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Committee Secretariat
Health Select Committee
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Via email: health@parliament.govt.nz

Re: Therapeutic Products Bill, No. 204-1

I am writing to express ExportNZ's support for Natural Health Products New Zealand (NHPNZ) and the Medical Technology Association's (MTA) submission on the Therapeutic Products Bill. The bill will provide much-needed regulation for the industry, which will benefit both consumers and exporters. The bill will provide both domestic and offshore consumers with assurance that the products being sold meet a high standard and are safe and effective. However it is important that regulation is proportionate to the benefits and risks.

New Zealand's natural health products industry has grown 64% in the last 5 years and now contributes more than $2.3 billion to New Zealand's economy per annum. Goods exports are worth $642 million per annum. However, potential for even greater growth is currently being hampered by internal barriers to trade because products must comply with NZ domestic regulations even when they are intended for export only and must comply with importing country's regulations that are different from ours. Our largest trading partners, including Australia, China, the EU and the UK have comprehensive regulations for natural health products. Furthermore, China and Canada are strengthening their schemes to improve product quality standards and improve the standard of information available to consumers. For New Zealand to compete on a global stage, a fit-for-purpose regulatory system that meets the requirements of our trading partners is vital to increase demand and open new markets for our exporters.

ExportNZ supports the Bill in principle but would like to highlight several amendments made to ensure that the regulatory burden, and additional costs associated do not have unintended consequences. It is important for a regulatory body to strike a balance between ensuring patient safety and promoting innovation and access to medical devices. As outlined in the MTA's submission:

> *"The Bill does not only seek to impose a disproportionate level of regulation onto the supply of medical devices within New Zealand: it also introduces a requirement for the Regulator to approve the export of any medical device. This would make New Zealand unique among the countries with which we trade and threaten a developing export industry worth some $760 million per year that various governments have previously championed and encouraged."*

The Bill's current state implies that exporters will need to comply with two sets of requirements instead of just one required by the export market. ExportNZ recommends that market authorisation should not be required for exported therapeutic products if they satisfy all the regulations set by the regulatory body of the receiving market.

ExportNZ also echoes the concerns outlined in both the NHPNZ and the MTA's submission on the ability of a regulator to be set up that has the resources to actively regulate the MoH estimate of 20,000 natural health products and approximately 250,000 medical devices that are currently in circulation. ExportNZ supports the MTA's recommendation:

> *"All medical devices notified to the WAND database be granted market approval, thereby eliminating the reassessment of some 250,000 devices already used safely and effectively in NZ. (This would not prevent the Regulator from auditing particular devices or categories if it chose to do so.)"*

To avoid any negative impacts on consumer choice, exports, sector innovation, and economic growth, realistic timeframes must be established in the transitional requirements to allow the regulator and industry to smoothly transition into the scheme.

Aligning domestic regulation with international trading partners will support the government agenda to transform New Zealand's economy from volume to value in this sector. A fit-for-purpose regulatory system will enhance the reputation of New Zealand as a source of high-quality therapeutic health products. However, the bill in its current form risks stifling innovation, interrupting the supply of products, and increasing the cost for consumers. It is important that regulation does not restrict economic growth and innovation without increasing public health outcomes.

Yours Sincerely,

Josie Hehir
Policy Advisor
ExportNZ