VAPING
REGULATORY
AUTHORITY

MINISTRY OF HEALTH
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22 February 2022

Vaping Regulatory Authority response to the reclassification of nicotine in liquid preparations – 67th meeting of the Medicines Classification Committee

Dear MCC,

Background

This letter is in regards to agenda item 8.2.2 discussed at the 67th meeting of the Medicines Classification Committee on 26 October 2021. On 9 November 2021, the Vaping Regulatory Authority were approached to provide advice on policy objectives relating to vaping, how nicotine in vaping products is regulated under the Medicines Act 1981, and any potential consequences of a reclassification of liquid nicotine. Therefore, this letter provides our response.

Response

The Ministry of Health administers the Smokefree Environments and Regulated Products Act 1990 (SERPA), which includes the regulation of the sale and supply of vaping products in New Zealand. This came into force as a response of the Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020 and commenced on 11 November 2020.

Section 3A of the SERPA outlines the key policy objectives towards vaping in New Zealand. The Act strikes a balance between ensuring vaping products are available for smokers who want to switch to a less harmful alternative and ensuring these products aren't marketed or sold to young people. Given this, our policy position towards vaping in New Zealand is vastly different to the approach in Australia. There are currently no plans to review our policy objectives.

Our position on vaping products is that their purpose is principally recreational rather than therapeutic, and that their use as a cessation aid for smokers is secondary. This means they are not classed as medicines or medical devices under the Medicines Act 1981. This is supported by two things; the continued availability of vaping products for all adults rather than just for those that are current smokers and section 2(4) of the SERPA, which states the following:

- Section 2(4)(b) - "a vaping device is not a medical device within the meaning of the Medicines Act 1981."
- Section 24(4)(c) - "a vaping substance is not a medicine within the meaning of the Medicines Act 1981."

A vaping product manufacturer or importer may choose to sell vaping products with smoking cessation as their whole or principal purpose. These products would be regulated under the Medicines Act 1981, rather than the SERPA, and would therefore not be vaping products. These products would need to be approved through the normal medicine's approval process under the

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Medicines Act 1981 and would not be subject to the SERPA. In this respect, New Zealand is already harmonised with Australia for vaping products that are principally or wholly for a therapeutic purpose. The significant difference is that it appears Australia is treating all vaping products as therapeutic, whereas in New Zealand we do not.

Given our position that vaping products are not medicines, we do not believe that scheduling nicotine in liquid preparations as prescription-only medicines under the Medicines Act 1981 would, in itself, affect vaping products or the operation of the SERPA. We also do not believe that this scheduling would achieve better harmonisation with Australia unless it was part of a broader decision to regulate vaping products under the Medicines Act. However, this would be against the current policy and would result in revoking large parts of the SERPA that have come into force only recently.

Overall, our view is that New Zealand is already as harmonised with Australia as it can and should be. Any further harmonisation would require a clear change in government policy. Furthermore, if scheduling nicotine in liquid preparations would be beneficial for the Medicines Act, then we do not believe that this would create a problem provided it is clear that vaping products that are principally for non-therapeutic use are regulated separately under the SERPA.

We trust that this provides a full response to the clarification sought.

Yours faithfully

Andrea Eng

Andrea Eng
Vaping Regulatory Authority

PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

29 March 2022

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 68th MEETING AGENDA Tuesday 26th April 2022

Thank you for the opportunity to submit comments on the agenda for the 67th meeting of the Medicines Classification Committee.

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 2,000 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 Nitrofurantoin (modified release) – proposed change to prescription classification statement

The Society supports the proposed reclassification for nitrofurantoin from prescription medicine to prescription except when supplied for oral use containing 100 mg per dose unit, when sold in a pack of 10 solid dosage units to a woman aged 16-65 years for the first-line empiric treatment of an uncomplicated urinary tract infection by a registered pharmacist who has successfully completed the New Zealand College of Pharmacists' training in the treatment of urinary tract infections.

The New Zealand College of Pharmacists has now become part of the Pharmaceutical Society of New Zealand and as a result the wording of the reclassification may need to be amended to reflect this change.

The Society currently provides support and training for the pharmacist provision of trimethoprim, to a woman aged 16-65 years, for the treatment of an uncomplicated urinary tract infection by a registered pharmacist, who has successfully completed training for the treatment of urinary tract infections.

Any training for nitrofurantoin would follow a similar approach and include:

- Identify the signs and symptoms of urinary tract infections (UTIs)
- List the side effects, contraindications and interactions of nitrofurantoin
- Identify when the supply of nitrofurantoin is appropriate
- Identify situations requiring referral to other health professionals
- Advise and counsel patients who require nitrofurantoin

The value of trimethoprim being available through the current classification has been shown to be beneficial and improves patient access to appropriate treatment.
Reclassification of nitrofurantoin to ensure patients have access to additional treatments for uncomplicated UTI's through a community pharmacy would be the next appropriate step.

The Society is of the view that it is important to ensure patients continue to have equitable access to appropriate treatments. We also have the expertise to develop the appropriate training programme to ensure this access and to mitigate any risks that may be perceived with the nitrofurantoin reclassification.

We are the opinion that the switch across to nitrofurantoin as the first line treatment, which is also accessible through a registered and trained pharmacist, is also safe and appropriate.

6.2 Naloxone – proposed down-scheduling change to classification

The Society supports increasing the access to naloxone for people requiring this medicine in an emergency. The current classification requires the manufacture to provide naloxone in an approved emergency kit for the treatment of opioid overdose before the medicine can be used without a prescription.

Due to the potential costs and work required to bring a product to market here in New Zealand this has not currently occurred. As a result, the initial intent of the Medicines Classification Committee reclassification in 2017 has not been met.

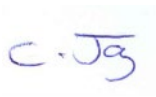
The applicant has provided some evidence to support why this classification should be revisited. However, due to the challenges of products available here in New Zealand, any movement in classification or wording of that classification may be difficult for the committee to consider.

In Australia, the Minister for Health, the Hon Greg Hunt MP, announced $10 million in funding for a Take Home Naloxone Pilot (THN) to run from 1 December 2019 to 30 June 2021. This is now running through to 30 June 2022 with an additional $3.9 million investment. The aim of the Pilot is to increase access to and availability of naloxone for at-risk groups in participating states (New South Wales, South Australia, and Western Australia) by making naloxone available for free and without a prescription from a variety of pharmacy and non-pharmacy settings. The Pilot also aims to further the evidence base for THN as an intervention to reduce the rate of death and other harms from opioid use in Australia.

The Society has been in discussion with the Pharmacy Branch at the Department of Health in Canberra regarding this Pilot. We would like to recommend that MCC consider gathering the evidence from their Australian colleagues in Canberra, to hopefully help inform their discussions and ultimately improve access to treatment and care for New Zealanders who require easier access to this live preserving medication.

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

30 March 2022

Medicines Classification Committee Secretary
Medsafe
Wellington

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

Dear Committee Members,

RE: Agenda for the 68th meeting of the Medicines Classification Committee

Thank you for the opportunity to provide feedback on the agenda for the 68th meeting of the Medicines Classification Committee (MCC), to be held in Wellington on 26 April 2022.

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 two agenda items. These are:

- Agenda item: 6.1 Nitrofurantoin (modified release) – proposed change to prescription classification statement
- Agenda item: 6.2 Naloxone – proposed down-scheduling change to classification

Each of these agenda items are discussed below.

Agenda item: 6.1. Nitrofurantoin (modified release) – proposed change to prescription classification statement

The Guild would like to strongly support the proposed amendment to the prescription classification statement for nitrofurantoin modified release.

The change would enable nitrofurantoin modified release to be supplied as a prescription medicine except when supplied for oral use containing 100 mg per dose unit when sold in a pack of 10 solid dosage units to a woman aged 16-65 years for the first-line empiric treatment of an uncomplicated urinary tract infection by a registered pharmacist.

This would align with New Zealand and international guidelines, wherein modified release nitrofurantoin (Macrobid®) 100 mg twice daily for 5 days is now the recommended first-line treatment for non-pregnant women with acute, uncomplicated cystitis and trimethoprim is no longer considered a first-line empiric choice owing to the high level of resistance.

Given that community pharmacies are a valuable first point of contact for the New Zealand population and are an accessible and affordable point of care and screening mechanism, pharmacists are perfectly placed to provide this service in a safe and effective manner. This will continue to reduce the strain and pressure on general practice and reduce preventable hospitalisation associated with complications of untreated urinary tract infections.

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We would request that any future medicine classification changes are undertaken in a consistent manner with previous classification changes. Differences in classification statements between medicines have potentially significant pharmacy quality audit implications and this can put unnecessary burden on pharmacies to meet these requirements when there are inconsistent and variable classification statements across similar medicines within the same classification. We believe that taking a competence-based approach puts the ownership back on the pharmacist to ensure their own competency to supply a specific medicine, while also being less prescriptive and allowing for greater flexibility.

We believe that mandating specific training course requirements can be a significant barrier for providing a service. This can impact the desired ready and equitable access to the service for patients, while also putting significant compliance requirements and potential financial burden onto pharmacists, while also removing choice for how a pharmacist becomes competent to supply this medicine.

We are also mindful of the implication that this potential reclassification will have on the current classification status of trimethoprim. The Guild believes that trimethoprim should remain available as an alternative option for pharmacists when supplying medicine for UTI's and where nitrofurantoin is not clinically suitable. We are confident that pharmacists possess the necessary competencies to make this assessment and would support changes to guidelines for pharmacist supply of trimethoprim to enable this.

Agenda item: 6.2 Naloxone – proposed down-scheduling change to classification

The Guild does not support the reclassification of naloxone to a general sale medicine. We support improvements to medicine access to the general population but believe this must occur safety with the appropriate advice mechanisms to ensure safe and equitable access to naloxone.

The Guild supports amending the prescription classification statement to "Prescription; except when provided, or intended to be provided, for the reversal of opioid overdose, along with equipment and instructions". We believe that this would be sufficient in removing obstacles in obtaining naloxone for emergency use. This would also align with international use and guidelines. If any need arises to further increase access to naloxone, the Guild would suggest amending the classification statement to "prescription medicine except when supplied by a pharmacist". This would enable pharmacists to supply naloxone with appropriate equipment and instructions, further improving access and equity but in a safe, controlled manner.

Thank you for your consideration of our response. If you have any questions about our feedback, please contact our Senior Advisory Pharmacist, Martin Lowis, at martin@pgnz.org.nz or on 04 802 8218.

Yours sincerely,

Nicole Rickman
General Manager – Membership and Professional Services

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

31 March 2022 Our ref: BB22-011

Jacinta Patel
Advisor Science (Secretary for the MARC and the MCC)
Medsafe
Ministry of Health
PO Box 5013
WELLINGTON

By email: committees@health.govt.nz

Tēnā koe Jacinta

Reclassification of Nitrofurantoin: Agenda item 6.1

Thank you for the opportunity to comment on the Medsafe proposal to reclassify Nitrofurantoin.

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.

Our submission addresses Agenda item 6.1. Nitrofurantoin (modified release) – proposed change to prescription classification statement.

Trimethoprim is the only antibiotic that Pharmacists can supply to women with symptoms of urinary tract infection (UTI), however, it is no longer recommended as the first line empiric treatment for uncomplicated UTIs. The proposed change to Nitrofurantoin would enable women to be treated in accordance with current evidence-based guidelines and pharmacists would be able to supply it without a prescription from a GP.

The College does not support the Medsafe proposal for the reasons outlined in our submission. We identify serious consequences regarding the approach to antibiotic prescribing by pharmacists, including, supply, transparency of prescribing without a prescription, and antimicrobial resistance.

Background

The Medicines Classification Committee of Medsafe (MCC) have received a proposal from Te Arai BioFarma, the supplier of Macrobid, to reclassify modified release Nitrofurantoin for supply to women aged 16-65 without prescription by a registered pharmacist who has successfully completed the New Zealand College of Pharmacists' training in the treatment of UTIs.

The classification sought is:
"Prescription Medicine except when supplied for oral use containing 100 mg per dose unit when sold in a pack of 10 solid dosage units to a woman aged 16-65 years for the first line empiric treatment of an uncomplicated urinary tract infection by a registered pharmacist who has successfully completed the New Zealand College of Pharmacists' training in the treatment of urinary tract infections."

Pharmacists have been able to supply Trimethoprim since it was reclassified in 2012. A 2015 application to the MCC to reclassify the immediate release formulation of Nitrofurantoin so it could be dispensed in a similar manner was unsuccessful.

Since the 2015 application there have been two developments relevant to Nitrofurantoin:

1. Macrobid was approved for use in New Zealand. It is a modified release form of Nitrofurantoin, requiring only twice daily dosing. The previous immediate release formulation of Nitrofurantoin was taken four times daily and was associated with significant side effects. Macrobid is claimed to be associated with fewer side effects. Pharmac funded Macrobid for the treatment of uncomplicated UTIs in March 2021.[1]

2. Nitrofurantoin replaced Trimethoprim as the recommended first line agent for the empiric antimicrobial treatment of urinary tract infections (UTIs) due to decreased susceptibility to Trimethoprim.[2]

Submission

The College considers that women presenting to a pharmacist for treatment of a UTI should not be supplied with an antibiotic no longer recommended as first line empiric antimicrobial therapy of UTIs.[2] We also have serious concerns with the supply of antibiotics without a prescription which we outline below.

a. **Contribution to antimicrobial resistance**

Since the successful application to reclassify Trimethoprim in 2012 and the unsuccessful application to reclassify Nitrofurantoin in 2015, the magnitude of the risk that antimicrobial resistance presents to global health has become appreciated.

In 2015 the World Health Organisation (WHO) agreed the Global Action Plan on Antimicrobial Resistance.[3] New Zealand followed with the New Zealand Antimicrobial Resistance Action Plan published in 2017.[4] Antibiotic stewardship is a key component of both action plans and promote the importance of antibiotics only being used when necessary.

The College considers research is needed to estimate the frequency with which antibiotics are supplied by a pharmacist, and when a bacterial UTI is not found on the culture. Similar research should also be undertaken in general practice. The results would provide an evidence base to inform both pharmacists and prescribers. Routine urine culture is not indicated, rather a representative sample should be selected for testing. It is important that women can access prompt treatment for UTIs, however measures to improve the accessibility of necessary treatment must not lead to an increase in the use of antibiotics in the absence of a bacterial infection. Research is needed to ensure to this is not occurring. We would encourage the MCC to approach the Heath Research Council to encourage the funding of applications for research.

In December 2021 The Office of the Prime Minister's Chief Science Advisor released the report 'Infectious disease and antimicrobial resistance'.[5] The report questions the supply of Trimethoprim by pharmacists. On page 207 it states:

> "In Aotearoa New Zealand, an antibiotic (trimethoprim) used for treatment of UTIs is available to be purchased from accredited pharmacists without a prescription if certain conditions are met. This approach was introduced in 2012 and is only available to women who are experiencing uncomplicated cystitis. While this approach may enhance access for some women, there is little oversight of this dispensing, and it is unknown how well pharmacists adhere to guidelines for providing trimethoprim for UTIs. It would be beneficial to collect and analyse data on the quantity and nature of trimethoprim purchased, and whether this treatment is effective.
>
> "An audit performed from June 2016 to August 2018 found that around one quarter of E. coli isolates causing cystitis in women were not susceptible to trimethoprim, a level of non-susceptibility

[1] https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/notification-2020-10-30-nitrofurantoin/ Accessed 28/3/22
[2] https://bpac.org.nz/antibiotics/guide.aspx#uti-adult Accessed 28/3/22
[3] https://ahpsr.who.int/publications/i/item/global-action-plan-on-antimicrobial-resistance Accessed 28/3/22
[4] https://www.health.govt.nz/publication/new-zealand-antimicrobial-resistance-action-plan Accessed 28/3/22
[5] https://cpb-ap-se2.wpmucdn.com/blogs.auckland.ac.nz/dist/f/688/files/2020/01/Full-report-FINAL-15122021-V2-PDF-160222.pdf Accessed 28/3/22

sufficiently high to suggest that use of trimethoprim as the empiric treatment should be reconsidered. Further, as discussed above, there is growing resistance to trimethoprim and some prescribing guidance now recommends nitrofurantoin as the first-line treatment for UTIs. This suggests that over-the-counter provision of trimethoprim should be reconsidered."
The supply of Nitrofurantoin by pharmacists is not specifically addressed in the report, which was released prior to the current proposal, however many of the concerns raised also apply to Nitrofurantoin.

b. **Monitoring the quantity of antimicrobials used**

The report from the Office of the Chief Science Advisor expresses concerns regarding the monitoring of the quantity of antimicrobials used in the human health sector:

- The report describes pharmacy trimethoprim sales as a "data gap" (p.19).
- That antimicrobials available without prescription from pharmacies are not captured in the Pharmaceutical Collection and ethnicity data is not collected to monitor equity-based outcomes and provides essential information to improve outcomes of antimicrobial stewardship (p.182).

c. **Serious adverse reactions to nitrofurantoin**

The Te Arai proposal[6] states that "Macrocrystalline nitrofurantoin afforded a greater cure rate (86% versus 76%, $p<0.05$) and a lower incidence of side effects (17% versus 39%, $p<0.05$) compared with microcrystalline nitrofurantoin." This was based on research published in 1974.[7] In their proposal they argue that Nitrofurantoin causes fewer side effects than trimethoprim based on retrospective chart audit.[8]

Nitrofurantoin may cause fewer side effects than Trimethoprim however the side effects can be serious, particularly hypersensitivity reactions causing lung disease. Fatal lung disease associated with nitrofurantoin has been reported in New Zealand.[9] While the proposal argues that "the risk of hypersensitivity reactions may be appropriately managed by adopting measures employed in the UK Patient Group Directive initiative (PGD)"[10] the College considers that the risk of side effects remains important. We note that "hypersensitivity reactions usually affect women aged 40-50 years"[11] and both the UK PGD and the current application permit supply to women up to 65 years of age.

d. **Communication with the patient's general practitioner**

The College's Medical Director, Dr Bryan Betty, says the lack of structured communication channels between pharmacy and general practice is a barrier to effective communication. In the ten years since Trimethoprim was reclassified, he had only been informed once about a patient being supplied with Trimethoprim by a pharmacist. There is no reason to expect that communication will be better with Nitrofurantoin, despite the additional risk of pulmonary hypersensitivity reactions.

Integration is an important enabler of effective and efficient patient centred care. The College supports protocols being developed which require reporting to a patient's GP when antibiotics are supplied. If the patient does not have a GP, then the system should still require pharmacist reporting.

Any interaction with the pharmacist should be considered a valuable opportunity to address disparities in access to health care by providing information to the patient on the advantages of enrolment and how to find a practice that is accepting new patients.

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[6] https://www.medsafe.govt.nz/profs/class/Agendas/Agen68/6.1Nitrofurantoin.pdf Accessed 28/3/22
[7] Kalowski S et al., Crystalline and macrocrystalline nitrofurantoin in the treatment of urinary-tract infection. N Engl J Med. 1974; 290: 385-387.
[8] Claussen K et al., How Common Are Pulmonary and Hepatic Adverse Effects in Older Adults Prescribed Nitrofurantoin? *J Am Geriatr Soc*. 2017; Jun;65(6):1316-1320. doi: 10.1111/jgs.14796.
[9] https://medsafe.govt.nz/profs/puarticles/nitrofurant.htm Accessed 28/3/22
[10] https://www.medsafe.govt.nz/profs/class/Agendas/Agen68/6.1Nitrofurantoin.pdf Page 14 Accessed 28/3/22
[11] Krause M, Ruef C. Miscellaneous antibacterial drugs. In Dukes MNG, Aronson JK (Eds). Meyler's Side Effects of Drugs 14th Edn. 2000: Elsevier BV, Amsterdam, p884-885.

e. **Screening tool and pharmacist training should the proposal be successful**

The College considers that the screening tool and training developed by the Pharmaceutical Society should not allow the supply of Nitrofurantoin to women who have had recent antibiotics. This would prevent frequent resupply and encourage further investigation.
Strategies for managing patient expectations around supply of antibiotics are needed, particularly when people are paying for a consultation. There is also a need to educate the health sector and patients about the importance of preventing AMR. Patients also need to know how to prevent UTIs and manage their symptoms and should be encouraged by the provision of simple educational materials.

Conclusion

The College considers that the MCC should revise the classification of Trimethoprim due to concerns regarding AMR, serious side effects, inadequate data capture, and the lack of structured communication channels between pharmacists and GPs. Fort these reasons, the College opposes the reclassification of Nitrofurantoin being supplied by pharmacists without prescription.

If you have any questions about this submission please contact Maureen Gillon, Manager Policy, Advocacy, Insights - maureen.gillon@rnzcgp.org.nz.

Nāku noa, nā

Dr Bryan Betty
MBChB, FRNZCGP (Dist.), FACRRM
Medical Director | Mātanga Hauora

NEW ZEALAND
Family Planning

Comment on Medicines Classification Committee Agenda - 68th meeting

30 March 2022

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Charities # CC11104

Comment on Medicines Classification Committee Agenda - 68th meeting

Introduction

1. Family Planning welcomes the opportunity to provide comment on the Medicines Classification Committee Agenda for the 68th meeting.

2. We comment on two agenda items: 1) the reclassification of nitrofurantoin from prescription medication to restricted medication and; 2) harmonisation of the New Zealand and Australian Schedule for estetrol monohydrate.

3. Family Planning is New Zealand's largest provider of sexual and reproductive health services and information. We are a non-governmental organisation (NGO) operating 29 clinics throughout Aotearoa New Zealand as well as services in schools and through community partnerships. We offer accredited clinical courses and workshops for doctors, nurses, midwives and other clinicians working in sexual and reproductive health. Each year we provide over 117,000 consultations for a range of sexual and reproductive health issues including for contraception and the treatment of urinary tract infections (UTIs).

Nitrofurantoin

4. Family Planning generally supports the submission from Te Arai BioFarma. Te Arai BioFarma seeks the following change in classification for nitrofurantoin:

> *Prescription Medicine except when supplied for oral use containing 100 mg per dose unit when sold in a pack of 10 solid dosage units to a woman aged 16-65 years for the firstline empiric treatment of an uncomplicated urinary tract infection by a registered pharmacist who has successfully completed the New Zealand College of Pharmacists' training in the treatment of urinary tract infections.*

5. Family Planning supports making nitrofurantoin a restricted medicine in certain circumstances. However, Family Planning notes that this medicine should be able to be provided not only by a registered pharmacist who has successfully completed the New Zealand College of Pharmacists' training in the treatment of urinary tract infections, but also by a registered nurse who has successfully completed training in the treatment of urinary tract infections. The provision of nitrofurantoin would fit within the scope of practice for many nurses, particularly Family Planning nurses. Some registered nurses are prescribers, and nitrofurantoin is on the list of medicines they can prescribe. However, not all nurses become prescribers. Family Planning would like registered nurses who are trained, but not prescribers, to be able to supply modified release nitrofurantoin to patients, as would happen in a pharmacy, but we understand that for this to happen, the medicine would need to be on PSO supply where a trained nurse can supply it under

standing order. The clinical assessment for acute UTI and exclusions is appropriate for registered nurses.

Estetrol Monohydrate

6. Family Planning supports New Zealand harmonising our Schedule with the Australian Schedule by approving Estetrol Monohydrate as a prescription medicine. Esterol monohydrate, combined with drospirenone, is used in a new oral contraceptive. The brand name for this new combined oral contraceptive in Australia is Nextstellis.

7. Family Planning has always advocated for increasing contraceptive options in New Zealand. Expanding contraceptive options promotes equity in access to effective contraception, as people need a range of options in order to choose the one that works best for them. While women are increasingly using long-acting reversible contraceptives (LARCs), the oral contraceptive pill is still the most popular method of contraception.[1] Family Planning is aware that Nextstellis (estetrol and drospirenone) is approved in Australia and Canada, and estetrol and drospirenone is approved under the brand name Estelle in other countries including the United States. It is important that New Zealanders have access to a similar range of contraceptive options as compared to people in other similar countries around the world. If estetrol monohydrate is approved by Medsafe, Family Planning would advocate for PHARMAC to fund this medication for contraception or allow it to be funded under special authority if other funded contraceptive options are not tolerated by a person.

In summary:

8. Family Planning supports the proposal to reclassify nitrofurantoin so it can be provided by trained pharmacists, but we note that trained registered nurses should also be able to provide this medication for uncomplicated UTIs.

9. Family Planning supports harmonisation with the Australian Schedule for estetrol monohydrate, so it is an approved medicine in New Zealand, and oral contraceptive options in New Zealand can be expanded.

Nāku noa, nā

Jackie Edmond
Chief Executive

[1] Ministry of Health. 2019. Contraception: Findings from the 2014/15 New Zealand Heath Survey. Wellington: Ministry of Health. https://www.health.govt.nz/publication/contraception-findings-2014-15-new-zealand-health-survey

pharmacycouncil
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31 March 2022

Medicines Classification Committee Secretary
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By email only: committees@moh.govt.nz

Pharmacy Council submission on the reclassification of nitrofurantoin 68th meeting on 26 April 2022

Council View

Te Pou Whakamana Kaimatū o Aotearoa / Pharmacy Council (Council) believes that pharmacists possess the competencies to appropriately supply nitrofurantoin as per the proposal in the application. However, we recommend that pharmacists be required to complete a formal training programme that focuses on assessment and triage of suspected urinary tract infection, supply of nitrofurantoin according to current practice and gazetted requirements, and provision of appropriate self-care and disease prevention measures.

Background

Council is a Responsible Authority established by the Health Practitioners Competence Assurance Act (HPCA Act) 2003. Our purpose is to protect the public by ensuring that pharmacists are competent and fit to practise. Some of Council's core functions are summarised below, though a more comprehensive list is mandated within section 118 of the HPCA Act.

- Specifying scopes of practice
- Setting professional competence and ethical standards
- Prescribing and accrediting qualifications required to register in a scope of practice
- Setting requirements and processing applications for registration and recertification
- Maintaining a public register
- Investigating complaints or notifications where a pharmacist may be practising at a level below the expected standard

It is important to note that while it is Council's role to promote education and training (HPCAA s118 (k)), Council is not legislated to provide education or practice support to practitioners. Instead, education provision is undertaken by providers able to provide training that meets the required criteria. This submission is therefore framed within the basis of this mandate. Though making this submission is not within Council's core functions, we believe that we are well placed to offer the Medicines Classification Committee (MCC) an independent opinion of pharmacists' competence. We believe that this opinion is necessary for MCC to make a decision in the public interest.

Application to MCC for reclassification of nitrofurantoin

Council's view is based on its responsibilities under the HPCA Act, observed practice of pharmacists when supplying non-prescription trimethoprim, and application of the joint Medicine Reclassification framework developed by the Pharmaceutical Society of New Zealand (the Society) and Council.[1]

[1] https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/Council-and-Society-Medicine-Reclassification-Framework.pdf

The framework is recognised and utilised by the MCC. It provides a structure that facilities a robust analysis that informs Council's opinion of whether pharmacists may be competent to supply a medicine without prior assessment by a prescriber. If it is determined that pharmacists do possess required competencies, the framework will help determine whether a formal training programme, self-directed up-skilling, or no up-skilling is required. The framework and this submission are not intended to provide specific details of a potential training programme or practical implementation of the proposal.

The Society and Council applied the framework independently but collaborated to ensure that a cohesive submissions are produced for MCC. The framework breaks the analysis down into four broad elements. These are: the consultation, the medicine, documentation, and professionalism.

Council is satisfied that pharmacists possess competencies appropriate under each category to the required level, but we note that some knowledge training is likely required. Our final opinion to MCC is informed by a holistic review against the Competence Standards for the Pharmacy Profession 2015 in their full form; however, a short commentary of each category follows with particularly pertinent competence standards highlighted. [2]

Consultation Elements

The consultation includes pharmacist activities to gather relevant information from the patient; form an appropriate treatment plan via shared decision-making; and convey information regarding safe use of the medicine, and recovery from and prevention of disease. These activities are described by the following competencies within the Competence Standards.

- M2.1: Communicate effectively
- M1.6: Make effective decisions
- O1.1: Consult with the patient
- O1.2: Provide healthcare
- O1.3 Review and manage patient's medicine therapy
- O2.2 Health promotion

Council notes that the diagnosis of uncomplicated urinary tract infection remains the same regardless of treatment options (trimethoprim or nitrofurantoin). Information from a patient consultation may be supplemented by on-site pharmacy medication records and/or clinical information sharing services. The empirical evidence since trimethoprim's reclassification demonstrates pharmacists' competence to triage presentations of urinary tract infection effectively, and determine whether differential diagnosis, non-prescription treatment, or referral to another health professional is appropriate.

A training programme will need to ensure that a pharmacist is familiar with the pathophysiology and aetiology of urinary tract infection, can diagnose a urinary tract infection, and determine when non-prescription supply or referral to another health professional is appropriate.

Medicine Elements

To determine whether a medicine is a viable option, a health professional must possess the competencies to access appropriate medicine data, and patient-specific medical and medicine history. They must also be able to integrate the information via a rational and evidence-based decision-making process. The competence standards that relate to these activities are below.

- O1.1: Consult with the patient
- O1.2: Provide healthcare
- O1.3: Review and manage patient's medicine therapy
- O1.5: Access, evaluate and provide medicines information

[2] https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/CompStds2015Web-1.pdf

Broadly speaking, the cautions and contra-indications for trimethoprim and nitrofurantoin are similar. Pharmacists' appropriate provision of trimethoprim since its reclassification again offers an additional level of assurance of competence to supply.

Training will focus on the cautions and contraindications, safe use, and expected treatment outcomes (including adverse effects) of nitrofurantoin treatment.

Documentation Elements

Competence standard O1.4: Deliver quality and safe services, includes behaviours which describe professional requirements to maintain effective documentation for the purposes of continuous quality improvement, continuity of care, and pharmacovigilance.

A documentation process must be developed and integrated into the training.

Professionalism Elements

Across all medicines, safe supply must meet legal, professional, and ethical requirements, while also seeking to deliver services that contribute to optimum clinical, cultural safety, access, and equity goals. These aspects of practice and the application were considered with reference to the competence standards below.

- M1.2: Comply with ethical and legal requirements
- M1.4: Practise pharmacy within New Zealand's culturally diverse environment
- M1.5: Understand Hauora Māori
- M1.6: Make effective decisions
- M2.2: Establish and maintain collaborative working relationships
- O1.5: Access, evaluate and provide medicines information

Training should provide information on the populations that benefit most from improved access to treatment. It should also reinforce that conversations regarding genitourinary health may be uncomfortable for some patients and consultations must be carried out in a culturally safe manner.

Training

Although Council's view is that pharmacists possess the competencies to supply nitrofurantoin without prescription as per the proposal in the application, we believe that additional knowledge training is required. The level of additional knowledge required is beyond what could be expected via self-directed upskilling, and so Council is recommending that a formal training programme be required. Training should ensure that pharmacists can effectively assess and triage a suspected urinary tract infection; (if appropriate) supply the medicine according to current practice and legal requirements; provide appropriate medicine use, self-care and disease prevention advice, and overview a documentation process.

Nathan Young
Quality Improvement Pharmacist

Michael A Pead
Chief Executive

Natural Ange Ltd
1728 Wainui Rd
R.D. 1
Kaeo 0478

25.3.22

Dear Members of the Medicines Classification Committee,

I am a Naturopath and former Registered Nurse. I have been in full time practice for 26 years.
In my practice, I advise the public on a regular basis with evidence-based methods for supporting their health and nutrition, sometimes through supplementation.
I attend webinars and keep up with clinical research in my field.

I rely on a variety of reputable suppliers in New Zealand - mainly I use 'practitioner-only' brands.
Levmefolate in its different forms in Dietary Supplements vary in doses of up to 1mg.
I always take great care to ensure that the products that I recommend are safe for clients when used as directed.

I see no reason for there to be a change to the use of levomefolate in foods, supplemented foods and dietary supplements in New Zealand. Consumer choice should not be restricted when there is such a high level of safety for this ingredient.

I agree with all points made by Natural Health Products New Zealand in their open letter to the Medicines Classification Committee (16 March 2022) and respectfully request that the Medicines Classification Committee makes no changes to the access of levomefolate in supplements, foods, and supplemented foods.

Yours sincerely

Angela Haldane
(Former) NZRN Comprehensive.
Dip Applied Sc. Naturopathy (Melb)
09 94661888 ; 0274860237

BePURE GROUP
Scientific Wellness

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BePure Clinic: 0800 52 54 52 ext. 1 | bepure.co.nz/clinic | clinic@bepure.co.nz
Eve Wellness: 0800 367 383 | evewellnessco.com | info@evewellnessco.com
PO Box 147602, Ponsonby 1144, New Zealand

28 March 2022

To the Members of the Medicines Classification Committee,

We, the BePure Group, on behalf of our three businesses BePure Health Ltd; Eve Wellness Ltd; and the BePure Health Clinic Ltd, submit this letter to the Medicines Classification Committee (MCC) upon receiving notification that the classification of levomefolate is on the agenda for the 68th meeting of the MCC[1].

The BePure Group seeks to ensure the currently permitted use of levomefolate in foods, supplemented foods and dietary supplements in New Zealand continues. Classification of levomefolate as a medicine would greatly restrict consumer choice, hinder the consumers accessibility to an incredibly important nutrient in its natural form and significantly disadvantage New Zealand in being a strong player within the global food, supplemented food and dietary supplement industry. We would like to see the current permitted use of levomefolate remain as is.

Folate is an essential B vitamin to basic human health. As a coenzyme, it is required for DNA synthesis and cell reproduction[2]. Levomefolate is the predominant naturally occurring form of folate in foods and the active metabolite our body converts folic acid into, becoming the major circulating form of folate in the human body[3]. It is also the primary form of folate found in breast milk[4].

Levomefolate (and its salts) is widely recognised as a safe form of folate globally and we ask where is the literature to show there is a risk of using up to 1 mg of folate in the form of L-methyltetrahydrofolate, calcium in dietary supplements or foods? Levomefolate is freely permitted for use in foods and dietary supplements in many respected international markets including the big global players in the industry such as the USA, Australia and Europe. Levomefolate carries a GRAS (Generally Recognized as Safe) notice, allowing its use within infant formula, foods and dietary supplements in the USA, regulated by the FDA[5]. The following table summarises the global permitted use of Levomefolate within New Zealand and these other industry leading countries who we believe New Zealand should be looking to when making decisions and classifications.

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[1] Agenda for the 68th meeting of the Medicines Classification Committee. https://www.medsafe.govt.nz/profs/class/Agendas/Agen68/agen68.htm
[2] Nutrient Reference Values for Australia and New Zealand. https://www.nrv.gov.au/nutrients/folate
[3] JEFCA Chemical and Technical Assessment of Calcium L-5-methyltetrahydrofolate, 2005. https://www.fao.org/3/at980e/at980e.pdf
[4] Page et al 2019. Total folate and unmetabolized folic acid in the breast milk of a cross-section of Canadian women. https://pubmed.ncbi.nlm.nih.gov/28298392/
[5] GRAS notice for the use of calcium l-methylfolate in infant formula. GRAS Notice (GRN) No. 915. https://www.fda.gov/media/140366/download

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Country	Regulating Body	Product Class	Permitted Use
New Zealand	MPI/MedSafe MPI	Dietary Supplement Supplemented food	Not restricted Permitted as a form of Folate as Methyltetrahydrofolate calcium up to a MDD of 500 mcg[6].
Australia & New Zealand	FSANZ/MPI	Food	Permitted as a form of folate as L-methyltetrahydrofolate, calcium[7].
Australia	TGA	Listed Medicine	Permitted as either levomefolate calcium or levomefolate glucosamine as an active ingredient in up to an equivalent MDD of 500 mcg levomefolic acid[8].
Canada	Health Canada	Natural Health Product	Permitted as a form of Vitamin folate up to MDD of 1000 mcg. Permitted as: L-5-Methyltetrahydrofolate L-5-Methyltetrahydrofolate, calcium salt L-5-Methyltetrahydrofolic acid, glucosamine salt[9].
Singapore	Health Sciences Authority	Quasi-Medicinal Product for supplemental purposes	0.9 mg Folic Acid (derived from the following source material(s): L-5- Methyltetrahydrofolate, L-5-Methyltetrahydrofolate calcium salt, L5-Methyltetrahydrofolate acid glucosamine salt)[10].
USA	FDA	Dietary Ingredient in Foods/Dietary Supplement	Generally recognised as safe – Upper tolerable limit 1 mg folate/day[11].

[6] Supplemented food standard user guide - Appendix 2: Vitamins and Minerals: Permitted Forms and Maximum Quantities. https://www.mpi.govt.nz/dmsdocument/13092-Supplemented-food-standard-user-guide
[7] Australia New Zealand Food Standards Code – Schedule https://www.legislation.gov.au/Details/F2021C00328
[8] Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2022 Schedule 1, Entries 3012 and 3013. https://www.legislation.gov.au/Series/F2022L00173
[9] Natural Health Products Ingredients Database http://webprod.hc-sc.gc.ca/nhpid-bdipsn/search-rechercheReq.do
[10] Singapore HAS Complementary Health Products (CHP) Classification Tool. https://www.hsa.gov.sg/chp-classification-tool
[11] National Institute of Health Folate Fact Sheet for Health Professionals. https://ods.od.nih.gov/factsheets/Folate-HealthProfessional/

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Europe	EFSA	Food, Food supplements, Foods for special medical purposes, Total diet replacement for weight control.	Calcium-L-methylfolate permitted up to tolerable Upper Limit of 1 mg folate/day[12][13].

In 2004, a review completed by European Food Safety authority (EFSA) Scientific concluded L-5-MTHF-Ca as a form of folate in foods does not pose a safety concern up to a maximum combined intake (from folic acid and L-5-MTHF-Ca) in adults of 1 mg per day[14]. It is now permitted for use in food supplements and foods as per EC Regulation 1170/2009folate/day[12] as well as in foods for special medical purposes and total diet replacement for weight control as per Regulation (EU) No 609/2013[13]. A 2020 safety review by the EFSA NDA Panel for the European commission, also concluded that its use is safe for infants and young children[15].

A 2008 FSANZ report concluded that levomefolate calcium does not pose any public health or safety concerns and should be approved for use in fortified foods as a permitted source of folate[16]. Following this report, L-5-MTHF-Ca was declared permitted in foods as a source of folate in Australia and New Zealand as per "Schedule 17-2 Permitted forms of Vitamins" of the Food Standards Code[17]. Schedule 4 of the Food Standards code also allows for multiple general level health claims for Folate reflecting its importance as a nutrient for general health and wellbeing. The permitted claims include "Contributes to maternal tissue growth during pregnancy", "Necessary for normal cell division" "Necessary for normal blood formation"[18].

The Dietary Supplement Regulations (1985) in New Zealand already greatly limit our potential, both as a company and collectively as a country, on the global stage as there are significant barriers to trade with our higher-regulated export partners. There is currently no exemption in New Zealand for companies to manufacture natural health products as "export only" should products made for export not meet New Zealand compositional requirements, thus any potential restrictions on the use of

[12] COMMISSION REGULATION (EC) No 1170/2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32009R1170&from=EN
[13] (EU) No 609/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32013R0609&from=en
[14] Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to Calcium L-Methylfolate. The EFSA Journal (2004) 135, 1-20. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2004.135
[15] Calcium L-methylfolate as a source of folate added for nutritional purposes to infant and follow-on formula, baby food and processed cereal-based food. https://doi.org/10.2903/j.efsa.2020.5947
[16] L-5-METHYLTETRAHYDROFOLATE, CALCIUM AS A PERMITTED VITAMIN FORM OF FOLATE. https://www.foodstandards.gov.au/code/applications/documents/A566%20L-Methylfolate%20FAR%20FINAL.pdf
[17] Australia New Zealand Food Standards Code – Schedule 17. https://www.legislation.gov.au/Details/F2021C00328
[18] Australia New Zealand Food Standards Code – Schedule 4 – Nutrition, health and related claim. https://www.legislation.gov.au/Details/F2017C00711

BePURE GROUP™

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levomefolate in dietary supplements in New Zealand, will further impede our industry's ability to export to, and compete in, the fast-growing natural health product global market.

We also strongly believe there is a critical need for the MCC and Medsafe to engage and consult with the likes of Natural Health Products New Zealand and other key stakeholders within the natural health industry when proposing any changes to the medicine classifications which may have a direct impact on dietary supplements and supplemented foods. Consultation with Natural Health Products New Zealand would greatly help to achieve the best possible outcome for our industry as well as the consumer.

We ask that the MCC carefully consider our submission and the implications outlined as well as wider global regulations to ensure the current permitted use of levomefolate in foods, supplemented foods and dietary supplements in New Zealand in dosages in accordance with the many respected international regulators (up to 1mg per day) is maintained. This is further supported by the 56th MCC Meeting agenda item for Folic Acid where the recommendation was also up to 1mg per day.

Yours sincerely,
BePure Group

Andrew Laloli
Chief Executive Officer

BLACKMORES
GROUP

Medicine Classification Committee

30 March 2022

Submission in response to the classification of levomefolate as a medicine, per the agenda of the 68th meeting of the Medicines Classification Committee

[redacted]

Blackmores Ltd
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Naturopathic Advisory Service
1800 803 760

22 March 2022

To the Members of the Medicines Classification Committee,

HealthPost Limited is submitting this letter to the Medicines Classification Committee in response to the potential classification of levomefolate as a medicine in New Zealand, as per the agenda of the 68th meeting of the Medicines Classification Committee (MCC).

HealthPost Limited is the largest online retailer of natural health products and functional foods in New Zealand. We stock over 200 reputable brands and have nearly 6000 products on our site, including some that contain levomefolate in various forms. We take great care to ensure that the products we sell are safe for customers when used as directed.

We see no reason for there to be a change to the use of levomefolate in foods, supplemented foods and dietary supplements in New Zealand. Consumer choice should not be restricted when there is such a high level of safety for this ingredient.

HealthPost agrees with all points made by Natural Health Products New Zealand in their open letter to the Medicines Classification Committee (16 March 2022) and respectfully requests that the Medicines Classification Committee makes no changes to the access of levomefolate in supplements, foods, and supplemented foods.

HealthPost encourages and welcomes further consultation on matters pertaining to dietary supplements.

Yours sincerely

Liz McNamara
Naturopath, Cosmetic Chemist
HealthPost Limited

Holistic Health & Wellness
16-18 Beckford Road, Christchurch
021 19 800 57

23 March 2022

To the Members of the Medicines Classification Committee,

RE: Potential Classification of Levomefolate as a Medicine

I wish to submit this letter to the Medicines Classification Committee in response to the potential classification of levomefolate as a medicine in New Zealand. I am *separately* registered as both a Naturopathic Practitioner (4-year bachelor's degree) and Clinical Nutritionist (2 year diploma) and seek to ensure the current permitted use of levomefolate in dietary supplements within New Zealand continues. Classification as a medicine would restrict consumer choice and significantly hinder my industry's ability to help those in need of this nutrient.

The issue of restricting levomefolate would subsequently rely on a General Practitioner's prescription of this nutrient. Nutritional supplementation falls more into a naturopath/nutritionist's scope of practice, understanding and training than that of a GP. In other words, GPs are not sufficiently trained in the actions, main indications, interactions and/or contraindications of levomefolate as a supplement.

As an example, levomefolate (folate/vitamin B9) has been identified as essential to human health and nutrition as a coenzyme critical for DNA synthesis and cell reproduction. Levomefolate is the predominant, naturally occurring form of folate in foods and the active metabolite our body converts folic acid into. It is also the predominant form in folate found in breast milk. Levomefolate is designated as a GRAS (generally regarded as safe) compound by the FDA.

If you have any questions regarding this submission, please do not hesitate to contact me.

Kind Regards,

Stephen Roigard - BNat Med, Dip.Nut, Dip.HerbMed
Registered Naturopathic Practitioner, Clinical Nutritionist & Medical Herbalist

HOUSE OF HEALTH
NUTRITION & HERBAL MEDICINE

Sharon Erdrich
NZRN, Reg Nutritionist (NSNZ)
888a New North Road
Mt Albert
Auckland 1025
P: 09 846 5566

23 March 2022

To the Members of the Medicines Classification Committee (MCC)

Re: Potential classification of levomefolate (5-MTHF) as a medicine in New Zealand, as per the agenda of the 68th meeting of the MCC [1]

Levomefolate – also known as 5-MTHF, levomefolic acid, L-methyltetrahydrofolic acid,and L-methylfolate - is the main naturally occurring form of folate in foods and the active metabolite resulting from conversion of folic acid and folinic acid. It is also the predominant form in folate found in breast milk[2] .

The European Food Safety Authority granted levomefolate "as a source of folate in foods for particular nutritional uses, food supplements and foods for the general population, with a tolerable upper level of 1 mg/adult person/day is not of concern from a safety point of view"[3] In the USA, levomefolate has GRAS (Generally Recognized as Safe) status, and is recognised as a safe form of folate which is widely used in nutritional products and dietary supplements globally.

Levomefolate is currently permitted as an ingredient in foods, supplemental foods, and dietary supplements in New Zealand, and there is no evidence of harm from this to date.
The current permitted use should continue. Inclusion of levomefolate as a medicine is not only inappropriate, but also unwarranted and would unnecessarily restrict consumer choice. Furthermore, it could have negative effects on New Zealand's supplement and supplemental food manufacturing and export industry.

I hereby submit that the MCC consider these implications and that the currently permitted use of levomefolate in foods, supplemented foods and dietary supplements in New Zealand is allowed to continue, in dosages in accordance with most international regulations.

Yours sincerely

Sharon Erdrich
MHSc (Hons), NZRGON, DipNat, DipMH. PhD Cand (USyd)

[1] https://www medsafe.govt.nz/profs/class/Agendas/Agen68/agen68 htm
[2] Page R, et al. Am J Clin Nutr. **2017** May;105(5):1101-1109. doi: 10.3945/ajcn.116.137968.
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02013R0609-20170711

PACIFIC HEALTH

Partnering Health Care Professionals in transforming the Vitality & Wellbeing of New Zealand

To whom it may concern

As you are aware a huge number of New Zealanders seek health support from natural health products.

We supply qualified health professionals with products containing the safe and effective form of vitamin B9, levomefolate, in several our products.

We believe that if you restrict this form to only be accessible through GP's many New Zealanders will miss out on what is the preferable and safe form of this vitamin.

We agree with and support all that is said in the following letter written by NHPNZ.

Please don't hesitate to contact us if you have any questions regarding this.

Yvonne McKay

Pacific Health

Total Natural Health Suppliers
PACIFIC HEALTH & FITNESS LTD
Ph + 64 9 815 0707 Fax + 64 9 846 9947
PO Box 56248 · Dominion Rd · Auckland · New Zealand · 1446

Jacinta Patel

From: Loula George <loula@mother-well.co.nz>
Sent: Thursday, 24 March 2022 12:24 pm
To: Committees
Subject: Submission for Reclassification of Levomefolate
Attachments: MCC_Public_Consultation_Cover_Sheet.docx

24th March 2022

An Open Letter to the Medicines Classification Committee:

I submit this letter to the Medicines Classification Committee in response to the potential classification of levomefolate as a medicine in New Zealand, as per the agenda of the 68th meeting of the Medicines Classification Committee (MCC).

As a naturopath who has specialized in fertility and pregnancy care for over 30 years, I understand the profound effect levomefolate has on having healthy pregnancies and babies. There are many general health claims for folate recognizing its importance in general health and fertility -" contributes to maternal tissue growth during pregnancy, necessary for normal cell division and normal blood formation". There are many genetic variants that do not enable individuals to utilize folic acid and metabolize it into its active form (methylfolate) that can then be utilised by the cells. It is therefore, vital that people are able to easily access the activated form of folic acid (levomefolate).

I seek to ensure the currently permitted use of levomefolate in foods, supplemented foods and dietary supplements in NZ continues. Classification as a medicine would restrict consumer choice and significantly hinder the industry's ability to export the product globally, unless provisions are made to ensure its current permitted use remains unaffected. Folate (vitamin B9) has been identified as essential to human health and nutrition as a coenzyme critical for DNA synthesis and cell reproduction. Levomefolate is the predominant naturally occurring form of folate in foods and the active metabolite our body converts folic acid it. It is also the predominant form in folate found in breast milk.

Levomefolate(and its salts) has substantial global recognition as a safe form of folate and is widely permitted in foods and health supplements in many markets worldwide. Levomefolate has GRAS status allowing its use as a dietary ingredient in infant formula, foods and dietary supplements in the USA.

A 2008 FSANZ report concluded that levomefolate calcium does not pose any public health or safety concerns and should be approved for use in fortified foods as a permitted source of folate. As a result of this report, Levomefolate in its calcium salt form is now permitted in foods as a source of folate in Australia and NZ.

I request that the MCC consider my submission and ensures the currently permitted use of levomefolate in foods, supplemented foods and dietary supplements in dosages in accordance with the majority of international regulators (up to 1 mg per day) is maintained.

Yours sincerely

Loula George BSc, Dip Nat, Med Herb, NZAMH member
Mother-Well Holistic Health
Director
820 Mt Eden Rd
Mt Eden
Auckland
09-6300067
www.mother-well.co.nz
www.nfwh.co.nz

I submit that Levomefolate, known as 5-MTHF not be reclassified as a medicine. It is a Dietary Supplement and as such, has been used by Naturopaths safely and effectively for many years.

Lynne Flood
Naturopath
Ph 09 6220436

MitoQ Ltd.

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mitoq.com

23/03/2022

An Open letter to the Medicines Classification Committee:

To the Members of the Medicines Classification Committee,

We, MitoQ Ltd, submit this letter to the Medicines Classification Committee in response to the potential classification of levomefolate as a medicine in New Zealand, as per the agenda of the 68th meeting of the Medicines Classification Committee (MCC)[1].

[redacted]

MitoQ Ltd.

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start small...

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[redacted]

[redacted]

Yours sincerely,

[redacted]

_____

[redacted]

Natalie Spooner

30a Blacks Road

Kerikeri 0230

30 March 2022

To the Medicines Classification Committee,

I am a health consumer and student member of the Naturopaths and Medical Herbalists of New Zealand.

I am writing to express my concern at the proposal to classify levomefolate as a medicine in New Zealand, as per the agenda of the 68th meeting of the Medicines Classification Committee.

As a consumer I have been a user of levomefolate and have found it to be safe and efficacious, and as a future practitioner I would like to continue to have access to this product, given its long history of safe use. I am dismayed at the prospect of consumers losing access to this nutritional supplement.

I request that the MCC maintains the currently permitted use of levomefolate in foods, supplemented foods and dietary supplements in New Zealand in dosages in accordance with the majority of international regulators (up to 1mg per day) is maintained.

Yours faithfully

Natalie Spooner

16 March 2022

An Open letter to the Medicines Classification Committee:

To the Members of the Medicines Classification Committee,

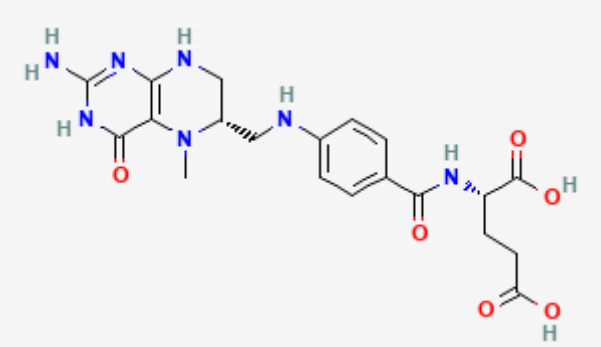
We, Natural Health Products New Zealand, on behalf of our members in the New Zealand Natural Health Products industry, submit this letter to the Medicines Classification Committee in response to the potential classification of levomefolate as a medicine in New Zealand, as per the agenda of the 68th meeting of the Medicines Classification Committee (MCC)[1].

Natural Health Products New Zealand is the peak industry body representing over 80% of the sector. Our members include manufacturers of ingredients and consumer brands of dietary supplements and functional foods.

Natural Health Products New Zealand seek to ensure the currently permitted use of levomefolate in foods, supplemented foods and dietary supplements in New Zealand continues. Classification as a medicine would restrict consumer choice and significantly hinder the industry's ability to export product globally, unless provisions are made to ensure its current permitted use remains unaffected. Folate (Vitamin B9) has been identified as essential to human health and nutrition as a coenzyme critical for DNA synthesis and cell reproduction[2]. Levomefolate is the predominant naturally occurring form of folate in foods and the active metabolite our body converts folic acid into[3]. It is also the predominant form in folate found in breast milk[4].

Levomefolate, Chemical formula $C_{20}H_{25}N_7O_6$, is listed in the literature and regulatory approvals worldwide as many different synonyms, including but not limited to levomefolate, levomefolic acid, L-methyltetrahydrofolic acid, L-methylfolate as well as the common salt form L-methyltetrahydrofolate calcium.

Figure 1: Structure of Levomefolic acid[5]



[1] Agenda for the 68th meeting of the Medicines Classification Committee. Accessed online at **https://www.medsafe.govt.nz/profs/class/Agendas/Agen68/agen68.htm**

[2] Nutrient Reference Values for Australia and New Zealand. Accessed online at **https://www.nrv.gov.au/nutrients/folate**

[3] JEFCA Chemical and Technical Assessment of Calcium L-5-methyltetrahydrofolate, 2005. Accessed online at **https://www.fao.org/3/at980e/at980e.pdf**

[4] Page et al 2019. Total folate and unmetabolized folic acid in the breast milk of a cross-section of Canadian women. Accessed online at **https://pubmed.ncbi.nlm.nih.gov/28298392/**

[5] Pubmed structure. Accessed online at **https://pubchem.ncbi.nlm.nih.gov/compound/Levomefolic-acid#section=3D-Conformer**

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Levomefolate (and its salts) has substantial global recognition as a safe form of folate and is widely permitted for use in foods and health supplements in many markets worldwide. Levomefolate has GRAS (Generally Recognized as Safe) status, allowing its use as a dietary ingredient in infant formula, foods and dietary supplements in the United States [6].

Table 1: Summary of Levomefolate Permitted Use Classification

Country	Regulating Body	Product Class	Permitted use
New Zealand	MPI/Medsafe	Dietary Supplement	Not restricted
New Zealand	MPI	Supplemented food	Permitted as a form of Folate as Methyltetrahydrofolate calcium up to a MDD of 500 mcg [7] (requires advisory statement for doses 200-500 mcg for consumption only by persons of or over the age of 14 years)
Australia and New Zealand	FSANZ/MPI	Food	Permitted as a form of folate as L-methyltetrahydrofolate, calcium [8]
Australia	Therapeutic Goods Administration	Listed Medicine	Permitted as either levomefolate calcium or levomefolate glucosamine as an active ingredient in up to an equivalent MDD of 500 mcg levomefolic acid[9]
Canada	Health Canada	Natural Health Product	Permitted as form of Vitamin folate up to MDD of 1000 mcg. Permitted as: L-5-Methyltetrahydrofolate L-5-Methyltetrahydrofolate, calcium salt L-5-Methyltetrahydrofolic acid, glucosamine salt [10]

[6] GRAS notice for the use of calcium l-methylfolate in infant formula. GRAS Notice (GRN) No. 915. Accessed online at https://www.fda.gov/media/140366/download

[7] Supplemented food standard user guide - Appendix 2: Vitamins and Minerals: Permitted Forms and Maximum Quantities. Accessed online at https://www.mpi.govt.nz/dmsdocument/13092-Supplemented-food-standard-user-guide

[8] Australia New Zealand Food Standards Code – Schedule 17 accessed online at https://www.legislation.gov.au/Details/F2021C00328

[9] Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2022 Schedule 1, Entries 3012 and 3013. Accessed online at https://www.legislation.gov.au/Series/F2022L00173

[10] Natural Health Products Ingredients Database Accessed online at http://webprod.hc-sc.gc.ca/nhpid-bdipsn/search-rechercheReq.do

Country	Regulating Body	Product Class	Permitted use
Singapore	Health Sciences Authority	Quasi-Medicinal Product for supplemental purposes	0.9 mg Folic Acid (derived from the following source material(s): L-5-Methyltetrahydrofolate, L-5-Methyltetrahydrofolate calcium salt, L-5-Methyltetrahydrofolate acid glucosamine salt) [11]
USA	FDA	Dietary Ingredient in Foods/Dietary Supplement	Generally recognised as safe – Upper tolerable limit 1 mg folate/day [12]
EU	EFSA	Food, Food supplements, Foods for special medical purposes, Total diet replacement for weight control.	Calcium-L-methylfolate permitted up to tolerable Upper Limit of 1 mg folate/day [14,15]

In 2004, a review conducted by the European Food Safety authority (EFSA) Scientific panel also assessed the use of L-methyltetrahydrofolate calcium as a source of folate in foods and concluded it does not pose a safety concern up to a maximum combined intake (from folic acid and L-5-MTHF-Ca) in adults of 1 mg per day[13]. It is now authorised for use in food supplements and foods as per EC Regulation 1170/2009[14] as well as in foods for special medical purposes and total diet replacement for weight control as per Regulation (EU) No 609/2013[15]. A 2020 safety review by the EFSA NDA Panel for the European commission, also concluded that its use is safe for infants and young children[16].

A 2008 FSANZ report concluded that levomefolate calcium does not pose any public health or safety concerns and should be approved for use in fortified foods as a permitted source of folate[17] . As a result of this report, Levomefolate in its calcium salt form (L-methyltetrahydrofolate calcium) is now currently permitted in foods as a source of folate in Australia and New Zealand as per "Schedule 17-2 Permitted forms of Vitamins" of the Food Standards Code[18]. Schedule 4 of the Food Standards code

[11] Singapore HAS Complementary Health Products (CHP) Classification Tool. Accessed online at https://www.hsa.gov.sg/chp-classification-tool

[12] National Institute of Health Folate Fact Sheet for Health Professionals. Accessed online at https://ods.od.nih.gov/factsheets/Folate-HealthProfessional/

[13] Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to Calcium L-Methylfolate. The EFSA Journal (2004) 135, 1-20. Accessed online at https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2004.135

[14] COMMISSION REGULATION (EC) No 1170/2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements. Accessed online at https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32009R1170&from=EN

[15] (EU) No 609/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. Accessed online at https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32013R0609&from=en

[16] Calcium L-methylfolate as a source of folate added for nutritional purposes to infant and follow-on formula, baby food and processed cereal-based food. Accessed online at https://doi.org/10.2903/j.efsa.2020.5947

[17] https://www.foodstandards.gov.au/code/applications/documents/A566%20L-Methylfolate%20FAR%20FINAL.pdf

[18] Australia New Zealand Food Standards Code – Schedule 17. Accessed online at https://www.legislation.gov.au/Details/F2021C00328

also permits a number of general level health claims for Folate recognising its importance in general health and wellbeing including "Contributes to maternal tissue growth during pregnancy", "Necessary for normal cell division" "Necessary for normal blood formation"[19].

The outdated Dietary Supplement Regulations (1985) in New Zealand are already posing significant barriers to trade with our higher-regulated export partners. There is currently no exemption in New Zealand for companies to manufacture natural health products as "export only" should products made for export not meet New Zealand compositional requirements, thus any potential restrictions on the use of levomefolate in foods or dietary supplements in New Zealand, will further impede our industry's ability to export to the fast-growing natural health product global market.

We would also like to inform the MCC and remind Medsafe that we represent stakeholders who have not been consulted on the proposed medicines classification of levomefolate and should have been. We have been informed that the composition of the MCC is mandated by the Medicines Act, however as our industry will be directly affected by any classification of levomefolate as a medicine, it is in the best interests of New Zealand consumers and industry that we are permitted to have a voice in such matters and we do not understand why this has not happened. We request that MCC and Medsafe do consult with us on such matters in the future and request engagement to establish a forum where this can and does occur.

We request that the MCC consider these implications and ensures the currently permitted use of levomefolate in foods, supplemented foods and dietary supplements in New Zealand in dosages in accordance with the majority of international regulators (up to 1mg per day) is maintained. This is further supported by the 56th MCC Meeting agenda item for Folic Acid where the recommendation was also up to 1mg per day.

Yours sincerely
Members of Natural Health Products New Zealand

Samantha Gray
Government Affairs Director

[19] Australia New Zealand Food Standards Code – Schedule 4 – Nutrition, health and related claim. Accessed online at **https://www.legislation.gov.au/Details/F2017C00711**

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30th March 2022

An Open letter to the Medicines Classification Committee:

To the Members of the Medicines Classification Committee

Re: The potential classification of levomefolate as a medicine in New Zealand, as per the agenda of the 68th meeting of the Medicines Classification Committee (MCC)[1] .

As a practising nutritionist, I feel obliged to submit this letter to the Medicines Classification Committee on behalf of my clients and potential clients. For various reasons, many of my clients are not meeting RDI or frequently EAR using diet alone. Clients on restricted calorie diets often require a temporary addition of a multivitamin/mineral. In other clients, it is sometimes necessary to recommend the use of dietary supplements while working to improve their dietary intake. The current food prices will undoubtedly see more clients presenting with inadequate dietary intakes. There are, of course, other reasons for low folate status, but these are less common in everyday practice.

Folate is an essential micronutrient, meaning that the body cannot make it and has to consume it either in food or as a supplement. It is essential in many metabolic pathways and as a coenzyme critical for DNA synthesis and cell reproduction[2]. Deficiencies in folate during pregnancy are associated with developmental neural tube defects[3] [Francesco]. Levomefolate is the predominant naturally occurring form of folate in foods. This naturally occurring form of folate exhibits several advantages over the synthetic form (folic acid). Firstly, it is well absorbed even with altered gastrointestinal pH (clients taking proton pump inhibitors, very common), and secondly, its bioavailability remains intact when there are metabolic defects

[Francesco]. Furthermore, using levomefolate instead of folic acid reduces the chance of masking a vitamin B12 deficiency[3,4] [Francesco] [Pietrzik].

Other concerns associated with folate deficiency include cardiovascular disease, cancer, and cognitive dysfunction. These are serious and real concerns. It is theoretically possible to obtain sufficient folate from dietary sources, but this is not happening. Adding folic acid to manufactured foods is not the answer and remains controversial.

Reclassifying levomefolate as medicine would restrict consumer choice and possibly harm. It would not be cost-effective, time-savvy, practical or feasible for each client requiring supplementation (at a nutritional level) to visit their GP and ask for levomefolate. Folic acid is not the same as levomefolate, for several reasons already discussed. In contrast, Levomefolate (and its salts) has undisputed recognition as a safe form of folate. Its use is permitted in foods and health supplements in many countries worldwide. Levomefolate has "Generally Recognized as Safe" (GRAS) status, allowing its use as a dietary ingredient in infant formula, foods and dietary supplements in the USA[5] .

This form of folate must remain freely available as a supplement and in nutritional products, including foods[6] [Niederberger]. It is essential to have a choice of folate[7] [Moazzen].

Thank you for considering my submission.

Niqi Butterworth

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1 Agenda for the 68th meeting of the Medicines Classification Committee. Accessed online at https://www.medsafe.govt nz/profs/class/Agendas/Agen68/agen68 htm

2 Nutrient Reference Values for Australia and New Zealand. Accessed online at https://www.nrv.gov.au/nutrients/folate

Niqi Butterworth PhD (Pharmacology), MSc (Hons), PG Dip (Nutritional Science), CKNS, BSc (Pharmacology and Physiology).

3 Francesco Scaglione & Giscardo Panzavolta (2014) Folate, folic acid and 5-methyltetrahydrofolate are not the same thing, Xenobiotica, 44:5, 480-488, DOI: 10.3109/00498254.2013.845705

4 Pietrzik K, Bailey L, Shane B. Folic acid and L-5-methyltetrahydrofolate: comparison of clinical pharmacokinetics and pharmacodynamics. Clin Pharmacokinet. 2010 Aug;49(8):535-48. doi: 10.2165/11532990-000000000-00000. PMID: 20608755.

5 GRAS notice for the use of calcium l-methylfolate in infant formula. GRAS Notice (GRN) No. 915. Accessed online at https://www fda.gov/media/140366/download

6 Niederberger KE, Dahms I, Broschard TH, Boehni R, Moser R. Safety evaluation of calcium L-methylfolate. Toxicol Rep. 2019 Sep 26;6:1018-1030. doi: 10.1016/j.toxrep.2019.09.012. PMID: 31673504; PMCID: PMC6816227.

7 Moazzen S, Dolatkhah R, Tabrizi JS, Shaarbafi J, Alizadeh BZ, de Bock GH, Dastgiri S. Folic acid intake and folate status and colorectal cancer risk: A systematic review and meta-analysis. Clin Nutr. 2018 Dec;37(6 Pt A):1926-1934. doi: 10.1016/j.clnu.2017.10.010. Epub 2017 Oct 28. PMID: 29132834.

Niqi Butterworth PhD (Pharmacology), MSc (Hons), PG Dip (Nutritional Science), CKNS, BSc (Pharmacology and Physiology).

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22 March 2022

Dear Members of the Medicines Classification Committee,

Naturopaths & Medical Herbalists Inc. (NMHNZ) would like to provide comments to the Medicines Classification Committee in response to the potential classification of levomefolate as a medicine in New Zealand, as per the agenda of the 68th meeting of the Medicines Classification Committee (MCC).

NMHNZ is the only association that represents Naturopaths in New Zealand, and are progressing application for regulation under the HPCA, and membership with Allied Health New Zealand. We are a member of the World Naturopathic Federation, an organisation who has a working relationship with the World Health Organisation, and who represents naturopaths globally, NMHNZ has over 500 members who are in a professional clinical setting with clients, or working within the dietary supplements industry.

NMHNZ members advise the public on a regular occurrence with evidence based methods for supporting their health and nutrition, sometimes through supplementation. NMHNZ members rely on a variety of reputable suppliers in New Zealand that are available throughout general sale in retailers, supermarkets, or through 'practitioner-only' brands. Levmefolate in its different forms in Dietary Supplements vary in doses of up to 1mg. NMHNZ members take great care to ensure that the products they recommend are safe for clients when used as directed.

We see no reason for there to be a change to the use of levomefolate in foods, supplemented foods and dietary supplements in New Zealand. Consumer choice should not be restricted when there is such a high level of safety for this ingredient.

NMHNZ agrees with all points made by Natural Health Products New Zealand in their open letter to the Medicines Classification Committee (16 March 2022) and respectfully requests that the Medicines Classification Committee makes no changes to the access of levomefolate in supplements, foods, and supplemented foods.

NMHNZ welcomes further discussion and consultation.

Yours sincerely

Liz McNamara
Chair - NMHNZ
Naturopath, Cosmetic Chemist

30 March 2021

To Members of the Medicines Classification Committee

Email: committees@health.govt.nz

The New Zealand Food & Grocery Council (NZFGC) makes this submission to the Medicines Classification Committee (MCC) in response to the potential classification of levomefolate as a medicine in New Zealand, as reflected in the agenda of the 68th meeting of the Medicines Classification Committee[1].

NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over $40 billion in the New Zealand domestic retail food, beverage and grocery products market, and over $34 billion in export revenue from exports to 195 countries – representing 65% of total good and services exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 45% of total manufacturing income.

NZFGC is concerned to ensure the currently permitted use of levomefolate in foods, supplemented foods and dietary supplements in New Zealand continues. Classification as a medicine would seriously and, in our view, unnecessarily restrict consumer choice and significantly hinder the industry's ability to export product globally.

Folate (Vitamin B9) has been identified as essential to human health and nutrition as a co-enzyme critical for DNA synthesis and cell reproduction[2]. Levomefolate is the predominant, naturally occurring form of folate in foods and the active metabolite our body converts into folic acid. It is also the predominant form of folate found in breast milk[3].

Levomefolate (chemical formula $C_{20}H_{25}N_7O_6$) is listed in the literature and regulatory approvals worldwide as many different synonyms, including but not limited to levomefolate, levomefolic acid, L-methyltetrahydrofolic acid, L-methylfolate as well as the common salt form L-methyltetrahydrofolate calcium.

Levomefolate (and its salts) has substantial global recognition as a safe form of folate and is widely permitted for use in foods and health supplements in many markets worldwide. The US FDA has granted levomefolate GRAS (Generally Recognized as Safe) status, allowing its use as a dietary ingredient in infant formula, foods and dietary supplements in the US[4]. It is also

[1] Agenda for the 68th meeting of the Medicines Classification Committee. Agenda for the 68th MCC Meeting (medsafe.govt.nz)
[2] Nutrient Reference Values for Australia and New Zealand. Accessed online at Nutrients | Nutrient Reference Values (nrv.gov.au)
[3] Page et al 2019. Total folate and unmetabolized folic acid in the breast milk of a cross-section of Canadian women. Accessed online at **https://pubmed.ncbi.nlm.nih.gov/28298392/**
[4] GRAS notice for the use of calcium l-methylfolate in infant formula. GRAS Notice (GRN) No. 915. GRAS Notice 915, Calcium L-methylfolate (fda.gov)

approved as a natural health product in Canada and Singapore and as a food and food supplement in the EU[5] [6].

In 2004, a review conducted a European Food Safety Authority (EFSA) Scientific panel also assessed the use of L-methyltetrahydrofolate calcium as a source of folate in foods and concluded it does not pose a safety concern up to a maximum combined intake (from folic acid and L-5-MTHF-Ca) in adults of 1 mg per day[7]. It is now authorised for use in food supplements and foods as per EC Regulation 1170/2009 as well as in foods for special medical purposes and total diet replacement for weight control as per Regulation (EU) No 609/2013. In 2020, a safety review by the EFSA NDA Panel for the European Commission, also concluded that it was safe to use for infants and young children[8].

In 2005/06, the WHO Expert Committee on Food Additives (JECFA) undertook a safety evaluation of calcium L-5-methyltetrahydrofolate as an alternative to folic acid in food fortification and supplementation. The assessment was very detailed and broad relevant to global use. JECFA "had no concern about the safety of the proposed use of calcium L-5-methyltetra-hydrofolate in dry crystalline or microencapsulated form as an alternative to folic acid in dietary supplements, foods for special dietary uses and other foods."[9]

In 2008, Food Standards Australia New Zealand (FSANZ) assessed levomefolate calcium and concluded that it did not pose any public health or safety concerns and should be approved for use in fortified foods as a permitted source of folate[10]. As a result of this report, levomefolate in its calcium salt form (L-methyltetrahydrofolate calcium) is now a currently permitted vitamin in foods as a source of folate in Australia and New Zealand and reflected in the *Australia New Zealand Food Standards Code* (Schedule 17—2 Permitted forms of Vitamins)[11]. Schedule 4 of the *Australia New Zealand Food Standards Code* also permits a number of general level health claims for folate recognising its importance in general health and wellbeing including "Contributes to maternal tissue growth during pregnancy", "Necessary for normal cell division" "Necessary for normal blood formation"[12].

The New Zealand Dietary Supplement Regulations (1985) are very outdated and continue to pose significant barriers to trade with our export partners. There is currently no exemption in New Zealand for companies to manufacture natural health products as 'export only' should products made for export not meet New Zealand compositional requirements. As a result, any future restrictions on the use of levomefolate in foods or dietary supplements in New Zealand, will further impede the New Zealand industry's ability to export.

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[5] COMMISSION REGULATION (EC) No 1170/2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements. EUR-Lex - 32009R1170 - EN - EUR-Lex (europa.eu)

[6] (EU) No 609/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. EUR-Lex - 32013R0609 - EN - EUR-Lex (europa.eu)

[7]. Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to Calcium L-Methylfolate. | EFSA (europa.eu)

[8] Calcium l-methylfolate as a source of folate added for nutritional purposes to infant and follow-on formula, baby food and processed cereal-based food (ulster.ac.uk)

[9] 9241660562_eng.pdf;jsessionid=7C59DAC94C6C1BBF203F6CCBD10CE1CB (who.int)

[10] Final Assessment Report Application A566 L-5-methyltrahydrofolate, calcium as a permitted vitmin form of folate Microsoft Word - A566 L-Methylfolate FAR FINAL.doc (foodstandards.gov.au)

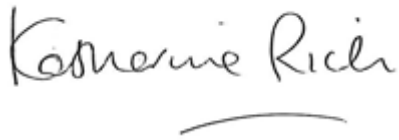
[11] Australia New Zealand Food Standards Code – Schedule 17. Federal Register of Legislation - Australian Government

[12] Australia New Zealand Food Standards Code – Schedule 4 – Nutrition, health and related claim. Federal Register of Legislation - Australian Government

It is also important for the MCC and Medsafe to note that food industry operators would not generally be alert to proposed medicines classifications nor of the prospective classification of levomefolate in particular.

We request that the MCC consider the implications of the proposed classification set out in the foregoing and ensures the currently permitted use of levomefolate in foods, supplemented foods and dietary supplements in New Zealand in dosages in accordance with the majority of international regulators (up to 1mg per day) is maintained. This is further supported by MCC56 Meeting agenda item for Folic Acid where the recommendation was also up to 1mg per day.

Yours sincerely



Katherine Rich
Chief Executive

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To the Members of the Medicines Classification Committee,

We are a nutraceutical company based in New Zealand. We submit this letter to the Medicines Classification Committee in response to the potential classification of levomefolate as a medicine in New Zealand, as per the agenda of the 68th meeting of the Medicines Classification Committee (MCC)[1] .

We are seeking to ensure the currently permitted use of levomefolate in foods, supplemented foods and dietary supplements in New Zealand continues. Folate (Vitamin B9) has been identified as essential to human health and nutrition as a coenzyme critical for many important biological processes[2] . Levomefolate is the predominant naturally occurring form of folate in foods and the active metabolite our body converts folic acid into[3].

Levomefolate has GRAS (Generally Recognized as Safe) status, allowing its use as a dietary ingredient in foods and dietary supplements in the United States[4] . Levomefolate (and its salts) has substantial global recognition as a safe form of folate and is widely permitted for use in foods and health supplements in many markets worldwide.

In 2004, a review conducted by the European Food Safety authority (EFSA) Scientific panel assessed the use of L-methyltetrahydrofolate calcium as a source of folate in foods and concluded it does not pose a safety concern up to a maximum combined intake (from folic acid and L-5-MTHF-Ca) in adults of 1 mg per day[5]. It is now permitted for use in food supplements and foods as per EC Regulation 1170/2009. A 2008 FSANZ report concluded that levomefolate calcium does not pose any public health or safety concerns and should be approved for use in fortified foods as a permitted source of folate[6]. Therefore, Levomefolate in its calcium salt form is now currently permitted in foods as a source of folate in Australia and New Zealand as per "Schedule 17-2 Permitted forms of Vitamins" of the Food Standards Code[7]. Schedule 4 of the Food Standards code also permits general level health claims for Folate including "Contributes to maternal tissue growth during pregnancy", "Necessary for normal cell division" "Necessary for normal blood formation"[8] .

We would like to be involved in the ongoing consultation regarding the proposed medicines classification of

[1] Agenda for the 68th meeting of the Medicines Classification Committee. Accessed online at https://www.medsafe.govt.nz/profs/class/Agendas/Agen68/agen68.htm
[2] Nutrient Reference Values for Australia and New Zealand. Accessed online at https://www.nrv.gov.au/nutrients/folate
[3] JEFCA Chemical and Technical Assessment of Calcium L-5-methyltetrahydrofolate, 2005. Accessed online at https://www.fao.org/3/at980e/at980e.pdf
[4] GRAS notice for the use of calcium l-methylfolate in infant formula. GRAS Notice (GRN) No. 915. Accessed online at https://www.fda.gov/media/140366/download
[5] Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to Calcium L-Methylfolate. The EFSA Journal (2004) 135, 1-20. Accessed online at https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2004.135
[6] https://www.foodstandards.gov.au/code/applications/documents/A566%20L-Methylfolate%20FAR%20FINAL.pdf
[7] Australia New Zealand Food Standards Code – Schedule 17. Accessed online at https://www.legislation.gov.au/Details/F2021C00328
[8] Australia New Zealand Food Standards Code – Schedule 4 – Nutrition, health and related claim. Accessed online at https://www.legislation.gov.au/Details/F2017C00711

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levomefolate. Our business and the industry will be directly affected by any classification of levomefolate as a medicine and feel that it is in the best interests of us and the industry that we are permitted to represent our voice in such matters.

We request that the MCC consider these implications and ensures the currently permitted use of levomefolate in foods, supplemented foods and dietary supplements in New Zealand in dosages in accordance with the majority of international regulators (up to 1mg per day) is maintained.

Yours sincerely