

Ministry of Health
PO Box 5013
Wellington New Zealand 6140
Email: therapeuticproducts@moh.govt.nz

Re: Therapeutic Products Regulatory Scheme consultation – draft Therapeutic Products Bill

Medicines Australia represents the discovery-driven pharmaceutical industry in Australia, many of whom also support arrangements for supply of medicines to New Zealand, based on a common supply chain. Our member companies invent, manufacture and supply innovative medicines and vaccines to the Australian and New Zealand communities. Those medicines keep Australians and New Zealanders out of hospitals, prevent disease and play a pivotal role in ensuring a productive and healthy community.

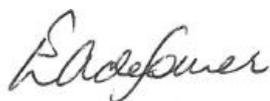
Medicines Australia welcomes the opportunity to respond to the New Zealand Ministry of Health consultation on the *'Therapeutic Products Regulatory Scheme consultation on the draft Therapeutic Products Bill'*. We also fully support the submission made on behalf of the industry by Medicines New Zealand. Medicines Australia has therefore highlighted key elements and overarching themes relating to the Medicines New Zealand submission that are of importance to our member companies and the operation of their business in New Zealand.

Our submission has been prepared with the expert input of Medicines Australia member companies as well as the Medicines Australia's Regulatory Affairs Working Group (RAWG). RAWG members are selected for their regulatory experience and industry knowledge and bring a whole-of-industry perspective to the consideration of regulatory issues that stand to impact our sector.

Our detailed feedback on the guidance is contained in Attachment 1 including answers to the specific questions included in the consultation paper. Our response includes suggestions for changes to provide better clarity on requirements which will support practical implementation as well as identifying key areas of concern.

We would be happy to discuss or provide further comment on any aspect of our response and we appreciate being kept up to date on further developments. Please feel free to contact Betsy Anderson-Smith if you would like further clarification on any aspect of our submission (banderson-smith@medaus.com.au).

Yours sincerely,



Elizabeth de Somer
CEO
Medicines Australia

Attachment 1

CHAPTER A – KEY FEATURES OF THE NEW REGULATORY SCHEME

A1 Do you support the general design of the new regulatory scheme for therapeutic products?

Medicines Australia supports the general design of the regulatory scheme.

CHAPTER B CONTENT OF THE DRAFT BILL

B1 – B19 Medicines Australia endorses the response to the consultation provided by Medicines New Zealand.

B1 Please provide any comments on the purpose of principles of the Bill (ss3 and 4)

Medicines Australia agrees with the purpose and principles as outlined in ss3 and ss4 and we support Medicines New Zealand's comments on definitions and meanings set out in the draft Bill. Medicines play an important role in supporting the health care needs of the population, recognizing that an investment in a healthier population provides benefits in terms of an active workforce that contributes to the overall economic health of the nation.

Medicines Australia is supportive of principles that support the timely availability of therapeutic products with regulation that is proportionate to the risks posed by those products. We also support the principle that the administration of the Act should be carried out in an open and transparent manner, and that there should be cooperation with overseas regulators, compliance with international obligations, and alignment with international standards and practice. Further detail on the principles is provided below:

- **Risk-proportionate regulation** – Medicines Australia supports the intent that regulatory requirements for different kinds of products and activities are to be tailored to accommodate their different characteristics and risk profiles. We also support the intent to have a wide and flexible range of product approval pathways, dependent on risk.
- **Timely availability of therapeutic products** – Medicines Australia believes that a successful regulatory scheme should not create undue delay and uncertainty to the availability of therapeutic products. This is an essential principle as regulatory schemes should ensure that people that need access to medicines are able to get access in the timeliest manner possible whilst ensuring that the medicine is safe, efficacious and of good quality. The regulatory scheme will need to establish transparent timeframe target setting and reporting of the regulator's performance to ensure that the regulator will be kept accountable to making decisions in a timely manner.
- **Open and transparent regulator** – Medicines Australia supports the principle that the regulatory scheme is administered openly and transparently. Transparency and fairness are key principles by which public sector regulation should be administered and there should be checks and balances to ensure these principles are realized.
- **Regulators reliance on overseas regulators work** – Medicines Australia supports the principle to have a regulator that cooperates internationally and recognises the work of trusted overseas regulators. This is increasingly important as New Zealand is small on the global stage, and with the challenging environment with respect to availability of medicines, many innovative sponsors do not consider New Zealand as a priority country in which to register medicines. It is therefore critical that the regulatory scheme relies on overseas assessments which can accelerate the

review and avoid duplication of effort. In Australia, the Comparable Overseas regulator pathways provide a good benchmark for a regulatory model that delivers significantly shortened review timelines.

CHAPTER C WHAT THE NEW SCHEME WOULD MEAN FOR DIFFERENT SECTORS AND HEALTH PRACTITIONER GROUPS

C1 – C53 Medicines Australia endorses the response to the consultation provided by Medicines New Zealand.

C3 Please provide any comments on the transition arrangements for existing medicine product approvals.

Medicines Australia believes that transition arrangements need to be more effectively addressed in order to meet the needs of patients currently being treated with s29 medicines – including the issue of stockpiling by wholesalers for those medicines that are needed promptly. Transition should include an automatic grandfathering clause where special clinical needs supply authorities (SCNSAs) are approved for a fixed period to allow product registration where this is appropriate. For example, a 2-year SCNSA may be automatically granted for medicines supplied under s29 at the commencement of the new legislation.

C16 Please provide any comments on the change in approach to regulating clinical trials

The proposed change formalises current practice into legislation.

C17 Please provide any comments on the transitional arrangements for clinical trials

Regarding 424, the 12-month transition period is understood, however consideration should be given to not transition clinical trials with up to 12 months remaining prior to closure.

Regarding 425, it is not understood why the Principal Investigator would need to apply as opposed to the person who lodged the section 30 application. Consistency for temporary license scenarios is recommended.

C18 What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?

Medicines Australia agrees with the approach to curtailing personal importation of prescription medicines. Patients should use the appropriate channels and they would need to follow the regulated supply channel for unapproved medicines (i.e. they would require a special clinical needs supply authority (SCNSA) and a prescription). This would then enable the issuer of the SCNSA, a pharmacy or wholesaler to import that product on that patient's behalf. This ensures that the medicine is quality controlled and it also ensures the quality use of medicines, including counselling and support for the patient by the pharmacist.



C36 Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?

Yes, a pharmacist should be able to provide clinical advice and oversight remotely. This is essential to reach rural patients and provide 'on-demand' consultation for those whom are unable to attend a pharmacy in person.

Appropriate activities would be; (i) after a product is prescribed and dispensed, any follow up questions on dosing, how to take the medicine(s) and any questions around potential or experienced side-effects.

For the future task-shifting is an important evolvement of medical treatment, so considering legislation that allows for prescribing pharmacists (i.e. (i) for a product that just needs a repeat script or (ii) to administer medicines or vaccines such as flu and travel vaccines), allows pharmacists to further contribute to patient health under an established model of shared care.

C37 Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?

No, this not required. Ethical behaviour from prescribers and pharmacists should always be paramount and regular audits from the government/professional bodies would identify any conflict of interests.

C41 Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?

No, all wholesale should go through the appropriate wholesalers as pharmaceutical companies have agreements with wholesalers to provide which include volume requirements. Any changes to this part of the supply chain may put contracts between wholesalers and pharmaceutical companies at risk, and therefore driving up additional costs for both parties.

C53 Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?

Medicines Australia supports Medicines New Zealand's response and the fact that the status quo regarding direct to consumer advertising (DTCA) is proposed to be maintained at this stage (with an enhanced range of enforcement options and higher penalties for breaches). DTCA of prescription medicines is a valuable tool for patients in order to promote health literacy and factual knowledge of what products are available to them. It also provides an opportunity for patients to take a proactive role in their own health management by visiting their healthcare professional and discussing what medicine is best for them.

However, our support for DTCA in New Zealand should not be interpreted as Medicines Australia seeking to similarly change our national approach which does not permit DTCA. Australia and New Zealand have taken different approaches with regard to DTCA for prescription medicines over many years and we are not aware of any reason to change either country's position.