Therapeutic Products Bill

Legislative Statement

Presented to the House in accordance with Standing Order 272 J.17

Overview of the Therapeutic Products Bill

1. The Therapeutic Products Bill is intended to replace the current Medicines Act 1981 and Dietary Supplements Regulations 1985 (made under the Food Act 2014) to provide for the comprehensive, risk-proportionate regulation of therapeutic products.

Omnibus Bill

2. The Bill is an omnibus Bill introduced in accordance with Standing Order 267(1)(a). That Standing Order provides that an omnibus Bill to amend more than 1 Act may be introduced if the amendments deal with an interrelated topic that can be regarded as implementing a single broad policy. The interrelated matters to regulate here include market availability and the safe use of medicines, medical devices and natural health products.

Purpose

3. Therapeutic products present benefits and risks. A guiding principle for regulating therapeutic products is that the likely benefits of those products should outweigh the likely risks associated with them, and their regulation should be proportionate to those benefits and risks.
4. The Bill will regulate therapeutic products in New Zealand, which are any products that are intended for use in, on, or in relation to humans for a therapeutic purpose, or for use as an active ingredient of a medicine. These include:
    a. medicines
    b. active pharmaceutical ingredients
    c. medical devices
    d. natural health products.
5. The Bill will also regulate blood products, advanced cell and tissue therapies, tissue grafts and whole organs. These are defined as ‘biologics’ in the Bill and will be regulated as either medicines or medical devices depending on their mode of action.
6. The Bill is comprised of 11 Parts.

Part 1 Preliminary provisions

7. This Part of the Bill provides the commencement date, the purpose of the Act (clause 3) and guiding principles that the regulator, Minister and other persons exercising a power under this Act must consider (clause 4).
8. Part 1 also gives effect to transitional provisions set out in Schedule 1 and includes a provision that binds the Crown. This provision also allows for the enforcement of the Act against Crown organisations for non-compliance with the Act if required.

Part 2 Interpretation

9. Part 2 of the Bill defines many of the key terms used in the Bill. Clause 19 of the Bill allows the regulations to bring a product that would not otherwise be a therapeutic product into the scheme, or to remove what would be a therapeutic product from the

scheme. These regulations can only be made if the criteria in clause 19 are met. Some products that are currently regulated as foods under the Food Act 2014, as well as some gym and fitness equipment, are likely to be removed from the scheme through regulation.

10. Part 2 provides for all medicines to be classified into one of four categories: prescription medicine, pharmacist medicine, pharmacy medicine and general sale. Different controls in the Bill apply to medicines depending on their classification.
11. Medical devices are also defined in Part 2 and special provisions are included to address advances in manufacturing systems and in software as a medical device.
12. Part 2 also sets out a 'fit and proper person test' that will be applied by the regulator in determining whether a particular person should be granted an approval, licence or permit to do something under the Bill.

Part 3 Dealing with therapeutic products

13. The Bill contains a default rule that importing, supplying and exporting therapeutics that are not authorised under Part 4 of the Bill, are prohibited and are punishable by fine, pecuniary penalty, imprisonment or other penalty.
14. Part 3 of the Bill sets out a range of mechanisms by which individuals (e.g., pharmacists, health practitioners, veterinarians and their workers) or businesses (e.g., pharmacies, wholesalers and clinical trial sponsors) can be authorised to deal with therapeutic products in the supply chain.
15. Part 3 of the Bill provides for limited circumstances in which a therapeutic product may not need to be authorised before it can be supplied. This includes custom-made medical devices, medicines requiring compounding and natural health products manufactured by a natural health practitioner as part of a health consultation with a client. It also includes some medicines that are personally imported into New Zealand (e.g., in a person's accompanied baggage).
16. Clauses 115 of the Bill provides for a broad regulation making power to allow other classes of individuals to engage in controlled activities (e.g., vaccinators, New Zealand Blood Service employees). This will provide flexibility for the regime to support new and innovative health service delivery models or to respond to unforeseen events, such as a natural disaster.
17. Clause 116 provides for the Chief Executive to make emergency arrangements in the event of a serious and unexpected event that presents a risk to the health of persons or animals in New Zealand. This provision enables the Chief Executive to issue an emergency arrangement notice that can allow for an authorised product to be used in a manner not consistent with that product's market authorisation (e.g., permitting a different class of individuals, such as vaccinators, to administer the product). It is intended that this power will be used rarely.

Part 4 Market authorisation for medicines, medical devices, and NHPs

18. This part specifies the different forms of market authorisation that a product's sponsor can apply for; and includes procedural provisions to support the evaluation of those applications. It also includes a suite of powers for the regulator to design and implement various risk-proportionate evaluation pathways for an application to determine the quality, safety and efficacy or performance of therapeutic products.
19. Three kinds of authorisation are contemplated for medicines and medical devices: standard authorisation, provisional authorisation and export authorisation. Natural health products will be able to obtain standard and export authorisations. The market

authorisation framework is intended to be flexible and support appropriate approval pathways based on risk profile.

20. A market authorisation sets out the approved indication or purpose of a medicine or medical device. For natural health products, a market authorisation will set out the authorised 'health benefit claims' that can be made in relation to the product. A claim about a natural health product is a health benefit claim that states or implies that the product is beneficial for a therapeutic purpose. Therapeutic purposes are listed in clause 15.
21. Part 4 includes wide regulation making powers to enable the regulator to set product standards and criteria for market authorisation. It also provides for the protection of certain data in fulfilment of New Zealand's international treaty obligations.
22. Finally, Part 4 sets out criteria for a person (i.e., a person ordinarily resident in New Zealand, a company incorporated in New Zealand or Crown organisation) who wishes to obtain market authorisation for a product so they can import, supply in or export from New Zealand. This includes meeting the 'fit and proper' test and having a legal relationship with the 'responsible manufacturer' of the product. A person who holds or is issued with a market authorisation is termed the 'sponsor' and has specific obligations under the Bill in relation to the product. Some of these sponsor obligations are set out in subpart 2 of Part 4.

Part 5 Licences and permits

23. Part 5 of the Bill provides a framework for the regulator to issue permits and licenses. It includes a range of criteria for permit and licence holders and grounds for suspending or cancelling licences.
24. Subpart 2 of Part 5 sets out some obligations on licensees, permit holders and 'responsible persons', including a requirement that licensees and permit holders must comply with qualification, training and competency requirements.

Part 6 Other prohibited conduct (tampering, misrepresentation, advertising, misleading information)

25. Part 6 includes a range of offences, including tampering with therapeutic products (and supplying tampered-with therapeutic products), making misrepresentations about a therapeutic product and preparing and supporting conduct, such as obtaining therapeutic products when supply is unlawful.
26. Part 6 also includes offences relating to advertising. The regulator will be able to determine 'advertising requirements' and 'distribution requirements' to control the content, mode of distribution and target audience of communications relating to therapeutic products. These provisions will be relied upon to carry over Cabinet's decision to retain direct-to-consumer advertising of prescription medicines, via secondary legislation.
27. Part 6 also includes offences relating to health benefit claims and an offence to offer an improper product inducement to health practitioners.

Part 7 Regulatory matters

28. Part 7 of the Bill provides for post-market surveillance and response systems to be established by both the regulator and product sponsors.
29. Part 7 also allows the regulator to make a series of regulatory orders, including recall orders, premises restriction orders, advertising remediation orders, product moratorium orders, prohibited product orders and medicine access limitation orders.

These orders provide important regulatory tools to address post-market safety issues involving therapeutic products.

Part 8 Enforcement

30. Part 8 of the Bill deals with enforcement and provides for a range of enforcement tools. These include: enforceable undertakings, injunctions, an infringement fine regime and criminal penalties. A civil pecuniary penalty regime is also established under the Bill for contraventions engaged in the course of business and – usually – with a commercial motive. This part also provides for how the Bill can be enforced against the Crown.
31. Part 8 also includes a range of defences for people charged with a breach of the Bill and allows for responsibility for a breach to be 'attributed to directors and senior managers' to ensure management and corporate boards cannot escape liability through wilful-blindness or poor governance practices.

Part 9 Regulator and cost recovery

32. Part 9 of the Bill establishes the regulator and sets out its objectives and functions. The regulator will be a branded unit within the Ministry of Health headed by an independent statutory officer (i.e., public service employee appointed by the Chief Executive of the Ministry of Health).
33. Part 9 also includes provisions allowing the regulator to recover costs through fees, charges and levies. This part also enables the regulator to use automated decision-making systems (e.g., as part of a self-assessment approval pathway) and for the regulator to share information with regulatory entities in New Zealand or overseas.

Part 10 Administrative matters

34. Part 10 of the Bill deals with various administrative matters, including the establishment of the therapeutic product register, procedural arrangements in relation to applications and the regulator's power to issue rules, regulator's notices and exemptions. Along with regulations made under the Bill, this secondary legislation will operationalise the Bill into a functioning regulatory regime.
35. This part also sets out the Minister's requirement to review the Act every five years. Cabinet has previously agreed Crown liability be considered at the first review.

Part 11 Repeals, revocations, and amendments to other enactments

36. The remaining provisions and parts relate to how the Bill will interact with other legislation, make consequential amendments and establish various transitional rules to provide for an orderly transition from the current regulatory regime to the Bill. For example, the Bill does not disturb current regulatory arrangements relating to medicinal cannabis or drugs controlled under the Misuse of Drugs Act 1975, or psychoactive substances controlled under the Psychoactive Substances Act 2013.

Schedule 1 Transitional matters

37. The Bill provides that, on commencement, an existing standard or provisional consent under the Medicines Act 1981 for a medicine becomes standard or provisional authorisation for the medicine under Part 4 of this Bill. The Bill provides for a 6 month to 2-year transitional window for people lawfully carrying on controlled activities at commencement, to obtain a licence or permit or make other arrangements to comply with the Bill.

38. Products that are not regulated under the Medicines Act 1981, such as medical devices and natural health products, will be transitioned in a more staged manner given the readiness of the affected sectors. The Bill provides a 3 to 5-year window for medical devices, depending on their posed risks (i.e., the highest-risk devices will be transitioned into the new regime within 3 years upon commencement). The natural health sector will have 2 years to obtain market authorisation for their products.

ENDS.