New Zealand Law Society
Te Kāhui Ture o Aotearoa

Therapeutics Products Bill

2/3/2023

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1 Introduction

1.1 The New Zealand Law Society | Te Kāhui Ture o Aotearoa (**Law Society**) welcomes the opportunity to comment on the Therapeutics Products Bill (the **Bill**).

1.2 This Bill represents a significant reform of the Medicines Act 1981 (the **Act**) and the Dietary Supplements Regulations 1985 to "provide for a comprehensive, risk-proportionate regulation of therapeutic products".[1] The Law Society supports the modernisation of the law relating to medicines (or "therapeutic products") as the current Act does not reflect the scale or complexity of the modern medicines system, often leading to situations of legal uncertainty. The Bill has been the result of extensive policy work over several years and the impact of any proposed changes to the Act will have far-reaching impacts on the lives of New Zealanders.

1.3 This submission has been prepared with input from the Law Society's Health Law Committee.[2] The Law Society's comments have been restricted to matters of workability and clarity in drafting, and natural justice or other process concerns and, where possible, amendments have been proposed to address these issues.

1.4 The Law Society does not wish to be heard.

2 General comments

2.1 The Bill repeals most provisions of the Act, except those relating to pharmacy ownership, and revokes the regulations made under the Act. As this is the most extensive review of the law relating to therapeutic products in recent years, it will take some time to implement.

2.2 Clause 2 of the Bill sets out when the Bill comes into force. This will be a date appointed by Order in Council, and if not before 1 September 2026, on that date. As the explanatory note to the Bill indicates, a significant amount of secondary legislation will need to be made before the Bill can come into force. A lot of this will relate to the work of the proposed Therapeutic Products Regulator (**Regulator**). The development of regulations will be a major undertaking and one that will need to be adequately resourced to be completed by the long stop date of 1 September 2026. This is at a time when the health sector is already under considerable strain as a result of Covid-19 and its impacts, major structural reforms, and other competing priorities. We invite the Committee to bear this in mind when considering the Bill and reporting back to Parliament.

3 Purpose of the Bill

3.1 The purpose of the Bill is to "protect, promote, and improve the health of all New Zealanders by providing for the—

a) acceptable safety, quality, and efficacy of medicines and APIs across their life cycle; and

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1 Therapeutic Products Bill, Explanatory Note, p 1.

2 More information regarding this committee is available on the Law Society's website: https://www.lawsociety.org.nz/branches-sections-and-groups/law-reform-committees/health-law-committee/

b) acceptable safety, quality, and performance of medical devices across their life cycle; and

c) acceptable safety and quality of NHPs across their life cycle."

3.2 We query whether this purpose statement is too narrow to fully serve its role as an aid to statutory interpretation and whether it should be broader to account for the wide-ranging situations the Bill covers. For example, the Bill also regulates exports of therapeutic products from New Zealand which has no obvious connection to the health of New Zealanders (but which will have clear economic benefits to New Zealand).

4 Part 3: Dealing with Therapeutic Products

Subpart 3: When activities are allowed - Personal use imports

4.1 Clause 105 sets out when a patient or carer is allowed to import a medicine for personal use. However, "carer" is not defined in the Bill. We suggest this term is defined to ensure there is legal certainty around who qualifies as a carer for the purposes of importing medicines for personal use (while also being subject to the general import requirements under clause 67), and to avoid any risk of these provisions being misused (for example as justification for activities which would otherwise be considered illegal).

5 Part 4: Market authorisations for medicines, medical devices, and NHPs

Subpart 1: Market authorisations

Duration of market authorisations

5.1 The Bill requires that a person must not import or supply a medicine or medical device unless it has a NZ authorisation or export a medicine or medical device unless it has a market authorisation (see clause 67). The Bill then sets out the three kinds of market authorisations that may be issued by the Regulator. These include a 'standard authorisation', a 'provisional authorisation', and an 'export authorisation' (see clause 117).

5.2 Under clause 131(1), a market authorisation takes effect when it is issued or at any later time set out in it. It remains in force until certain events take place. In relation to a provisional authorisation, it will remain in force until either its expiry date (subclause 131(2)(b)(i)) or the Regulator issues a standard authorisation for the product (subclause 131(2)(b)(ii)), whichever occurs first. If it ceases due to the Regulator issuing a standard authorisation, we consider the cessation should be contingent on the standard authorisation taking effect (not merely being issued) as subclause (1) makes it clear that these need not be at the same time.

Cancellation of market authorisation

5.3 Clause 136 sets out the grounds that allow the Regulator to cancel a market authorisation. Subclause 136(d) provides there are grounds to cancel market authorisation if "the likely risks associated with the product outweigh its likely benefits". We consider this should say "the likely benefits do not exceed the likely risks" given the possibility that sometimes the risks and benefits will be equal or very finely balanced. Reframing this ground in this way would also be in line with the principle at clause 4(a) that the "likely benefits of therapeutic products should outweigh the likely risks associated with them".

Subpart 2: obligations of sponsors

5.4 Clause 145 sets out when a sponsor of a reportable product must notify the Regulator of a likely shortage. Although this requirement is a welcome development, the trigger for the sponsor's obligation to make such a report is if there are "reasonable grounds to believe that demand in New Zealand for a reportable product is likely to exceed supply at any time in the next 6 months". This is a subjective standard which may lead to either noncompliance or an overwhelming volume of 'defensive' reporting by sponsors. We consider it would be preferable to have a more objective standard for reporting, for example referencing the actual usage of the reportable product over a previous period of time and comparing this to available supply.

David Campbell
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