Minutes of workshop on natural health products (NHPs) on 25 February 2019

Purpose	To re-engage with NHP industry organisations and better understand the industry.
Participants	**Facilitator** Landa van den Berg, Change Navigator **Natural Health Products New Zealand** Alison Quesnel, Public Affairs Director Lorraine Moser, Board member Samantha Gray, Board member **New Zealand Wellness Associations)** Joanne Bisset, General Manager Simon Lusk, Strategy, Campaign Manager and Political Career Planning Graeme Clegg, Chairman New Image Group **Naturopaths and Medical Herbalists NZ** Liz Jury, President **NZ Association of Medical Herbalists** Phil Rasmussen, Technical Director Phytomed Medicinal Herbs Ltd **Natural Health Alliance** Patrick Fahy, Chairman Lisa Hansen, Barrister **Ministry of Health** Michael Roberts, Manager, Safety and Access, System Strategy and Policy Haley Ataera, Senior Policy Analyst, Prevention, System Strategy and Policy **Ministry for Primary Industries** Rebecca Berendt, Manager, Food Policy Vicky Scott, Senior Policy Analyst, Food Policy
Date	Monday 25 February 9am – 12:45pm 2019
Venue	Novotel Auckland Airport, Auckland
Items	**1. Welcome and introduction** Landa ven den Berg (facilitator) opened the meeting. **2. Setting the scene** Haley Ataera gave a short presentation outlining where the NHP regulatory review process is at. The Natural Health and Supplementary Products (NHSP) Bill was terminated by the Government at the end of 2017 and the Dietary Supplements Regulations 1985 expire on 1 March 2021. Learnings from previous work, both in terms of what worked and what didn't, will still be relevant when developing options for Ministers by mid-year 2019; however, previous information is now outdated or incomplete. Government agencies would therefore like to better understand business practices to analyse the impacts of options on industry. The government process for developing regulation was discussed, noting that timelines can't be predicted at this stage. Industry views are diverse and collaboration will be important in progressing the work.

3. Feedback on the regulatory review process

Some participants were concerned about the expiry of the Dietary Supplements Regulations. Haley pointed out that all NHPs would become non-compliant food if they expired. Officials explained that they will take steps to ensure the Regulations do not expire before new legislation is in place.

Some participants queried why the NHSP Bill was terminated. There were a number of suggestions that it was for political reasons. A view that it would have imposed unreasonable costs on industry was also expressed. Another participant suggested that the NHSP framework could be used to help build a new regime (rather than the Bill itself), noting that much was ok with it while some parts were not ok. Others, however, did not agree and considered a fresh approach was needed, with more consensus.

One participant stated that a quality regime is needed for exports and to ensure safety. The participant noted that New Zealand is the only country without a requirement for GMP. A discussion followed that highlighted many of the principles raised in the next section. There were some clear points of differences as discussed below.

Landa concluded this session by stating that the group may never agree but agencies have to develop advice for ministers.

Regulatory principles for the new legislation

Rebecca Berendt presented the Government's expectations for the design of regulatory systems.[1]

Participants considered the following principles relevant:

- Supporting and improving health;
- Supporting consumer rights above producers' rights;
- Providing consumer information. This would incentivise research (i.e. there is a need to talk about products). Other participants later suggested that a discussion on common elements such as country of origin labelling was important;
- A permissive system that includes WHO traditional products and ingredients;
- Risk proportionate regulation (e.g. the manufacture of herbal medicines would require high levels of control compared to a lower risk product such as a food (e.g. berry extract). Risk would relate to manufacture, ingredients and products. The WHO Traditional Medicines Strategy 2017-2023 is relevant;
- A cost effective regime, which enables innovation and an ability for new companies to come in to the market;
- Supporting exporters to ensure they can get access to overseas markets;
- An ability to make health benefit claims based on evidence;
- A flexible/adaptive system that enables innovation and global competitiveness for exports and imports;
- Practitioners' exemption (for those suitably trained) from requirements to only use ingredients from an approved list. An alternative is to allow practitioners to use higher doses than those prescribed OTC (e.g. melatonin);
- Alignment with other regulatory regimes to help with the acceptance of New Zealand products. Some noted, however, that alignment with restrictive regimes makes it difficult

[1] New Zealand Government (April 2017). Government Expectations for Good Regulatory Practice. https://treasury.govt.nz/sites/default/files/2015-09/good-reg-practice.pdf

to compete with e-commerce and that companies such as Amazon have changed the landscape.

Participants disagreed on the following:

- whether there should be a white or black ingredient list. Some participants supported a very broad permitted ingredient list (a white list) to ensure safety, with an ability to make applications to extend the list. This approach was seen as necessary for the regulator for monitoring purposes and would require the regulator to be adequately resourced, including with specialist practitioner expertise. Others supported a permissive approach that lists prohibited ingredients (black list) because those participants considered NHPs were inherently safe. A black list was also seen as not stifling innovation and not providing the ability to slip in to a pharmaceutical regime;
- whether NHPs are therapeutic products. Some participants supported NHPs being considered therapeutic on the basis that it would lend weight and credibility to the products, including enabling them to make therapeutic claims. Others, however, opposed NHPs being therapeutic because they were concerned it will result in a prescriptive regime similar to or the same as that for medicines.

All participants were concerned that there was no definition for NHPs because it makes it difficult to gather the information officials are seeking. They did not consider the definition in the NHSP Bill was adequate.

It was suggested that government review the NHP principles applied in other countries.

4. Gathering evidence

Haley Ataera gave a short presentation that sought feedback on the concept of a business survey to understand their practices, which will help government better develop regulatory options. She explained that good policy requires hard data and an ability to understand the impacts that might be imposed on affected parties. The information required includes business sizes, and what other health related products business are involved in (e.g. food, medicines etc).

One industry organisation said their response rates from surveying members are typically low (i.e. 10-20%) so any government survey could be low and not representative of the industry. Some suggested that targeted individual interviews would be useful in addition to a survey (e.g. with 2-3 large, medium and small businesses) and said they could provide individuals to interview.

Participants:

- queried how to target the right people for the survey when there is no definition for 'natural health products';
- queried how size would be measured. Percentage turnover (or a range of percentage turnover), SKUs, volumes, the number of people employed (either domestically or domestic and international) and the contribution to the economy (money invested and people employed) were all suggested as ways to measure size;
- noted that a closed question about the NHP business should include categories such as manufacturers, importers, exporters, marketers, distributors, retailers, practitioners and combinations of them;
- said that a question about exports should relate to where products are exported to, their value and the product types according to a list;
- noted a 2014 PwC survey and Ministry of Business, Innovation and Employment (MBIE) data on export sales and an independent MBIE industry review;

	• said that a list of interface product categories should split general foods from functional/supplemented foods; • considered the main future issues were e-commerce, a potential review of the US FDA's regulations on dietary supplements, marketing (e.g. via social media and testimonials) and an increasing trend in self-empowerment in health care. A representative from NHPNZ suggested that the Ministry of Health discuss the survey during their presentation at NHPNZ's Summit in March 2019. **5. Final comments and closure** Haley stated that the Ministries of Health and Primary Industries would draft a survey by around 6 March, which it would then test with participants. The Ministry of Health intend updating their NHP site to note the workshop and provide a link to the survey. Ministers will be updated on the survey results.