

## Appendix 1

23 October 2015

Dear Colleagues,

### **Feedback Sought**

#### **Amendment to the Medicines (Standing Order) Regulations 2002**

### **Purpose**

The Ministry is seeking feedback on:

1. The timing of an amendment to the Medicines (Standing Order) Regulations 2002 to authorise nurse practitioners to issue standing orders
2. The potential benefits and risks of amending the Medicines (Standing Order) Regulations 2002 now rather than through the review of the therapeutics regulatory regime.

Please take the time to consider the issues and provide feedback.

- See Appendix 1 for a question and response form to submit your views.
- See Appendix 2 for a description of the review of the regulatory regime for therapeutic products.
- See Appendix 3 for a table showing potential risks and benefits of amending the Regulations.

### **Background**

The Medicines Amendment Act 2013, enacted in July 2014, provided nurse practitioners and optometrists with the same prescribing authority as medical practitioners, dentists, and midwives. The Act was aligned with policy to improve access to healthcare by removing barriers to health practitioners practicing to the full extent of their scope of practice.

The Minister of Health, Dr Jonathan Coleman, has asked the Ministry to progress work towards an amendment of the Medicines (Standing Order) Regulations 2002 (the Regulations) to allow nurse practitioners to issue standing orders, outside of the current review of the regulatory regime for therapeutic products (see below),

The role of standing orders, including whether they are fit for purpose, will be part of the broader policy work related to the review of therapeutic products regulation. The Ministry will be consulting more widely on the use of standing orders, who issues them and alternative means to supply or administer medicines without a prescription as part of the work. Changes to the status quo for standing orders through this process will take at least two years. See Appendix 2 for more information on the review of the therapeutic products regulatory regime.

An amendment to the Regulations now, will mean nurse practitioners can issue standing orders in the period before the new regulatory regime for medicines is implemented.

### **Standing orders**

The Medicines Act 1981 defines a standing order as a written instruction issued by a practitioner, registered midwife, nurse practitioner or optometrist in accordance with any applicable regulations.

Currently the applicable regulations, the Medicines (Standing Order) Regulations 2002, only allows practitioners (defined as medical practitioners and dentists), to issue standing orders. Extending this

authority to nurse practitioners requires an amendment to the Regulations, through the addition of nurse practitioner to the definition of practitioners authorised to issue standing orders.

The standing order permits a specified class of persons engaged in delivering health services to supply and/or administer specified medicines or controlled drugs to a specified class of persons in specified circumstances without a prescription. A standing order does not enable a person to prescribe medicines, only to supply and/or administer prescription medicines and some controlled drugs.

## **Nurse Practitioners**

Nurse practitioners are regulated under the Health Practitioners Competence Assurance Act 2003. There are currently 151 nurse practitioners registered with the Nursing Council of New Zealand.

The Nursing Council of New Zealand sets the scope of practice, educational requirements and competencies for nurse practitioners.

### *Nurse practitioner scope of practice*

Nurse practitioners are expert nurses who work within a specific area of practice incorporating advanced knowledge and skills. They practise both independently and in collaboration with other health care professionals to promote health, prevent disease and to diagnose, assess and manage people's health needs. They provide a wide range of assessment and treatment interventions, including differential diagnoses, ordering, conducting and interpreting diagnostic and laboratory tests, and administering therapies for the management of potential or actual health needs. They work in partnership with individuals, families, whanau and communities across a range of settings. Nurse practitioners prescribe medicines within their specific area of practice. Nurse practitioners also demonstrate leadership as consultants, educators, managers and researchers, and actively participate in professional activities, and in local and national policy development. [Nurse Practitioner Scope and Competencies](#)

Nurse practitioners are authorised prescribers under [the Medicines Amendment Act 2013](#)

## **Consultation**

We seek your feedback on amendment to the Medicines (Standing Order) Regulations. Please use the response form in Appendix 1 to record your feedback.

Please send your feedback to:

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Ministry of Health  
PO Box 5013  
Wellington 6145

OR

Email: [Alison\\_hussey@moh.govt.nz](mailto:Alison_hussey@moh.govt.nz)

Responses must be received by 5pm, **24 November 2015**.

## Appendix 1

### Consultation on amendment of the Medicines (Standing Order) Regulations to enable nurse practitioners to issue standing orders

Please respond to the questions below.

1. What do you see as the potential benefits of an amendment to the Regulations to authorise nurse practitioners to issue standing orders **now** rather than as part of the review of the regulatory regime for therapeutic products?

2. What do you see as the potential risks of an amendment to the Regulations to authorise nurse practitioners to issue standing orders **now** rather than as part of the review of the regulatory regime for therapeutic products?

3. Please provide examples to show the implications of an amendment to the Regulations to authorise nurse practitioners to issue standing orders **now** rather than as part of the review of the regulatory regime for therapeutic products?

The following documents can be accessed online

- Medicines Act 1981 [www.legislation.govt.nz](http://www.legislation.govt.nz).
- Medicines Regulations 1981 [www.legislation.govt.nz](http://www.legislation.govt.nz).
- Medicines (Standing Orders) Regulation 2002 [www.legislation.govt.nz](http://www.legislation.govt.nz).
- Competencies for the Nurse Practitioner Scope of Practice <http://www.nursingcouncil.org.nz/Nurses/Scopes-of-practice/Nurse-practitioner>

## Appendix 2

### **The review of the therapeutic products regulatory regime**

The Ministry is commencing a review of the prescribing framework as part of the work agreed by Ministers to develop a new regulatory regime for therapeutic products. The new regime will replace the Medicines Act 1981 and its Regulations. This follows the cessation of the Australia New Zealand Therapeutic Products Agency (ANZTPA) project. As well as replacing and modernising the regulatory arrangements for medicines, the new regime will provide regulation of all therapeutic products.

#### *Consultation and timeframes*

There will be a range of opportunities and methods for the public and sector to inform the therapeutic products review process. A paper that outlines some options for changes to the prescribing, supply and administration of medicines in NZ will be released to the sector for early feedback during November 2015. Additional initial consultation on prescribing will occur through December and January.

A draft of a Therapeutics Products Bill will be released for public consultation in mid-2016. This process enables the Bill to be improved based on public and stakeholder feedback before it is introduced to Parliament, expected to be at the end of 2016. It will continue to pass through the parliamentary process, becoming the Therapeutic Products Act in 2017. Development of the regulatory detail to support a new Therapeutics Act will be ongoing throughout 2016 and we will continue to engage with stakeholders during this time.

### Appendix 3

Analysis of potential risks and benefits of amending the Medicines (Standing Order) Regulations 2002 to authorise nurse practitioners to issue standing orders.

Potential Risk	Response
Nurse practitioners (NPs) do not have sufficient diagnostic, prescribing or pharmacology knowledge to safely issue standing orders.	<ul style="list-style-type: none"> <li>NPs work under the Health Practitioners Competence Assurance Act 2003. They are bound by their scope of practice and are professionally responsible to undertake only those activities within that scope of practice, and their knowledge and skills.</li> <li>See NP scope of practice. NPs have a minimum of 5 years nursing experience and a Masters degree.</li> </ul>
NPs issue standing orders for administration by registered nurses (RNs) who do not have appropriate competency.	<ul style="list-style-type: none"> <li>This risk currently exists for doctors and dentists issuing standing orders.</li> <li>There are risks in the status quo where RNs may be working under standing orders with inadequate supervision from the medical practitioner who is the issuer.</li> <li>NPs work closely with RNs and understand their scope of practice.</li> <li>NPs take their prescribing responsibilities as seriously as other authorised prescribers and understand the accountability for their prescribing decisions.</li> <li>NPs are known (anecdotally and through research evidence) to be safe and cautious prescribers.</li> </ul>
Standing orders are widely and potentially in some cases inappropriately used; authorising nurse practitioners as issuers could increase the unsafe use of standing orders.	<ul style="list-style-type: none"> <li>NPs are equally likely to comply with the conditions in the Regulations as other prescribers.</li> <li>Authorising NPs to issue standing orders is unlikely to exacerbate the current situation.</li> <li>As issuers of standing orders NPs will be obliged to comply with the regulatory requirements for monitoring and audit of the standing orders they issue.</li> </ul>
There is not sufficient policy to support amendment of the Regulations to authorise NP to issue standing orders.	<ul style="list-style-type: none"> <li>The policy platform for the Medicines Amendment Act 2014 and the ongoing Government commitment to making the best use of the health workforce alongside the HPCAA provide a sufficient foundation to progress the amendment.</li> </ul>
Potential benefits	Response
<p>NPs will be enabled to work to the full extent of their scope of practice to support models of care that improve access for priority populations</p> <p>Access to medicines will be improved in NP led practice settings.</p> <p>Improved teamwork and efficiency between doctors, NPs and RNs.</p>	<ul style="list-style-type: none"> <li>See NP scope of practice. NPs can provide full care for people, in some cases they own a practice and employ a medical practitioner part time only.</li> <li>In settings such as youth health, sexual health and family planning, nurse and nurse practitioner teams provide full care with minimal medical oversight.</li> <li>In other settings such as aged care and rural there are shortages of medical practitioners and the NP is the main prescriber providing care for people and supervising the supply and administration of medicines by RNs.</li> </ul>
<p>Best use of the knowledge and skills of the health workforce.</p> <p>Reduce the burden on medical practitioners and free up all practitioners to deliver the right care at the right time.</p>	<ul style="list-style-type: none"> <li>Duplication will be reduced – there are known instances where the NP advises the medical practitioner of the RN competence to supply or administer medicines under a standing order the doctor has issued.</li> </ul>