GE Free New Zealand

In Food And Environment Inc.

PO Box 13402, Wellington, NZ

3 March 2023

RE Therapeutic Products Bill

Tēnā koe Minister Little,
We would like to be heard in relation to this Bill,

We support and endorse the submission from Physicians and Scientists for Responsible Genetics (PSRG).

We oppose the Therapeutics Products Bill (TPB) in its current form when relating to Natural Health Products and urge that it is amended to address our concerns. We support the Bill in requiring the regulation relating to the safety of synthetic, biologics and chemical medicines and devices.

The Bill imposes excessive regulations on natural products with a long history of safe use. Consumer protection under the Fair-Trading Act and reporting to Manatū Hauora is better and more proportional approach.

Natural medicines and foods have been shown to be a beneficial, safe, effective and affordable natural health option, relied upon by thousands of New Zealanders. The choice of people to use the type of health care is an important human right.

Natural products have strict pharmacy preparation rules and source materials come from the plant, animal and mineral kingdoms. Further, Natural Health Products (NHP) on sale are required to be manufactured under the guidelines for Good Management Practice (GMP) and certified by Medsafe

The Bill is an omnibus amalgamation of the Medicines Act and Dietary Supplements Act.
It, however, is of concern that this Bill has the potential to severely undermine the ability of Complementary Alternative Medicine (CAM) therapists /practitioners to carry out their professional duties within their scope of practice as specified by the purpose in section 3 (2) (b) of the Health Practitioners Competence Assurance Act 2003.

The Bill has the potential to restrict and limit remedies and NHPs for their patients. Rongoā Māori (Māori traditional healing) practitioners that use Rongoā rākau, Te reo Māori, and mātauranga Māori (Māori traditional knowledge) must not be unfairly burdened.

The permits and licenses will place a punitive cost burden on people accessing Natural Health Products (NHP) indicated for the patients as was defined under section 32 of the Medicines Act 1981. This will again affect the Complementary Alternative Medicine (CAM) therapist's livelihood,

employment and the right to practice within their scope and skills. It will add unnecessary cost and licence conditions that will be a barrier to ensuring that they are able to carry out their professional duties.
The Bill fails to achieve or implement strong accountability mechanisms. It does not show transparency or escape from conflicts of interest or capture through industry-funded pressure to decide what is to be regulated. It is only at the whim of the Regulator who will be able to decide whether the products they use are available to the patient.

There has been a negligible level of risk associated with Natural Health products. Most cases are related to improper off label taking of the medicines.

Given specifics have not yet been provided around who will be regulating, and how, and what rules may apply we request that the Bill not proceed and that more progress and disclosure is made around this area before the Bill progresses further.

Below are the clauses we would like to have considered –

4(c) **- Guiding Principles**

We do not agree with the objective of aligning Aotearoa New Zealand's natural healthcare with standards and regulations set overseas and subject to influence by industry players.[1]

International countries have sovereign rights and are governed under these laws. Aotearoa New Zealand has a unique multi-cultural responsibility to protect New Zealanders, based on indigenous Rongoā and existing natural herbal knowledge.

The report on Traditional Māori Healing and Wellness Outcomes[2] supports the findings of the Waitangi Tribunal Wai262 claim and recognises that Rongoā Māori (Māori traditional healing) that uses Rongoā rākau, te reo Māori, and mātauranga Māori (Māori traditional knowledge) is a taonga. This should be clearly identified in the Bill by placing a sub clause on consultation with Māori advisory bodies Te Paepae Matua mō te Rongoā and Rongoā practitioners.

15 (h) *supporting or sustaining human life:*
(i) providing vitamin, mineral, or other human nutritional supplementation.
(j) maintaining or promoting human health:

Clause 15 is of great concern; a breach of human rights and sub points (h-j) should be removed. Air, water, spices, herbs and dairy products food have the potential to be considered as Therapeutics if they are promoted as part of a healthy lifestyle. It is unacceptable that healthy eating using Aurevedic and dietary recommendations could be regulated under therapeutic purpose. The extraordinary breadth of capture will ensure that the cost of maintaining a healthy lifestyle, minimising pollution products is out of reach for many.

[1] https://www.cambridge.org/core/journals/european-journal-of-risk-regulation/article/abs/independent-scientific-advice-comparing-policies-on-conflicts-of-interest-in-the-eu-and-the-us/B50C2902282E129E759BF2A6A000B1E2

[2] https://researchcommons.waikato.ac.nz/bitstream/handle/10289/9479/Nga%20Tohu%20o%20te%20Ora%20Research%20Report%20June%202012_FINAL%20pdf.pdf?sequence=2&isAllowed=y

16 (1) (a) *a product that is intended for use in, on, or in relation to humans for a therapeutic purpose:*

It is important to be able to differentiate between lifestyle choice of eating food and plants for maintain health and taking synthetically patented medicine whose active ingredient has been manufactured chemically or genetically engineered. *See L-tryptophan.

As Natural Health Practitioners many of the natural health products that are prescribed for people have been prepared and given in their whole natural form. There are no active ingredients isolated. Medicinal herbs have been widely used for thousands of years to promote health and treat diseases. The active constituents in these plants are rightly balanced within the plants, and any possible untoward or toxic effects of one component would be neutralized by the presence of complementary constituents.

Edwards *et al* (2015) outline the range of proven history of safe medicinal use in food and plants[3]. For example –Aspirin (acetyl salicylic acid) synthetic active ingredient in the pharmaceutical drug is derived from Willow bark (Salix alba) or Meadowsweet (*Filipendula*)[4].

18 *Naturally occurring thing may be product*

It is recognised that CAM therapies and Rongoā Māori practitioners use products that have been processed by decoction, distillation, infusion (tisanes) and salves, which should also be exempted (see below) should this bill proceed.

19(2) (b) *in all the circumstances it is appropriate for the product not to be regulated under this Act.*

The use of natural herbs, spices and foods for therapeutic use in over-the-counter (OTC) medicines or prescribed by a complimentary health professional for use everyday life must be preserved.

We ask that all herbal products that are made with recognised MPI good manufacturing processes using pure ingredients and products that have not been subject to engineered biologic compounds are exempt from regulation by the Regulator/Minister.

This is because the likely risks associated with the product are sufficiently small and have been identified through historical use that regulation is not necessary.

30 (1) *NHP ingredient, recognised NHP ingredient, and additive or formulation aid*

Natural Health Products should not be captured under the Therapeutic Products Bill, unless they are synthetic biologics. The NHP sections are contradictory and open to abuse by the regulator. An OIA published on The Ministry of Health website referring to adverse reactions from natural health products provided only one example, *Arthrem*[5], was recorded as removed from sale due to

[3] Phytopharmacy: An Evidence-Based Guide to Herbal Medical Products https://onlinelibrary.wiley.com/doi/book/10.1002/9781118543436

[4] https://www.healthyhildegard.com/meadowsweet-herb/

[5] https://nzphvc.otago.ac.nz/Arthrem.pdf

adverse effects in NZ. The statistics reported came from the Australian Therapeutic Goods Administration (TGA)[6] reporting

> *"To November 2022, the TGA has received over 8000 adverse event (AE) reports associated with complementary medicines (CM) dating back to 1994. Of these, approximately:*
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> - *28% relate to vitamins, minerals or vitamin/mineral combination products*
> - *24% relate to multi-ingredient products that include herbal ingredient(s)*
> - *19% relate to herbal medicines*
> - *9% relate to other multi-ingredient products with no herbal ingredients*
> - *2% relate to Traditional Chinese Medicines (TCMs) or Ayurvedic medicines.*

The average population of Australia has increased from 17+ million 1994 to 25.6 million in 2022. Eight thousand people or 296 per year or 1/100,000 ($4e^{-}8$) people who reported adverse events for natural Health Products, no deaths were reported. For comparison, the TGA Database of Adverse Event Notifications (DAEN)[7] reported 460,768 cases or 17065 per year, and 10,978 deaths or 406 per year from all pharmacy drugs. Over the 27 years for Paracetamol containing pharmaceuticals, there were 3,912 reported cases and 254 deaths.

This shows that NHPs relating to Complimentary Medicines do not pose a threat to health and should not be captured in the Therapeutic Products Bill, unless they are products made from engineered biologics or a multi complex of pharmaceutical and herbal extracts.

31 *Low concentration NHPs and Biologic components*

Clause 31 defines low concentration NHPs as being not more than 20 parts per million (or any lower concentration set out in the rules). Lower concentrations can be zero, thereby including all homeopathic remedies.

Clause 32 defines biological components used in therapeutic products. Biological substances used to produce natural health products are not present in Anthroposophical and Homeopathic remedies, therefore they would not and should not be classified as Biologics. Subsections (2a) and (2b) appear to provide for this fact. If not, it is essential that the zero-risk nature of the relevant homeopathic remedies is recognised and acknowledged within the Act and the regulations.

32 ***(2) (c)*** *material that is derived from anything in subsection (2)(a) or (b) (whether modified, engineered, or otherwise)*

(3) *However, something that is the product of something referred to in subsection (2)(a) or (b) is not a biologic component.*

The danger of genetically engineered biologics has been proven in the 1989 disaster with L-Tryptophan (L-Tryp), manufactured by Showa Denko. The Showa Denko L-Tryp was produced by fermentation using a genetically engineered strain of *Bacillus amyloliquefaciens*. (Klarskov K. *et al*, 2018).[8] It was sold to the market mostly to body builders and athletes. Before being recalled in

[6] https://www.health.govt.nz/system/files/documents/information-release/h2022018873_response.pdf

[7] https://daen.tga.gov.au/medicines-search/

[8] Klarskov, K. *et al.* (2018) "Structure determination of disease associated peak AAA from L -tryptophan implicated in the eosinophilia-myalgia syndrome," *Toxicology Letters*, 282, pp. 71–80. Available at: https://doi.org/10.1016/j.toxlet.2017.10.012.

1990, the genetically engineered biologic caused 136 deaths and 1500 people afflicted with a new illness Eosinophilia-Myalgia Syndrome (EMS). EMS is a chronic, multi- systemic disorder characterized by peripheral eosinophilia and sub- acute onset myalgia.[9]

Mayeno and Gleitch (1994) found that

> *"All the findings indicate that the illness **[EMS](our addition)** was probably triggered by an impurity formed when the manufacturing conditions were modified. This outbreak highlights the need for close monitoring of the chemical purity of biotechnology-derived products, and for rigorous testing of such products following any significant changes to the manufacturing process."*[10]

This clause **32** implies that the Regulator would be able to exempt genetically engineered biologics (precision fermentation) without any history of safety and would to be falsely promoted as equivalent to natural products and escape regulation. This is both deceptive to consumers seeking authentic products derived from nature, not synthetic engineered copies and opens the public up to unknown and life-threatening illnesses.

69 – *Controlled activity prohibited unless allowed by licence*

This will seriously impact CAM therapists ability to practice and continue a viable business. With the low-risk profile of NHPs that do not contain any material made from engineered biologics, a licence should not be required. Unless excluded from the Bill this wrongly and unreasonably imposes costs and restricts access for people.

112 (4) (*a) Personalised NHPs*

Clause 112 allows Natural Health Practitioners to supply NHPs to their clients and to manufacture personalised NHPs for a client. As a part of their practice, natural health practitioners sometimes prescribe and dispense natural products, overseas if the client is internationally based. This clause limits practitioners' ability to prescribe for patients overseas, and in some cases, import natural health products for use in New Zealand. There is a need to maintain the flexibility to manufacture personalised remedies for their individual clients. Given New Zealand based and registered NHPs often have clients in other countries and carry out consultations, we recommend that 112 (4) (a) is removed entirely to allow practitioners to continue to serve their international clients.

126 *Content of market authorisation*
Section (1) (h) it is important for all over-the-counter (OTC) NHPs sold to be appropriately labelled with a description of their use. This allows for the public to have information on the product ensuring safety of the product.

330 *Therapeutic Products Regulator*

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[9] Varga J, Jimenez SA, Uitto J. L-tryptophan and the eosinophilia-myalgia syndrome: current understanding of the etiology and pathogenesis. *J Invest Dermatol*. 1993 Jan;100(1):97S-105S. doi: 10.1111/1523-1747.ep12356368. PMID: 8423409.

[10] Mayeno, A.N. and Gleich, G.J. (1994) "Eosinophilia-myalgia syndrome and tryptophan production: A cautionary tale," *Trends in Biotechnology*, 12(9), pp. 346–352. https://doi.org/10.1016/01677799(94)90035-3.

We would like to see two regulators be appointed – one for Medicine and Medical Devices and one for Natural Health Products. Regulating both under the same regime is completely inappropriate given the lower risk for natural health products.

The Natural Health Products regulator must be New Zealand based, have a thorough understanding of natural health products, be qualified in this area and have extensive clinical practice. Experience in the different natural health modalities should include, but not limited to, Homeopathy, Naturopathy, Nutrition, Rongoā Māori (Māori traditional healing) that uses Rongoā rākau, te reo Māori, and mātauranga Māori (Māori traditional knowledge) and Traditional Chinese Medicine.

332. *Functions of Regulator*: *Engagement with other entities*

(f) *to engage and co-operate with relevant government, local government, and non-government entities, including by sharing information under* ***section 343****:*

Natural Health practitioners should be consulted with meaningfully when there is any engagement over regulation of a Natural Health Product. We ask that subsection (1) (f) added wording "Complimentary Alternative Health therapists, Rongoā practitioners and public."

In summary

- The Bill should not proceed and represents an unreasonable overreach
- Bio-engineered Biologics for supplements should be regulated.
- Natural Health Products have a safe history of use and should be exempt from The Therapeutic Products Bill
- Rongoā Māori should be exempt from the Therapeutic Products Bill and
- Complimentary Medicine practitioners and Rongoā Māori practitioners are not subject to licence fees.
- Engagement with Complimentary Alternative Health therapists, Rongoā practitioners and public when NHPs are being considered.

Ngā mihi,
Jon Muller
Secretary GE Free NZ