5 March 2023

Chairperson
Health Select Committee
Freepost Parliament
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Parliament Buildings
WELLINGTON 6160

Email: Therapeutic Products Bill - New Zealand Parliament (www.parliament.nz)
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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the *Therapeutic Products Bill.*

Yours sincerely

Raewyn Bleakley
Chief Executive

Therapeutic Products Bill

Submission by the New Zealand Food & Grocery Council

5 March 2023

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council ("NZFGC") welcomes the opportunity to comment on the *Therapeutic Products Bill* ("**the Bill**").

2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over $40 billion in the New Zealand domestic retail food, beverage and grocery products market, and over $34 billion in export revenue from exports to 195 countries – representing 65% of total good and services exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 45% of total manufacturing income. Our members directly or indirectly employ more than 493,000 people – one in five of the workforce.

OVERARCHING COMMENTS

3. In relation to natural health products ("**NHP**"), their current coverage by the Dietary Supplements Regulations 1985 under the Food Act 2014 is no longer fit-for-purpose and we are pleased to see this being addressed in the Bill. However, many of the provisions in the Bill directed at NHPs are not clear or duplicative and give us no comfort that the critical interface between food and NHPs is workable. The decisions on NHPs according to the Bill are very much up to Ministers, regulations and presumably officials' advice. We note it is important that definitions regarding NHPs and NHP ingredients are clear and easy to understand. There is otherwise a risk of over-regulation of ingredient manufacturers and a potential to draw in other foods as NHPs when this was not the intention.

4. Besides there needing to be a clear distinction between medicines, natural health products and food, we firmly believe this needs to be risk proportionate and appropriately regulated at reasonable cost. On this we are aligned with the concerns of the Natural Health Products New Zealand submission. We are concerned at the prospect of, on the one hand, a heavy-handed regulatory approach, and on the other, of provisions that would be less than is required for foods in the general food supply domestically and internationally. Ideally, substances/foods for general population supply should reflect lesser regulation than NHPs and medicines. We see the risk delineation between medicines and NHPs but not between NHPs and any other products including food.

5. We are particularly concerned to ensure that supplemented foods and special purpose foods as defined and regulated under the Australia New Zealand Food Standards Code are not covered by the Bill in any intended or unintended way.

6. Supply and exports of NHP are of concern. Market authorisations, licences and permits appear extensive and we would hope that export arrangements are much clearer going forward especially in relation to certification, content and replacement in the event of loss.

7. Finally, we believe provisions relating to advertising may extend the reach of the regulator off-shore and into other national or international territory. This raises the issue relevant to NHPs: the reach of New Zealand legislation into the advertising laws of another country.

8. NZFGC is strongly opposed to any intention for cosmetics to come within the scope of the Therapeutic Products Bill and believe the most cost-effective measures are already in place in the Cosmetic Products Group Standard 2020 HSR002552 (the Group Standard)[1] made under the *Hazardous Substances and New Organisms Act 1996* ("**HSNO Act**)". The

[1] Cosmetic-Products-Group-Standard-2020-HSR002552.pdf (epa.govt.nz)

Group Standard covers all forms of cosmetics and the safety matters including carcinogenicity and environmental impacts.

9. The Group Standard has regard to international standards and recognises the current labelling requirements for cosmetic products of several of New Zealand's trading nations. It is comprehensive, familiar to industry and is highly regarded as an effective and efficient legal instrument that has stood the test of time for the products it covers.

10. We also strongly oppose sunscreen products being included in the scope of the Bill and strongly support them remaining within the scope of the *New Zealand Sunscreen (Product Safety Standard) Act 2022* ("**the Sunscreen Act**") for compliance. There has been a substantial government and industry cost to the development of the Sunscreen Act just months ago and repeal now wastes that effort. The Group Standard continues to cover the safety, labelling and ingredients of sunscreens. For the avoidance of doubt, such products should be explicitly excluded in the Bill.

11. NZFGC is very concerned that a vast array of products sold generally to the public in supermarkets and pharmacies that are to be considered medical devices. While the explanatory note to the Bill states that there are many such devices for which there will likely be no supply or use restrictions (such as bandages intended for household use) we are concerned at the cost of determinations and the evaluation of risk for determining 'no supply or use restrictions' when that is currently the case.

12. As with the products described above, the uncertainty and over-regulation this suggests is disturbing. Since many of the products are imported, we are concerned that any added cost whether in records or financial, will be a deterrent to supplying New Zealand and potentially create shortages in an area that is low risk.

DETAILED COMMENTS

Natural Health Products

1. Natural health products are currently regulated by the Dietary Supplements Regulations 1985 under the Food Act 2014. We agree that this regulatory arrangement is not fit-for-purpose in terms of currency, safety, quality, marketing or labelling. However, the provisions in the Bill are not clear, duplicative and give us no comfort that the critical interface between food and natural health product is workable. The decisions on NHPs according to the Bill are very much up to Ministers, regulations and presumably officials' advice. The definitions are of concern in this area.

2. Section 29 NHP, states that an NHP is a therapeutic product if section 16 says so but section 16 Therapeutic product, refers in turn to section 19(1) which says that the regulations can determine what is or is not a therapeutic product and therefore a NHP. This is of no help. It could be helpful from a user perspective if section 19(2)(a)(i) (which refers to a product not being a section 16(3) product if "the product is adequately regulated by other means") was to include the example of the *Food Act 2014.* Without this, it is guesswork from the outset.

3. Section 29(2)(b)(i) states that a therapeutic product is an NHP if it consists of one or more NHP ingredients. This would make any vitamin, mineral, amino acid or microorganism an NHP when they are also treated as part of the food supply. This raises concerns around whether NHP ingredient manufacturers will be required to run dual compliance regimes. That is, ingredient manufacturers would be excessively regulated by the need for dual compliance regimes under the Food Act and Therapeutic Products Bill. If this is the outcome, it does not fit within the principles of a risk proportionate regulatory regime.

4. Besides there needing to be a clear distinction between medicines, natural health products and food, we firmly believe this needs to be risk proportionate and appropriately regulated at reasonable cost. We are concerned at the prospect of, on the one hand, a heavy-handed regulatory approach, and on the other, of provisions that would be less than is required for foods in the general food supply. Ideally, substances/foods for general population supply should reflect lesser regulation than NHPs and medicines. We see the risk delineation between medicines and NHPs but not between NHPs and any other products such as food.

13. We are particularly concerned to ensure that supplemented foods and special purpose foods as defined and regulated under the Australia New Zealand Food Standards Code are not covered by the Bill in any intended or unintended way.

5. Section 30 NHP ingredient, recognised NHP ingredient, and additive or formulation aid, is excessively detailed and includes reference to many food substances. For example, other than some novel foods, section 30(1)(a) appears to cover all food ("*plant, plant material, an alga, a fungus or non-human animal material*"). At section 30(1)(b)-(g), all substances used in food are listed ("*vitamin or provitamin including salts and other compounds*", "*a mineral or mineral compound*", "*an amin acid*", "*a microorganism*" and "*a synthetic equivalent*" of any of these). In sections 30(1)(b) and 30(3)(a) and (b) another raft of food substances are covered ("*preservative, antioxidant, colouring, flavouring, or sweetener*" as well as substances used as carriers).

6. In terms of cost for NHPs, we are very concerned. An example of this is in section 48 Manufacture of NHP which is a controlled activity requiring a licence. Section 48(c)(i) and (ii) extend the reach of 'manufacture' to 'procure' (the example of human blood is no comfort to the usual meanings related to purchase, produce or obtain) and to 'prepare' (by almost any means). The result is that a licence will be required for activities that have generally been left to the manufacturer to self-manage as commercial arrangements adding cost for no tangible benefit.

7. Supply and exports are of concern. Section 55 Supply, in section 55(1)(a) refers to supply to another person in New Zealand. There is no connect with section 59 Export standards which relate to supplying another person not in New Zealand or to section 67 Market authorisation required to import, supply or export. Clearly there is an intent to regulate import and export supplies as well as the New Zealand domestic supply. Clarity at early occurrence of 'supply' in section 55 would be helpful and connect with the phrase used elsewhere in the Bill 'import, supply and export'.

8. In relation to section 68 Sponsor's consent required to import product with NZ authorisation, it would be helpful to have further detail about this requirement and what it would mean in practice.

9. Part 4 Market authorisations for medicines, medical devices and NHPs and Part 5 Licences and permits are extensive (sections 117-186) and these are problematic not just in the resource cost implications. Of key concern is that an export authorisation (section 117(1)(c)) appears only required if a standard authorisation for New Zealand supply is not allowed. Some markets require additional certification even if a product can be sold in New Zealand. If such certification is not available, export orders may be lost. This issue is repeated in relation to permits in section 160(1)(b) which refers to a permit being granted to "*export a therapeutic product even though it does not have a market authorisation*".

10. Another concern is that section 124 Criteria for market authorisations of NHP, in section 124(1)(c) requires that "*the NHP will meet the product standards that apply to it*". This

should read ‘any relevant standards that apply to it' since there may be NHPs that do not have standards applying to them. Alternatively, and for consistency, the wording used in section 124(1)(f) could be used “*meet any export standards that apply to it*”.

11. In relation to section 126 Content of market authorisations, section 126(1)(b) requires a description of the product. A provision about commercial-in-confidence information is required for this if it goes beyond the label description.

12. There are provisions for variations, suspensions, cancellations or transfers but no provision or reference to when a permit might be ‘lost’ or mislaid and reissue is required. This is important where paper documentation is still required in export markets.

13. Section 194 Advertising appears to extend the reach of the regulator off-shore and into other national or international territory. Section 194(1)(a)(ii) states that an advertisement for a therapeutic product must not be distributed outside New Zealand unless it has a market authorisation. This raises two issues relevant to NHPs: 1) New Zealand legislation cannot reach into the advertising laws of another country that may allow advertisements not allowed in New Zealand and 2) not all NHPs will have a market authorisation for New Zealand. They may be prepared to overseas market requirements. We note the penalties for this are significant (section 253) highlighting the importance of removing the section.

Potential duplication with Cosmetic Products Group Standard 2020

14. The Cosmetic Products Group Standard 2020 HSR002552 (the Group Standard)[2] is made under the *Hazardous Substances and New Organisms Act 1996* (“**HSNO Act**)”. The scope of the Group Standard is stated in section 4(2) of the HSNO Act as:

    “*This Group Standard applies to any substance imported or manufactured for use as a cosmetic product, where that cosmetic product classifies as hazardous according to the hazard classification criteria as set out in the Hazardous Substances (Hazard Classification) Notice 2020*”.

15. It covers all forms of cosmetics including aerosols and solid pack and the safety matters include oral, dermal, inhalation and specific target organ toxicity, skin corrosion, irritation and sensitisation, eye damage and irritation, germ cell mutagenicity and carcinogenicity and environmental impacts.

16. The Group Standard contains a comprehensive definition of cosmetic product (Attachment A). It has regard to the International Fragrance Association, International Nomenclature Cosmetic Ingredient names and recognises the current labelling requirements for cosmetic products of Australia, USA, Canada and the European Union. It covers packaging, storage and disposal.

17. The Group Standard is comprehensive, familiar to industry, highly regarded as an effective and efficient legal instrument that has stood the test of time for the products it covers.

18. NZFGC strongly opposes any intention for cosmetics to come within the scope of the Therapeutic Products Bill.

Sunscreen legislation

19. The Sunscreen Act came into force in September 2022. The Bill foreshadows the repeal of the Sunscreen Act after just a few months operation (Clause 383 Repeals and revocations identifies the repeal in clause 383(1)).

[2] Cosmetic-Products-Group-Standard-2020-HSR002552.pdf (epa.govt.nz)

20. The Sunscreen Act mandates the joint Australian/New Zealand Standard AS/NZS 2604 for compliance. Sunscreens are also required to meet the provisions of the Cosmetic Products Group Standard for safety, labelling and ingredient restrictions and requirements. Cosmetics New Zealand and NZFGC participated, through Standards New Zealand, in the development of AS/NZS 2604. It reflects current best practice internationally and operates across both Australia and New Zealand in application for local and imported products. The Bill does not reference AS/NZS 2604.

21. In our view, adding or replacing the current arrangements with capture under the Bill will add cost for no benefit. In fact, it will have a negative impact for consumers by adding costs to a product that both countries consider essential for public health and safety year round. Additional costs in the current environment of cost-of-living increases will be a major deterrent on the use of sunscreens going forward.

22. NZFGC is strongly opposed to the prospect of sunscreen products being included in the scope of the Bill and strongly supports them remaining within the scope of the Sunscreen Act for compliance and the Product Standard for safety, labelling and ingredients. For the avoidance of doubt, such products should be explicitly excluded in the Bill.

Medical devices, over regulation and band aids etc

23. NZFGC is very concerned that a vast array of products sold generally to the public in supermarkets and pharmacies that are to be considered medical devices as reflected in the description in the explanatory notes:

    "*A therapeutic product is a medical device if it achieves its principal intended action by means other than pharmacological, immunological, metabolic, or genetic means (see clause 24). Any therapeutic product that is not a medicine, API* [active pharmaceutical ingredient]*, or NHP* [natural health products] *is a medical device. This includes a vast array of products from tongue depressors and bandages to implantable devices (such as pacemakers), diagnostic software, and robotic surgery machines*".

24. We note that the explanatory notes also state that:

    "*Because of the range of different medical devices, the nature of the restrictions will vary considerably. There are many for which there will likely be no supply or use restrictions (such as bandages intended for household use). There are others for which there will be significant restrictions (such as implantable devices or robotic surgery machines).*"

25. While the first principle set out at the start of the Bill (Clause 4(a)) states that:

    "*the likely benefits of therapeutic products should outweigh the likely risks associated with them, and their regulation should be proportionate to those benefits and risks*",

    this gives us no comfort in terms of the cost applied for evaluating risk or determining 'no supply or use restrictions' when that is currently the case. We are concerned this could attract an annual fee to maintain status for example.

26. As with the products described above, the uncertainty and over-regulation this suggests is very disturbing. We consider existing arrangements to be more than adequate especially since many of the products are imported. We are concerned that any added cost whether in records or financial, will be a deterrent to supplying New Zealand and potentially create shortages in an area that is low risk.

Attachment A

Definition of ‘cosmetic product’ in the Cosmetic Products Group Standard 2020

> “**cosmetic product** means any product or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition”.