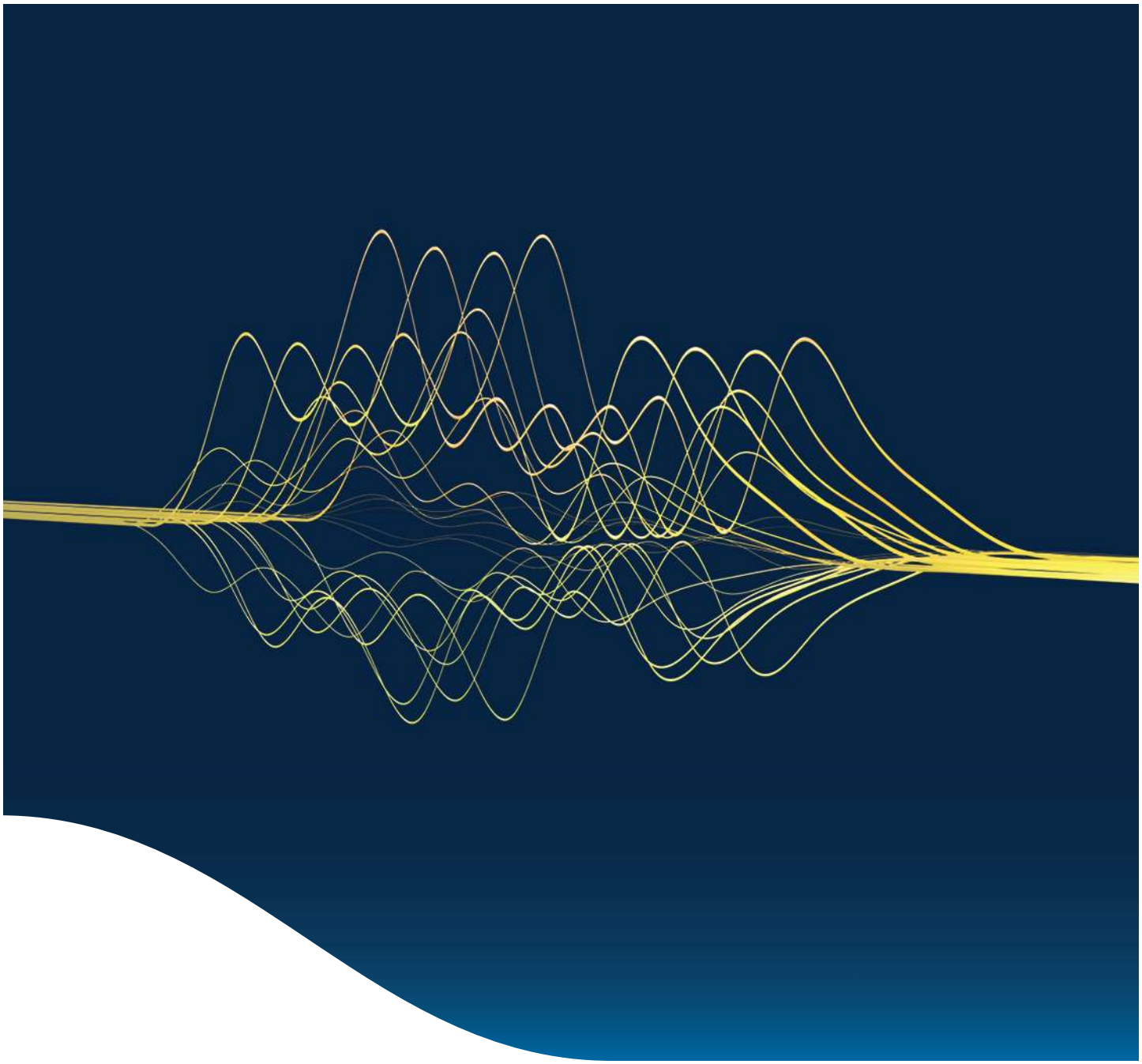

Almost what the doctor ordered…

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Almost what the doctor ordered…

Long-awaited reform of therapeutic product regulation is underway in Aotearoa New Zealand following passage of the Therapeutic Products Act 2023 but there is still a way to go. We summarise below:

- Timing and implementation
- What is covered by the new regime
- Key changes to the existing regime:
  - Market authorisations — the process to bring medicines, medical devices and NHPs to market.
  - Controlled activities — what types of activity will be captured.
  - Advertising — significant changes to the existing requirements.
  - Increased liability for senior managers — a more onerous approach to potential liability.
  - Enforcement — the teeth of the new regime including more significant penalties.
  - The new Therapeutic Products Regulator.

These are just the highlights. If you have any questions or concerns about how the new Act will impact you or your business, please get in touch with our experts.

Timing and implementation

When it comes into force, the new Act will have broad impact, representing a significant expansion in scope as compared to its predecessor. More products will be regulated and requirements on activities previously subject to a light touch will be expanded. With the variety of regulations and rules that will be introduced over the coming years, the complexity of navigating the therapeutic products space in New Zealand is likely to increase.

Most of the Act is set to come into force on 1 September 2026 and there is much to be done before then:

- The Act provides a very high-level framework, with the nuts and bolts to be determined by regulations and rules yet to be developed.
- The long lead in time is to enable Manatū Hauora (the Ministry of Health) to undertake a complex programme of work including three major workstreams:
  - Development of a large and comprehensive body of secondary legislation including new regulations, rules and Regulator's notices, together with guidelines and policies to support industry, practitioners and applicants.
  - The new digital platform necessary to provide the new regulator and regime with a digitally enabled operating model.
  - Establishment of the new Regulator (predicted to be 2-3 times larger than Medsafe).

Manatū Hauora is developing an engagement approach to enable both general and specific engagement with stakeholders over the coming months and years. This will include establishment of technical working groups, consultation on regulations, sector funding and more.

We will continue to provide updates as more information becomes available.

What is covered

All therapeutic products are caught — this means products that: have a therapeutic purpose, are determined by regulations to be therapeutic products or are intended to be used as an active ingredient in medicine.

This is a wider scope than the old regime so it is crucial to confirm whether your products are caught if you are involved in controlled activities such as: manufacturing, wholesaling, supplying, exporting, importing, prescribing and dispensing, administering and/or using for clinical trials, medical devices or in pharmacies.

For completeness, we note the Act does not amend the regulatory amendments relating to medical cannabis or drugs controlled under the Misuse of Drugs Act 1975 or Psychoactive Substances Act 2013.

Key to this will be assessing whether products have a therapeutic purpose, being a purpose *connected to* any of the following:

- preventing and treating diseases, ailments, defects, and injuries (and activities in between – such as monitoring and palliative care);
- influencing, inhibiting, or modifying human physiological processes;
- testing susceptibility of humans to particular diseases or ailments;
- influencing, controlling or preventing human conception, and testing for pregnancy;
- investigating anatomy and bodily processes;
- nutritional supplementation;
- health maintenance and promotion; or
- disinfecting medical devices.

Within the regime, products are divided into 4 types — medicines, medical devices, active pharmaceutical ingredients (known as APIs), and natural health products (known as NHPs):

Product type	Description	The key points
Medicines	Products that achieve their intended action by pharmacological, immunological, metabolic, or genetic means.	The Act distinguishes between prescription medicines, pharmacist medicines, pharmacy medicines and general-sale medicines. All these categories will be defined in the new regulatory framework that the Ministry will be preparing and consulting on in the coming three years.
Medical devices	Products that achieve their intended action by means other than pharmacological,	The new medical device framework will be one of the most significant changes of under the Act and sees a shift from the previously light touch notification-only approach to

Product type	Description	The key points
	immunological, metabolic, or genetic means, even if assisted by such processes.	requiring pre-market authorisation for all devices (with different requirements depending on type). Software as a medical device (**SaMD**) is now expressly captured to include software with a therapeutic purpose but no associated hardware and/or that will be used to augment another product by using its hardware or components (e.g., heart rate monitors in smart watches). Some medical devices will be supply-restricted devices and use-restricted devices. Those devices will be subject to restrictions on who may supply or use them, the circumstances of their use and supply, and how the devices are to be supplied or used. There is also specific provision for personalisation, with patient-matched devices (i.e., made for a specific patient to match their morphology and circumstances) and custom-made devices being new medical device sub-categories in the Act.
APIs	Products that are active ingredients for medicines but not yet incorporated into a medicine.	The Act distinguishes between APIs, biologic APIs (containing a biologic component) and prescription APIs (where the medicine in which it is the only API is (or, if manufactured, would be) a prescription medicine).
NHPs	Products that contain NHP ingredients within specified levels. NHP ingredients are broadly defined. NHPs therefore include dietary supplementation (e.g., for vitamins, minerals amino acids etc.) and herbal remedies.	The Act will regulate NHPs, including naturally occurring things, but *only* where they are intended for a therapeutic purpose. This has been the area of most controversy (and misunderstanding) but remains one to keep a watchful eye on as further rules and regulations are proposed. In particular, it might pay to look out for: • **Recognised NHP ingredients**: contrary to claims on social media, there is no list of prohibited or restricted herbal products in the Act. However, Manatū Hauora will be consulting on a list of recognised NHP ingredients to be developed as secondary regulation. • **Rongoā**, traditional Māori medicines, treatments and healing practices, may be regulated as NHPs if manufactured by a rongoā practitioner and are intended for use in a rongoā service or activity. In most cases under the Act, rongoā products are not regulated. However, rongoā products will be regulated where they are made for commercial export and some wholesale activities. A specific rongoā advisory committee will be established to advise Government and the new Regulator. • **Cosmetics:** these may be captured if they have a therapeutic purpose — for example, a range of skin care including products containing SPF, some shampoos, certain toothpastes etc.

Key changes

Market authorisations

Market authorisations, as the name suggests, will be the primary route for bringing medicines, medical devices and NHPs to market – i.e., importing, exporting, and supplying them.

Different standards apply to different medicines and medical devices, and to NHPs. In summary, however, to get a market authorisation an applicant will need to satisfy the new Regulator as to the product's safety and quality, and product's efficacy (medicines), performance (medical devices) or proposed health benefit claims (NHPs).

Different authorisations exist for different purposes:

- **Standard authorisations** allow ongoing import, supply and export and therefore have stricter requirements.
- **Provisional authorisations** allow import, supply and export for a limited term (maximum 2 years) and are for products where the Regulator cannot determine whether they have met standard authorisation requirements (e.g., because they need more information) but thinks that this more limited authorisation is appropriate.
- **Export authorisations** allow export even though the product does not meet the criteria for standard authorisation that would allow it to be supplied in Aotearoa.

For any product, the new Regulator can impose additional conditions than and/or provide exemptions to any regulations, rules and standards that would otherwise apply.

Market authorisations must include sponsor and manufacturer details. Sponsors have various obligations under the Act. For example:

- To ensure compliance with the terms of the market authorisation, including where it requires other people to do something.
- To ensure that the product meets applicable standards, have surveillance and response systems.
- To report to and notify the Regulator in various circumstances.

As under the old regime, the Act expressly permits some authorised persons (e.g., health practitioners, pharmacists) to undertake certain activities with respect to medicines and medical devices that have not received relevant authorisation. Some downstream activities and personal imports and exports are also permitted.

Engaging in Controlled Activities

In addition to the requirement for market authorisation, those dealing with therapeutic products must be properly authorised to do so by provisions in the legislation or pursuant to licences/permits issued under the Act.

The Act imposes controls on manufacturing, supplying, exporting, prescribing and dispensing, possessing, administering/using, conducting clinical trials and carrying on a pharmacy business (**Controlled Activities**).

Generally, a person may only engage in Controlled Activities where they have applied for and received a licence or permit. Licences and permits will be issued by the new Regulator and allow holders to carry on specified activities in relation to specific products. The Regulator is entitled to include

conditions that it thinks appropriate and with which the holder must comply. Licences and permits are subject to restrictions on their duration, with a maximum of 5 and 2 years respectively.

Pharmacists, healthcare practitioners, veterinarians, product sponsors, manufacturers and NHP practitioners (among others) are variously authorised by the Act to carry out some controlled activities without needing further permit or licence. The Act provides that regulations may be made to authorise further classes of persons to carry out specific controlled activities.

The Act imposes obligations on licensees, permit holders and their responsible persons, and other authorised persons to comply with any applicable rules. These rules will be developed by the Ministry over the next three years. There is no detail on them yet, but they will include requirements relating to:

- Conduct of the Controlled Activity.
- Product and consumer information.
- Packages, packing, labelling and identification of products.
- Storage, handling, security, transport and disposal.
- Surveillance and response of products.
- Record keeping, auditing and giving information to the new Regulator.

The Act also regulates other people in therapeutic product supply chains that are not engaging in Controlled Activities. While a case-by-case assessment is required, there are typically less onerous obligations on people in this situation.

A new approach to advertising?

New Zealand has previously been unique amongst comparative jurisdictions in its liberal approach to advertising of therapeutic products. The new Act brings significant changes to the regime. Any communication made, in any way, to promote a therapeutic product will be caught by the sections and regulations made in relation to advertising. Any person who distributes an advertisement must comply. Distribution includes making available or bringing to the notice of the public any advertisement. This would include retailers such as pharmacies displaying advertisements that they did not produce themselves.

Various official communications are explicitly excluded from the definitions of advertisements such as public safety announcements, recall orders, public health campaigns, pharmaceutical schedules and other communications made pursuant to the law or regulations made under the Act.

Advertisements for distribution in New Zealand must:

- Be for a product that has standard or provisional authorisation.
- Contain the name of the person who is using the advertisement to promote the product.
- Contain any information required by the rules or regulations.
- Not contain any information directly or impliedly inconsistent with the product's market authorisation.
- Not contain misleading information.
- Meet any standards set out in the regulations.

In addition:

- If the advertisement is for a medicine or medical device, it must not promote the product for off-label use.

- If the advertisement is for an NHP, it must not make a health benefit claim which is not permitted for NHPs.

If the advertisement is to be distributed overseas only, any market authorisation is sufficient for the purposes of New Zealand law but all other requirements apply.

Authorisation requirements can be waived in circumstances which the regulations permit or where the product is a rongoā product or personalised NHP. Additionally, authorisation will not be required where a licence or permit allows it, or the product is an API. The regulations can also permit certain products to be advertised for an off-label use.

Further detail will be provided in subsequent regulations.

Increased liability for senior managers

One aspect of dealing with therapeutic products that appears to have received less attention is the increased scope for liability of senior managers of body corporates. Where the body corporate for which they are senior manager contravenes a provision of the Act, they are deemed to also have contravened the Act. It is on the senior manager to show that they either:

- Did not know, and could not reasonably be expected to have known, of the contravention; or

- Took all reasonable steps to ensure that the conduct constituting the contravention did not occur.

This represents a significant shift from the old regime which requires that the prosecutor prove the senior manager knew about and/or failed to take reasonable steps to prevent the contravention.

Enforcement

The penalties in the new Act are an update to the existing penalties. The new penalties are broadly in line with similar regimes.

The Act creates both criminal and civil liability, as well as infringement offences. Criminal offences are split into strict liability (i.e., if you do the action, you are liable even if you did not intend it) and knowledge and intention offences (i.e., you must have had a specific intention or knowledge as well as done the contravening action).

Somewhat surprisingly, the Level 1 strict liability offences listed at section 268 in fact require interrogation of a defendant's state of mind. This has the potential to lead to problems with implementation and enforcement down the road.

Maximum penalties for strict liability offences depend on the category of the offence:

- Level 1: $500,000 for a company or $100,000 for an individual.

- Level 2: $250,000 for a company or $50,000 for an individual.

- Level 3: $170,000 for a company or $30,000 for an individual.

For knowledge and intention offences, the maximum penalties are:

- For a company, a fine up to $1 million.

- For an individual, a fine up to $200,000 *or* a custodial sentence up to five years.

The maximum fine for civil liability is the greatest of:

- The payment received for a contravening transaction.
- If the contravention resulted in the person making a commercial gain or avoiding a loss, three times the gain or avoidance.
- $250,000 for an individual; $2 million for a company.

As is common practice, infringement penalties are to be set in regulations.

The Regulator

The Act creates a new Therapeutic Products Regulator. Their objective will be to "foster and maintain an independent and effective system to regulate therapeutic products to achieve the purposes of this Act".

In exercising their functions and powers, the Regulator is required to act independently of the Chief Executive, Ministry and Minister. Nonetheless, they will be subject to any general policy directions given by the Minister, provided those directions are consistent with the purposes and principles of the Act.

The Regulator has functions and responsibilities relating to:

- Regulating therapeutic products, including through market authorisations, licences, and permits. This extends to post-market surveillance, addressing safety, quality and efficacy issues as well as enforcement and compliance.
- Engaging with other entities, in New Zealand or overseas, where relevant.
- Information, including collection, analysis, and provision of information relating to Therapeutic Products and their safety quality or efficacy, or the claims they make. This function extends to the provision of guidance, advice and information to those caught by the Act, others concerned with Therapeutic Products and the public.
- Engaging with Māori and other population groups in a way that reflects their needs and aspirations in relation to therapeutic products.
- Advising the Chief Executive and Minister.
- Any other functions conferred under the Act or any other Act.

The Regulator is required to make available a regulatory strategy setting out how they will exercise their functions and powers. It is required to set out:

- Key areas of focus, including the key risks being targeted in those areas.
- The regulatory approach the Regulator will take in performing their functions and exercising their powers.
- How the Regulator's performance of their functions and exercise of their powers will be assessed.
- How the Regulator will give effect to the principles of te Tiriti o Waitangi in performing their functions and exercising their powers.
- How the strategy will be reviewed and, if appropriate, updated.
- Any other information required by the regulations.

Another point to watch is that the Regulator may use automated electronic systems to carry out some of its functions, including evaluation of applications and decisions, provided that the system is reliable and there is a process by which an affected person can require the Regulator to review the decision. It will be interesting to see how this interacts with the expanding role of machine learning and artificial intelligence.

Notably, the Regulator may also rely on reports, assessments, decisions, and information from designated overseas Regulators, organisations, or other persons or bodies that the Regulator is satisfied has knowledge and expertise of the relevant subject matter.

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