

1 April 2015

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Agenda for the 53rd meeting of the Medicines Classification Committee

Dear Sir/Madam

The New Zealand Medical Association (NZMA) wishes to provide comment to the Medicines Classification Committee (MCC) regarding the agenda for the 53rd meeting scheduled for 5 May 2015. Our feedback is limited to items 6.1 and 6.2 plus general comment on the expansion of clinical services by pharmacy.

1. The NZMA is the country's largest voluntary pan-professional medical organisation with approximately 5,000 members. Our members come from all disciplines within the medical profession and include general practitioners, doctors-in-training, specialists, and medical students. The NZMA aims to provide leadership of the medical profession, and promote professional unity and values, and the health of New Zealanders. Our submission has been informed by feedback from our Advisory Councils (including our General Practice Advisory Council) as well as the Board.

Item 6.1 Nitrofurantoin – proposed reclassification from prescription medicine to restricted medicine (Green Cross Health Limited)

2. We note that item 6.1 entails the proposed reclassification of nitrofurantoin from prescription medicine to restricted medicine for the treatment of uncomplicated cystitis in women aged 16–65 years by pharmacists that have undergone the training that was required to be able to supply trimethoprim. The NZMA is opposed to this proposal for the reasons outlined below.

3. We are concerned that the proposal may exacerbate antimicrobial resistance in the community through injudicious overuse by pharmacy (partly as a result of diagnostic imprecision). Antibiotic resistance is already a growing problem in New Zealand.^{1,2} We note that if adopted, the proposal would enable pharmacists to supply two of the most common antibiotics used as empiric treatment for suspected urinary tract infections (UTIs). This would leave only norfloxacin and antibiotics based on urine testing available for practitioners of diagnostic medicine to use, to make a difference, if trimethoprim and nitrofurantoin use (and resistance) increase. As part of the NZMA's overall concerns, our General Practice Council also considers that nitrofurantoin is generally not as well tolerated or safe as a three day course of trimethoprim.

4. Some women presenting with UTI-like symptoms in general practice actually have alternative diagnoses (eg, sexually transmitted infection). Some women may have cystitis but no infection. Accordingly, the diagnosis of UTI and the decision to initiate treatment with antibiotics (as well as the choice of antibiotic) are not always straightforward. We believe that these decisions are best determined by a doctor in a general practice setting. An additional important aspect of a consultation in general practice is that it affords an opportunity to address other aspects of a patient's health and well being, something that it is difficult to envisage taking place in a pharmacy setting.

5. The proposal will not enhance integrated patient-centric care and, rather, has the potential to fragment care. While the proposal alludes to 'the importance of informing the patient's doctor of a nitrofurantoin supply', our association has some reservations as to whether (and how) this will be implemented in practice.

Item 6.2 Oral contraceptives – proposed reclassification from prescription medicine to restricted medicine (Green Cross Health Limited)

6. We note that item 6.2 includes proposals for the reclassification from prescription medicine to restricted medicine for selected oral contraceptives to allow supply by a pharmacist who has successfully completed a training course for the supply of oral contraceptives and is complying with approved guidelines. The NZMA remains strongly opposed to these proposals for the reasons outlined below.

¹ Thomas MG, Smith AJ, Tilyard M. Rising antimicrobial resistance: a strong reason to reduce excessive antimicrobial consumption in New Zealand. *N Z Med J*. 2014 May 23;127(1394):72–84. Available from: https://www.nzma.org.nz/data/assets/pdf_file/0003/34662/content.pdf

² Williamson DA, Heffernan H. The changing landscape of antimicrobial resistance in New Zealand. *N Z Med J*. 2014 Sep 26;127(1403):41–54. Available from: <https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2014/vol-127-no-1403/6315>

7. We are not convinced that the requirement for a prescription constitutes a significant barrier to accessing oral contraceptives in New Zealand. Furthermore, we believe that any existing concerns about access to the oral contraceptive pill can be satisfactorily and safely addressed via a delegated collaborative model of prescribing, now available under the Medicines Amendment Act 2013.

8. One of the most important aspects of prescribing the oral contraceptive pill is the advice and counselling about its use and about sexual health in general, particularly for younger females. It is difficult to envisage how this can be done well in a pharmacy setting. It can sometimes be difficult even for experienced clinicians to broach sexual health when dealing with a young patient. In some cases, the patient will present asking for advice on contraception or sexually transmitted infections (STIs), but in the majority of cases, opportunistic intervention will be necessary. Yet on average, in our experience, teenagers are seen at general practice less than once a year. As such, the potential for opportunistic medical interactions, as well as the act of forming a therapeutic relationship with a medical practitioner at a time of personal change, is already low. It is still our view that the proposed reclassification would undermine the opportunity for opportunistic intervention and screening for at risk behaviours in an important patient group.

9. The use of oral contraceptives is also not without risks that must be carefully considered before they are used and during their use. For example, combined oral contraceptives increase the risk of stroke in women who suffer from migraines with aura. They should not be started by women of any age who suffer from migraine with aura.³ Combined oral contraceptives also increase the risks of venous thromboembolism (VTE) and are contraindicated for women with a current or past history of VTE and best avoided for those at high risk.⁴ Various drugs interact with oral contraceptives to potentially decrease their efficacy, and it is important that patients are fully aware of these. Before prescribing oral contraceptives, therefore, it is necessary to obtain a thorough medical history, including cardiovascular risk factors, concurrent medications, allergies, and health problems (past and current). In many instances, a physical examination may be indicated (eg, when there is a suspected STI). We are not convinced that the tick box checklists that pharmacists are supposed to use before supplying oral contraceptives as part of this proposal will necessarily capture the requisite information to ensure the safe use of these medicines.

10. Finally, we believe that the proposed reclassification of selected oral contraceptives from prescription to restricted medicines is likely to further fragment patient care with potentially serious consequences for patients, including unintended pregnancy or life-threatening adverse events. We note that the pharmacist checklist forms as currently structured require the patient to opt in to inform their doctor of supply, a requirement that is not conducive to genuine integration with primary care.

General comment

11. The NZMA has reservations that proposals seeking an expansion in clinical services by non-medical professions, including the two proposals discussed above, could undermine integration and compromise patient safety. We are also concerned about the underlying

³ Roberts H. Combined oral contraceptive: issues for current users. BPJ April 2012(12):21–9. Available from www.bpac.org.nz/BPJ/2008/April/docs/bpj12_contraceptive_pages_21-29.pdf

⁴ Ibid

drivers behind such proposals. We note that the submission in support of the proposal for the reclassification of nitrofurantoin states that “Pharmacy as an industry has become proactive, driving new initiatives.” Our association has developed a position statement on the principles of workforce redesign,⁵ which we suggest Medsafe refer to during consideration of the above (and subsequent) proposals. We attach a copy of this for the Medicines Classification Committee’s and Medsafe’s consideration. Specifically, we draw Medsafe’s attention to principle #8 which is to ‘Maintain or improve integration between involved medical services as well as integration of the patient within the healthcare system’.

We hope that our feedback to the Committee on these items is helpful and that our comments will be given careful consideration during its deliberations at the upcoming 53rd meeting. We look forward to learning the outcomes from this meeting.

Yours sincerely



Dr Mark Peterson
NZMA Chair

Attachments

1. NZMA. Principles of Health Workforce Redesign. February 2013.

⁵ NZMA. Principles of Health Workforce Redesign. February 2013. Available from http://www.nzma.org.nz/_data/assets/pdf_file/0018/1458/Principles-of-Health-Workforce-Redesign-2013.pdf