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18 March 2021

Medicines Classification Committee Secretary
Medsafe
PO Box 5013
Wellington
New Zealand

Email: committees@moh.govt.nz

Dear Secretary,

Comments on Proposed Agenda Items of the 66th Medicines Classification Committee (MCC) Meeting

GlaxoSmithKline Consumer Healthcare New Zealand ULC (GSK) appreciates the opportunity to provide comment in relation to the 66th MCC meeting agenda item detailed below.

Agenda item 5.1b Two valid objections were received regarding the Committee's recommendation to not amend the classification of Ibuprofen 400 mg.

In reconsidering the application for reclassification of ibuprofen 400 mg in a pack of 12 dosage units from Restricted Medicine to Pharmacy Medicine, GSK would like to highlight that should there be a positive recommendation by the MCC, the proposed wording of the schedule entry will also inadvertently capture two applications currently under "additional evaluation" by Medsafe for ibuprofen 300 mg modified release tablets namely, Nurofen Long Lasting modified release 300 mg and CO Ibuprofen Long Lasting modified release 300 mg. Modified release formats of ibuprofen did not appear to be included in the scope of the applicant's submission, which was instead specific to 400 mg immediate release ibuprofen. Given such modified release formats have yet to be approved by Medsafe and have no market experience in New Zealand, it is suggested that should the MCC recommend classification of 400 mg ibuprofen as a Pharmacy Medicine that the proposed wording of the schedule entry be amended to specify **immediate release** 400 mg ibuprofen to avoid unintended scheduling consequences.

GSK would also like to highlight to the MCC to carefully consider RB's proposition of immediate release ibuprofen 400 mg for **"those seeking relief of strong pain"**. Immediate release ibuprofen 400 mg is only a different dose related offering (one tablet dose compared with two tablet dose for ibuprofen 200 mg) and should not be perceived as an efficacy alternative.

Yours sincerely,

[redacted]

PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

14 April 2021

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 66th MEETING AGENDA Tuesday 11th May 2021

Thank you for the opportunity to submit comments on the Agenda for the 66th meeting of the Medicines Classification Committee.

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 3,200 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:

6.1 Allopurinol – proposed change to the prescription classification statement

The Society supports the proposed reclassification for Allopurinol from prescription medicine to prescription except when.
The value of the Owning my Gout (OMG) management programme has been independently evaluated by Synergia. The Community Pharmacy Gout Management Service Training has already been developed and is running in several DHB's across the country. With a small amount of additional education built into this package, it could also deliver on the requirements outlined in this proposed reclassification.

6.2 Choline salicylate – proposed reclassification from general sale medicine to pharmacy only medicine

The Society supports the proposed reclassification from general sale medicine to pharmacy only medicine. However, we would recommend that a defined age is used instead of the wording "infant teething".
If the committee are concerned about the use and risks associated with choline salicylate in children, we would suggest they consider adopting the recommendations of the Medicines and Healthcare products Regulatory Agency (MHRA) and Commission on Human Medicines (CHM). This would also prevent the medicine being used in any person under the age of 16 years, especially where there is potential harm and the evidence around benefit is potentially lacking.

6.3 Ibuprofen 300mg in powder form – proposed reclassification from prescription medicine to pharmacy only medicine

The Society does not support the proposed reclassification for Ibuprofen 300mg powder from prescription medicine to pharmacy only medicine at this stage.
We are aware that this product is not currently available in New Zealand and is also being evaluated by Medsafe's product regulatory team at the same time as the reclassification submission.
The addition of a paracetamol/ibuprofen combination product in powder form will increase consumer choice for the management of cold and flu symptoms when analgesics are required. However, it may also potentially increase confusion for patients where there are already multiple medicines for these conditions on the market.
The authors of the submission state that there is a lack of evidence to suggest that powder formulations are misused, and it is difficult to dissolve multiple doses in a single cup of water.
It would be useful if the applicants could provide some additional information to support these statements.
The applicants also reference the 2015 Medsafe review of cardiovascular safety of Ibuprofen. This document was updated in June 2019 which found that all NSAIDs, including both traditional and COX-2 selective NSAIDs, increase the risk of a cardiovascular adverse event. (Prescriber Update 2019 40(2)).

6.4 Topical Oral Benzocaine, Tetracaine Hydrochloride (Amethocaine), Lidocaine (lignocaine) and Prilocaine – proposed reclassification from prescription medicine to prescription except when classification

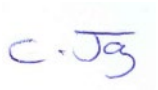
The Society supports the proposed reclassification for the above products from prescription medicine to prescription except when.
The risk-benefit is low compared to other treatments already used by this health professional group. It will also enable dental therapists and oral health therapists to provide access to timely to treatment whilst working in their scope of practice.

6.5 Hyaluronidase – proposed reclassification from general sale medicine to prescription medicine

The Society supports the proposed reclassification for Hyaluronidase from general sale medicine to prescription medicine. It would bring the classification into alignment with other jurisdictions.
The reclassification would also enable appropriate control over an injectable product and will be administered by a registered health professional and on the direction of a registered health professional who is also a prescriber.
It will also give assurance to the patient that the medicine is being treated in a similar fashion to other injectable medicinal products on the market in New Zealand.

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

PHARMACY GUILD OF NEW ZEALAND

15 April 2020

Medicines Classification Committee Secretary
Medsafe
Wellington

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

Dear Committee Members,

RE: Agenda for the 66th meeting of the Medicines Classification Committee

Thank you for the opportunity to provide feedback on the agenda for the 66th meeting of the Medicines Classification Committee (MCC), to be held on 11 May 2021.

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 three agenda items. These are:

- Agenda item: 6.1 Allopurinol – proposed change to the prescription classification statement
- Agenda item: 6.2 Choline Salicylate – proposed reclassification from general sale medicine to pharmacy only medicine
- Agenda item: 6.3 Ibuprofen 300mg in powder form – proposed reclassification from prescription medicine to pharmacy only medicine

Each of these agenda items are discussed below.

Agenda item: 6.1 Allopurinol – proposed change to the prescription classification statement

The Guild **supports** the proposal to reclassify allopurinol to prescription medicine except when provided by a pharmacist who has completed gout training with the Pharmaceutical Society of New Zealand.

Under the current classification, patients need to make regular visits to their General Practitioner (GP) to get continuation prescriptions for allopurinol to effectively manage their gout conditions. Evidence shows that only one in four people with gout are on long term medication.

We support reclassification changes that will improve access and equity to gout services provided through community pharmacy. Equity of access to gout services is particularly important for Māori and Pacific Island patients who are disproportionately affected by gout.

Community pharmacies currently provide gout specific services in several District Health Boards (DHBs). This includes the Gout Stop Programme in Northland DHB, the Own My Gout Programme in Counties Manukau DHB and a Gout Education and Support service in the Waikato DHB.

Arthritis New Zealand commissioned an evaluation of the Gout Stop Programme and the Own My Gout Programme and both demonstrated significant benefit to patients, particularly to helping to address the inequities in Māori and Pacific Island patients.

Current programmes require a regular prescription from a doctor or a standing order to enable supply through a community pharmacy.

Reclassification to the prescription except when classification will provide greater autonomy for community pharmacists to support the management and continuation of allopurinol to patients that have previously been prescribed allopurinol by a doctor. The reclassification will also remove barriers for other community pharmacy gout services to be developed around the country.

Allowing pharmacists to initiate the continuation of allopurinol without a prescription will help to reduce barriers for gout patients, by allowing better and easier access to long-term preventative management, improving patient medication adherence and health outcomes.

Agenda item: 6.2 Choline Salicylate – proposed reclassification from general sale medicine to pharmacy only medicine

The Guild **supports** reclassification of choline salicylate from general sale medicine to pharmacy only medicine when used for infant teething.

We have significant concerns about the risk of salicylate poisoning in infants, therefore we strongly support the conclusion of the Medsafe submission where *"the expected benefit of this reclassification is an increase in the likelihood of a parent discussing use of the oral gel with a pharmacist. This in turn will reduce the risk of overdose".*

We also note the significant number of calls that the National Poisons Centre has received relating to exposure to choline salicylate in children.

Pharmacy staff understand that teething in infants can be an uncomfortable and distressing time for both the infant and parents, and without receiving specific advice from a health care professional, this may lead to unintended excessive use of the teething gel.

When a parent comes into a community pharmacy to purchase choline salicylate for an infant, pharmacy staff will ensure that the medicine is both safe and appropriate for the infant, while providing specific information on the use and dosage of the product. This includes specific advice around maximum usage of the gel and to highlight the risk of overdose in an infant when too much gel is applied or the gel is used too often.

The use of medicines available in a general sale setting has normalised the expectation of the general public that general sale medicines are safe to use, with no real concerns or significant risk of overdose. The general public will often not be aware of the potentially significant risks associated with the excessive use of choline salicylate.

The proposed reclassification will mean that choline salicylate will still be available for purchase in a general sale setting for use of relieving the pain and discomfort associated with mouth ulcers. However, it is also important to note that the two choline salicylate

products available for purchase in New Zealand are the exact same formulation but are marketed separately as a teething gel (Bonjela – Teething and Mouth Ulcer Gel) and as a mouth ulcer gel (Bonjela – Mouth Ulcer and Teething Gel).

As the Bonjela products have been approved for use in New Zealand since 1966, the use and acceptance of the product over the generations will likely mean that the use of Bonjela will be synonymous with helping to relieve discomfort and pain associate with infant teething.

We are very concerned that people will continue to purchase the products through a general sale setting to be used for infant teething even though the medicine packaging may not specify use in infant teething first and foremost. We request that the Medicines Classification Committee consider reclassifying choline salicylate to pharmacy only medicine for all indications of use. This will ensure that there is always professional oversight to ensure the safe and appropriate usage in infant teething and to ensure the appropriate use of the mouth ulcer formulation.

Agenda item: 6.3 Ibuprofen 300mg in powder form – proposed reclassification from prescription medicine to pharmacy only medicine

The Guild has concerns for the potential medicine safety implications of the proposed reclassification of ibuprofen 300mg in powder form from prescription medicine to pharmacy only medicine. We are aware anecdotally that often patients may not be aware that hot drinks such as the proposed Maxigesic Lemon Hot Drink and other existing products such as Lemsip Hot Drink products contain medicated ingredients. It is common practice for staff in a community pharmacy to highlight this to all patients as part of the advice and counselling processes for medicated hot drinks and to ensure that all patients are aware to not accidentally double dose on the active ingredients of these products.

We request that the Medicines Classification Committee add requirements for the proposed Maxigesic product to explicitly highlight that the product is a 'Medicated' Cold & Flu hot drink. We also request that the following statement is more clearly distinguishable on the information panel of the proposed Maxigesic products: *"do not use with other products containing paracetamol, ibuprofen, aspirin or other anti-inflammatory medicines".*

With the renewed safety concerns around paracetamol containing products, we want to ensure that if the medicine is to be reclassified, that the above statements are clear to help reduce any risk of patient confusion, mitigating the incidence of accidental overdose through the consumption of these products.

Thank you for your consideration of our response. If you have any questions about our feedback, please contact our Professional Services Pharmacist, Alastair Shum, at alastair@pgnz.org.nz or on 04 802 8209.

Yours sincerely,

Nicole Rickman
General Manager – Membership and Professional Services

120 Featherston Street
Wellington

Monday, 12 April 2021

TO: Medsafe, NZ Medicines & Medical Devices Safety Authority

FROM: Philip Kearney, Chief Executive, Arthritis NZ

Dale-Lynne Sherman-Godinet, Health Advice Manager, Arthritis NZ

Dave Cox, Arthritis Educator, Clinical Lead, Arthritis NZ

RE: 6.1 Allopurinol – proposed change to the prescription classification statement (individual submission)

Arthritis NZ have read the submission and fully support all aspects of this submission. Arthritis NZ believes that this submission will reduce barriers for our clients when seeking fair and equitable treatment.

It should be noted that Gout Arthritis has a huge impact on Maori and Pacific populations and reducing of barriers for Maori and Pacific to access Allopurinol would be of huge benefit and make significant impact on reducing the health inequities for Maori and Pacific.

Dave Cox (Clinical Lead) has suggested a couple of observations be added:

- He notes there is no suggestion of offering prophylaxis with NSAIDs or Colchicine in the scenario where a Pharmacist up-titrates the Allopurinol dosage. This is welcome as it should prevent any further risks of possible adverse reactions to NSAIDs/Colchicine. However, there may be the odd instance where up-titration may precipitate an acute gout attack, so patients should be advised to seek advice from their doctor should this happen.
- The offering of support from Arthritis New Zealand services would be a welcome addition to the risk mitigating strategy.

Philip Kearney
Chief Executive, Arthritis NZ

Clinical Advisory Pharmacists Association

To: Medicines Classification Committee

From: Penny Clark, Chair, CAPA

For: 66th Meeting, 11th May2021

Re: Agenda item 6.1 **Reclassification of allopurinol to allow continuation supply and dose modification by community pharmacists to improve access and equity**

Tēnā koe

Thank you for the opportunity to comment on Agenda Item 6.1.

The Clinical Advisory Pharmacists Association (CAPA) is an association of pharmacists with postgraduate qualifications and includes many pharmacists and pharmacist prescribers working in primary care.

We have concerns about the proposal for reclassification of allopurinol to allow continuation supply and dose modification of allopurinol by community pharmacists and do not support this proposal for the following reasons:

1. Equity
   The population at risk of gout require on-going review for cardiovascular disease, diabetes and mental health as gout is associated with complex long-term conditions. There is need for holistic care, as fragmentation of care risks further increasing health inequities. There are also many social needs that need to be met, which can be identified at points of contact and are an opportunity for holistic intervention and help. These needs might go unidentified and unaddressed if the person is seen only at the community pharmacy for a single medical condition. In particular, young Māori and Pacific males with gout often also have stress, and complex issues that need to be reviewed medically, even if this is opportunistically when contacting the general practice, health care home or Marae based clinic.

   With a growing trend for primary care general practice models to include integrated health professionals such as clinical pharmacists, pharmacist prescribers, nurse practitioners, nurse prescribers, social workers, psychologists, physiotherapists and health improvement practitioners, this is an opportunity to develop further a more holistic model for encouraging allopurinol prescribing as well as dose titration to address the source issues of low rate of allopurinol prescribing and avoid fragmentation of care. The proposed model of community pharmacy continuation supply of allopurinol does not address the source issues of low rates of people prescribed allopurinol and increases the risk of fragmentation of care for those already on it which increases the equity gap.
   A gap that has become evident is re-enforcement of information and education on gout and the benefit of allopurinol when it is prescribed.

2. Access
   The rationale for the proposed change to the classification for allopurinol on an access basis is unclear. Access to medicines as a barrier to adherence has reduced considerably. Primary care general practice clinics or other clinics such as Marae based clinics have improved access as many offer extended hours, phone triage with a GP, virtual consults and portal communication or in some cases home visits by the integrated practice team including health improvement practitioners, which improves access plus facilitates access to medical review and holistic care if needed. E-prescribing further improves timely access for patients to prescriptions as they are sent directly to the pharmacy, whether that be for allopurinol, or medicines for flares or prophylaxis that are individualised for the person as well as allopurinol. Online pharmacies with courier delivery may improve assess for those who find it difficult to access community pharmacy, such as the at-risk young men, those working long hours, working away from home, living in remote areas or without transport. Other options such as Marae clinics, rural hub or development of a whanau-based service could be developed.

3. Adherence
   It appears that reminders or recalls to collect repeats from the community pharmacy are considered an answer to non-adherence, but this is not always the case. While repeat reminders are a useful tool, they are not sufficient to ensure adherence and may result in medicines being collected, but not taken. This can result in excess medicines in the community and may give the false perception of adherence.

4. Comparator
   The Scottish community pharmacy model quoted for a comparator was only in emergency supply situations, not continuation. In addition, the population and the Scottish model cannot and should not be compared with Aotearoa New Zealand. Our indigenous Māori population and our Pacifica population have a vastly increased incidence of gout at 9% and 14% respectively, and also gout with complications and co-morbidities, compared to Scottish people whose incidence of gout is approximately 3%.

5. Proposed indication
   It is also concerning that tophaceous gout and gouty arthritis which are complicated conditions, and are associated with significant morbidity, are included under the proposed reclassification for community pharmacists. Tophaceous Gout is a separate complex condition with significant comorbidity and also requires a different target serum urate from uncomplicated gout. It is important people with tophaceous gout are under the care of an appropriate clinician who is able to monitor the condition appropriately.

6. Review period
   There is no indication of the review period –ie how long the “repeat” by community pharmacists is continued before review of the medical condition. This is important as we have noted that what was previously considered to be gout of the knee, for example, is more likely to have become osteoarthritis, resulting in a different approach to management. This is very important in populations with high unmet health needs as this group of people may have employment that involve heavy physical work and hence experience osteoarthritis earlier. Constant medical review is important to distinguish changing musculoskeletal conditions.

7. Gout flares
   There is no indication of what to do for people who have breakthrough gout while being titrated by the community pharmacist. Further medical review or advice is required rather than the risk of the person purchasing of NSAIDs from community pharmacy, as the at-risk populations of Māori and Pacifica have a greater propensity for kidney disease than non- Māori or Pacifica and so NSAIDs are inappropriate. OTC supply of NSAIDs to these people would further increase health inequities by increasing the risk of kidney disease. Continuation of supply of allopurinol from community pharmacist limits the opportunities for the patient’s prescriber to be alerted to requests for NSAIDs and review the person or prescribe a safer alternative. There is also the risk of interactions with other medicines to be accounted for.

8. Reintroducing allopurinol
   There is no indication at this stage of a plan for "cover" for people who have had a period of time without taking allopurinol before it is reintroduced by the community pharmacist; although this is mentioned as a possible later application for supply of colchicine and NSAIDs by community pharmacists, which in itself is concerning. It would be inequitable to introduce a plan to restart allopurinol to people who have had a period of time without taking it without a plan for cover as is suggested in this proposal. People who have stopped allopurinol need an individualised review from a prescriber who is competent in this area of practice as most people would generally require cover with colchicine, NSAID or prednisone when reintroducing allopurinol to prevent a flare and prevent subsequent self-discontinuation and distrust of allopurinol, thus increasing inequity; however "cover" needs individualisation of dose and duration and is not appropriate for community pharmacists to determine this as the person's full medical history needs to be taken into account. It would be inequitable to not consider this aspect. In addition, long term NSAID is inappropriate for Māori and Pacifica due to the increased propensity for kidney damage.

9. Assumption re: side effects
   There is an assumption that anyone having a continuation of supply would have had the tablets before hence the potential for allergic reaction is excluded however the person may have not taken the tablets or may still develop a rash or other side effects at a later stage.

10. Dose
    We are concerned at the proposed doses for initiation suggesting starting at a dose of 200mg daily for a person with an eGFR > 130ml/min or 150mg once daily for an eGFR 91-130ml/min. Accepted best practice is to start at a maximum of 100mg daily to avoid a flare or hypersensitivity and it is very seldom we would now initiate a higher dose. A lower start dose is necessary if the eGFR is under 60ml/min. In addition, the laboratory parameters for eGFR are reported differently in different DHBs with some reporting as a maximum of GFR > 90ml/min or > 60ml/min rather than > 130ml/ml. Therefore it is inappropriate to use one DHB's pathway, as opposed to standard and up to date best practice recommendations.

11. Proposed dose range for dose adjustment
    There is concern that the upper limit of dose range of 900mg is suggested as suitable for community pharmacists to titrate allopurinol to. In reality, although this dose may be necessary for some people, most experienced prescribers hesitate to prescribe this dose but would seek advice or peer support if the dose was thought to be required to be increased to above 600mg. Therefore, we consider this proposed dose range inappropriate for community pharmacists and it is concerning that it is in the proposal.

12. Renal function
    There is no indication of the lower limit of kidney function the allopurinol would be able to be reinitiated at, whereas people with low eGFRs, such as < 30ml/min, should be managed by a prescriber with expertise in gout with concurrent kidney disease due to complexity of multiple medical conditions, medicines and risk of allopurinol hypersensitivity syndrome.

13. Laboratory monitoring
    There is no indication in the proposal of when it would be appropriate to refer back to the GP for laboratory tests; for example, if there was a length of time without allopurinol it is likely the person would also require new laboratory monitoring before restarting allopurinol to ensure appropriateness of starting dose or red flags for referral, e.g. in case of declining renal function. They may also require usual monitoring for other parameters such as HbA1c, LFTs, lipids, CBC in case of change. e.g. if the person had been self-medicating with NSAIDs and renal function or CBC was adversely affected; had developed diabetes in the interim; or was due for annual CVRA or other checks. Laboratory tests need to be requested by and interpreted by the GP or patient's prescriber to avoid fragmentation of care.

14. Other Safety considerations

The proposal states “there are no withdrawals for safety reasons to our knowledge” whereas, as well as hypersensitivity which can be severe although rare, adverse effects from allopurinol such as haematological abnormalities, deranged LFTs, diarrhoea and drowsiness have all been reasons for withdrawal of therapy. Drug interactions with azathioprine are a known concern but are not mentioned under interactions.

15. Conflict

There is potential conflict and safety issues arising if this proposal resulted in dispensing one’s own prescriptions. Prescribing and dispensing should ideally be kept separate to enable an independent clinical check at each stage to safeguard the patient and also to avoid any conflict of interest.

Summary

There is an underpinning concern that this proposed change in classification will not actually increase equity. Although the re-classification proposed is not suggesting implementation of the Gout Stop and Owning My Gout programmes, it has quoted these programmes as evidence that pharmacist dose titration and education can help. However, it should be noted that both these programmes that seemed like a good approach and concept, actually increased inequity instead of reducing it. The study outcomes were just for 91 days, and at this time while 40% of non-Māori / non-Pacific people had a serum uric acid concentration of less than 0.36%; 29% Pacific people and only 18% of Māori had achieved this target. This means that good intentions do not necessarily translate to reduced inequity but can serve to widen the equity gap.
There is a need for a specific a study to look at the impacts, and also consider the impact on inequity. Evidence is important, as the above example demonstrates.

We agree that gout is a problem in New Zealand, but it is part of a complex long-term condition that needs to be addressed holistically – using the psycho / socio / biomedical approach rather than in isolation. Fragmenting care by continuation of allopurinol and dose adjustment by community pharmacists and thereby reducing the potential contacts with the medical health care team members may be detrimental to the overall health of the individual and widen the equity gap. Evidence that this is not inferior care overall needs to be obtained before any proposed changes are considered.

Thank you for your consideration

Penny Clark

Dip Pharm (dist), PGDipClinPharm (dist), PGCertPharmPres, PGCertPharm, FPSNZ, MNZCP, MCAPA, MNZHPA, Reg Pharm NZ (prescriber)

CAPA Chair, on behalf of the CAPA board

027 358 1142 / 021 405 266
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Nicola Dalbeth MBChB MD FRACP
Rheumatologist and Professor

THE UNIVERSITY OF AUCKLAND
Te Whare Wānanga o Tāmaki Makaurau
NEW ZEALAND

MEDICAL AND HEALTH SCIENCES

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7th April 2021

The Chair,
Medicines Classification Committee (MCC)
Medsafe

To the Chair,

Re: **Allopurinol – proposed change to the prescription classification statement**

I am a Rheumatologist and Professor of Medicine with more than 20 years' experience in gout management. I am writing in support of the application to change to the prescription classification statement for allopurinol.

Gout is a major form of musculoskeletal disability in Aotearoa New Zealand. Māori and Pacific peoples across New Zealand are disproportionately affected by gout. More than a quarter of older Māori and Pacific men have gout. Gout affects Māori and Pacific peoples at a younger age and more severely than NZ European/other ethnicities, significantly affecting employment and family and community participation.

Best practice clinical treatment for long-term gout management is the commencement and continuation of a urate-lowering medicine if the person has had two gout flares in the last 24 months. Allopurinol is by far the most commonly used urate-lowering therapy in Aotearoa New Zealand. Treatment of gout flares is short term use of prednisone or nonsteroidal anti-inflammatory drugs (NSAIDS).

In Aotearoa New Zealand gout treatment rates with urate-lowering medicines are poor for all populations, with NZ European having the best rate of 44%. This means that the majority of people with gout continue to be treated with prednisone and NSAIDS when presenting with acute gout flares. The underlying cause of gout can only be treated with urate-lowering medicines. Continued use of prednisone and NSAIDS causes other significant health problems such as chronic kidney disease, cardiovascular disease and diabetes.

Although Māori and Pacific peoples are more affected by gout, recent data from the 2021 update of the Atlas of Healthcare Variation shows that Māori and Pacific peoples continue to be less likely to receive regular urate-lowering therapy such as allopurinol. The cumulative effect of increased prevalence and inequitable treatment appears as presentation to acute services, e.g. in 2019 Māori and Pacific peoples had four to nine times as many hospital admissions due to gout than those of European/other ethnicities.

THE UNIVERSITY OF AUCKLAND
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NEW ZEALAND

MEDICAL AND HEALTH SCIENCES

Adopting strategies to reduce barriers to regular urate-lowering therapy is of central importance to achieve health equity in gout management. This includes a process to increase access to regular allopurinol. Pharmacy-led gout management programmes have been demonstrated to be safe and superior to usual care, both overseas and in Aotearoa. I am reassured that the proposal includes certification of pharmacists using training that has been developed by the Pharmaceutical Society of New Zealand, and that appropriate risk mitigation plans are presented in the application to ensure safe use of this medication.

Kind regards,

Yours sincerely,

Nicola Dalbeth
Rheumatologist and Professor of Medicine
Department of Medicine
University of Auckland

Jacinta Patel

From: Peter Gow (CMDHB) <Peter.Gow@middlemore.co.nz>
Sent: Wednesday, 24 March 2021 12:43 pm
To: Committees
Subject: FW:Allopurinol reclassification submisssion
Attachments: MCC_Public_Consultation_Cover_Sheet (3).docx

Dear Sir/Madam
I am writing to give my support for the reclassification of allopurinol for pharmacists to provide ongoing dispensing of allopurinol, with appropriate dose adjustments basead on urate monitoring, after it has
Been initially prescribed by a medical practitioner, nurse practitioner or prescribing nurse specialist, or a pharmacist with current prescribing right
The rationale for this is well set out in the application, the main reason being that data in the HQSC Gout Atlas of Variation, which shows that although there is an increasing incidence of patients with gout being prescribed allopurinol for gout by their general practitioners, this is not sustained, for a variety of reasons, including the cost of attending the general practioner, and the lack of time avialble for healthliteracy education to explain the importance of not only having ongoing continuous treatment, but the importance of uptitrating the dose to achieve urate target levels which significantly reduce further attacks of acute gout. This not only prevents significant pain and loss of income from work absenteeism, but reduces the risk to the kidneys of repeated prescriptions of NSAIDs, or risk to diabetes management of prednisone, both of which are common comorbidities. There is also evidence that normalisation of serum urate reduces mortality. All these issues occur more commonly among Maori and Pacific patients, so that there are issues of equity

However, the key issue to allow this reclassification to occur is the safety of the patient. This will require adequate training and accreditation of pharmacist by an accountable governing body, along with appropriate adults, as occurs with nurse specialists, for whom regulations have been put in place recently by the nursing council to ensure the safe prescription of allpurinol
Details of this process, together with audit mechanisms, will provide safe prescription of reclassified allopurinol, for the better outcome of patients with gout, for whom current data suggests do not have their gout controlled in approximately 60 percent of patients or more, with the current classification practice.

Yours faithfully
Peter J Gow MbChB BMedSci FAFRM FRACP
Consultant Rheumatologist and Clinical Associate Professor of Medicine
CMDHB and South Auckland Clinical School

Leanne Te Karu
P.O Box 42013
Taupo 3330

Medicines Classification Committee
C/- The Secretary
(committees@health.govt.nz)
PO Box 5013
Wellington 6140

Re: Allopurinol reclassification

Nei rā te mihi ki a koutou

I am writing in response to the submission for allopurinol reclassification and, importantly, lodging my strong objection to this application.

I am doing so premised on three decades of clinical delivery, research and engagement with individuals, communities, Hapū and Iwi around gout management. In international fora, it is asserted by others that I have the most experience globally as an Indigenous clinician across these domains.
I acknowledge there will have been good intent with the application, and I understand it is hoped that the submission will help address the inequity of health outcomes for those with gout in Aotearoa.
However, my experience asserts such a move will only further fragment care for those carrying the significant burden of this health condition – Māori and Pasifika.
Every part of every engagement I have had with respect to gout informs me that viewing Indigenous health as a problem of poor health indicators to be solved through targeted service delivery tactics is reductionist. With respect to gout, there are examples of this existing in Aotearoa, New Zealand where programmes have been designed to address gout management and inequity and instead have led to anti-equity outcomes. For instance, the 'Gout Stop' programme (a collaboration between general practitioners, community pharmacists) and The 'Owning My Gout' programme (a model where community pharmacists and nurses work under standing orders from general practitioners to supply urate-lowering therapy). Despite both programmes' good intentions, the engagement with Non-Māori, Non- Pasifika peoples has been greater than that with Māori and Pasifika. As a result, inequity has increased with Non-Māori, Non- Pasifika more likely to achieve clinical success.
Compartmentalising Indigenous health outcomes is the opposite of what is required and voiced by whānau. As but one small example, in those with gout enrolled in a South Auckland general practice, 94% had multimorbidity. To ignore those other health conditions is to act contrary to the principles of Hauora, Mauriora and Toiroa.

Furthermore, in my opinion, only suitably qualified pharmacists who understand and have the skillset to manage such complexity are appropriate to do so. Anything otherwise only perpetuates the inequity that currently exists. Equally not to prescribe cover for allopurinol implementation will be met with the same outcome.
I strongly recommend a change to the paradigm from a linear view of adjusting isolated and consecutive components to a macro view of the complexities and emergent outcomes. Thus the retrofitting of a response and removing from a holistic health care model to one of biomedical fragmentation runs contrary to every voice I have listened to over the past 30 years.
I am available for further comment if deemed necessary.

Nāhaku noa
Nā

Leanne Te Karu

(Ngāti Rangi, Ngāti Kurawhatia, Muaūpoko)

Medicines Classification Committee

Comments on Submissions Cover Sheet

Meeting	Medivines Classification Committee, 66th meeting, May 11th 2021
Agenda item	6.1
Name	Linda Bryant
Occupation and / or Company or Organisation	NA
Contact phone number and email address	lindajmb@icloud.com

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

I have concerns regarding the proposed extension of prescribing privileges for allopurinol for gout prevention, and the planned extension to include other medicines for acute gout though community pharmacies.

Gout is not a benign medical condition. In addition to the medical complications and association with cardiac, renal and joint co-morbidities, there is a large impact on the person and whanau's social, psychological, and spiritual well-being. It increases inequity.

New Zealand has one of the highest prevalences of gout internationally. For Europeans this is 3.2%; for Māori 6.1% (9.6% in men); and for Pacific people 7.6% (12.3% in men). The prevalence rate is over 25%[1] for Māori and Pacific men over 65 years old. Yet we still have not achieved optimal care as shown by our annual hospitalisation rates of 1%, though this is 1.7% for Māori and Pacific people with gout.

So, gout is a very serious problem resulting in inequity, but the association of gout with many other long term conditions such as cardiovascular disease and diabetes means that there needs to be a coordinated team approach rather than fragmentation of care and a piecemeal approach. As well as cardiovascular disease and diabetes, the population who have gout are those with a high risk of distress, anxiety and depression – our young Māori and Pacific males. These are people who need to be seen within an integrated, wide general practice team, including medical, social and psychological support.

It is important that we investigate the cause of the problem of poorly controlled gout. because providing solutions. Working in an area with a high prevalence of gout, the Porirua basin, we have 17% of our Samoan population over 20 years old; 14% of our Cook Island Maori population over 20 years old and 9% of our New Zealand Maori population over 20 years old who have gout. The problem is not the prescribing of allopurinol *per se* but the many factors that influence adherence. This includes providing regular, consistent information and adherence support in a culturally appropriate way, an area that we have found needs to be addressed first.

Utilising research by Leanne Te Karu, a preferred model of care is being developed using community involvement through use of health improvement practitioners, health coaches, champions, shared medical consults and investigating a marketing / social media strategy .

Being cognisant of the Gout Stop projects, it appears that although there was an improvement in achieving target uric acid concentrations at 91 days, this was only for 18% of Māori and 29% of Pacific people, compared to 40% of European, indicating that this was a model that worked for the European population, but increased inequity for the populations that most needed the treatment. The concept is good, but not sufficiently effective for the target population.

Rather than fragmenting services by taking on a one-disease focus for prescribing, it would be preferable if there was a broader focus on the core issue of providing advice and support in a culturally appropriate way, and look at other models for encouraging the high risk people to engage with their general practice team, which is more extensive and can focus on the other problems that are associated with gout. It is not access to prescribing that is a problem, but access to consistent and evidence-based advice from a range of health care providers, and access to support for the co-morbidities.

One thing we have found very useful for adherence is blister pack for the first six months while titrating allopurinol. Attention to this and consistent advice / counselling when collecting the blister packs would be helpful.

There are other conditions that can be more ring fenced that would be preferable for the extension of prescribing privileges.

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[1] Winnard D, Wright C, Taylor W, Jackson G, Te Karu L, Gow P et al. National prevalence of gout derived from administrative health data in Aotearoa New Zealand. Rheumatology. 2012;51: 901-909

Linda Bryant
MClinPhgarm, PhD, PGCert(prescribing)
FNZHPA, FNZCP, FPSNZ, Gold Medal (PSNZ), MCAPA, RegPharmNZ

The Royal New Zealand
College of General Practitioners
Te Whare Tohu Rata o Aotearoa

14 April 2021

Our ref: BB21-154

Jacinta Patel
Advisor Science (Secretary for the MAAC and the MCC)
Medsafe
Ministry of Health
WELLINGTON

via email: committees@health.govt.nz

Tēnā koe, Jacinta

Agenda of the 66th Meeting of the Medicines Classification Committee (MCC)

Thank you for giving The Royal New Zealand College of General Practitioners the opportunity to comment on Agenda of the 66th 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 Agenda Item 6.1: Allopurinol – proposed change to the prescription classification statement.

The College has significant concerns regarding this proposal which will not necessarily reduce inequity related to gout management and may worsen existing inequity in the management of gout and other coexisting diagnosed and undiagnosed conditions.

The College recommends that the Medicines Classification Committee request that Dr Gauld discusses the proposal with the leaders of existing gout management programmes, the College, and other relevant stakeholders and resubmits a revised application to a future meeting if there is support for reclassification.

Classification sought

Allopurinol is currently classified as a prescription medicine.

The classification sought by the applicant, Dr Natalie Gauld, is:

> "Prescription medicine except when provided by a pharmacist who has completed gout training with the Pharmaceutical Society of New Zealand and is providing the medication to

a person who has previously been prescribed allopurinol tablets to prevent gout, and where the supply meets the approved criteria."[1]

Gout and equity

Gout is estimated to affect around 6 percent of the New Zealand population aged 20 and over, however, it is much more common among Māori and Pacific peoples. Among those aged 20-44 years for example, the prevalence of identified gout for Māori is three, and for Pacific peoples, seven times that of non-Māori, non-Pacific populations.[2]

Māori and Pacific people with gout are slightly more likely than non-Māori, non-Pacific to receive urate lowering therapy such as allopurinol. However, Māori and Pacific with gout are less likely than non-Māori, non-Pacific to receive ***regular*** urate lowering therapy. Analysis of data from 2019 found only 39 percent of Māori and 36 percent of Pacific people with gout were ***regularly*** dispensed urate-lowering therapy, compared with 43 percent of the non-Māori, non-Pacific population with gout.[2]

For uric acid lowering treatment to be effective it must be taken continually, so these findings are concerning on two levels; the low percentage of gout patients on preventative therapy and the inequity that is demonstrated.

Maintaining regular allopurinol intake is challenging, particularly for patients who are not accustomed to taking daily medication. Once the pain from the gout flare has gone, the need to continue treatment is no longer front of mind. In addition, starting or restarting allopurinol can provoke a gout flare. Patients may then associate taking allopurinol with worsening symptoms, a further barrier to taking the medication.

Gout Stop and Owning My Gout (OMG) programmes

These two gout management programmes have been established in areas with a high prevalence of gout, to improve the utilisation of urate lowering medication, in particular allopurinol.

Gout Stop began as a pilot in 2015. It now involves all general practices and 35 of the 36 pharmacies in Northland. Patients presenting to general practice who have experienced two or more gout flares within a year are referred to the programme. They are prescribed one of the four medication pack options, (*Fig 1*) which are preloaded in the practice management system. The community pharmacist and Kaiāwhina are involved in monitoring and educating the patient and blood test results are sent to the patient's GP.[3]

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[1] https://www.medsafe.govt.nz/profs/class/Agendas/Agen66/Allopurinol.pdf Accessed 12/4/21

[2] https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/gout/#[References] accessed 12/4/21

[3] https://www.arthritis.org.nz/wp-content/uploads/2020/07/Gout-Programmes-Evaluation-Report-April-2020.pdf Accessed 12/4/21

Figure 1 : Gout Stop Pack prescription options based on renal function and diabetes status [3] (p18)

Renal function (eGFR)	Blister Pack 1 (14 days)	Blister Pack 2 (28 days)	Blister Pack 3 (28 days)	Blister Pack 4 (21 days)
Option 1 eGFR >60	Prednisone 40 mg for 4 days, 20 mg for 4 days, 10 mg for 3 days, 5 mg for 3 days.	Allopurinol 100 mg daily Colchicine 500 mcg twice daily	Allopurinol 200 mg daily Colchicine 500 mcg twice daily	Allopurinol 300 mg daily Colchicine 500 mcg twice daily *Laboratory form
Option 2 eGFR 31–60	Prednisone 40 mg for 4 days, 20 mg for 4 days, 10 mg for 3 days, 5 mg for 3 days.	Allopurinol 50 mg daily Colchicine 500 mcg once daily	Allopurinol 100 mg daily Colchicine 500 mcg once daily	Allopurinol 200 mg daily Colchicine 500 mcg once daily *Laboratory form
Option 3 eGFR 10–30	Prednisone 40 mg for 4 days, 20 mg for 4 days, 10 mg for 3 days, 5 mg for 3 days.	Allopurinol 50 mg every other day Colchicine 500 mcg every other day *Laboratory form	Allopurinol 50 mg daily Colchicine 500 mcg every other day *Laboratory form	Allopurinol 100 mg daily Colchicine 500 mcg every other day *Laboratory form
Diabetes alternative eGFR >60	Naproxen 500 mg twice daily	Allopurinol 100 mg daily Colchicine 500 mcg twice daily	Allopurinol 200 mg daily Colchicine 500 mcg twice daily	Allopurinol 300 mg daily Colchicine 500 mcg twice daily *Laboratory form

Owning My Gout (OMG) is a smaller but expanding programme which began in 2017 in Counties Manukau DHB. Patients are referred from general practice to community pharmacists who dispense allopurinol under a standing order. Community pharmacists work with practice nurses to educate patients and titrate allopurinol doses with the aid of point of care uric acid testing using a BeneCheck© meter.[3]

The College supports both these programmes. The design of both programmes ensures integration with general practice and minimises fragmentation of care.

By contrast, the College is concerned about the model of care that will be created by the proposed reclassification. While the reclassification application states that the intention is that the "reclassification is intended to help ensure pharmacists can provide allopurinol to patients enrolled in a gout programme", there is nothing in the application that would ensure supply occurs within a well-designed and integrated gout management programme to ensure comprehensive continuity of care.

College concerns

1. Assessment of renal function

Safe titration of allopurinol dose requires measurement of the patient's renal function. This cannot be obtained from the point of care testing device for uric acid but requires a blood test analysed at a laboratory. Gout is associated with worsening renal function. Patients who have previously taken allopurinol should have had an assessment of their renal function at some stage, and the pharmacist will be able to access this in many regions in New Zealand. However, an up-to-date assessment is necessary as renal function can deteriorate, especially in patients with gout. Community pharmacists are not able to order laboratory tests.

2. ‘Cover’ while initiating allopurinol

Initiating allopurinol can provoke a gout flare. Medications such as colchicine, and non-steroidal anti-inflammatory medications (NSAIDs) are used to provide ‘cover’ while allopurinol is being initiated to decrease the incidence of flares. ‘Cover’ medication is often required for an extended period, and the most appropriate medication should be selected based on medical assessment, past medical history, and assessment of renal function. This requires medical input. In addition, colchicine is only available on prescription. NSAIDs should be used with caution, particularly in the elderly and those with renal impairment, both conditions also associated with gout. Some NSAIDs are available without prescription however only in limited amounts. The need for ‘cover’ medications to be prescribed is a further reason for GP involvement.

3. Management of gout flares

If a flare does occur, medications such as prednisone, NSAIDs and colchicine are used to decrease the inflammation and pain. NSAIDs have been mentioned above.

Neither colchicine nor prednisone are available without prescription and they both carry a risk profile that would preclude this. There are obvious advantages for patients to be managed and monitored in general practice

4. Integration with general practice

As mentioned previously the Gout Stop and Owning My Gout programmes are both well integrated with general practice and community pharmacy. We have already noted above our concern that the proposal could allow prescription without this sort of integration in place.

5. Review period

The proposal would see pharmacists able to prescribe 3 months of allopurinol at a time (Part A section 5) with no limit on how long the patient can continue to receive allopurinol without medical review. The College is concerned that not only will the necessary review of symptoms, uric acid and renal function not occur but also that the management of the many other conditions that frequently coexist with hyperuricemia may be neglected. For example, in New Zealand 40% of people with gout have diabetes and/or cardiovascular disease.[4]

6. Multiple prescribers

The risk of potentially inappropriate drug combinations increases with the number of physicians involved in the medical management of an elderly patient.[5] Pharmacist supply will in effect be adding an additional prescriber. This risk must be mitigated by ensuring that care is integrated rather than fragmented. The current proposal will not guarantee this.

[4] Winnard D, Wright C, Jackson G, et al. Gout, diabetes and cardiovascular disease in the Aotearoa New Zealand adult population: co-prevalence and implications for clinical practice. N Z Med J 2012;126:53–64.
[5] https://bpac.org.nz/BPJ/2006/October/docs/polypharmacy_pages_24-25.pdf Accessed 12/4/21

7. Will the risk mitigating strategies mentioned be implemented and effective?

We note that Section 10 of the application states that "Risk mitigating strategies will be agreed with a panel of experts". There have been previous instances where risk mitigating strategies have been put into place with similar reclassifications to 'prescription except". There has been little evaluation of these changes and what auditing that has occurred has revealed that risk mitigating strategies are not always followed.[6]

Is reclassification of allopurinol needed?

The widespread use of patient portals and increasing use of virtual consultations have decreased the need for time off work and travel, which is cited as a barrier to gout management in general practice.

We were surprised to find that GPs involved in the existing gout programmes were unaware of the plan to make an application for reclassification of allopurinol. Certainly, there is no suggestion that the application has been made as the result of those involved in these programmes identifying a need for reclassification.

We note that while the recent evaluation of the Gout Stop and Owning My Gout management programmes includes a section on 'informing future roll out' it makes no mention of reclassification of allopurinol among its recommendations.

Appreciation of the role of genetic predisposition to gout.

Gout used to be known as a disease of kings and associated with high living and rich food. More recently evidence has appeared that downplays diet as a risk factor for gout and establishes a genetic predisposition as being more significant. Neither patient understanding nor medical guidelines appear to have taken on board this new understanding.

This is unfortunate due to the whakamā (shame, feeling of disadvantage) associated with gout resulting from the assumption that the patient's diet is at fault, and this has been cited as one of the barriers to patient engagement with general practice.[7]

It is concerning to see that sources of GP guidance such as patient pathways[8] and the 2018 BPAC guidance on gout[9] perpetuate the misapprehension that gout is primarily the result of the patient eating the wrong foods. The College considers that there is an important opportunity here to improve both practitioner and population understanding.

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[6] https://www.nzdoctor.co.nz/article/news/audits-highlight-issues-around-correct-supply-sildenafil Accessed 12/4/21

[7] http://www.journal.mai.ac.nz/sites/default/files/MAI_Jrnl_2020_V9_2_TeKaru_FINAL.pdf Accessed 12/4/21

[8] https://3d.communityhealthpathways.org/ Accessed 12/4/21

[9] https://bpac.org.nz/2018/gout-part1.aspx Accessed 12/4/21

Kaimoana (seafood) is one of the food groups associated with gout. The gathering and eating of kaimoana has cultural significance for Māori and Pacific peoples, and the association of this cultural practice with the experienced whakamā of gout adds a further barrier to access to treatment for Māori and Pacific patients. Greater appreciation of the role of genetics, and a resulting decrease in the exclusive focus on diet, can potentially overcome this cultural barrier in addition to the shame felt by many gout sufferers.

Support by professional bodies and other relevant organisations

Among the list of parameters that must be considered when changing the legal classification of a medicine is the support of professional bodies[10]. Therefore, we were surprised that this application has been made by Dr Gauld as an individual rather than by the Pharmaceutical Society, of which Dr Gauld is the Vice-President[11]. In addition, as mentioned earlier, we would have expected the application to mention support from the leaders of the Gout Stop and Owning My Gout management programmes, if indeed they are in favour of the submission.

Conclusion

The College considers that many patients are missing out on the benefit of urate-lowering medication and further the burden of poorly controlled gout is inequitable and borne disproportionately by Māori and Pacific peoples, who already suffering from health inequity.

The College considers that the current proposal is not the best way forward but agrees that current management of gout is sub-optimal. The message that the urate lowering therapy should not be delayed while dietary improvements are pursued needs to be reflected in the clinical guidance available to health practitioners. There would also be benefit in more visible health promotions activity around the benefits of urate-lowering therapy.

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

Dr Bryan Betty
MBChB, FRNZCGP, FACRRM
Medical Director | Mātanga Hauora

[10] https://www.medsafe.govt.nz/downloads/How_to_change_medicine_classification.pdf Accessed 12/4/21

[11] https://www.psnz.org.nz/Category?Action=View&Category_id=97 Accessed 12/4/21

HEALTH · HYGIENE · HOME

19 March 2021

The Secretary
Medicines Classification Committee
Medsafe
committees@health.govt.nz

Dear Sir/Madam,

Re: Reclassification of Choline Salicylate – agenda item for 66th MCC meeting on 11 May 2021

Reckitt Benckiser (RB) notes the proposal from Medsafe to reclassify choline salicylate when used for infant teething from general sale to pharmacy-only medicine. While RB has no objections to this reclassification and supports the submission, it is important to note that the key issues being raised by Medsafe in its submission to the MCC is not related to the safety of choline salicylate as a topical pain reliever but rather it's pattern of use by parents/carers in managing infant teething pain. It's important to be clear that it's use by adults to relieve discomfort associated with mouth ulcers and sores and new dentures or dental braces is safe and not to be considered as part of this proposal.

Bonjela was first approved by Medsafe in 1966 and has been available to NZ parents/carers to help manage pain associated with teething for over 50 years. During this time NZ CARM has received two reports of overdose resulting in hospitalisation whilst in Australia the Therapeutic Goods Administration (TGA) has received 14 adverse event reports for choline salicylate containing products since 1983. Of these, 10 are for infants/small children. Two are coded for overdose. While the incidence of overdose with Bonjela teething is low the consequences are serious.

It is has been accepted by Medsafe that when used as directed, the safety of choline salicylate containing products such as Bonjela in children is acceptable. However, it has been recognised that these products tend to be overused/misused by parents/carers not realising the consequential harm of consistent high doses of salicylate in infants.

Labelling

The current labelling for Bonjela has the following instructions:

- Wash your hands, apply enough Bonjela to cover the tip of the index finger (about a pea-sized amount) and massage into the affected area.
- This can be repeated after 3 hours if necessary. Do not apply more often than once every 3 hours. No more than 6 doses should be given in 24 hours.
- Warning: Do not exceed recommended dose. Excessive or prolonged use can be harmful. If symptoms persist, seek medical or dental advice.

It is clear that the warning about not exceeding the recommended dose may need to be made more prominent. RB is planning to make changes to its labelling to address this. An additional safety related statement is proposed to be added to the front of the pack tube and the front of the pack carton in contrasting colour *"If symptoms do not improve after 3 days stop using and seek medical advice. Not suitable for frequent or long-term use. Excessive use could be harmful".*

Reclassification wording

RB proposes that the reclassification wording be amended to:

*Prescription medicine; **except** when specified elsewhere in this schedule; except in medicines containing 10% or less and in pack sizes of 15 grams or less*

Pharmacy-only; in medicines containing 10% or less and in packs sizes of 15 grams or less for the treatment of teething in children under 18 months of age.

General sale; in medicines containing 10% or less and in pack sizes of 15 grams or less.

To conclude, the safety of our consumers is of utmost importance to RB. As such RB has no objection to the reclassification of choline salicylate when used for relieving pain associated with teething in children under 18 months of age.

Yours sincerely,

[redacted]
Director Regulatory and Medical Affairs ANZ
Reckitt Benckiser (Australia) Pty Limited

HEALTH · HYGIENE · HOME

12 April 2021

The Secretary
Medicines Classification Committee
Medsafe
committees@health.govt.nz

Dear Sir/Madam,

Re: Ibuprofen 300mg in powder form – proposed reclassification from prescription medicine to pharmacy only medicine (AFT Pharmaceuticals Ltd) to be considered at the 66th meeting of the Medicines Classification Committee on 11 May 2021

The fixed dose combination of paracetamol/ibuprofen (500 mg/150 mg and 1000 mg/300 mg sachets) to be dissolved in a hot drink formulation for the management of cold and flu symptoms is a new product yet to be approved for use in New Zealand and yet to be launched in any country in the world. As a new ibuprofen format, with no in-market experience, reclassifying this from a Prescription Medicine to Pharmacy Only medicine is atypical and inappropriate.

A more appropriate classification is Restricted Medicine as it ensures that the pharmacist is involved to educate consumers, determine the suitability based on the needs of the individual and to support its safe and effective use. Further reasoning for this position is outlined below.

There is no in-market experience with Maxigesic® Cold & Flu Hot Drink and there is very limited in-market experience with ibuprofen in any powder formulations

In addition to the fact that Maxigesic® Cold & Flu Hot Drink has no in-market experience to establish its safety and suitability for self-selection, globally there is very limited availability of any ibuprofen products in powder formulations. There are only a small number of countries which have self-selection classifications for ibuprofen powder formats and no post-marketing surveillance data has been provided by AFT Pharmaceuticals to support the safety profile of ibuprofen in this dosing format.

Until there is sufficient in-market experience with Maxigesic® Cold & Flu Hot Drink it would be more appropriate for the use to be with pharmacist oversight, that is as a Restricted Medicine.

The intended use of Maxigesic® Cold & Flu Hot Drink is for the "relief of moderate to strong pain typically experienced by patients with heavy cold and flu symptoms". This use is not appropriate for self-selection and should be managed with pharmacist intervention.

The common cold is a mild upper respiratory viral illness. Common symptoms of colds include rhinitis, nasal congestion, sore throat, cough, and malaise. Fever and body aches/pains are uncommon. Fever, if present tends to be low grade.(1, 2)

Influenza or the flu generally begins with the abrupt onset of fever, headache, myalgia, and malaise. These symptoms are accompanied by manifestations of respiratory tract illness, such as non-productive cough, sore throat, and nasal discharge. Fever is common and is generally between 38°C and 40°C, but can be higher.(3) Symptoms are generally more severe in people with the flu than for common colds.(2)

Strong pain however, is not a symptom typically associated with the common cold or uncomplicated influenza.(1, 3) Having a medication for the relief of strong pain associated with heavy cold and flu symptoms has the potential to mask and delay the diagnosis of more serious medical conditions. For example, severe neck pain and unilateral sore throat are signs of a deep neck space infection, while nasal symptoms plus a severe headache may be suggestive of meningism.(4)

The intended use of Maxigesic® Cold & Flu Hot Drink is to reduce fever, yet this combination is no more effective than ibuprofen alone.

The proposed labels for both strengths of Maxigesic® Cold & Flu Hot Drink hot drink include the indication to reduce fever. Unlike for the management of pain where the combination of ibuprofen and paracetamol has demonstrated superior efficacy versus either ingredient alone, the simultaneous use of paracetamol and ibuprofen for fever is not as conclusive and the use of this combination for fever is not consistent with the quality use of medicines.

The published clinical trials in this area are in children, and we acknowledge that this reclassification application is for adults and children 12 years or older. However, the clinical evidence is that the combination of paracetamol plus ibuprofen is not significantly more effective in reducing discomfort associated a fever more than ibuprofen alone. Noting that the primary reason for managing a fever with antipyretics is to reduce discomfort rather than treating the thermometer.(5-7) Therefore, having this product for self-selection to reduce fever associated with a cold or the flu, without pharmacist oversight, potentially exposes the consumer to the use of additional actives when management with ibuprofen alone is likely to be as effective and of lesser risk.

Ibuprofen safety and public health need

AFT Pharmaceutical's reclassification application makes a strong case for the safety of OTC doses of ibuprofen, for both a 400 mg single dose and the total daily dose of 1200 mg/day. We agree that these doses are well tolerated and are suitable for self-selection use.

We agree with AFT Pharmaceuticals that there is a consumer need for additional therapies to manage strong pain, given the recent reclassification of codeine-based analgesics to Prescription Medicines.

We also agree that a significant number of consumers have difficulty swallowing solid dosage forms and that alternative solutions that addresses this burden will be of consumer benefit.

These three components of AFT Pharmaceutical's reclassification application are consistent with and support Reckitt Benckiser's application for the reclassification of 400 mg tablets and capsules also being considered at this meeting.

However, there are multiple hot drink powder formulations for the symptomatic relief of cold and flu available in New Zealand. These include formulations containing paracetamol alone; paracetamol in combination with a decongestant phenylephrine hydrochloride; and

paracetamol in combination with a decongestant phenylephrine hydrochloride and an expectorant guaiphenesin. Given that nasal and respiratory symptoms are common in patients suffering from the common cold or flu, these powder formulations represent a viable range of self-selection treatment options for use by New Zealand consumers. In principle, we agree that there is a need for more self-selection treatment options, but these options need to have adequate in-market experience, either locally or internationally, to establish that they can be used safely as self-selection medications. As this is not established for Maxigesic® Cold & Flu Hot Drink or for ibuprofen in powder formulations a more appropriate classification is one that includes direct oversight of a healthcare professional.

As Reckitt Benckiser also has a reclassification application to be addressed at this same meeting, we believe the amended wording for the classification of ibuprofen after consideration of both applications should be as follows with the changes highlight in red font:

Ingredient	Conditions (if any)	Classification
Ibuprofen	**except** when specified elsewhere in this schedule	Prescription
Ibuprofen	for oral use in tablets or capsules containing up to 400 milligrams per dose form and in packs containing not more than 50 dose units and that have received the consent of the Minister or the Director-General to their distribution as restricted medicines and that are sold in the manufacturer's original pack labelled for use by adults and children over 12 years of age for oral use in powder form containing up to 300 milligrams per dose form with a recommended daily dose of not more than 1.2 grams, and sold in the manufacturers original packs containing not more than 12 dose units, and labelled for use by adults and children over 12 years of age. **except** for oral use in tablets or capsules containing up to 400 milligrams per dose form with a recommended daily dose of not more than 1.2 grams and in packs containing not more than 12 dose units when sold in the manufacturer's original pack labelled for use by adults and children over 12 years of age	Restricted
Ibuprofen	for oral use in liquid form with a recommended daily dose of not more than 1.2 grams for the relief of pain and reduction of fever or inflammation when sold in the manufacturer's original pack containing not more than 8 grams; for oral use in tablets or capsules containing up to 400 milligrams per dose form with a recommended daily dose of not more than 1.2 grams and in packs containing not more than 12 dose units when sold in the manufacturer's original pack labelled for use by adults and children over 12 years of age for oral use in solid dose form containing not more than 200 milligrams per dose form and with a recommended daily dose	Pharmacy Only

	of not more than 1.2 grams when sold in the manufacturer's original pack containing not more than 100 dose units; **except** in divided solid dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams and when sold in the manufacturer's original pack containing not more than 25 dose units	
Ibuprofen	for external use; in divided solid dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams and when sold in the manufacturer's original pack containing not more than 25 dose units per pack	General sale

Yours sincerely,

[redacted]
Reckitt Benckiser (New Zealand) Pty Limited

References:

1. Sexton D, McClain M. The common cold in adults: Diagnosis and clinical features. UpToDate. 2019.
2. Health Promotio Agency, Ministry of Health. What to do with colds and 'flu'. 2020.
3. Dolin R. Seasonal influenza in adults: Transmission, clinical manifestations, and complications. UpToDate. 2020.
4. Antibiotic Expert Group, Therapeutic Guidelines Complete March 2021 online edition.
5. Wong T, Stang AS, Ganshorn H, Hartling L, Maconochie IK, Thomsen AM, et al. Combined and alternating paracetamol and ibuprofen therapy for febrile children. Cochrane Database Syst Rev. 2013(10):CD009572.
6. Hay AD, Costelloe C, Redmond NM, Montgomery AA, Fletcher M, Hollinghurst S, et al. Paracetamol plus ibuprofen for the treatment of fever in children (PITCH): randomised controlled trial. BMJ. 2008;337:a1302.
7. Erlewyn-Lajeunesse MD, Coppens K, Hunt LP, Chinnick PJ, Davies P, Higginson IM, et al. Randomised controlled trial of combined paracetamol and ibuprofen for fever. Arch Dis Child. 2006;91(5):414-6.

15 April 2021

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

Submitted via email to committees@health.govt.nz

Dear Sir/Madam,

RE: Public Comment on Agenda for 66th Meeting of Medicines Classification Committee
Agenda Item 6.4 – Topical Oral Benzocaine, Tetracaine Hydrochloride (Amethocaine), Lidocaine (lignocaine) and Prilocaine - proposed reclassification from prescription medicine to prescription except when classification

On behalf of Dentsply Sirona, we appreciate the opportunity to provide further comments on Medsafe's Agenda Item 6.4, specifically on Lidocaine (lignocaine) and Prilocaine, for the proposed 66th Meeting of Medicines Classification Committee (MCC), 11th May 2021.

Dentsply Sirona supports the Dental Council Submission and proposal to reclassify Lidocaine (lignocaine) and Prilocaine for topical use from 'prescription medicine' to 'prescription except when classification'. Reclassification of these chemical entities *for topical use* will align its use and restriction with the current exemption for prescription for dental therapists and oral health therapists registered with the Dental Council *for injection use*.

Product(s) affected by the proposed reclassification

Dentsply Sirona is the NZ sponsor for the topical oral local anaesthetic, Oraqix® Peridontal Gel, containing lidocaine (lignocaine) 25 mg/g, prilocaine 25 mg/g. This product has been in supply in New Zealand for more than a decade.

Safety and Usage of Oraqix

The safety and usage of Oraqix use are well established. Please refer to Appendix 1 for Pharmacovigilance Data and Appendix 2 for Sales Data in New Zealand over the last 5 years.

The information provided supports the long and extensive use of this product in dental work in New Zealand and confirms the low risk associated with the use of this product by dental healthcare professionals.

Dentsply Sirona welcomes the Committee's decision to consider and review the reclassification of Lidocaine (lignocaine) and Prilocaine to prescription except when classification.

Should you have any questions regarding our consultation feedback or data, we welcome the opportunity to discuss them further.

Yours sincerely,

Dr Joanne Challinor- Rogers
Director of Quality Assurance and Regulatory Affairs, ANZ region
Dentsply Sirona (N.Z.) Limited/Dentsply Sirona Pty Ltd (Australia)

Appendix 1 – Pharmacovigilance Data

[redacted]

Appendix 2 – Sales Data in New Zealand (last 5 years)

We have the solutions
HEALTHCARE ESSENTIALS

09/03/2021

TO WHOMSOEVER CONCERNED

Healthcare Essentials Ltd are suppliers of Dental products in New Zealand. This letter is to confirm that we support the reclassification of the topical local anaesthetic gel proposed for the Dental Therapists registered with the Dental Council. The proposal is consistent with the safety of the ZAP gel as per manufacturer's instructions. We had sold [redacted] units last year and [redacted] date this year. The following Government departments purchase ZAP from us.

1) [redacted]
2) [redacted]
3) [redacted]
4) [redacted]
5) [redacted]
6) [redacted]
7) [redacted]
8) [redacted]
9) [redacted]
10) [redacted]
11) [redacted]

Thank You.

Regards,

[redacted]

HealthCare Essentials Limited

7/489 Hutt Road, Alicetown, Lower Hutt 5010, New Zealand
Telephone (64-4) 387 3874 or NZ toll-free *0508* 802 5577
E-mail sales@healthcareessentials.nz Website www.healthcareessentials.nz

ANZCA
FPM

Te Whare Tohu o
Te Hau Whakaora

15 April 2021

Medicines Classification Committee
PHARMAC
PO Box 10254
The Terrace
Wellington 6143

Via email: committees@health.govt.nz

To the attention of: PHARMAC Medicines Classification Committee

Support for reclassification of Hyalase as a prescription medicine

The Australian and New Zealand College of Anaesthetists (ANZCA), which includes the Faculty of Pain Medicine (FPM), is responsible for the training and examination of anaesthetists and pain medicine specialists and for the standards of clinical practice in New Zealand and Australia. ANZCA's mission is to serve the community by fostering safety and high quality patient care in anaesthesia, perioperative medicine and pain medicine.

We offer our support to the submission made to the Medicines Classification Committee by the New Zealand Society of Cosmetic Medicine and the Cosmetic Nurse Network for the reclassification of Hyaluronidase, also commonly known as Hyalase, to a prescription only medicine.

Currently New Zealand is one of, if not the only, country to offer Hyalase as a non- prescription medicine. We are not aware of any reasons why Hyaluronidase should continue to be offered for general sale to the public.

Nāku noa, nā

Dr Sally Ure, FANZCA
Chair, New Zealand National Committee
Australian and New Zealand College of Anaesthetists

07 April 2021

Medsafe
New Zealand Medicines and Medical Devices Safety Authority
PO Box 5013
Wellington 6140

Via email: committees@health.govt.nz

Dear Sir/Madam,

Re: Medicines Classification Committee – Public Consultation on Agenda Items: Submission for Reclassification of Hyalase as a Prescription Medicine

The Royal Australian and New Zealand College of Ophthalmologists (RANZCO) welcomes the opportunity to review and comment on the New Zealand Society of Cosmetic Medicine (NZSCM) submission in support of the reclassification of Hyalase to prescription medicine.

RANZCO endorses NZSCM's submission on the reclassification of Hyalase to prescription medicine. Prescription medicine classification allows the monitoring of the outcomes of the use of Hyalase, which can cause adverse reactions without proper administration, to ensure patient safety. Adverse reactions include IV injection, oedema obstructing an airway, anaphylaxis, and in the worst-case scenario, damage or death arising from infection. In essence, reclassification of Hyalase to prescription medicine would reduce the occurrence of these adverse reactions by inhibiting access by the untrained public prone to inappropriate use.

Further, reclassification would bring New Zealand in line with the classification of Hyalase in all other countries. Hyalase is a prescription medicine in Australia, United Kingdom, Ireland, South Africa, and Brazil. The Hyalase brand is not available in the United States of America and Germany. However, all hyaluronidase brands (Vitrase, Hylenex, Hylase Dessau) are prescription medicines. In Switzerland, Sweden and Norway, a regular prescription is not sufficient for hyaluronidase. Instead, a particular prescription where the doctor takes more responsibility is required. Therefore, reclassification of Hyalase to prescription medicine would be in alignment with global classification standards of Hyalase.

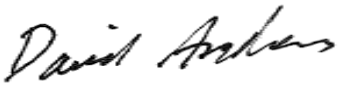
Moreover, there do not appear to be any risks of harm arising from reclassification. Currently, systems are in place for use as a prescription medicine by both wholesalers and health professionals because both assumed it was a prescription medicine, as in other countries.

Finally, without reclassification, Hyalase becomes more freely available to the public. As a result, the systems developed by suppliers and users who assumed Hyalase was a prescription medicine

will now be unnecessary and discarded. Consequently, this will remove a restriction to access that has almost certainly reduced the chance of adverse events associated with Hyalase.

Should you require any clarification regarding this matter, please contact Policy Officer Nosa Omokaro at nomokaro@ranzco.edu.

Yours sincerely,



David Andrews
RANZCO CEO