NZMA
New Zealand Medical Association

20 January 2016

Dr Angela Mansell
Principal Policy Analyst
Sector & Services Policy
Ministry of Health
PO Box 5013
Wellington 6145

By email: Angela_Mansell@moh.govt.nz

Draft options for the regulation of prescribing and dispensing in New Zealand

Dear Angela

Thank you for inviting the New Zealand Medical Association (NZMA) to provide feedback on the above consultation document.

1. The NZMA is New Zealand's largest medical organisation, with more than 5,500 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of all New Zealanders.

2. We welcome the commencement of work on a new comprehensive regime to replace the Medicines Act 1981 and its Regulations. We note that the current consultation is seeking feedback on some early draft options concerning the regulation of prescribing and dispensing of medicines/therapeutic products, and that this feedback will help inform components of the exposure draft of the new Therapeutic Products Bill. We understand that subsequent consultations will explore other aspects of the new Bill (eg, Direct to Consumer Advertising, Pharmacy operations). Accordingly, our feedback is focussed on the current consultation document.

3. The NZMA agrees that a new regulatory regime for therapeutic products needs to both reflect the needs of modern clinical practice as well as accommodate future pressures and shifting contexts. We also agree that any proposed changes need to bring about benefits to patient care and result in improved health outcomes. However, as the consultation document itself acknowledges, medicines are not ordinary items of commerce due to the potential for serious harm. Legislation and regulations are necessary to ensure that effective products are used safely. While patient convenience is an important factor to consider, it should not supersede safety considerations.

4. We have previously expressed our concerns with the proliferation of independent designated prescribing rights for various non-medical health practitioner groups under the existing legislation.[1] Prescribing cannot be considered in isolation from diagnosis and/or monitoring of disease progression. These require knowledge and skills built on years of study of anatomy, physiology, pathology, pharmacology (including clinical pharmacology), accompanied by training in clinical methods. For these reasons, and to encourage collaborative team-based healthcare, the NZMA has supported delegated prescribing rights for appropriate non-medical health practitioner groups. We note that the Ministry is now considering whether to discard the delegated prescriber category in the new regulatory regime. We contend that it is essential to retain this category of prescribing.

5. A key aspect of the new Bill will be to ensure that there is clear accountability around prescribing. We submit that the new Bill needs to state that the person who prescribes a drug has the following obligations: a) they take legal responsibility for being confident that the correct diagnosis has been reached; b) they take legal responsibility for any drug interactions; c) they take legal responsibility to ensure that the patient has appropriate follow up to monitor outcomes.

6. We also have concerns with the existing process for establishing a new group of prescribers, which is essentially managed by the professional group seeking professional rights. We believe that the development of a new regulatory regime for prescribing and dispensing in New Zealand represents an opportunity to rectify these concerns, while at the same time establishing a regulatory regime that is fit for purpose and affords patient safety the highest priority.

7. We note that the consultation is proposing to shift the authorisation of who is entitled to prescribe to Responsible Authorities (RAs) regulating health practitioners under the HPCA Act 2003. We also note that the document proposes that a registered health practitioner must only prescribe therapeutic products within his/her scope of practice and competence. RAs have the statutory accountability for establishing scopes of practice, prescribing the qualifications necessary for registration within that scope, and for the ongoing competence and activities of their registered health practitioners. We have serious reservations about this proposal as it stands, particularly in relation to public safety.

8. A major flaw with the above proposal is that existing scopes of practice for most RAs are insufficiently specific to cover safe and appropriate prescribing restricted to a practitioner's competency. Furthermore, given that scopes of practice are self-defined by RAs, an RA wanting to assume prescribing rights for its profession could simply redefine its own scope of practice, undertake a consultation process and then report back to HWNZ and

[1] NZMA Position Statement. Non-medical prescribing. July 2013. Available from http://www.nzma.org.nz/__data/assets/pdf_file/0005/16979/Non-medical-prescribing-2013.pdf

the Ministry of Health. HWNZ has little competency to assess clinical considerations, so what a profession's RA says tends to be what we end up with. This is of particular concern given that RAs are not set up, or funded appropriately, to be able to appropriately oversee safe prescribing of all allied health practitioner groups. It is likely that only the very worst cases of inappropriate prescribing are likely to be reported to them.

9. In addition to concerns around public safety that arise from inappropriate prescribing, other consequences of the proposal as stated are likely to include confusion among patients when it comes to who they can get their prescriptions from, and fragmentation of patient care in the absence of a national shared-care electronic health record. We draw attention to the existing difficulties in reconciling prescriptions between primary and secondary/tertiary care, as well as the large numbers of sentinel events related to discrepancies between what is prescribed in the community versus the hospital, and compared with what the patient is actually taking. These difficulties are likely to increase with the proposals.

10. We contend that the proposal may lead to the exacerbation of antimicrobial resistance. Inappropriate prescribing is already a significant contributing factor in the development of antimicrobial resistance. We would like to see the Ministry give specific consideration to antimicrobial stewardship when formulating its proposals.

11. While there is provision in the HPCA Act 2003 for RAs to resolve disputes with respect to scopes of practice, these provisions are unlikely to be sufficient to address negative consequences unless they relate directly to public safety.

12. If prescribing rights are to be tied to scopes of practice, then we believe it is necessary to acknowledge that most of the current scopes for RAs are inadequate for that purpose (or for that matter many other purposes).[2] In addition, if the current proposal is to be progressed, we consider it essential to establish a system where scopes of practice are not independently determined by the profession's RA, but must instead be agreed by all of the professional groups where there is an overlap of scope. We suggest that instead of abrogating responsibility for prescribing to RAs, the Ministry has an important role to play in overseeing this system.

13. If the proposal is to be further developed, it will be necessary to provide RAs with the appropriate tools to collect information on prescribing. The HPCA Act 2003 was not envisaged to work directly alongside a new Medicines Act. We are aware that RAs currently face significant challenges in obtaining information on prescribing from the Medicines Control team within the Ministry of Health. We suggest that any future Bill address the mechanisms that would enable the sharing of prescribing patterns of different health practitioner groups and provide the necessary feedback loop to measure prescriber safety.

14. We have reservations over the notion of a single competency framework for prescribing. As we have alluded, prescribing is not a discrete activity but rather a tool in the practice of medicine and the overall care of the patient. We envisage major feasibility barriers in developing and implementing a single competency framework for prescribing that considers the wider context of patient care, including diagnosis and monitoring.

---

[2] NZMA Supplementary Submission on Health Practitioners (Replacement of Statutory References to Medical Practitioners) Bill. 21 October 2015. Available from http://www.nzma.org.nz/__data/assets/pdf_file/0005/45338/supsubHealth-Practitioners-Replacement-of-Statutory-References-to-Medical-Practitioners-Bill.pdf

15. It appears that the consultation document makes a number of assumptions relating to patient access to medicines. We would like to request any evidence the Ministry has relating to whether limitation of prescribing to authorised prescribers constitutes a barrier to patient access to medicines. It is our understanding that cost is likely to be a bigger barrier than availability of prescriber. As such, we would be interested in any evidence the Ministry may have on the fees charged by new prescriber groups over the long term. We are also interested in evidence the Ministry may have on the impact of extending prescribing rights to new prescribing groups on integration and patient access, as well as to the pharmaceutical budget.

16. Finally, if there are to be more prescribers, it is vital to have robust IT infrastructure to ensure that there is 'connected up health care'. The development of a national, shared-care electronic health record should be a priority, and its use by all prescribers will be essential to mitigate against fragmentation of care and the associated risks.

We hope that our feedback has been helpful and we look forward to continuing our engagement with the Ministry on this very important initiative.

Yours sincerely

Stephen Child
NZMA Chair