NATURAL HEALTH PRODUCTS

Fiona Ryan. Manager Therapeutics Policy
Strategy, Policy & Legislation

NATURAL HEALTH PRODUCT NZ SUMMIT AUGUST 2022

OVERVIEW

MINISTRY OF HEALTH
MANATŪ HAUORA

- Background
- Key features of the Therapeutic Products Bill
- Approach to regulation of NHPs under the Bill

The current situation

Dietary Supplements Regulations 1985

(SR 1985/208)

David Beattie, Governor-General

Order in Council

Food Act 2014

Public Act 2014 No 3

Date of assent 6 June 201

Commencement see sectior

- Outdated regulations and legislation
- Fragmentation
- Barriers to innovation and export
- Lack of international recognition
- Expectations and requirements are not clear

Key features of the Therapeutic Products Bill

MINISTRY OF HEALTH
MANATŪ HAUORA

- A fit-for-purpose and comprehensive regulatory regime for therapeutic products, which will repeal and replace the Medicines Act
- It is a priority for the Government – to be introduced in to the House later this year.
- The Bill takes on board:
  - sector feedback
  - the work underway on the health & disability system reforms
  - new health technology changes
  - lessons from COVID-19
- The Bill includes medicines, medical devices, biologics, gene, cell and tissue therapies, and natural health products

Why are NHPs in the Therapeutic Products Bill

MINISTRY OF HEALTH
MANATŪ HAUORA

- Risk-proportionate approach
- Lifecycle regulation

Provide acceptable safety and quality

Support industry

- Better alignment with the international best practice
- Ability to make health benefit claims
- Export certification

Improve consumer information

- Labelling and advertising requirements
- Informed customer choice

Te Tiriti o Waitangi

Open & transparent

- Recognition & protection of rongoā Māori
- Public register of products

The Bill is just part of the scheme

MINISTRY OF HEALTH
MANATŪ HAUORA

The Bill/Act

- the purpose and principles
- sector roles & obligations
- Regulator's powers, duties and functions
- regulation making powers

Regulations

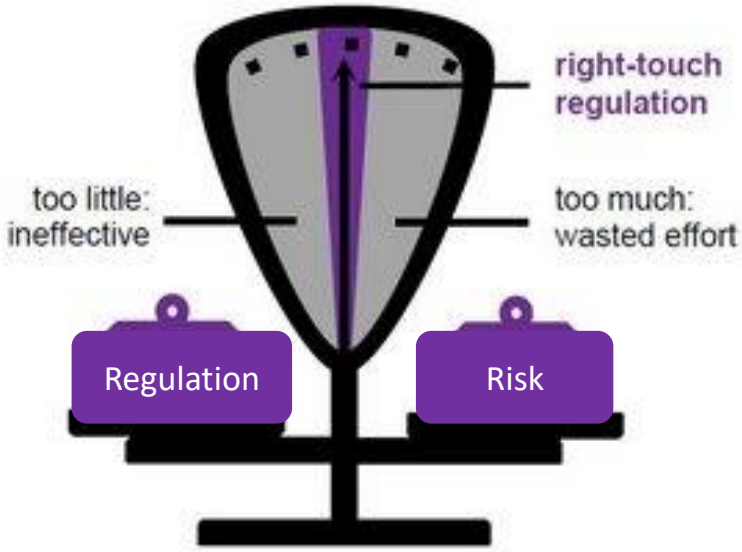
- technical and operational requirements
- [high-level] risk classifications
- cost recovery
- advisory committees

Rules and notices

- detailed standards/specifications
- permitted substances
- Permitted claims
- evidence requirements to substantiate claims

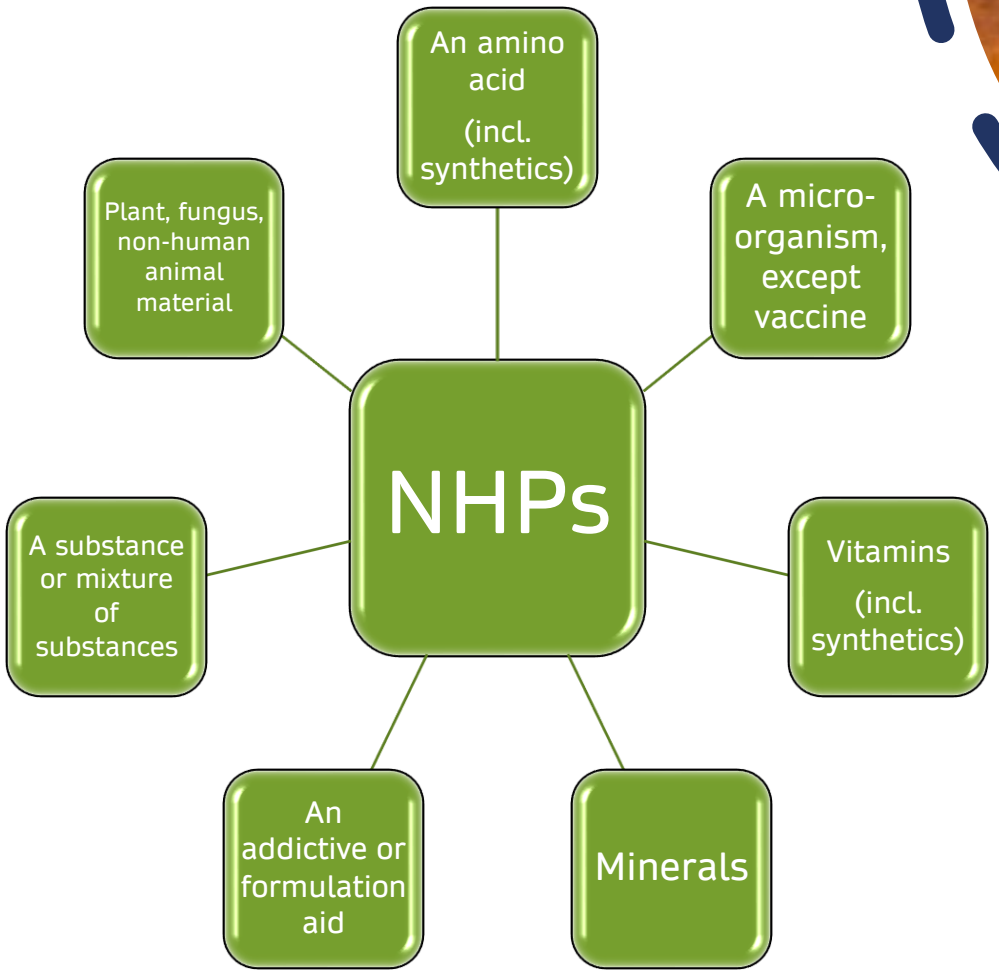
A snapshot of future NHP regulation

- A self-declaration pathway for market authorisation
- Risk-proportionate manufacture requirements
- A list of permitted substances
- A list of permitted indications/health benefits
- Health benefit claims based on scientific and traditional evidence
- International alignment and export certificates
- Labelling and advertising
- Post-market monitoring



Source: Professional Standards Authority for Health and Social Care (UK)

Natural health products



Natural health products - Definition

- A definition based on:
  - being for human use
  - contains only ‘natural’ substances
  - the primary purpose is for a health benefit
  - not a food, medicine, psychoactive substance

Health benefit claims

- The Bill will set the broad framework and will enable health benefit claims to be made.
- Permitted claims/indications & evidence will be developed in regulations and rules
- Evidence:
  - Scientific – different types of well-designed, appropriately sized & critically analysed studies
  - Traditional – different forms of oral and written evidence and meaning of ‘tradition’, where there is demonstrated continued use over a long period.

Therapeutic Products Bill - Exports

- Export authorisation will be available for:
  - Export-only NHPs
  - NHPs with NZ authorisation but that require an exemption to meet the requirements of importing countries eg labelling
- Export certificates will be provided for, whether exporting via export or NZ market authorisation
- The details will be in regulations

Transition

- The Bill will:
  - revoke the Dietary Supplements Regulations 1985
  - amend the ‘meaning of food’ in the Food Act 2014
- There will be a transition period of about two years after the regulations are passed.
- The Bill will ensure the Dietary Supplements Regulations are not revoked until the transition period is finished.

Have your say

- The Bill will be introduced to parliament this year
- You can make a submission when the Bill goes to Select Committee
- Regulations will be developed 2-3 years after enactment of the Bill – there will be specific regulations for NHPs
- You can make a submission during public consultation on the regulations