PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

Draft Therapeutic Products Bill – Submission Overview

The release of the draft Therapeutic Products Bill represents a significant milestone. The Society appreciates the opportunity contribute to the achievement of a regulatory regime for therapeutic products that achieves its goals to ensure therapeutic products in New Zealand meet acceptable safety, quality and efficacy requirements across their lifecycle now and into the future.

Controlled activities and authorisations

The Society supports the approach of clearly defining controlled activities with provision for authorisation of different groups to undertake certain controlled activities as this provides enhanced clarity for the sector. However, we note that this improved clarity has increased the visibility of dispensing as a controlled activity that could be carried out by all health practitioner prescribers creating potential for the practice to become more widespread. In certain situations, this authorisation (prescriber dispensing) is important to facilitate access to medicines (e.g. after hours, rural areas). However, it should be the exception rather than the rule. Pharmacists are the most comprehensively trained on subject matters such as pharmacology, pharmaceutics, therapeutics and the optimal use of medicines and utilise their knowledge around the provision of safe, effective and appropriate medicines for their patient population. Pharmacists are able to utilise this skill set to work in partnership with prescribers and other members of the healthcare team. The separation of prescribing and dispensing provides an important mechanism for additional clinical and safety checks. Avoidance of self-checking when dispensing was advocated in a recent Health and Disability Commission report. Any future prescriber dispensing will need to be appropriately regulated.

Recognising the benefits of timely access to medicines, we are supportive of the proposed authorisations for health practitioners in relation to category 3 (pharmacy) medicines. However, requirements for this supply must provide the same safeguards as those available in a pharmacy environment such the overall supervision by, and ready access to, a registered health professional. Proposals mentioned during the consultation forums such as a requirement for the clinical decision to be made by the health practitioner and supply to take place during a consultation would potentially mitigate the need for supervision and training of their staff. Without such requirements, training and supervision would be required.

We understand the policy intent to develop a regulatory regime for therapeutic products that is safe and cost-effective. We are concerned that any inconsistencies in relation to authorisations could undermine the ability of the regime to provide the necessary assurance that New Zealanders will receive consistently safe provision of medicines regardless of point of contact. All health practitioners authorised to undertake a particular controlled activity (e.g. dispensing) should be governed by the same processes (see further discussion of this point under the pharmacy licences and permits heading).

Pharmacy licences and permits

The Society is supportive of the flexible approach proposed for the granting of licences and permits. Given the range of options enabled by this legislation, a high degree of transparency around the granting of licences and permits will be important to ensure confidence in the governance and consistency of regulatory processes. Some form of online database or register may be beneficial in achieving this.

Under the proposed legislation, when undertaking controlled activities such as dispensing, pharmacists are required to obtain a licence (or permit) and comply with the associated regulatory processes. However, when the same activities are undertaken by a health practitioner, there is no such requirement to secure a licence and meet the requirements of that licence. There is a risk that variation in requirements will result in different standards and introduce potential for inconsistency in safe provision of medicines. The Society considers that requirements should be consistent for all parties. We are more than happy to work with the Ministry to achieve regulatory process surrounding controlled activities in relation to medicines and licence and permit requirements that are consistent and work in practice for patients and practitioners across the health sector.

The Society supports the concept of a responsible person but raises concerns about the use of the term competency, especially in relation to workers without a defined process of certification/ competency assurance (such as that in place for registered health practitioners). We understand the intent but consider that clarification is needed on the definition of competency and expectations for how a responsible person would verify competence in this context.

Prescribing

The Society recognises the benefits of embedding prescribing authority within health practitioner scopes of practice such as enabling the health workforce to adapt to the changing needs of New Zealanders. We support this development as long as there is a mechanism in place to ensure a consistent approach across all health practitioner regulatory authorities.

Regulator form

We understand that the form of the Regulator has yet to be determined. Given the breadth and depth of the responsibilities proposed for this body, it is essential that this be presented to the sector with some urgency. The Society is supportive of the powers given to the Regulator, provided there is a high level of transparency and sound governance systems are in place. We also highlight that regulation is just one component of ensuring safe effective use of medicines and draw attention to the need for cohesive policy direction and coordination between stakeholders in this area. We do not support the development of a Crown Agency due to the potential prohibitive costs involved.

Pharmacy business and activities

We recognise that the architecture required for this legislation to enable flexibility in granting licences and permits for innovative delivery of pharmacy services in relation to supply of therapeutic products necessitates a move away from a single definition of operating a pharmacy. However, the Society questions the need for the word "business" in the proposed Bill. If an organisation or individual is undertaking specified controlled activities in relation to medicines, they could still be considered to be operating a pharmacy, though the new legislation enables a pharmacy to take different forms.

Pharmacy ownership

The Society supports a pharmacy ownership model that retains a requirement for pharmacist ownership. The term pharmacy is synonymous with the professional practice of pharmacists. Pharmacy practice inherently deals with both physical aspects of medicines, including processes for safe manufacture and supply, and clinical application of information and evidence that inform the optimal use of medicines to achieve the best outcomes for patients. We understand that the therapeutic product legislation is primarily focused on components related to manufacture and supply of therapeutic products. However, separation of these aspects from the broader pharmacy practice can be problematic as it fails to recognise their inherent connection. For example, pharmacies are recognised in government policy as a location for the provision of health services such as management of minor ailments and provision of public health messages.

Pharmacist ownership retains professional governance over areas of pharmacy practice that are not covered by the therapeutic product legislation but are vital to optimal use of medicines and provision of high quality primary care health services. No evidence has been presented to support the need for change or on the likelihood that a change will bring about the mooted benefits.

Pharmacies in New Zealand currently have a variety of different models of investment but still have a pharmacist with majority ownership to maintain a professional influence on overall service provision and development as well as quality processes related to medicines supply. Enabling legislation and continued system investment in current and new pharmacy services is essential to ensure all patients in New Zealand have access to high quality medicines and pharmacy services. The ownership model should allow for integrated care models to develop that contribute to pharmacists being appropriately positioned to work as part of the multidisciplinary team and utilise their skill set to deliver effective health outcomes for New Zealanders.

Direct to consumer advertising

The fundamental principle to consider is the need for the New Zealanders to have access to unbiased information about medicines to support informed decision-making for optimal health outcomes. Some argue that direct to consumer advertising contributes to informing the public about potential treatment options. However, careful monitoring of standards and messages is required to ensure information directed at the public is not biased towards a specific outcome or objective. The government may need to consider methods of providing independent, unbiased, evidence-based information for consumers similar to the steps it has taken towards provision of independent unbiased information for health professionals with development of the New Zealand Formulary medicines resource.

The Society does not see the need to change the long-standing current regulations for direct-to-consumer advertising. However, the Society notes the Ministry's earlier consultation on direct to consumer advertising which led to the identification of various policy options to consider as an alternative to the current approach. The Society consider that this previous work would provide useful foundation for contemplation of this issue, with additional consideration given to the contemporary information environment in which health consumers and health professionals operate.

Unapproved medicines and off label use of approved medicines

The consultation document clearly articulates the need to achieve balance between retaining access to therapeutic products that have not been approved in New Zealand in certain circumstances while minimising their use given the lack of regulatory oversight of the quality and safety of such products. It also recognises that the off-label use of medicines that have been approved in New Zealand may be clinically appropriate. A process is needed that satisfactorily acknowledges these circumstances but that:

- avoids unnecessary administrative burden on the sector;
- recognises the differential risk levels associated with off-label use of products approved in New Zealand, use of products that are not approved in New Zealand but are approved in other jurisdictions where regulatory authorities are recognised by New Zealand, and use of products that are not approved in any recognised jurisdictions;
- provides clarity around the responsibility and process for ensuring compliance; and
- does not prevent patients receiving needed therapy in a timely manner.

The Society does not consider that the proposed approach meets these criteria and further development of the model is needed.

Next steps

The Society recognises this is the beginning of the journey and welcomes the opportunity to work with the Ministry of Health over the coming months as feedback on the exposure draft is analysed. Please do not hesitate to make contact for further clarification or discussion of issues raised.