



PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

27 January 2016

Dr Angela Mansell

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Ministry of Health

via email: Angela_Mansell@moh.govt.nz

Dear Angela,

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

Thank you for the opportunity to submit comments to your paper presenting some initial considerations related to the regulation of prescribing and dispensing, as part of the therapeutic products legislation review.

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 3,000 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.

As the profession responsible primarily charged with the handling and dispensing of prescriptions and for acting upon the instructions of a prescription, pharmacists have a unique understanding of the day to day application of the regulatory requirements of prescribing and dispensing. Due to this, pharmacists also have strong opinions on prescribing standards, consistency and the problems seen with the activity of prescribing. Pharmacists have commented on the standard of prescribing of many prescriber types, with extensive complacency in ignoring the regulatory requirements of a prescription, and in treatment choices, dosing – clinical competencies.

General Comment

PSNZ supports a “lean, principles-based Act containing only the central regulatory requirements, with details contained in regulations and subordinate instruments. However, the detail that will sit outside the Act and how this is managed affects our views on the Bill.

We also support the notion that medicines are not ordinary items of commerce and must be regulated with a different perspective to other commercial products.

Specific Role of Pharmacists and Exemptions Provided in Current Legislation

PSNZ notes the education, training, practice and competence of pharmacists focusses specifically on the dispensing, supply and optimal use of medicines. The licensing of pharmacies sets defined standards and requirements for how dispensing and medicines supply services should be delivered. By virtue of pharmacists' education, practice and competence, we believe pharmacists should continue to be exempted from many restrictions placed on medicines and their supply and storage. For example, we would see the exemptions granted in Section 26 of the Medicines Act 1981 and Regulation 29 of the Regulations would be preserved in an appropriate way.

Prescribing

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Prescribing within the current Medicines Act and Regulations predominantly focuses on permitting access to, administration of, and possession of medicines classified as a prescription medicine. However a prescription may be written for any medicine as the intent for a patient to be treated with that medicine, in accordance with the clinical and dosing instructions stated by the prescriber. Prescribing also serves to provide access to pharmaceutical funding for eligible patients. That is, a medicine that is not a prescription may be “prescribed” and this dispensed and funded. So the act of prescribing provides access and potentially funding to a medicine, as well as indicating treatment intent.

PSNZ supports the proposal to remove the list of medicines that may be prescribed from legislation and move to scope of practice.

PSNZ supports the prescribing practice to fall within a scope of practice, we do not support the proposal to shift the authorisation of who is entitled to prescribe to Responsible Authorities. We understand the reasoning behind this proposal – certainly the current non-medical RAs defining and regulating prescribing competencies largely do this well. However our concern is for those professions under the HPCA Act that do not have the same degree of education or training in pharmacotherapy, deciding to develop a prescribing scope. RAs are inherently governed by members of their profession, and while we would expect extensive consultation in developing a prescribing scope of practice, the lack of professional independence could be seen as biased perspective. What, for instance, would prevent an RA largely ignoring submissions that opposed a prescribing scope of practice – or certain aspects of the proposed scope, such as access to specific medicines or classes of medicine? Also, how do we ensure there is consistency between the RAs in defining scopes, practice and competencies?

PSNZ supports the development of a prescribing competence framework that would apply to ALL prescribers regardless of scope or profession. We would also like to see a defined mechanism for RAs seeking approval of new scopes of practice including prescribing.

The paper describes on page 11, an “Example scope of practice outline to authorize prescribing”. The statements describe “reference to the qualifications required for registration in the scope of practice”, whereas PSNZ believes both a defined qualifications AND EXPERIENCE required for registration in a prescribing scope of practice. This might certainly be incorporated in a qualification component, however the Pharmacist Prescriber scope of practice requires an element of practice experience before a qualification may be commenced.

Delegated Prescribers

PSNZ has supported the role of a delegated prescriber, as comparable, but safer alternative to the authority granted under a standing order. Under a delegated prescribing order, a prescription is generated – which can then be dispensed by a pharmacist. This provides a second health professional check of the appropriateness and safety of a medicine prior to the patient receiving it. We understand that some professions see their futures lying in full authorised prescribing rights for all practitioners, however PSNZ believes the delegated prescriber role would be useful where either professions, or practitioner type do not have the qualifications or experience to supply medicines.

Standing Orders

The Standing Order is used as a de facto prescribing function of sorts. Any prescriber permitted to authorize a standing order must do so from a common standpoint – of consistent training and prescribing competence. This would help to ensure that the assessment of the patient and decision to supply or administer a medicine would be performed appropriately and consistently. Perhaps further consideration needs to be given to refining the requirements/competencies of the person acting under the standing order – while the

authorized prescriber issuing the standing order is responsible for ensuring appropriate training and competence of those acting under a standing order, we are aware of examples where even medical centre receptionists have supplied medicines – “supposedly” under standing orders.

Classification of Medicines

The paper refers to the classification of medicines in the context of how access to medicines is provided. We understand from the paper that the classification of medicines will be tested in the exposure draft.

We understand from the paper and from earlier discussions, that the wording of medicines classifications are being reviewed. Should the wording change from a venue/professional wording (eg. Pharmacy only or pharmacist only), then the Ministry must consider provisions in the current Medicines Act 1981 that currently relate to pharmacy/pharmacist practice – and how these might apply to non-pharmacy/pharmacist supply. For example advertising, storage and security requirements (S42B, 47), Reg29, records of sale (Reg54A, 55, 56),

Dispensing

As with prescribing, there are a number of issues related to dispensing legislation that actually sit in the regulations as opposed to the primary Act. We believe many of these will be addressed in the subsequent development of regulations and look forward to offering advice at an appropriate time.

A key aspect of dispensing a medicine pursuant to a prescription is ensuring the authenticity of the prescription and prescriber.

While current RAs do publish their practitioner registers online, pharmacists need to have this information kept very current –so that the credentials of a prescriber can be reviewed and the prescription authorized to dispense. Some RAs are not timely in their maintenance of scopes and areas of practice in their registers. Verifying a prescriber's scope of practice or area of practice can be extremely problematic for dispensing pharmacists.

Similarly, poor prescribing, in the sense of writing a prescription and meeting the legislative requirements of that prescription, is extremely common. Unfortunately it falls by default to the dispensing pharmacist to pick up these errors and omissions and ensure they are corrected. We would like consideration given to how legislative documents describe the responsibility for prescribers to meet the legal requirements of 'the prescription'. This would support timely and effective dispensing.

Thank you for consideration of this submission. I would be happy to discuss any aspect of this submission further, if required. Thank you also for the extra time permitted to submit these comments

Yours sincerely,



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