

Natural and Traditional Health Products Industry

Executive Summary of the Proposal for the Regulation of Natural and Traditional Health Products for Manufacturers, Importers, Exporters and Distributors

The New Zealand Natural and Traditional Health Products Industry is a NZ\$650 million sector with approximately \$300 million wholesale generated in domestic sales and \$350 million in export sales.

Current legislation is failing to deliver a regulatory framework that can grow the Natural and Traditional Health Products (NaTHP) industry and provide improved health outcomes.

NaTHP are not foods or medicines in the traditional sense of those terms. The industry does not accept either the Dietary Supplements Regulations 1985, (under the Food Act 1981) or the Medicines Act 1981 as appropriate models for the regulation of NZ manufactured, exported or imported natural health products.

The following NaTHP industry, practitioner and consumer representative organisations have consulted widely and have agreed to the core principles of a proposal for New Zealand Regulation of NaTHP:

NZ Health Trust – An independent, consumer focused charitable trust acting to educate New Zealanders to make informed decisions about their health & wellbeing and to ensure natural health products & services are not limited in range, are reasonably priced and that consumer information about them is freely available.

Natural Products New Zealand – A national industry organisation representing NZ companies in the natural products, functional foods, complementary medicines, cosmeceuticals and nutraceuticals industry that manufacture and market ingredients and finished products for the NZ and international markets.

Natural Health Alliance – A Natural Health Industry body that supports health legislation that is risk appropriate, encourages innovation and ensures freedom of choice for consumers.

Canterbury Nelson Nutraceuticals – New Zealand's largest regional Natural Health Products Cluster focused on fostering growth, exports and collaboration with & between our members in the nutraceutical, functional food, cosmeceutical & natural health product industries.

The intention of the proposed regulatory framework is to establish in New Zealand a responsive, risk proportionate, robust and sustainable regulatory environment to provide quality natural health products, whilst acknowledging that this class of products has a generally low risk profile.

A detailed proposal is available. The following are the fundamental points agreed upon for the development of a New Zealand regulatory framework for NaTHP:

Health Select Committee recommendations

- The Health Select Committee recommendations formed an important part of the proposal, reflecting many of the concerns of various stakeholders as expressed in submissions to the Health Select Committee inquiries/hearings into the Joint Trans-Tasman Therapeutic Goods Agency/ANZTPA.

Separate Regulator for NaTHP

- NaTHP are legislated and regulated as a separate class of products
- The business unit must be an independent regulator (separate from foods and medicines), dealing only with regulation of NaTHP and interface issues
- Internationally credible independent regulator with a high degree of autonomy
- Accountable to the public interest and providing freedom of choice

Compliance Costs and Funding

- A government/industry co-regulatory partnership will fund the stand-alone business unit
- Cost of regulation is to be proportionate to established risk and split between the government and industry with industry's share being no more than 50% of the cost of co-regulation
- To be overseen by a governing body comprising of both government and industry representatives

Risk Proportionate Risk Management Programme or Good Manufacturing Practice

- All products to be manufactured and distributed under a described Risk Management Programme (RMP) or recognised Code of Good Manufacturing Practice (GMP), proportionate to safety risk profile
- All businesses, ingredients and products are to be notified to the regulator via a simple online Risk Management System (RMS)

Product Claims/ Levels of Evidence/ Ingredients

- Science-supported and traditional claims allowed for NaTHP
- Internationally respected Pharmacopoeia and similar documents will be recognised for claims purposes
- Claims are not compulsory however any claims must be supported by a prescribed standard of evidence held for the claim and comply with the Fair Trading Act 1986
- Products required to be true to label
- Claims currently made for 'functional foods' to be recognised also for NaTHP in dosage form
- Unilateral recognition of ingredients approved in other countries with recognised regulatory bodies e.g. TGA - Australia, Health Canada, FDA in the USA
- Prohibited list of ingredients will be incorporated into the RMS

Appropriate Regulatory Advertising Code

- To be developed in conjunction with industry, and approved by the regulatory body
- Appropriate risk proportionate advertising code – aligned with evidence based claims

Products Exported from New Zealand

- NaTHP manufactured for export-only are to be covered by an RMP and are to meet the regulatory requirements of the importing country
- Regulator is to provide appropriate export certificates when required

Streamlined Audits

- New Zealand regulating agencies (MAF, Medsafe, NZFSA in conjunction with the NaTHP regulator) are to streamline audit processes so all regulators have one mutually recognised audit
- The Regulator will recognise third party auditors

Mutual Recognition with Key International Markets

- The Regulator to promote mutual recognition arrangements with major export countries
- The Regulator to unilaterally accept products from countries with recognised regulatory bodies e.g. TGA – Australia, Health Canada - Canada, FDA in the USA, EFSA in Europe

The Natural and Traditional Health Products (NaTHP) Bill will replace overlapping regulatory frameworks that are ineffective, inappropriate and excessive for the NaTHP industry which is generally considered low risk.

The NaTHP Bill will enable future economic growth and innovation within the New Zealand NaTHP industry.

The NaTHP Bill offers the public freedom of choice along with appropriate, risk proportionate, quality assurance and safety controls.

The NaTHP Bill provides for the regulator to know in real time who is in the market and what is in the market.

The NaTHP Bill provides regulatory balance as provided for in the code of Good Regulatory Practice.

Further and more detailed information regarding the proposed regulatory model is available.

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