Update: Therapeutic Products Act 2023

Recently, Complementary Medicines Australia met with representatives of the New Zealand Ministry of Health as part of our representation on the ComTech forum, to discuss the progress and implementation of the new regulatory scheme for Natural Health Products in NZ, and how Australia and CMA can be involved in the process, supported by our lengthy experience in a medicinal regulatory scheme for natural and complementary medicines.

The New Zealand Therapeutic Products Bill received Royal assent and became the Therapeutic Products Act 2023 (the TP Act) on 26 July 2023. Most provisions in the Act will not come into effect until 1 September 2026 at which time transition arrangements to the new regulatory scheme will begin. Under the Act, natural health products (NHPs) will have their own regulations and a new regulator. NHPs include such things as plants, fungi, microorganisms, vitamins, minerals, animal materials, synthetic versions of any of these, as well as anything the rules say is an NHP ingredient: for a full list see section 30 of the TP Act. The Act creates a market authorisation framework, and a requirement for market authorisation of most commercially available natural health products in NZ.

There are currently around 20,000 natural health products in NZ representing around $NZ 2.3billion. According to the latest export statistics, NZ is Australia's second largest export destination after China/HK. Given Australian products make up a large portion of NZ's complementary medicine market, establishment of the new therapeutic products regulatory regime will have a direct and significant impact to Australian complementary medicines business who export their products to NZ.

A significant amount of complex and large-scale work remains to be undertaken by the commencement date, 1 September 2026, which will be led by the Ministry of Health (the Ministry). The implementation program includes three major workstreams:

- Establishing **comprehensive secondary legislation** (creating policy, regulations, and regulatory instruments) for the effective implementation of the therapeutic goods regime;
- Building the **IT platform**, to enable an efficient market authorisation framework and licence and permit regime;
- Appointing an independent statutory officer as **the Regulator** as well as establishing a **branded business unit** within the Ministry.

CMA has summarised the key administrative points and legislative timeframes for the implementation of the Act, based on what we know so far and the Ministry's presentation at the ComTech meeting.

Key Administrative Matters

- The Regulator (for all products) will be in development from 2024 and begin operations in 2026. The current projection is that it will require around 200 staff, however that number may change.
- There will be two years for natural health products to apply for full market authorisation, beginning September 2026 and ending August 2028, with the possibility of extending this if required. During this time a temporary market authorisation will be given to existing products.
- While a license or permit for manufacturing most products will be required, decisions about the level of GMP expected for NHPs are still to be made. Licenses might be subject to condition that there are an appropriate number of responsible persons – this is still be determined and set out in the rules. However, it might not be needed for some licences.

- Similarly to the Australian scheme, some NHPs will *not* be required to have market authorisation, including practitioner-made NHPs, compounded medicines, personal imports, and low concentration NHPs (homeopathics) containing 20 parts per million or less of every active ingredient (see section 32 of the TP Act).
    - Rongoā Māori medicines will also not be required to have market authorisation, provided they are not for commercial supply.
    - To allow for cottage industries and home based practices, exceptions have been made for those conducting "in-person interaction" in Section 114 of the TP Act.
    - Further specifics about exemptions will become available as the scheme develops.
- Similar to listed medicines in Australia, NHP market authorisation will be via an online self-declaration process. The sponsor will provide information, declare the information is correct, pay a fee and submit the application, after which authorisation will (in most cases) be automatically given. The Regulator must accept declarations unless there is evidence to the contrary.
- The NZ Government is developing their own ingredient list, which will largely take into consideration Australia's and Canada's lists. They will also take into consideration the previous Permitted Substance List (PSL). Product standards will be set for all therapeutics. For NHPs, standards can also include anything relating to their safety and quality, maximum concentrations of NHP ingredients, and compositional matters, per section 64 of the TP Act.
    - Any role and/or positioning of practitioner only medicines for NHP / CM practitioners within the regulatory scheme requires further information, however this topic has been raised by CMA and there are suggestions the Ministry is considering the matters.
- A pre-determined list of "standard health benefit claims" will be developed. If a sponsor wishes to have a "custom health benefit claim" then the role of the regulator will shift in terms of substantiation of those claims. It will NOT be a test of "efficacy", it is a substantiation of use. Substantiation will be scientific evidence, evidence of traditional use, or both. Pharmacopoeias for traditional use will be listed in the regulations. See sections 62 and 63 of the TP Act.
- The Regulator will step in for further assessment if the applicant wants to use a new ingredient or new health benefit claim. In such cases, the Regulator must assess and approve the claim before the product can be imported, supplied in NZ or exported.

Projected Timeframes

2024	
Targeted Consultation (first half of 2024)	Targeted Consultation with industry and practitioners; i.e., those who will be regulated more closely under the regime.
Public Consultation (at the end of 2024)	Public consultation on the policy behind the regime, followed by refining proposals in late 2024.
Scoping & costing the new Regulator (Begin mid 2024)	Establishing an indicative idea of the size, scope and cost of the Regulator, including IT systems. It is expected to take two years to establish the Regulator, under the charge of its first Chief Executive.
2025	
Draft of Secondary Legislation	Following consultations, the Ministry of Health will begin the task of drafting the secondary legislation.
Staffing	Once the Regulator is established, decisions around staffing will be made. The Regulator will go live in 2026.

2026	
Commencement 1 Sep 2026	All of the Act's provisions must be in place and Regulator will be live.
NHP Transition Period 1 Sep 2026 – 31 Aug 2028	○ Temporary market authorisation for most NHPs ○ 2-year licence for activities involving many types of NHPs ○ License can apply for new licence or permit during this time

EOI: Natural Health Products Advisory Group

The Ministry is seeking EOIs from individuals with significant and relevant expertise to join their Natural Health Products Advisory Group. The Group will support the development of secondary legislation under the Act by providing independent non-binding advice to the Ministry. The EOIs close 5pm, 16 November 2023, NZ time. Please read more on Natural Health Products (NHP) Advisory Group.

CMA Advocacy

CMA has actively been engaging on this matter with the TGA, DFAT, the Australian High Commission in NZ, and Austrade, and is pleased to witness the high level of engagement between Australia and NZ on this important matter.

CMA understands that the NZ Ministry is keen to work with the Australian Government, particularly the TGA, to better understand its regulatory regime at a more detailed level in order to align standards and practice where appropriate. The Ministry and the Ministry of Foreign Affairs and Trade (MFAT) acknowledge the importance of trade in complementary medicines/natural health products between Australia and NZ and are also interested in working with DFAT to ensure open and well-functioning markets. We also note that the TGA and DFAT have been working closely on export matters, so the NZ situation will be dealt with in a similar manner.

The next two-year phase which will set in place the secondary legislation, will be crucial for the Australian complementary medicines industry. Given Australian products make up a large portion of NZ 's NHPs market and already meet one of the highest regulatory standards, the new regime should work towards incorporating and streamlining with as many elements of the Australian complementary medicine therapeutic goods regime as possible to reduce duplication and regulatory barriers to trade.

CMA is also committed to continuing to raise our concerns with the current extremely tight timeframes. We have questioned the Ministry of Health implementation team and understands that the team will be constantly communicating to NZ Government about timeframes and whether there will be a need to extend them. CMA remain cognizant of this and considering the likelihood of greater time for industry being required, intends to remain in communication with NZ and advocate as needed for an extension to the temporary market authorisation period for NHPs to ensure products required to have a market authorisation will have sufficient time to transition.

CMA will continue our active role in this space on behalf of the Australian complementary medicine businesses, to ensure the NZ regulatory regime harmonises with Australian regulations to the greatest extent possible.

Resources:

- Ministry of Health Presentation on NZ Therapeutic Products Act
- Background to Policy Decisions: Therapeutic products regulatory regime
- Therapeutic Products Act 2023
- Sign-up the NZ Ministry Newsletter: Subscribe to Therapeutic Products updates
- Email with Inquiry about the Act to NZ Ministry: therapeuticproducts@health.govt.nz