

5 March 2023

Chairperson
Health Select Committee
Freepost Parliament
Parliament Buildings
WELLINGTON 6160

Kia ora Chairperson,

Following is our consultation document on the Therapeutic Products Bill, we also support the submission made by Natural Health Products NZ.

Yours sincerely



Richard Barge

NZHIA Chair



New Zealand Hemp Industries Association Inc

PO Box 38 392, Howick, Auckland

Phone: 09 533 6690

Mobile: 021 706 690

Web: www.nzhia.com

Email: richard@hemptastic.co.nz



Therapeutic Products Bill Consultation Document



The Therapeutic Products Bill is intended to seize the opportunity for Aotearoa New Zealand to have a thriving natural health foods sector that boosts economic growth and facilitates affordable and reliable means to improve consumers' wellbeing. Many helpful preparations made from plants and foods will be captured by this legislation, making it a steep regulatory compliance hurdle for persons and businesses who are not a sizeable manufacturer or pharmaceutical company, to be able to supply Natural Health Product ingredients (NHPi). (NHPi are currently used by approximately 50% of the population in products such as vitamins, dietary and other supplements). In addition, this proposed bill implicitly reaches into the practice of rongoā, traditional Chinese medicine, homeopathy and herbalistes, whose practitioners will find it difficult to comply with the new legislation given the wide number of ingredients used and the lack of resources available to have all ingredients approved.

The New Zealand Hemp Industries Association (NZHIA) is an industry body representing the farmers, entrepreneurs, and scientists who champion industrial hemp for its remarkable potential to provide nutritious food and health supplements, amongst many other industrial uses for the hemp plant. The Therapeutic Products Bill will not affect the legal status of cannabis, which unfortunately keeps the restrictive status quo in place. In fact, it represents a missed opportunity for cannabis-derived Natural Health Products (NHP) to be absent from the market authorisation mechanisms this bill aims to establish. Allowing regulatory compliance earns consumer confidence and bolsters growth expectations for the industry, which drives investment and innovation. On the other hand, CBD is currently in the Medicinal Cannabis framework and is a prescribed medicine, which restricts it more than other NHP, even though CBD and the rest of the non-psychoactive cannabinoids are widely available to consumers in markets overseas - from Thailand to Canada.



Once unleashed from regulatory inhibition, the industrial hemp industry will easily transition to a circular economy enabling Aotearoa to be prosperous, more resilient and have a cleaner environment.

Change is welcomed so long as the scope of market certification doesn't tie-up access to plant-based food as therapeutic products. These naturally occurring plants help people live better, healthier lives. An equitable industry that enables people to use reliable and safe health products from trusted sources is within our reach.

Thank you for your mahi ensuring this Bill proceeds as it is in the interests of all.

Concern	Solution	Outcome
<p>1. Cannabis-derived NHP ingredient(s) are subject to the strict Ministry of Health (MOH) industrial hemp licensing regime, making it less available to industry compared to less sustainable alternatives. This reduces the likelihood that industrial hemp can be grown and processed into NHPs, diminishing an industry that is estimated to be worth billions of dollars.</p>	<ul style="list-style-type: none"> Remove low THC industrial hemp (as defined by the 2006 industrial hemp regulations), from being a prohibited plant under MODA. Integrate the therapeutic benefits of industrial hemp derived nutrients, oils, and cannabinoids into the therapeutic products register. NHP with low THC industrial hemp derived NHPi can receive market authorisation. Higher THC levels may be regulated using novel legislation or be integrated into existing legislation such as the Psychoactive Substances Act 2013. Repurpose the MOH hemp licensing system: The Ministry of Primary Industries (or other relevant governing body) could regulate the agricultural production of industrial hemp, as permitted by the Misuse of Drugs (Industrial Hemp) Regulations 2006 Amendment in 2018. 	<ul style="list-style-type: none"> Hemp seeds, leaves, roots, and flowers (containing various ingredients that are rich in healthy properties) would be classified as NHP ingredients or food grade. This would encourage farmers to grow industrial hemp on a horticultural scale which would significantly reduce their overall carbon footprint. Boosted exports as kiwis in every corner of Aotearoa would have access to participate in the billion-dollar global hemp based health and wellness industry. Drug control established for THC that does not interfere with industrial hemp.
<p>2. Natural Health Products (NHP) require a 'market authorisation' of one of three classes: standard; provisional; and export. The regulatory compliance costs of this authorisation will add a barrier to participating in the NHP industry with consequences likely to include:</p> <ul style="list-style-type: none"> - reduced competition, which may reduce information available and increase prices for consumers. - Decrease the availability of products that contain NHP ingredients, and - a likely shift in agricultural production away from products that contain NHP ingredients. 	<ul style="list-style-type: none"> The NHP registration scheme needs to be voluntary, allowing for those that wish to export or make therapeutic claims to comply, but leaving unfettered access for those that want to make use of plant-based ingredients within New Zealand. The Regulator could undertake a generally regarded as safe (GRAS) review of NHPi that have known, traditional and safe use, and include them in the therapeutical products register, allowing these products to be publicly available. If NHP's or ingredients are making therapeutic claims they will need to have a market authorisation. Any products without market authorisation, cannot be called an NHP, and cannot have claims about therapeutic uses, apart from 'standard health benefit claims'. The "standard" authorisation needs to allow for 'generic' applications on behalf of industry representative bodies on behalf of their members for approval for a specific NHP or NHPi that the members of the industry body produce. The Therapeutic Products Bill should clarify how market authorisation applies to research and development, to encourage new product innovations to reach market. 	<ul style="list-style-type: none"> Regulatory requirements remain in place for businesses that wish to participate in the manufacture, sale, and promotion of NHPs for export and/or for maintaining consumer confidence in approved NHPs. GRAS exception allows for smaller companies to produce products without the costly 'market authorisation' requirement. This ensures that foods, herbs, spices, oils and plant matter containing an NHPi continue to be sold to the public without providing any therapeutic claims.

<p>3. Therapeutic Products Bill may criminalise people who practice rongoā and create traditional medicines containing NHP ingredients that are created for personal use and/or limited supply to the public. These natural plant materials have traditional and customary uses, which must be protected.</p>	<ul style="list-style-type: none"> • Allow exemptions to the Therapeutic Products Bill for the personal supply and/or local trade of rongoā and traditional medicines that contain NHP ingredient(s) and would otherwise require market authorisation. • Traditional medicines that do not have market authorisation can only make standard health benefit claims and can only be sold non-wholesale. Market authorisation can be sought in order to make therapeutic claims in marketing and to sell wholesale. 	<ul style="list-style-type: none"> • A deliberate exemption would allow practitioners in cottage industries to continue to serve personal and local needs, which may be more economical and improve health outcomes for themselves and their communities compared with relying on approved consumer product availability.
<p>4. The Therapeutic products register may steer customers towards established brands and products which may reduce competition by limiting the visibility of smaller companies' products.</p>	<ul style="list-style-type: none"> • The Therapeutic products register should be searchable by the NHPi within products in order to view approved products containing the NHPi • The register needs to provide information to consumers about the research and evidence supporting the health claims of products on the register. 	<ul style="list-style-type: none"> • Having a therapeutic products register that comprehensively catalogues the approvals, products, and is searchable by NHP ingredient(s) would be fair and accessible for all industry participants and build consumer confidence
<ul style="list-style-type: none"> • 5. The black market provides the majority of cannabis-based preparations, which excludes legitimate commercial interests. This impacts the production of quality and verifiable products, limiting consumers choices. 	<ul style="list-style-type: none"> • Products with naturally occurring CBD (and other cannabinoids) not making therapeutic claims should be allowed as food not restricted to prescription only medicine. • All product labels should include details of the cannabinoids in the product. Only authorised NHP or medicinal cannabis products can make therapeutic claims. 	<ul style="list-style-type: none"> • All naturally occurring cannabinoids are unrestricted and available as food, when permitted by the food code. • Products marketing therapeutic claims will still need to be registered as NHP or medicines, ensuring consumer confidence

We would like to present at the Select Committee stage as we note, currently there are no published rules and regulations accompanying the Therapeutic Products Bill.

We support the submission made by Natural Health Products NZ on the Bill.

Richard Barge,
richard@beok.co.nz
 Ph: 021 706 690

The NZHIA looks forward to ensuring this regime is workable:

- We support a regulatory framework for natural health products for export, that is workable and complies with the requirements of our export partners.
- We support a voluntary registration for those who wish to market and make claims that their products have therapeutic benefits in local markets.
- Access for naturally occurring foods, herbs, spice and plant material must be retained for all, allowing for less arduous compliance requirements for businesses, lower consumer costs, and increased industry innovation.
- We support, as a fundamental right, the access to herb, spices and plant material as food