# A background document regarding the draft Therapeutic Products Act 2022 - Consultation closes, 5 March 2023 @ NZHIA 22 February 2023

**Observations**

Natural Health Products for export need a regulatory scheme, as compliance with a suitable framework is needed for overseas jurisdictions to allow the import of our NHP's

Many helpful preparations made from plants and foods will be captured by this legislation, making it economically difficult for those who are not large manufacturers, pharmaceutical companies, pharmacies and doctors, to be able to remain supplying natural ingredients (which are currently used by approximately 50% of the population - vitamins, dietary supplements etc) These herbalist, Chinese Medical and Ayurvedic practitioners etc, will find it difficult to comply with the new legislation given the wide number of ingredients used and the lack of resources to have them all approved.

I have not gone into detail on the far-reaching implications of this Bill, for more information please check out the links below

The current TP bill is light on detail of how the proposed new regulator will administer the TP Act in 2026, we do not know what the licencing costs are going to be (including annual fees, manufacturing licence fees), how the application process to make medical claims will work and the cost and what natural products are to be effected.

A general requirement that most NHPs obtain a 'market authorisation' before being imported into, supplied in or exported from New Zealand, may have the unintended consequence of reducing the NHP's available and the additional compliance cost (even under a self-assessment/declaration pathway) will make them more expensive and reduce the amount of information provided by suppliers, thus reducing the information and data available to consumers to make informed decisions.

Hemp seed food products are available under the Food Code and arguably by the Dietary Supplements Act. The Medical Cannabis Scheme covers medicinal use of cannabis and CBD. However, hemp products made from industrial hemp, in the form of functional foods, dietary supplements, natural health products and nutraceuticals will not be covered, this will exclude us from a potential $1.5 Billion industry (link to Dr Marsh report)

On paper and in spirit this this legislation can enable the industry but given the wide range of therapeutic products potentially included, there is scope for the regulator to significantly curtail the availability of traditional used and proven natural products. While allowing many synthetic products to replace their natural alternatives as the pharmaceutical companies have the patents and intellectual property to manufacture, advertise and supply them direct to the public and via the medical profession.

**Problems for industrial hemp – as a Natural Health Product**

The main problem for iHemp is highlighted in page 4 of the "Explanatory Note" *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.*

The new act includes natural health products but does not affect Medicinal Cannabis or the Misuse Drugs Act and revokes the Dietary supplements Act. CBD is already in the Medicinal Cannabis framework and is a prescribed medicine within the current Medicines Act. We note work is being done to move this classification down to pharmacy only and then to "over the counter", at various doses and pack sizes. This is a slow incremental process, but will only cover the CBD cannabinoid.

**It would seem that under the Therapeutics Products Act, iHemp natural health products will not be included.** Clearly if we have iHemp removed as a prohibited plant, then it would not be controlled by Moda and may then be covered under the new TP Act

Currently everything between hemp seed food (Food Act) and medicinal cannabis (Medicines Cannabis Scheme and Medicines Act) is in a grey area. Hemp products such as a functional food, dietary supplements, natural health products and nutraceuticals are in limbo and the TP Act will not change this.

There seems to be no provision for the cannabinoids, terpenes and flavonoids that are naturally occurring in industrial hemp to be included as NHP.

- This is having a devasting effect on the emerging industry, significantly limiting our ability to supply a growing consumer demand in and outside New Zealand. Excluding us from a potential $1.5 billion industry (1) (1) Dr Nick Marsh's report
- We are unable to achieve whole plant utilisation, depriving the consumer from accessing the entourage effect of hemp products derived from naturally occurring cannabinoids, terpenes and flavonoids.

**Our feedback on consultation therefore has to focus on:**

- The missed opportunity to improve the health of our people, by bringing safe and affective NHP to NZ and overseas consumers, who are interested in accessing these products.
- The missed economic opportunity of marketing new brands and products, locally and internationally with the associated regional development implications coming from increased economic activity, in a sustainable and environmentally friendly way

The draft Bill was shared on 30 November and we need to decided whether we "object" to the legislation or are we going to make a "submission", during this short consultation period ended 15 February 2023.

Specifically

- Industrial hemp, should not be a prohibited plant and be removed from Moda
- This will allow our hemp products to be approved under the TP bill
- Regulation should apply for export business who need this registration process, or those businesses who find it useful to comply.
- GRAS, and traditional recognised benefits and claims should be acknowledged by the regulations and this information should be made publicly available and allowed to be used to market these ingredients/products.
- An option to opt out of the regulatory framework, should be available for R&D purposes, to encourage new product development and for those practitioners and suppliers who are too small to afford the costs of compliance, when using traditional products in historically safe and well established ways.

**Background**

The ministry of health should be taking a no harm approach, however this bill has the potential to reclassify many foods, herbs and spices into medicines. We have used these ingredients for millennia in cooking and herbal preparations. Many cultures and practices make use of natural products to heal and nurture, Chinese herbal medicines, ayurvedic approaches, homoeopathy etc are all under threat of being consumed by the TP bill and the cost of compliance at this high “medicine level” or the slightly lower threshold for “Natural Health Products” will result in many ingredients no longer being available, or to expensive to use. And will result in less information being available to consumers as the cost to register health claims will mean that suppliers will no longer provide the information, or have to pass the costs on to users.

The above situation does not suit an open and thriving market, as the natural products we have used for nutrition and as functional foods may not be available, leaving only synthetic products, many of which have been approved for use in New Zealand already, but lack the evidence of safety and efficacy and in some cases are banned by overseas jurisdictions, such as the FDA (USA) and EU…

This is not the same as natural products which have a long history of safe and effective use, which will be put beyond the reach of manufacturers and consumers, due to their reclassification as medicines and the associated compliance costs with registering them and providing the suitable evidence to support medical and health claims, which are common knowledge currently.

If we look back to 2017 when the control of NHP was last mooted, Labour provided a list of 300 common herbal ingredients which was provided by International Coalition of Medicines Regulatory Authorities (ICMRA) of which Medsafe is a member. ICMRA is a non governmental body, funded by industry that provides information to the worlds health ministries.

**Problems**

The regulator may not be as independent as defined in the bill, as they will naturally be inclined to support the medical fraternity, given their past performance and political links and funding streams.

NHP and Medicines, are all treated as therapeutic products, and we are concerned the thresholds for control of these different therapeutic products are not going to be appropriate?

There is a lack of a list of permitted NHP ingredients (to be developed in secondary legislation) and details of the licencing/approval fees and the associated costs of compliance means we are not well informed about the implications on Rongoā, functional food, dietary supplements, natural health products and nutraceuticals. This will have the unintended consequences of restricting the availability of products and increasing the costs and compliance for those that supply them which will put many smaller and traditional users out of the market, affecting consumer freedom of choice.

The regulations may meet the need of those exporting companies that require a regulatory framework that will allow their products to be exported into overseas jurisdictions, however the bill is very wide reaching and could capture many foods that naturally contain a range of compounds, which have beneficial health effects and force unnecessary regulation upon them, when they have been safely used for millennia.

The regulations should focus on the safety of unnatural synthetic products and provision should be made for the exemption of natural products that have a proven use, by various health approaches, including but not limited to Chinese herbal medicine and Ayurvedic traditions. The bill has a lack of detail about the use of “pre-authorised claims” and what health benefit claims they will cover.

A general requirement that most NHPs obtain a ‘market authorisation’ before being imported into, supplied in or exported from New Zealand, may have the unintended consequence of reducing the NHP’s available and the additional compliance cost (even under a self-assessment/declaration pathway) will make them more expensive and reduce the amount of information provided by suppliers, thus reducing the information and data available to consumers to make informed decisions.

Additional clauses to be aware of:

See or extracts from the Act – pdf here.

S 26 – Medical Devices – including software which could include apps that are considered to provide a therapeutic benefit

S 377 Future rules don’t exist, so don’t know how it will affect foods, this maybe covered by S17, intended for use as TP vs mainly used as a food … this may protect your access to herbs and spices used as food…. but could include things like tea?

S252 fines and potential imprisonment, are excessive if an offence is committed by traditional practitioners, who lack the big budgets of major NHP and Pharmaceutica companies.

Links

Medicines control – links

- Act https://www.legislation.govt.nz/bill/government/2022/0204/latest/DLM7482809.html?path=bill%2fgovernment%2f2022%2f0204%2flatest&col=bill&fid=DLM7482809&search=sw_096be8ed81cd49a1_1975_25_se&p=1&sr=2
- Press release https://www.beehive.govt.nz/release/therapeutic-products-bill-introduced
- Consultation https://www.parliament.nz/en/pb/sc/make-a-submission/document/53SCHE_SCF_BILL_130084/therapeutic-products-bill