some time and discussed at various MCC meetings. While measures have been put in place to help minimise the issues associated with overdose, at the core of many of the intentional overdose cases is the mental health and wellbeing of New Zealanders. Important in considering how to best mitigate the use of single active solid dose paracetamol products in intentional overdose by people who intend to suicide it is important that the Ministry of Health explore opportunities for providing support and education to people struggling with their mental health. In addition to this, it is [redacted] view that any changes to consumer access should be accompanied by

consumer education on the safe and appropriate use of single active solid dose paracetamol – how much, how long, as well as the dangers of using more than recommended. In addition, given the changes in clinical management guidelines for conditions such as back pain and osteoarthritis, education should also focus on healthcare professionals to ensure they are recommending/prescribing /dispensing the most effective analgesic for a given consumers needs.

Paracetamol toxicity

Paracetamol poisoning is the most common cause of acute liver failure in the developed world (1). Paracetamol is involved in a large proportion of deliberate self-poisoning cases and is the leading pharmaceutical agent responsible for calls to the Poisons Information Centres in Australia and New Zealand (2,3).

It is clear, that the issues associated with paracetamol overdose are specific to single active solid dose paracetamol products and not combination products or single active powders. There are no reported cases of severe overdose with these products. The on-line information regarding how to overdose on paracetamol is specifically focused on single active solid dose paracetamol, that is tablets/caplets/capsules because of its ease of consumption. Dissolving more than a few sachets of 1000mg of powdered paracetamol in a glass of water is very difficult. The alternative would be having to drink 10 glasses of water which would simply not be practical.

In addition to the issues with intentional overdose are issues associated with unintentional overdose due to consumers beliefs that paracetamol is safe. Many unintentional overdose situations occur as a result of lack of efficacy of paracetamol. Both lower back pain and osteoarthritis management guidelines are moving away from recommending paracetamol as a first line pharmacological option for managing these pain states due to lack of data supporting its efficacy in these situations. Moreover, paracetamol has been marketed as a safe medicine without education on the dangers of a slight overdose which can and does occur when relief is not effective. Even healthcare professionals continue to recommend/prescribe paracetamol over more efficacious OTC medicines due to their belief that it is safe. Consequently, many consumers are not aware of the dangers of the slightest overdose of single active solid dose paracetamol products.

Responsible self-care

As a self-care industry it's important that access to effective and safe medicines to manage acute pain continue to be available. The issue of toxicity due to overdose whether intentional or otherwise is specific to single active solid dose paracetamol products. There is no evidence to suggest that other OTC analgesics, combination products or paracetamol powders are used for the purpose of intentional or unintentional overdose. In addition, the use of more effective combination products containing paracetamol can in some instances reduce the overall dosage of paracetamol taken per day and provide more effective pain relief (4). Consequently, in the interest of self-care and making safe effective medicines available to NZ consumers the discussions and decisions of the committee should be focused on the issue at hand, single active solid dose paracetamol products.

Purchase limits and pack size reduction for single active solid dose paracetamol products

[redacted] supports attempts to implement guidance on purchase limits for single active solid dose paracetamol products to help mitigate the paracetamol toxicity issues associated with overdose. Although purchase limits on their own may be insufficient to address the paracetamol toxicity issues as this would be a self-regulatory initiative and unless written into the legislation, this would be difficult to enforce and monitor. Many paracetamol overdose incidences are impulsive and tend to involve use of single active solid dose paracetamol products in the home, hence restricting access to large packs could be a more suitable level of protection, in order to prevent overdose. In addition, the availability of large pack sizes in pharmacies which can be purchased through online pharmacies without professional supervision adds another level of complexity. A survey by Freeman & Quigley (2015) found that there were numerous online outlets in NZ where paracetamol could be purchased in large quantities, in the absence of suitable monitoring for the safety of consumers (3).

It's important to highlight that the dosage form of single active paracetamol has also been closely related to its chance of misuse with lower pack limits globally for solid oral dosage forms in comparison to powders, granules and effervescent formats where there is a lack of evidence of deliberate overdose. In the UK current scheduling allows for 10grams of powdered paracetamol to be available

as a general sale medicine vs 8 grams for solid dose single active paracetamol products.

To reiterate, this issue before the committee is specifically one associated with single active solid dose paracetamol products. There are no reported cases of severe overdose with combination products or powdered paracetamol given the impracticality of having to consume 10 glasses of water. This is supported by the attached statement from Dr Rose Cairns (Lecturer, Sydney Pharmacy School, The University of Sydney & Director of Research, New South Wales Poisons Information Centre) (Appendix 1).

Scheduling changes to single active paracetamol analgesics

Should the committee decide that general sale pack sizes for paracetamol products should be limited to 8 grams, it is [redacted] view that this should be specific to single active paracetamol solid dose formats (tablets/caplets and capsules) which are implicated in overdose situations and not combination products or paracetamol powders where evidence in overdose is lacking. This is the approach taken in the UK with the current scheduling allowing for 10 grams of powdered paracetamol to be available as a general sale medicine vs 8 grams for solid dose single active paracetamol tablets/capsules.

Conclusion

Paracetamol poisoning is the most common cause of acute liver failure in the developed world. Paracetamol is involved in a large proportion of deliberate self-poisoning cases and is the leading pharmaceutical agent responsible for calls to the Poisons Information Centres in Australia and New Zealand.

Concerns related to paracetamol overdose (intentional and unintentional) and toxicity have been known for some time and discussed at various MCC meetings. While measures have been put in place to help mitigate the risk of overdose these have not sufficiently reduced the incidence of overdose nor it's severity.

As a self-care industry it's important that access to effective and safe medicines to manage acute pain continue to be available. The issue of toxicity due to overdose whether intentional or otherwise is specific to single active solid dose paracetamol products and as such any discussions regarding restricting access should be specifically aimed at addressing the issue at hand and as such

continue to maintain an effective self-care environment. There is no evidence to suggest that combination products or paracetamol powders are used for the purpose of intentional or unintentional overdose. This is reflected in the UK scheduling of paracetamol where general sale limits for paracetamol powders is 10g vs 8 grams for solid dose single active paracetamol tablets/caplets and capsules.

Importantly education of both consumers and healthcare professionals regarding appropriate use and recommendation/prescribing of solid dose single active paracetamol products should form an important part of any changes implemented.

Consequently, [redacted] proposes that any measures introduced to restrict access be specifically focused on single active solid dose paracetamol formats which are implicated in overdose situations.

Regards,

[redacted]

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21 October 2020

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committees@moh.govt.nz

Dear Sir/Madam

Submission: Item 5.2 of the MCC's Agenda re Coroner's Recommendations on Paracetamol

Foodstuffs has become aware of the discussion the Committee will hold at its upcoming meeting in response to the Coroner's recommended changes to the regulation of Paracetamol, including tighter restrictions on the sale of Paracetamol in the general sales channel. Having the largest footprint of supermarket and grocery stores in New Zealand, more than 500 stores in total, Foodstuffs wishes to register its interest in the review.

We understand the MCC's consideration of the regulatory settings for Paracetamol is at the formative stage and more substantive work on this is likely to commence after the meeting.

Should the MCC decide to initiate a formal review for Paracetamol, Foodstuffs is very willing to engage on this, including discussion on possible self-regulatory options.

In this regard, I will be the primary contact for further engagement and can be contacted at Melissa.Hodd@foodstuffs.co.nz, and phone numbers: (04) 471 4810 and (021) 667 439.

Yours sincerely

[redacted]

Melissa Hodd
General Manager
Government Relations

PHARMACY GUILD OF NEW ZEALAND

23 October 2020

Medicines Classification Committee Secretary
Medsafe
Wellington

Sent via email to: committees@moh.govt.nz

Dear Committee Members

RE: Agenda for the 65th meeting of the Medicines Classification Committee

Thank you for the opportunity to provide feedback on the agenda for the 65th meeting of the Medicines Classification Committee (MCC), to be held on 27 October 2020.

The Pharmacy Guild of New Zealand (Inc.) (the Guild) is a national membership organisation representing the majority of community pharmacy owners. We provide leadership on all issues affecting the sector.

Our feedback covers the following agenda items. These are:

- ***Agenda item 5.2*** *– Paracetamol – recommendation received from the coroner*
- ***Agenda item 6.1*** *– Fexofenadine – proposed change to pack size limit and reclassification from pharmacy only to general sale (Telfast, Sanofi-Aventis New Zealand Limited)*
- ***Agenda item 6.2*** *– Ibuprofen 400mg – proposed reclassification from restricted medicine to pharmacy only medicine (Nurofen 400 Double Strength, Reckitt Benckiser (New Zealand) Pty Limited)*
- ***Agenda item 6.3*** *– Flurbiprofen – proposed reclassification from pharmacy only medicine to general sale medicine (Flurbiprofen lozenge, Reckitt Benckiser (New Zealand) Pty Limited)*
- ***Agenda item 6.4*** *– Hyoscine butylbromide – proposed addition of oral liquids in the current classification (Gastrosoothe, AFT Pharmaceuticals Limited)*

Each of these agenda items are discussed below.

Agenda item 5.2 – Paracetamol – recommendation received from the coroner
We support the coroner's recommendation that restrictions are implemented on the quantities of paracetamol available under the various medicine classifications. However, we do not agree with the specific quantities for each classification that has been recommended by the coroner.

On prescription
We do not support implementing a restriction on the maximum quantity available by prescription. Restricting the quantity of paracetamol prescribed for patients with chronic pain conditions would be unreasonable and not in the best interest of good patient outcomes. Paracetamol when taken correctly works well as a long-term medicine and is normally prescribed at the dose of 1g four times a day, ie, 240 x 500mg tablets per 30 days. Patients with long term chronic pain conditions are under the care of a general

practitioner and their community pharmacist who are both responsible for regular assessment of their therapeutic needs.

Currently, PHARMAC require pharmacies to dispense paracetamol tablets in quantities of up to 90-day all-at-once lots, ie, 720 x 500mg tablets. We would recommend PHARMAC implement a monthly restriction on the amount of paracetamol tablets dispensed for patients with long term chronic pain conditions. This would minimise stockpiling, reduce the quantity of paracetamol tablets available in households throughout our communities, and allow the community pharmacist to provide regular medication oversight to optimise patient outcomes.

However, we would also recommend PHARMAC to implement a restriction on "when required" (PRN) prescriptions to a maximum of 100 x 500mg paracetamol tablets per dispensing, as this would help reduce unnecessary stockpiling in the community.

As a general sale medicine

We note from the background information provided at previous MCC meetings, that Medsafe had written to the Pharmacy Council of New Zealand, the Pharmaceutical Society of New Zealand, Retail New Zealand and the Grocery Council to highlight the potential purchase of general sale packs of paracetamol for deliberate self-harm and there were mixed views from the retailers about the effectiveness of limiting the sale of multiple packs and ceasing the sale of paracetamol via online channels.

While the UK has reported a corresponding reduction in paracetamol-related deaths, hospital admissions, and liver transplants following the reduction in paracetamol pack sizes to 16 x 500mg tablets, the smallest pack size commonly available in New Zealand and Australia for general sale is 20 x 500mg paracetamol tablets/capsules. Reducing the pack size in New Zealand to 16 x 500mg tablets/capsules would come at a substantial cost to suppliers, and it will also affect the Trans-Tasman Scheduling Harmonisation.

We are concerned that general sale retail outlets do not have the expertise to provide the level of advice and support required to ensure sufficient public safety for a medicine such as paracetamol when sold as a general sale medicine. Therefore, limiting the pack size to 16 x 500mg paracetamol tablets per transaction when sold by retail outlets will not effectively address the issues of unintentional overdose and harm reduction.

Based on our concerns above, we do not support implementing a limit of 16 x 500mg tablets per transaction when sold by retail outlets as a general sale medicine. We would instead recommend that the MCC go a step further and reclassify all paracetamol containing products to pharmacy-only. Public convenience should not be more important than public safety which is best supported by advice and oversight from an appropriately trained health professional.

Even if retail outlets are individually able to limit the sales to 16 x 500mg tablets per transaction, this comes down to a voluntary decision by each retail outlet, which will lead to inconsistencies around how this limit is enforced.

As a pharmacy only medicine

We note that MCC at the 57th meeting recommended the pharmacy only entry be amended to a single pack size of a maximum of 100 tablets/capsules. We are

comfortable when paracetamol is sold through the pharmacy channel it is safe and controlled, therefore we would not support the coroner's recommendation to limit sale to 32 x 500mg tablets.

Paracetamol is the most commonly used pain relief medicine in New Zealand, and taken at the recommended doses, paracetamol is usually safe and well tolerated.

Paracetamol is readily available in a diverse range of products marketed to treat different types of pain including headache, migraine, period pain and aches and pains associated with colds and flu. We are concerned this can lead to confusion for the public when self-selecting and self-medicating in a general sale environment, as they would not necessarily be aware of the total daily paracetamol content being consumed and the dangers related to overdose.

Therefore, we would recommend that all medicines containing paracetamol are reclassified as pharmacy-only medicines. Pharmacy staff are under the supervision of a pharmacist and trained to advise customers on the appropriate use of over-the-counter analgesics and can refer to the pharmacist when needed.

Agenda item 6.1 – Fexofenadine – proposed change to pack size limit and reclassification from pharmacy only to general sale (Telfast, Sanofi-Aventis New Zealand Limited)

The Guild does not support the Sanofi-Aventis New Zealand Limited company submission proposing a change to pack size limits and the reclassification from pharmacy only to general sale.

The proposal to change fexofenadine underestimates the value of the important role that community pharmacy plays in ensuring medicine safety in the primary care setting. Medicines when supplied by a community pharmacy have the oversight of a pharmacist who has significant clinical expertise and where needed, patients can be provided with medicines information, advice and verbal reinforcement.

We have concerns that changing the general sale restrictions will encourage the public to put off or prolong the time before engaging with a health care professional. Seasonal allergic rhinitis is commonly confused with a range of other diagnoses, such as a simple cold, a sinus infection, conjunctivitis, and serious eye conditions. Due to the prevalence of misdiagnosis, there is potential risk to deterioration of a person's health due to inappropriate treatment.

We believe that medicines should only be available as a general sale medicine to provide access to a particular medicine when a consumer cannot access a health care professional and when there are no other suitable alternatives available as general sale.

A pack size limit of five days provides sufficient coverage for a member of the public until they can access a health professional, eg, over the weekend or out of normal business hours. In the instances where a patient requires more than five days supply of a medicine, consumers should always access these medicines on the advice of a health professional to ensure the medicine is the most appropriate treatment for their condition.

We believe there are sufficient antihistamine alternatives that currently exist as general sale medicines, including an additional strength of fexofenadine, 180mg. This could lead to confusion for consumers, particularly as the dose frequency for the different strengths of fexofenadine are different.

Currently, there are also no enforceable methods to control the limits of how many packs of a medicine a customer can purchase from any general sale environment. Until there are robust processes in place to limit restriction to the quantity of packs that can be purchased in a general sale environment, to maintain patient safety, pack sizes of medicines should be restricted to the minimum quantity of medicines needed until they can access a health professional.

Agenda item 6.2 – Ibuprofen 400mg – proposed reclassification from restricted medicine to pharmacy only medicine (Nurofen 400 Double Strength, Reckitt Benckiser (New Zealand) Pty Limited)

The Guild does not support the proposed reclassification of ibuprofen 400mg from restricted medicine to pharmacy only medicine. We have general concerns over the potential confusion that consumers may have with the 200mg tablet form of ibuprofen, leading to the potential for unintentional overdosing of ibuprofen.

In New Zealand, ibuprofen has generally only been available in the 200mg tablet form and it is only in recent years that the 400mg tablet form has been available for sale over the counter as a restricted medicine. In addition, only the 200mg tablet form is funded on the PHARMAC schedule, and we believe that consumers will be most familiar with the 200mg tablet form.

The proposed packaging for the Nurofen Double Strength presentation is illustrated on page 30 of the reclassification document 'Application for the reclassification of ibuprofen 400mg from Restricted Medicine to Pharmacy Only Medicine' submitted by Reckitt Benckiser. We believe the subtle design elements proposed by Reckitt Benckiser, do not go far enough to clearly distinguish that the product is a different strength to the standard 200mg tablet form. The colour combinations and the general design layout of the packaging are essentially identical, which leads to significant risk of confusion for the consumer between the two dose forms. This proposed packaging is also in contradiction to other Nurofen products which are clearly differentiated by the use of different colours in combination with the silver background.

In February 2019, paracetamol modified release was reclassified from a pharmacy only medicine to a restricted medicine due to concerns from Medsafe over unintentional overdose of paracetamol modified release, caused by confusion over the similar dose forms of paracetamol. The MCC noted the importance of consumer interaction with a pharmacist so that appropriate advice can be given to consumers to ensure the correct dosing of the medicine.

We believe that due to the decision made by the MCC around modified release paracetamol to protect patient safety, the same approach should be taken with ibuprofen 400mg tablets, to mitigate any risk of consumers accidentally taking the incorrect dose of the 400mg tablet form. This also provides consistency for health professionals when considering the rationale for the different classifications of medicines.

We believe the risks associated with having a double strength tablet form available over-the-counter far outweigh the consumer benefit, when the usual prescribed adult dose of ibuprofen is two tablets of the 200mg tablets. The consumer benefit is minimal when compared to the significant potential for harm if a consumer accidentally takes twice the recommended dose of ibuprofen. If it is determined that there is a clinical need for an individual consumer to be recommended the ibuprofen 400mg tablet dose form, then the supply should always be accompanied by the oversight and advice of a pharmacist.

Agenda item 6.3 – Flurbiprofen – proposed reclassification from pharmacy only medicine to general sale medicine (Flurbiprofen lozenge, Reckitt Benckiser (New Zealand) Pty Limited)

The Guild does not support the proposed reclassification from pharmacy only medicine to general sale medicine (Flurbiprofen lozenge, Reckitt Benckiser (New Zealand) Pty Limited). We have significant concerns around the implications of reclassifying flurbiprofen to general sale where it may lead to delayed detection and diagnosis of streptococcal throat infections, the use of flurbiprofen in pregnancy, and may lead to consumers unintentionally doubling up on anti-inflammatories.

Community pharmacies provide several functions in primary care around the management of sore throats in their communities. This ranges from providing a basic triage function in identifying and providing symptomatic relief for uncomplicated cases of sore throat, referring potential cases of streptococcal throat infections onto general practice for follow up testing, providing diagnosis of streptococcal throat infections through rapid testing instore, to pharmacies being contracted by DHBs to provide streptococcal throat swabbing services.

New Zealand continues to be an outlier in the incidence of acute rheumatic fever, which is typically an illness more prevalent in developing countries. In New Zealand, high risk groups for rheumatic fever include Māori and Pacific children aged between 4 to 19 years. By reclassifying flurbiprofen to general sale, this will increase the availability of a medicine which masks the symptoms of sore throats, and without the advice of a health professional, this may significantly impact our current incidence of untreated streptococcal throat infections, through delayed detection and diagnosis. Flurbiprofen is indicated for the relief of sore throat from the age of 12 years, which falls within the age range where children are at the greatest risk of developing rheumatic fever.

We also have concerns around the use of flurbiprofen in pregnant women. There is limited evidence available to demonstrate whether it is harmful or not. However, the general advice around NSAIDs is to avoid use during the third trimester to minimise the risk of the premature closure of the fetal ductus arteriosus in utero and persistent hypertension of the newborn.

We believe that it is insufficient to rely solely on medicine labelling to ensure that pregnant women do not take anti-inflammatories available in the general sale environment. Pregnancy and breastfeeding checks form part of the routine assessment of all patients who come into a community pharmacy seeking treatment and advice. If a woman is identified as being pregnant, pharmacist clinical knowledge and checks against pregnancy clinical references are conducted to ensure that all medicines are appropriate for the woman to take during her pregnancy.

We have further concerns around consumers purchasing and using flurbiprofen containing products from a general sale environment and where they may also be taking cold and flu preparations and other forms of pain relief that contain other anti-inflammatories. For example, Nurofen Cold and Flu PE and other Nurofen products that are available as general sale. A significant proportion of sore throat lozenges contain antiseptic agents without pain relief and provide symptomatic relief of a sore throat by providing a soothing effect by coating the affected areas of the throat.

We have concerns that consumers will be unaware that flurbiprofen sore throat lozenges contain an anti-inflammatory and therefore may be unintentionally doubling up on anti-inflammatories. In the community pharmacy setting, pharmacy staff act as a safeguard as they are trained to advise consumers at the point of sale that flurbiprofen is an anti-inflammatory and to avoid the concomitant use of other products that contain anti-inflammatories.

Agenda item 6.4 – Hyoscine butylbromide – proposed addition of oral liquids in the current classification (Gastrosoothe, AFT Pharmaceuticals Limited)
The Guild supports the proposed addition of oral liquids to the current classification of hyoscine butylbromide for oral use in medicines containing not more than 20 milligrams per dose.

Currently, hyoscine butylbromide is available through the consultation and advice of a pharmacist. The addition of the oral liquid preparation will provide benefits through allowing incremental dosing and by providing an alternative dosage form, particularly beneficial for those who may have difficulty swallowing tablets.

Thank you for your consideration of our response. If you have any questions about our feedback, please contact our Professional Services Pharmacists, Alastair Shum (alastair@pgnz.org.nz or 04 802 8209) or Linda Joe (linda@pgnz.org.nz or 04 802 8214).

Yours sincerely,

[redacted]

Nicole Rickman
General Manager – Membership and Professional Services

PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

16 October 2020

Medicines Classification Committee Secretary
Medsafe
PO Box 5013
Wellington 6145
via email: committees@moh.govt.nz

Dear Jacinta,

MEDICINES CLASSIFICATION COMMITTEE (MCC)
COMMENTS TO THE 65th MEETING AGENDA Tuesday 27th October 2020

Thank you for the opportunity to submit comments on the Agenda for the 65th meeting of the Medicines Classification Committee.

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 3,700 pharmacists, from all sectors of pharmacy practice. We provide to pharmacists professional support and representation, training for continuing professional development, and assistance to enable them to deliver to all New Zealanders the best pharmaceutical practice and professional services in relation to medicines. The Society focuses on the important role pharmacists have in medicines management and in the safe and quality use of medicines.

Regarding the agenda items for the above meeting of the Medicines Classification Committee, the Pharmaceutical Society would like to note the following comments for consideration:

5.2 Paracetamol – recommendation received from the coroner

The Society welcomes the opportunity to provide feedback around the potential future provision of paracetamol to patients and members of the public.

Paracetamol is an effective analgesic for a variety of clinical conditions and can also be used as an antipyretic.[1] Paracetamol has been on the market for over 50 years. Currently patients and their carers can access paracetamol through a variety of different avenues including prescriptions, pharmacies (both physical and online) and various retail outlets, including supermarkets and dairies.

Paracetamol has been accepted by the public as an easy to access medicine for the management of acute conditions. In addition to over the counter and patient self-selection, 2,940,467 individual prescriptions for paracetamol were written and dispensed in New Zealand during 2019.[2]

Paracetamol is still one of the most commonly used medications for overdose.[3] Reducing the pack sizes of paracetamol that patients and their carers can purchase has reduced estimated deaths due to paracetamol overdose.[4] However, with continuing cases of overdose, it suggested that "further preventive measures should be sought" and pack size reduction may not resolve the issue.[4]

The Coroner's recommendations reflect those currently implemented in the United Kingdom, with the exception of the prescriber restrictions. New Zealand legislation has a slightly different medicines category system including the potential to use a restricted (Pharmacist-only) classification. To support the discussions around equitable access to appropriate treatment,

which is balanced against the safety profile of paracetamol, the Society would like to suggest the following recommendations, if paracetamol is considered for reclassification:

Pharmacy only: 10g per transaction (i.e. 20 x 500 mg tablets)

Restricted (Pharmacist only) supply: 50g (i.e. 100 x 500mg tablets)

Prescription only supply: Decision by prescriber in collaboration with the patient, pharmacist, and wider healthcare team, where appropriate.

If changes are required, these proposed classifications will ensure that patients still have access to paracetamol for the management of acute conditions and could potentially help mitigate any risks associated with inappropriate use.

However, MCC may also wish to consider working with other business units across the Ministry, especially with the current Governments approach to mental health, wellbeing and suicide prevention.[5-7] This will ensure patients are supported with their care and the appropriate position of paracetamol.

6.2 Ibuprofen 400mg – proposed reclassification from restricted medicine to pharmacy only medicine

The Society does not support the proposed reclassification from restricted medicine to pharmacy only medicine.

The literature does indicate that 400mg dosing of Ibuprofen may be clinically appropriate for certain conditions.[8] Ibuprofen 200mg is already available as a single agent for self-selection in packaging of up to 100 dose units and patients can choose to take one or two tablets depending on their requirements.

The study provided by the applicant to explain the challenges patients face with swallowing medicines relates to altering the formulation rather than specifically the number of tablets being consumed. The 400mg strength can currently be provided to patients as a restricted medicine and this aligns with the current TGA recommendations.[9] Providing a double strength (400mg) self-selection product could also increase the risk of harm to patients, with the potential for an overdose.[4]

We would propose that the current restricted medicine classification remains.

6.3 Flurbiprofen – proposed reclassification from pharmacy only medicine to general sale medicine

The Society does not support the proposed reclassification for Flurbiprofen from pharmacy only to general sale medicine.

Topical oral products such as flurbiprofen are indicated for relief of pain, swelling and inflammation associated with sever sore throat. When a person has severe, sore throat, it is important that they have access to a health professional to assess whether it could be a more serious condition such as glandular fever or streptococcal infection. The latter is a significant issue for certain population groups in New Zealand.
Although pharmacists and their support teams are not able to diagnose these conditions, they are well placed to provide an effective triage and refer at-risk patients to the GP for diagnosis

and appropriate treatment. This approach also aligns with the Heart Foundation and Ministry of Health Guidance for the management of sore throats. [10,11]

If this product is reclassified, patients with more serious conditions may be further delayed in having health professional intervention which could lead to greater complications and related health system costs.

Thank you for consideration of this submission. I would be happy to discuss any aspect of this submission further, if required.

Yours sincerely,

Chris Jay
Manager Practice and Policy
p: 04 802 0036

References

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21 October 2020 KM20-131

Jacinta Patel
Secretary for the MAAC and the MCC
Medsafe
Ministry of Health
PO Box 5013
WELLINGTON

Via email: committees@health.govt.nz

Kia ora Jacinta,

Agenda for the 65th meeting of the Medicines Classification Committee

Thank you for giving The Royal New Zealand College of General Practitioners the opportunity to comment on the Agenda for the 65th meeting of the Medicines Classification Committee (MCC).

The Royal New Zealand College of General Practitioners is the largest medical college in New Zealand. Our membership of 5,500 general practitioners comprises almost 40 percent of New Zealand's specialist medical workforce. Our kaupapa is to set and maintain education and quality standards for general practice, and to support our members to provide competent and equitable patient care.

Submission

The College wishes to comment on the following three agenda items;

- 5.2 Paracetamol
- 8.2.1.a Zolmitriptan
- 8.2.1.b Mometasone

5.2 Paracetamol

Pursuant to section 57B (3) Coroners Act 2006, the Coroner has made a recommendation to the Committee proposing that the following restrictions be implemented as to the quantities of paracetamol available for purchase in New Zealand:

(a) Pharmacy sales: 16 g per transaction (i.e. 32 x 500 mg tablets)

(b) All other outlets 8 g per transaction (i.e. 16 x 500 mg tablets)

(c) A maximum of 50 g (i.e. 100 x 500 mg tablets) by prescription.

The College considers that public awareness of the danger paracetamol presents when the recommended dose is exceeded either inadvertently or deliberately must be increased. We are pleased to see that the Health Research Council, Medsafe and ACC are funding research into on the safe use of paracetamol for children.[1] As is indicated by the recent coroner's case, safe use in adults is also a problem.

[1] https://mailchi.mp/hrc/celebrating-30-years-of-health-research-achievements?e=69b9329363#Paracetamol_RFP Accessed 20/10/2020

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Reducing the quantities available under general sale from 20 tablets to 16 tablets and the quantity available from pharmacies from 100 tablets to 32 tablets may help in changing the public perception of paracetamol as free from risk.

Reducing the quantity available on prescription to 100 tablets will however significantly disadvantage those patients who take paracetamol regularly to manage chronic pain. Many of these patients are elderly with [redacted]arthritis. The alternatives such as non-steroidal anti-inflammatory drugs [redacted] many of these patients. They may be prescribed up to 1g (two tablets) of [redacted] daily, hence may require up to 240 tablets per month. Should such patients [redacted]ould need to visit the pharmacy for a repeat prescription every 12 days.

[redacted] risk of exceeding the recommended dose, arising from limiting dispensing to 100 tablets, is unlikely to be in proportion to the access problems and inconvenience that such a limit would cause. The College considers that there should not be a limit on the amount of paracetamol available on prescription. Efforts to reduce the risk of excessive dosage should instead focus on public education and the development of resources for prescribers, including new prescribers, to remind them of the risks of paracetamol and assist them in educating their patients regarding this risk.

8.2 Decisions by the Secretary to the Department of Health and Aging in Australia (or the Secretary's Delegate)

New Zealand has a policy of harmonisation[2] with Australia regarding the classification of medicines, consequently changes to the classification of a medication in Australia prompt consideration of whether the same change should also be made in New Zealand. The College has concerns about two of the medications that have recently been down-scheduled in Australia.

8.2.1.a Zolmitriptan

The Schedule 4 (prescription) entry for Zolmitriptan was down-scheduled to Schedule 3 (restricted) when in divided oral preparations containing 2.5 milligrams or less per dosage unit and when sold in a pack containing not more than 2 dosage units for the acute relief of migraine in patients who have a stable, well-established pattern of symptoms.

The College considers that it is inadvisable for a similar down scheduling to occur in New Zealand and the classification of Zolmitriptan should remain prescription only.

Migraine treatment needs to be prescribed in the context of the patients overall health and with regular review. Zolmitriptan should be prescribed with caution in patients with hypertension, cardiovascular disease or a history of TIA or stroke. There is also a risk of serotonin syndrome in patients taking anti-depressants.

8.2.1.b Mometasone

The Schedule 4 (prescription) entry for mometasone was down-scheduled to Schedule 3 (restricted) as the only therapeutically active substance in preparations for dermal use containing 0.1 percent or less of mometasone in packs containing 15 g or less.

The College considers that it is inadvisable for a similar down scheduling to occur in New Zealand and the classification of Mometasone should remain prescription only.

Where topical mid strength steroid cream is required for the treatment of eczema a suitably qualified health practitioner should review the patients response to treatment and overall control. Overuse and underuse of steroid responsive skin conditions is an ongoing concern. Topical steroids of this potency should be prescribed in the context of the patients overall medical conditions with frequent review of diagnosis and management and with concomitant patient education.

[2] https://www.medsafe.govt.nz/profs/class/harmon.asp accessed 20/10/2020

We hope you find our submission helpful. If you have any questions, or would like more information, please email us at policy@rnzcgp.org.nz

Nāku noa, nā

Kylie McQuellin
Head of Membership Services

Consumer Healthcare Products Australia

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23 October 2020

The Secretary, Medicines Classification Committee
Medsafe
PO Box 5013
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New Zealand

Sent by email: committees@moh.govt.nz

Dear Sir/Madam,

Re: Response to public consultation for the Medicines Classification Committee Agenda for 65th meeting – Item 5.2 Paracetamol

Thank you for the opportunity to comment on the agenda for the 65th meeting of the MCC. Consumer Healthcare Products Australia (CHP Australia) would like to provide some comment on item 5.2 of the agenda on the proposed restrictions to quantities of paracetamol available for purchase in New Zealand.

CHP Australia is the leading voice and industry body for manufacturers and distributors of consumer healthcare products in Australia, which includes non-prescription medicines. We strive to advance consumer health through responsible Self Care and were previously known as the Australian Self Medication Industry (ASMI). Our key priorities for the industry include improving health literacy, growing the consumer healthcare products industry and increasing access to medicines where appropriate.

Most sponsors that market paracetamol products in Australia also market these same products in New Zealand and are members of both CHP Australia and CHP New Zealand (CHPNZ). Most of these products are currently harmonised across both markets as General Sales (GSL) or Pharmacy medicines, with the same finished product characteristics as well as labelling. The ability to market harmonised products is very important for economic viability given that both Australia and New Zealand are relatively small markets individually. We refer in this context to the MCC's statement on general principles of Trans-Tasman Scheduling Harmonisation here.

We also refer the MCC to the submission made by Consumer Healthcare Products New Zealand (CHPNZ) and would like to make the MCC aware that any changes to the paracetamol classification in New Zealand may also have an impact in Australia.

In summary, CHP Australia's position is that:

- The classification of paracetamol should not be changed. There should be no change to pack sizes available for sale in Pharmacy and GSL outlets

- CHP Australia supports restrictions on the number of packs of single ingredient paracetamol in solid dose forms that consumers can access from all online (non-pharmacy and pharmacy) and GSL retailers, i.e. purchase limits
- GSL retailers should consider a best practice guidance for limits on in-person purchases of paracetamol tablets from GSL outlets
- Purchase limits are not needed for in-person pharmacy sales where pharmacists and pharmacy assistants can assess need and supervise sales
- Medsafe and Pharmac should review the quantities available to consumers by prescription as it is our understanding that pharmacists can dispense up to 720 tablets on a single occasion
- CHP Australia supports better education for consumers on how to use paracetamol safely

CHP Australia does not support the proposal to reduce the pack sizes of GSL and Pharmacy Medicine paracetamol. The majority of consumers use paracetamol products safely and responsibly and we believe there are other options available to limit the amount of paracetamol without the need for pack size changes. Pack size changes will result in increased cost to consumers and a very high impact on businesses in New Zealand and Australia.

CHP Australia believes that introducing purchase limits for all online purchases and GSL purchases outside of pharmacy will substantially mitigate risk without the regulatory and business impact of making changes to pack sizes.

It is important that consumers be discouraged from stockpiling large quantities of paracetamol irrespective of the point of purchase. We therefore hold concerns regarding the large quantities (up to 720 tablets) that are available to New Zealand consumers on prescription (Pharmac tender product). Currently it is possible for consumers to cheaply stockpile large quantities of prescription paracetamol.

Medsafe additionally ought to be clear on the scope of the proposal, as there is no evidence for extending any restrictions to purchases of combination cold and flu products, or products containing paracetamol in other dosage forms e.g. sachets. These products should remain out of scope as purchase habits are different and there is no evidence of abuse in these product categories.

Any change to the classification in New Zealand will also have consequences for Australia as it will significantly impact the ability of sponsors to supply harmonised products across both markets.

Thank you for considering this submission.

Yours sincerely,

Consumer Healthcare Products Australia

Medicines Classification Committee Agenda for 65th meeting – Item 5.2 Paracetamol

Consumer safety is of paramount concern to CHP Australia and our members. CHP Australia notes that the proposal for changes to pack sizes of paracetamol was submitted to the MCC by the NZ Coroner. As an industry we are aware and very concerned about the use of paracetamol or any other medicine for deliberate self harm and are saddened by the recent tragic case of the death of a young woman, as reported in recent media. As an industry association we support the quality use of medicines and recognise the mental health burdens facing many in the community.

The vast majority of consumers use paracetamol safely in accordance with label instructions and the instructions of their healthcare professionals. Access to this commonly used medicine for relief of pain and fever is very important to consumers.

Consumer need

Paracetamol is one of the most widely used medicines throughout the world. It is on the WHO Model List of Essential Medicines[1]. It is used widely for relief of pain and fever. Its use for self care of minor ailments such as headaches, muscle aches, backaches, pain associated with arthritis and osteoarthritis, dental pain, period pain, as well as cold and flu relief and fever relief enables consumers to obtain effective pain relief when needed. It is well tolerated when taken according to label instructions in doses up to 4000 mg per day in divided doses in adults. The overwhelming majority of consumers use paracetamol products responsibly and in accordance with label instructions.

Any changes in classification to significantly reduce pack sizes, as proposed, are not supported by industry. Smaller pack sizes will limit choice and increase costs to consumers. Availability of analgesics for self care is extremely important for consumers.

Scope of the reclassification proposal

Usually, the Medsafe agenda contains the reclassification proposal so that stakeholders who wish to submit comments have the benefit of understanding the detail and rationale for the proposal. This agenda item does not contain that information, and other than the historical background into past discussions on purchase limits, there is no information on the rationale or justification for the proposed pack sizes.

It should be noted that the proposal refers only to immediate release paracetamol 500 mg tablets, however there are many different presentations and dosage forms of paracetamol, including (but not limited to):

[1] World Health Organization Model List of Essential Medicines 21st List 2019 https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf?ua=1

- Combination analgesics that contain paracetamol
- Paracetamol in other dosage forms e.g. sachets that contain powder for reconstitution
- Combination cold and flu products that contain paracetamol

The proposal is lacking in relevant detail regarding its scope and CHP Australia is very concerned with this lack of clarity and transparency. The proposal will have an impact on all paracetamol formulations and dosage forms (mentioned above) given the way that Medsafe classification rules are applied, and there is no evidence that any concerns regarding self-harm extend to combination analgesics, cold and flu products or other dosage forms such as sachets that contain powder for reconstitution.

Regarding cold and flu products containing paracetamol, the usage and purchase patterns differ to analgesics. Sales are clearly seasonal and in marketing terms are referred to as "distress" purchases for an acute episode of cold and flu. Medsafe should clarify and provide evidence to justify extending the scope of any regulatory intervention to cold and flu medicines that contain paracetamol.

In the interests of transparency and equitable access to information being used by decision-makers, CHP Australia recommends that the MCC publish the application, in line with standard practice and provide all stakeholders with the opportunity to comment on a detailed, well considered and justified proposal as well as accompanying evidence of a need for regulatory change.

Proposed reduction of pack sizes of paracetamol

CHP Australia members do not support the proposal to reduce pack sizes to those described in the agenda paper:

- GSL outlets: 16 tablets of 500 mg paracetamol (8 g paracetamol)
- Pharmacy outlets: 32 tablets of 500 mg paracetamol (16 g paracetamol)
- Prescription: 100 tablets of 500 mg (50 g paracetamol)

A pack size of 8 tablets represents a single days' supply for one adult, and a pack size of 32 tablets 4 days' supply. Within a large household, for example two or more adults who may need to use the product, this will severely impact consumer access and convenience as well as cost if consumers need to buy multiple packs from different retailers in order to obtain a supply adequate to relieve, for example, an episode of backache or cold and flu. Having to source multiple small packs while in acute pain or discomfort is inconsistent with consumer requirements and preference.

With respect to safety, the risk of developing liver injury to the individual patient who uses paracetamol according to directions is extremely low. Paracetamol is well tolerated when taken at the recommended dose (up to 4000 mg/day); data from

prospective studies (involving more than 30,000 patients) have shown that repeated use of a true therapeutic paracetamol dosage is not associated with hepatic failure[2]. General sales availability of 20 tablets allows consumers to use paracetamol up to the maximum daily dose of 4g/day for 2 to 3 days consistent with the directions on pack for consumers to only take for a few days without medical advice.

Some consumers require paracetamol for longer periods, and in these cases the larger packs available in pharmacies fulfil requirements for those with longer term needs or who experience frequent episodes of pain.

Compared to the number of people who use paracetamol safely and appropriately, CHP Australia believes that the number of people who deliberately misuse paracetamol is very low.

On the related issue of stockpiling, CHP Australia is aware that prescribers in New Zealand can currently prescribe up to 720 paracetamol tablets (360 g) at a time in some cases. This is very concerning. By comparison in Australia, paracetamol is available under the Pharmaceutical Benefits Scheme (PBS) only to specific patient groups, in quantities of 100 tablets with repeats that can be dispensed at certain specified intervals. People with chronic arthropathies require a medical practitioner to obtain a PBS Authority to prescribe larger quantities. Most people who are not eligible patients under the PBS must buy unsubsidised paracetamol. Although we have no direct evidence as to whether the availability of large quantities in New Zealand by prescription contributes to stockpiling, the ability to purchase 720 tablets at once appears excessive. The recent paper by Kumpula, Norris and Pomerleau[3] also found that prescribed paracetamol was the main source of large stocks in households.

Controls on number of packs that can be purchased

The background reading of the agenda item provides a summary of attempts to introduce purchase limits in New Zealand, and as the industry association for sponsors of paracetamol in Australia/New Zealand, we would like to comment briefly on this issue.

CHP Australia supports, in principle, the introduction of purchase limits that prevent consumers from purchasing multiple packs of single ingredient paracetamol tablets at once. We believe that a limit of two packs of 20 tablets for online and GSL purchases is appropriate for all online purchases (including online pharmacy) and in person purchases within the GSL retail environment, e.g. supermarkets, dairies, petrol stations,

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[2] Dart RC, Bailey E. Does therapeutic use of acetaminophen cause acute liver failure? Pharmacotherapy 2007 September; 27(9):1219-30.

[3] Kumpula E-K, Norris P, Pomerleau AC (2020) Stocks of paracetamol products stored in urban New Zealand households: A cross-sectional study. PLoS ONE 15(6): e0233806. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0233806

convenience stores where there is no professional oversight. This in our view represents an appropriate balance between the requirements of consumers for self care, considered against risk to vulnerable people in the community.

CHP Australia would like to see a Code of Practice or Guideline / Supply Protocol (or similar initiative) for supply of paracetamol in GSL retail environments, so that staff are appropriately trained and have the confidence to refuse sales of more than a certain number of packs, e.g. two packs of 20. The ability to apply purchase limits to Point of Sale technology should also be investigated.

CHP Australia does not support purchase limits within pharmacies, as pharmacists and pharmacy assistants are well trained to intervene for large purchases, and they can provide professional supervision and advice to people who have longer term pain and may require dosing for longer periods.

We are aware that on occasion, owners of small businesses such as dairies and convenience stores will try to purchase larger quantities of paracetamol from discount retailers that they then on-sell. It may be feasible to require identification and evidence of a business ownership as part of a sale of larger quantities. These and other implementation issues could be considered as part of the implementation process.

We believe that purchase limits will present an obstacle that may limit consumers' easy access to large quantities of paracetamol. Coupled with oversight by pharmacists and pharmacy staff, these initiatives may help signal to consumers that there is a danger in having easy access to large quantities of paracetamol and may help reduce unnecessary stockpiling in the home.

The scope of this proposal is related to single ingredient immediate release paracetamol tablets, and no evidence has been presented that there ought to be purchase limits on cold and flu products or combination analgesic products containing paracetamol, or products in sachets or other dosage forms. CHP Australia will consider these groups of products separately based on convincing evidence regarding intentional misuse and requests Medsafe provide further clarity on this issue.

CHP Australia encourages retailers, pharmacy bodies, industry and Medsafe to work together to establish a Code of Practice / Best Practice Guidance that may obviate the need for costly regulatory changes to pack sizes, as the aim is for access that is commensurate with consumer needs in a responsible manner.

Education

Any changes to consumer access should be accompanied by consumer education and training of retailers. CHP Australia supports the development of educational material in simple consumer language, to help educate on safe use of paracetamol – how much, how long, as well as dangers. We also encourage pharmacists and pharmacy assistants

to be vigilant when supplying larger pack sizes of paracetamol. Consumers should be engaged as part of the process.

Conclusion

CHP Australia is very concerned with the proposal as outlined in the agenda and does not support any change to pack sizes. The minimal detail around scope, the lack of transparency and lack of evidence presented has made it difficult for respondents. There is no evidence or submission provided as part of the proposal to suggest that a change in current classification of paracetamol (including current pack size restrictions) is warranted.

While CHP Australia opposes reductions to pack sizes on the basis of increased regulatory burden and cost pressure that will be passed on to consumers, industry is supportive of further work being done to establish purchase limits, and a best practice approach to limiting the number of packs that can be sold online and in non-pharmacy environments. Pharmacists and pharmacy assistants are well placed to advise consumers and monitor pharmacy purchases.

At this point we have not seen any evidence as to why there should be any impact on combination cold and flu products or powdered products containing paracetamol as these have not to our knowledge been implicated in any inappropriate use or intentional misuse. Medsafe should justify the scope of the proposal and provide further evidence and detail as to whether there is a need for change.

As the industry association representing sponsors of paracetamol products, we are deeply concerned with intentional misuse of paracetamol and support initiatives for safe use of these products. However we also acknowledge that the burden of mental health problems facing some people in the community is a serious matter that needs to be addressed holistically and we are of the view that more needs to be done to address this concerning matter. Reduction of paracetamol purchases in isolation will not ease the burden felt by vulnerable members of the community.

Johnson & Johnson Pacific

Friday 23rd October 2020

The Secretary
Medicines Classification Committee
PO Box 5013
Wellington 6145

Dear Sir/Madam,

Re: Agenda for the 65th meeting.
Item 5.2 Paracetamol – recommendation received from the coroner

Johnson & Johnson (New Zealand) Ltd (JJNZ) appreciates the opportunity to comment on agenda item 5.2 at the 65th meeting of the MCC on the proposal to restrict the quantities of paracetamol available for purchase in New Zealand.

JJNZ is the sponsor of cold and flu products that contain paracetamol, in combination with phenylephrine and other cough, cold and flu ingredients, as both Pharmacy Medicines and General Sale medicines. These products are indicated for the relief of the self-limiting symptoms associated with cough, colds and flu under the brand names Codral® and Sudafed®. JJNZ does not market single active or combination analgesics containing paracetamol in New Zealand.

Quality use of medicines and safety always remains a priority for JJNZ, and paracetamol is safe and effective when used in accordance to the directions for use. It is one of the most widely used analgesics globally and is included in many cold and flu products.

It is clear from the coroner led agenda item that this proposal relates to single ingredient immediate release paracetamol tablets because of the tragic circumstances of death of [redacted] caused by single ingredient paracetamol overdose with the intention of self-harm but not suicide. However, we are concerned that the lack of detail and rationale presented with the agenda item could unintentionally include cold and flu products within the scope as there is no clear differentiation. At the outset we want to ensure these products remain out of scope as there is no current or historical evidence of widespread inappropriate use of paracetamol containing cold and flu products.

Notwithstanding this, JJNZ does not support the proposal to restrict pack sizes of Paracetamol tablets. The majority of consumers using paracetamol products do so responsibly and in line with the directions for use on the label. Restricting pack sizes in General Sale and Pharmacy will not necessarily address the issue of intentional self-harm, and we believe that there are other measures that could address this concern, including limiting the amount of single ingredient paracetamol in the household coupled with the right support/education without restricted pack sizes any further within these OTC channels.

[redacted]

Any change to the classification in New Zealand will also have consequences for Australia as it will significantly impact the ability of sponsors such as JJNZ to supply harmonised products across both markets. This is important to ensure commercial viability. A change in pack size in New Zealand which is not aligned with Australia will often result in discontinuation of a product in New Zealand, impacting the New Zealand consumer. trans-tasman harmonisation remains key and the importance of this is also acknowledged by the MCC.

JJNZ's Position

COLD & FLU COMBINATION PRODUCTS CONTAINING PARACETAMOL

- JJNZ maintains the position that the evidence shows that there is no abuse or misuse of paracetamol containing cold and flu products, therefore they should be clearly differentiated and out of scope of this agenda item
- Cold and flu products are often distress purchase during the cold and flu season as indicated by sales data
- Cold and flu products containing paracetamol often have multiple therapeutically active ingredients and these, together, might diminish abuse/misuse.

PARACETAMOL SINGLE INGREDIENT PRODUCTS

- The classification of paracetamol should not be changed
- There should be no change to pack sizes available for General Sale and Pharmacy
- JJNZ believes there are other options to limit the amount of paracetamol without restricting OTC pack sizes
- JJNZ supports better education for consumers on how to use paracetamol safely

JJNZ supports the proposal to include purchase limits within General Sale outlets to a maximum of 2 pack counts of 20 dosage units across all paracetamol containing products

Cold and Flu products containing paracetamol should not be within scope

As mentioned above, this is coroner led agenda item relating to single ingredient immediate release paracetamol tablets. The pack count proposal are as follows:

Outlet	Current Paracetamol pack count limit (500mg tablets)	Proposed Paracetamol pack count limit (500mg tablets)
General Sale	20	16
Pharmacy Only	100	32
Prescription	N/A	100

However, the proposal is lacking detail regarding its potential scope and we are concerned cold and flu products could unintentionally get captured within the scope despite no evidence of inappropriate use in this category.

Cold and flu is different to pain. They are transient, transmitted easily within family members warranting larger pack sizes. Purchase behaviour is also different as supported by sales data. Consumers purchase and use these products episodically for self-limiting cold and flu conditions, rather than continuously, which supports the evidence that cold and flu products are not used inappropriately and they are not stockpiled within the home.

- Symptoms associated with colds and flus are episodic and self-limiting
- It is well recognised that cold and flu is easily transmitted among household family members, warranting larger pack sizes to accommodate the entire family
- Purchase behaviour of cold and flu products is often distress purchase as signalled by sales data, with peak sales during the winter season indicating that they are not stockpiled
- Consumers are less likely to dose escalate or self-treat with cold and flu products for extended periods of time, mitigating any potential for inappropriate use.
- Cold and flu products containing paracetamol often have multiple therapeutically active ingredients and these, together, might diminish inappropriate use.
- Reported misuse or inappropriate use of cold and flu products is extremely rare and no submissions asserted that there was evidence indicating a problem.

[redacted]

[redacted]

[redacted]

Purchase limits

We understand the Coroners request to introduce reduced pack sizes of paracetamol containing products, however JJNZ rather supports the introduction of purchase limits of immediate release paracetamol tablets to prevent consumers from purchasing multiple packs of paracetamol containing products which will help to ensure stockpiling is minimised. We believe this is a more feasible approach that will help reduce excessive purchase while also ensuring limited impact to product availability in NZ. Our view is that any reasonable measure that can help reduce excessive purchase is positive.

Whilst the scope of this proposal is related to single ingredient immediate release paracetamol tablets, and while there is no evidence to suggest that cold and flu products are inappropriately used or stockpiled, we have no objection for all online and in person purchase of paracetamol containing products within the **general sale** environment to have a purchase limit. JJNZ would support any initiative to help bring this to life through industry guidelines.

We believe a purchase limit of 2 packs of 20 dosage units of paracetamol containing products is reasonable as this represents an appropriate balance between the requirements of consumers in an OTC environment. This intervention may also mitigate against the burden of increasing cost on consumers and industry, which would occur if pack sizes were reduced especially given the evidence is not clear that restricting pack size actually addresses the issues of self-harm.

For products sold in pharmacies, we do not feel that a purchase limit is relevant as this is an environment where a HCP (pharmacist) is available for intervention along with pharmacy assistants who are well trained to intervene for large purchases, and counsel patients appropriately. Pharmacy Assistants are already well trained through the J&J training platform in line with health Authority requirements and our own internal healthcare Compliance guidelines.

Education

JJNZ supports consumer education on the safe use of paracetamol and training of retailers, We also encourage pharmacists and pharmacy assistants to be vigilant when supplying larger pack sizes of paracetamol, especially as it is our understanding the approximately 80% of paracetamol supply is through Pharmac which potentially poses the biggest issue in relation to stockpiling.

Conclusion

JJNZ is concerned with the lack of detail and the lack of transparency of what is within scope of this agenda item, however we maintains that there is no evidence to demonstrate inappropriate use or misuse of paracetamol containing cold and flu products, therefore they should be clearly differentiated and out of scope of this agenda item as supported by the evidence.

Colds and flu are transient, transmitted easily within family members which justifies larger pack sizes and purchase behaviour is different as supported by sales data. Consumers purchase and use these products episodically for self-limiting cold and flu conditions, rather than continuously,

JJNZ maintains that the current classification for paracetamol remains appropriate and there should not be a change to pack sizes available for in General Sale and Pharmacy. Restricting pack size could have detrimental impact to the viability of OTC paracetamol within New Zealand due to lack of Trans-Tasman harmonisation. There are other options available to address issues of inappropriate use including limiting the amount of paracetamol within a home via introducing purchase limits, and more importantly better education.

JJNZ however supports the proposal to include purchase limits within General Sale outlets to a maximum of 2 pack counts of 20 dosage units across all paracetamol containing products,

Thank-you for this opportunity to provide comment on the classification proposal for Paracetamol. Please feel free to contact me should you need provide further data or information.

Yours faithfully,

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

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.[PQ1]

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.

<u>All other Outlets 16 tablets (8g)</u>

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 <u>means</u> 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.[PQ5]

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.