## Key themes from submissions on the Therapeutic Products Bill

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| **Topic** | **Key themes** |
| ***Medical devices*** | |
| Ensuring harmonisation with international regulation and device appropriate provisions | Submitters from the medical device sector are concerned to ensure that the new regulatory scheme for their products is aligned with international approaches and uses familiar concepts and terminology. |
| Transitioning into the scheme | The medical device sector raised concerns about the transition approach and the proposed timeframe. The sector also felt that either the regulatory scheme or Pharmac’s procurement process should be delayed so they did not happen at the same time. |
| ***Clinical trials*** | |
| Cost and timeliness | Many submitters sought reassurance that the regulatory process would run in parallel with the ethics approval and be speedy, risk-based, and not stifle innovation through regulatory delays or a burdensome application process. DHB submitters were particularly concerned about potential impacts on observational studies and investigator-led trials. |
| Medical devices | Submitters commented on the requirement that clinical trials of medical devices would, for the first time, require approval by the regulator. Some were concerned to ensure that requirements were not onerous and duplicative of other processes. Others were very supportive and see the lack of this requirement as a significant gap in the current arrangements. |
| Technical matters | Submitters asked for the definition of *clinical trial* to be aligned with international norms, with some DHB submitters considering it was currently too broad and would capture some clinical practices. They also sought clarity on a number of specific issues. |
| ***Hospital settings*** | |
| Prescribing, compounding, dispensing, and administering | Many DHB submitters asked for more tailored arrangements to reflect the way medicines are handled within a hospital, including use of imprest supplies in hospitals and the way medicines are charted, prepared for administration, and then administered. |
| Medical devices made and put into service | Several submitters commented on the importance of the oversight of hospital practices including manufacturing devices for use in surgery so they are fit for purpose. |
| ***Health practitioner authorisations*** | |
| Ability of prescriber to dispense and supply | Some submitters expressed concerns about allowing health practitioner prescribers to dispense and supply medicines. These submitters emphasised the importance of separating prescribing from dispensing and supply, as this provides an additional clinical check of the prescription. They commented that the same requirements that apply to pharmacies should apply to health practitioners if they dispense and supply (ie a licence). |
| Process for establishing a professions’ authority to prescribe | There was general support for the proposal to establish the authority to prescribe via the relevant health practitioner profession’s scope of practice (rather than listing professions that can prescribe within the Bill or regulations under it). There were a number of concerns and questions raised, which largely reflected confusion on what the change would mean and how it would be implemented. |
| Ability for health practitioners to supply category 3 medicines | Reponses were mixed as to whether health practitioners (that are not prescribers) should be able to supply Category 3 (pharmacy) medicines.  Many submitters supported it as they considered it would improve access. A larger number of submitters did not think it would be appropriate. They expressed concerns that health practitioner practices do not have the same controls and monitoring as pharmacies (eg, temperature monitoring and oversight by the pharmacist of the medicines storage and supply). |
| Ability for health practitioner workers to supply category 3 medicines | While there was some support, the majority of submitters did not support allowing health practitioner workers (those working in a practice that are not registered health practitioners) to supply category 3 (pharmacy) medicines.  This was because they do not have the same training as pharmacy workers, the health practitioner would be unable to provide suitable supervision (as they are generally in a consulting room) and these premises are not licensed, so do not have the same standards and monitoring as pharmacies. |
| Sector specific concerns | Submitters from particular health care settings raised concerns about how the authorisations or requirements would apply to them and outlined the authorisations they consider they need. |
| ***Pharmacist & pharmacy worker authorisations*** | |
| Definition of dispensing | Submitters expressed concern that the definition of dispensing:   1. doesn’t include reference to the clinical practice aspects associated with dispensing 2. defines dispensing as part of manufacturing |
| Supervision requirements for pharmacy workers | The authorisations for pharmacy workers were generally supported. There was some confusion regarding how the authorisations would apply to different pharmacy workers roles and requests for a lower level of supervision being allowed in particular circumstances. |
| ***Pharmacy regulation*** | |
| Enabling different distribution and supply arrangements | Submitters were generally supportive of enabling new pharmacy models as long as these were focused on promoting better patient outcomes.  There was some concern regarding whether medicines could be dispensed safely outside a pharmacy dispensary.  There was also concern that the Bill enables a split between the dispensing and advice activities within a pharmacy. |
| Remote pharmacist presence and supervision | Feedback was mixed. Overall there was slightly more support for allowing remote pharmacist presence and supervision (with some submitters including caveats or limiting their support to particular situations). Reasons for support included advances in technology, opportunities for new models, and as a way to provide clinical advice to people that have difficultly accessing traditional pharmacy services.  Those that did not support it highlighted the importance of face to face consultation and direct oversight. |
| Pharmacy ownership | The majority of submitters, particularly those within the pharmacy sector, supported the option of strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit). They expressed concerns about the impact that removing the majority ownership requirement would have on the quality of services and safety. For some, support was contingent on removing the requirement that the pharmacist receive the majority of financial benefit. These submitters supported retaining a pharmacist ownership requirement based on stronger and clearer requirements for the pharmacist to have the majority of governance rights and effective control of the pharmacy.  Some submitters supported the option of open ownership with licence requirements targeted at pharmacist control of quality systems and practices and considered system controls more important than ownership for ensuring quality, and that replacing the ownership requirement with specified requirements for responsible pharmacists would increase efficiency and access and enable different pharmacy service models to develop. |
| Prescriber interest in pharmacies | Submitters generally supported retaining the restriction on prescribers from taking any interest in pharmacies. |
| ***Direct-to-consumer advertising*** | |
| Direct-to-consumer advertising (DTCA) | DTCA attracted a lot of interest in the consultation with strong views both for and against. Generally speaking, submitters from the advertising sector, industry sector, and parts of the pharmacy sector supported DTCA continuing whereas health practitioners and their representative groups did not. Consumers were both for and against, but generally were opposed to it.  The main arguments in favour of DTCA were that advertisements are informative, empower consumers with knowledge, encourage dialogue with health practitioners, and enable informed choices about treatment options.  Arguments against DTCA included that advertisements, by their very nature, are primarily aimed at encouraging consumers to buy products and can provide an unbalanced view of prescription medicines by emphasising benefits over harms leading to possible pressure on prescribers, unnecessary prescriptions, and potentially increased costs to consumers and the health system. Some submitters noted that although not generally the subject of DTCA, prohibition is aligned with antimicrobial resistance initiatives. |
| ***Product approvals and changes to approved products*** | |
| Who can apply | Some submitters were concerned that the requirement for an approval-holder to be either normally resident in NZ, or a body incorporated in NZ, would have a negative impact on companies that are an affiliate of a multi-national or Australian company.  Some submitters were also concerned that they do not have a direct contractual relationship with the manufacturer, as that is usually managed through corporate headquarters. |
| Process for obtaining a product approval | While understanding that these will be set in legislative instruments under the Bill, submitters sought greater information and clarity about the processes and requirements for obtaining a product approval. |
| ***Access to unapproved medicines*** | |
| Requiring a Special Clinical Needs Supply Authority (SCNSA) for off-label use of medicines | Some submitters support the provisions in the draft Bill that would require a prescriber to complete a SCNSA as part of a prescription for an off-label use of a product (ie when an approved product is being sought for a particular use, or a population, not covered by the approval). These submitters considered it would ensure patients received appropriate advice and care to make informed decisions in these situations.  The majority of submitters expressed concerns or indicated they did not support it. These submitters considered it would be impractical and burdensome in practice, particularly in hospitals. They highlighted a number of areas (eg, paediatrics) where off-label use of medicines is very common. |
| Authorising only medical practitioners to issue a SCNSA | There was mixed support to the proposal to restrict the ability to issue a SCNSA for medicines not approved in New Zealand, to medical practitioners, but allowing other prescribers to prescribe the unapproved medicine for that patient once a SCNSA has been issued. There were some concerns that the requirement for a SCNSA would be too burdensome.  Some submitters, including those representing particular health practitioner prescriber groups, requested that all prescribers be able to issue SCNSA as long as the medicine is within their scope of practice.  These submitters considered the relevant health practitioner prescriber has the most knowledge regarding the medicines suitable for those conditions / diseases of their patients. Requiring the patient to go to a medical practitioner for a SCNSA when the required medicines was unapproved would add costs, and not add any clinical benefit. |
| ***Personal import authorisations*** | |
| Personal import | There was generally support for the proposal to disallow the personal import of category 1 (prescription) medicine by courier / mail, but permit for category 2 (pharmacist), 3 (pharmacy), & 4 (general sale) medicines and medical devices. There was some support for widening the prohibition to include category 2 and 3 medicines.  A few submitters opposed the prohibition on the personal import by courier / mail of prescription medicines due to concerns for patients or patient groups dependent on medicines not funded here.  Views on whether it would be appropriate to use permits to authorise personal import in particular situations were mixed, but were slightly more in favour. |
| ***Scope*** | |
| Merits review | Most submitters’ comments related to the timeframes for the appeal process and views from some submitters that anyone should be able to appeal a decision, not just the aggrieved applicant. |
| ***Scope of products*** | |
| Exclusion of Natural Health Products (NHPs) | While submitters were not asked for feedback on the regulation of natural health products, some chose to comment. Some commented that they considered NHPs should be regulated under the Therapeutic Products regulatory scheme, while others commented that they should not. The Ministry is currently exploring options to regulate Natural Health Products. |
| Sunscreens | With the exception of those from the cosmetics sector, submitters supported regulating products used as primary sunscreens. The cosmetics sector generally supported mandatory compliance with a standard but believed it should be able to choose to meet a US, European or ANZ standard. |
| Device-like products | There are a number of products that have similar characteristics and risks to medical devices, but have only a cosmetic, not therapeutic, purpose (eg coloured contact lenses that have no corrective power and lasers for hair removal). Some countries regulate such products as a special category of device under their medical device regulatory schemes.  Submitters were asked whether they thought such products should be subject to strengthened regulation and many commented that they should be brought under the therapeutic products scheme. |