Submission on the Therapeutic Products Bill

3 March 2023

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NATURAL HEALTH PRODUCTS NEW ZEALAND'S SUBMISSION
ON THE THERAPEUTIC PRODUCTS BILL

INTRODUCTION AND SUMMARY

1. Natural Health Products New Zealand (Natural Health Products NZ) is pleased to have the opportunity to submit on the Therapeutic Products Bill on behalf of our membership.

2. Natural Health Products NZ conditionally supports the Bill. For the reasons explained in this submission, Natural Health Products NZ submits that a number of significant issues require consideration by the Health Committee, and subsequent amendment to the Bill. Our conditional support of the Bill is contingent on these issues being satisfactorily addressed by amendments to the Bill through the select committee process.

3. Natural Health Products NZ wishes to appear before the Committee to speak to its submission.

About Natural Health Products NZ

4. Natural Health Products New Zealand (formerly Natural Products NZ) is the peak industry body representing over 80% of the New Zealand natural health products sector. We were established in 2002 by industry and with support of New Zealand Trade & Enterprise.

www.naturalhealthproducts.nz

Contribution to New Zealand's economy – volume to value

5. The natural health products sector is a rising star of NZ's economy[1] and plays an important and increasing role in transforming primary produce from volume to value by developing research and development rich innovative products for NZ consumers and export markets[2].

- Contributes more than $2.3 billion p.a. to NZ's GDP
- Growth of 64% over 5 years (CAGR 10%).
- Exports goods worth at least $642 million per annum. More than 74% of the sector are exporters.
- Researches, develops and manufactures high quality health products from the best of New Zealand ingredients and around the world.
- Takes New Zealand primary produce up the value chain from volume to value in internationally sought-after products with evidence-based health benefits.
- Supports local communities with training and job opportunities in state-of-the-art raw material production, branded and contract finished goods manufacturing, research, marketing, sales and support functions. Job opportunities range from unskilled labour through skilled machine operators, research and development to c-suite commercial roles.

[1] https://www.survey.naturalhealthproducts.nz/ accessed 1 March 2023
[2] https://toolkit.nzstory.govt.nz/assets/402105?tags=Natural%20Health,Brand%20Video accessed 1 March 2023

- Our most recent sector survey identified that poor state of New Zealand government regulations is the most significant barrier to industry growth.

Natural Health Products NZ Members

6. Our members include around 140 entities ranging in size from small to large, privately held and publicly listed companies, and government owned organisations from across the industry sector. They include manufacturers, raw material suppliers, producers, contract manufacturers, branded manufacturers, brand owners and distributors, and other entities collectively employing in excess of 4000 New Zealanders. A full list of members is available on our website, and in the appendix.

Regulatory reform is urgently needed

7. Natural Health Products NZ has worked constructively and actively with government and ministries for more than 20 years in various attempts by successive governments to provide industry and New Zealanders with a modern, workable and affordable regulatory regime for manufacturing, marketing and selling natural health products. Having a modern, risk proportionate and fit for purpose regulatory framework will bring many benefits, including enabling consumers to be fully informed of the evidence-based health benefits of NHPs.

NZ's Current Regulatory Framework for NHPs

8. The current regulatory framework in NZ for NHPs is a disparate mix of legislation and regulations that are confusing, out of date, not fit for purpose, not risk proportionate and that do not work properly together.

9. This does not serve NZ consumers or the industry well creating a situation where:

- Consumers are prevented from being fully informed about the evidence-based health benefits of products on the market as such claims are expressly prohibited by the regulations
- Exporters cannot access significant and growing export opportunities and markets. Natural Health Products NZ estimates the cost of this is net loss of more than $500 million in lost trade per annum[3]
- The domestic market is an uneven playing field where compliant product and manufacturers must compete with noncompliant product and unknown manufacturing quality (including products from overseas) and the regulators appear unable to address this
- Risk proportionality of rules and regulations is not achieved consistently
- It is difficult and confusing for industry to understand the requirements of the regulations which can result in unintended non-compliances with subsequent impacts to consumers and industry

Overview of our position on the Bill

10. Natural Health Products NZ is encouraged that once again there is legislation before the house to reform the regulatory framework for NHPs.

[3] Natural Health Products NZ data on file

11. Natural health products are low risk products. Regulation of NHPs should be risk proportionate and therefore light touch. The data supports this. In 2019, (the most recent year that Medsafe published data is available) the number of suspected adverse events for complementary or alternative medicines (CARM data) was 28, or 0.6 per 100,000 population. That year there were 4219 suspected adverse events for medicines (86 per 100,000 population).[4] The available cumulative data from 1992 to March 2009 shows that only 344 reports to CARM over the 12 year period identified a complementary medicine as a suspect medicine. Of the 344 reports received only 25% described serious adverse events.[5] Recent CARM data (2019, 2020 and 2021) reported suspected adverse events for complementary or alternative medicines at rates of 27, 28 and 19 events per year.[6] Anyone may report adverse events to CARM[7] so reports from any type of health professional and self-reporting by patients and consumers is captured.

12. As NHPs are general retail products that are available for consumers to choose and purchase from a variety of retailers, and many are predominantly orally consumed, a comparison to adverse events for foods is also relevant. In 2019 there were 13,261 cases of food borne notifiable diseases (270 per 100,000 population) resulting in 1065 hospitalisations with food borne notifiable disease as a primary diagnosis[8]. Additionally, for food allergies, the average annualised rate of hospital food-induced anaphylaxis was 4.8 per 100 000 adults during 2002-2011.[9]

13. Furthermore, calls to the NZ National Poisons Centre across all age groups between 2018 and 2020 resulted in an average of 83 calls per year requiring a medical referral for ingestion of product categorised as a supplement, which is 1.7 per 100 000 population[10] compared to all calls to the Poisons Centre requiring medical referral averaging 4621 or 94 per 100 000 population per year (2018-2019).[11] The number of these medical referrals that required any medical intervention is not available.

14. The above data shows that NHPs are low risk products .

15. The intention of the Bill is to regulate NHPs in a risk proportionate manner and the previous Natural Health and Supplementary Products Bill 324-2 (NHSPB) was intended to inform the Bill for the regulation of NHPs.

16. The RIS[12] and Cabinet minutes[13] justify that no consultation was required for NHPs to be included in the Bill because extensive consultation was undertaken previously to inform the drafting of the NHSPB. The RIS states “The option of regulating under the Therapeutic Products Bill (the preferred option) has not been publicly consulted and has not been explicitly tested with the sector.

17. We submit that the Bill does not treat the regulation of NHPs in the same way that the NHSPB did. Effectively the content of Bill (with regard to NHPs) has not been consulted on

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[4] https://www.medsafe.govt.nz/profs/PUArticles/March2020/Adverse-reaction-reporting-2019.html accessed 3 March 2023

[5] https://www.medsafe.govt.nz/publications/prescriber-update.asp accessed 3 March 2023

[6] https://www.health.govt.nz/system/files/documents/information-release/h2022018873_response.pdf accessed 3 March 2023

[7] https://nzphvc.otago.ac.nz/reporting/#who-can-report accessed 3 March 2023

[8] https://www.mpi.govt.nz/dmsdocument/42874/send accessed 3 March 2023

[9] https://pubmed.ncbi.nlm.nih.gov/27053518/ accessed 3 March 2023

[10] By email NZ poisons centre data on file Natural Health Products NZ

[11] https://journal.nzma.org.nz/issue-id/vol-134-no-1528-5-january-2021 accessed 3 March 2023

[12] https://www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements/regulating-natural-health-products accessed 1 March 2023

[13] https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime released 17 March 2022, accessed 1 March 2023

as the justification that extensive consultation was carried out to inform the NHSPB does not hold up because the content of the Bill for NHPs has materially and significantly changed.

18. There are a number of areas where the Bill does not achieve either the cabinet objectives for risk proportionate regulation of NHPs or industry requirements that we have detailed to officials prior to the drafting process. For these reasons we support the Bill in principle but with a number of recommended amendments.

19. Our submission is designed as a proactive and constructive approach to amending the bill to achieve its intended objectives of risk proportionate regulation of NHPs for the benefit of NZ and New Zealanders.

Summary of Key Submission Points

Structure & content of the Bill

20. NHPs should be a separate dedicated section within the Bill. Under the Bill NHPs are lumped in with medicines, medical devices and APIs resulting in the potential for many unintended consequences. This has created a situation where regulation appropriate for medicines has attempted to accommodate NHPs. This has created a situation where terms fit for medicines (such as “authorisation”) are used to regulate NHPs. The result is regulation that is not risk proportionate for NHPs. Consequently, the Bill is difficult to navigate and confusing to interpret. Regulation for NHPs should be easy to interpret and navigate so that stakeholders can ensure they are compliant without confusion.

Costs (fees and levies)

21. The regulatory functions created under the Bill that incur costs to industry should be risk proportionate for NHPs which are low risk. The offences and penalties are not risk proportionate for NHPs and are set under a pharmaceutical model. The cost recovery model has insufficient detail and industry remains concerned about the potential cost impact of direct and indirect regulation that the Bill may impose. Fees and levies, and increases in fees and levies, are not capped. Only regulatory functions that are required to be in place due to the proportionate risk should be in place, and any costs should be minimised.

The Regulator

22. NHPs must be regulated by a dedicated regulator (separate business unit) that is adequately resourced and funded and with appropriate expertise. The regulator must establish an advisory committee for NHPs with >50% representation of NHP experts including representation from Natural Health Products NZ. The regulator must be required to meet the requirements of regulatory stewardship under the Public Services Act so that continuous improvement of the performance of the Bill and secondary legislation (regulations and rules) occurs in a consultative, open and transparent manner with stakeholders, including industry. Natural Health Products NZ remain concerned about the ability of a new regulator to be set up that has the resources to actively regulate the MoH estimate of 20000 NHP products in the NZ market let alone the hundreds of thousands of medical devices. Therefore, regulation must be risk proportionate for NHPs which is light touch.

Health Benefit Claims

23. Although we are encouraged that the Bill recognises that NHPs are therapeutic products and can make health benefit claims, we remain concerned that secondary legislation may restrict health benefit claims unnecessarily. We submit that all appropriate health benefit claims for

NHPs must be permitted (for example those permitted in Australia and Canada). Although the Bill does not detail which of the therapeutic purposes will be permitted by health benefit claims for NHPs in the regulations (secondary legislation), Natural Health Products NZ seeks clarification from the Minister that all health benefit claims permitted by the TGA (for listed complementary medicines) and by Health Canada for (natural health products) will be permitted for NHPs so that New Zealand consumers can be properly informed about the evidence based health benefits of products and so that exporters can compete in international markets. This is also necessary for New Zealand to be able to meet our obligations as participants in the WHO strategy for Complementary and Traditional Medicines[14].

NHP Market Notification

24. NHP Market Authorisation must be changed to a Market Notification process. NHPs should be market notified by a self-declaration process that does not permit assessment by the regulator. Previous consultation for NHPs established a notification process in the dumped Natural Health and Supplementary Products Bill which had passed its third reading prior to being removed from the order paper in 2017. The procedures for making changes to market notification (currently authorisation) must be fit for purpose, flexible and risk proportionate for NHPs. Major changes should be limited to those that change the quantities or proportions of active ingredients effectively creating a new product. Minor changes should be made by a self-declaration variation to the notification. Sponsors, manufacturers, responsible people should also be able to be changed by a self-declaration variation to the notification.

NHP Ingredients

25. NHP ingredients definitions and requirements must be risk proportionate and future proofed. The NHP ingredients definition must allow any methods of chemical transformation to permit ingredients that are commonly used in global best practice. This will also future proof to enable innovation so that IP rich new ingredients can be developed to support the health of consumers and grow high value export trade. NHP ingredients manufacturing should not be captured by the requirements of NHP product manufacturing as this is not aligned with risk proportionality or global best practice.

Exports

26. Although we are encouraged that the Bill attempts to address the current internal barriers to trade of not having an export-only category for NHPs, the Bill does need some work as once again a medicines model has been applied to the regulation of NHPs for export. Market authorisation (notification) is not required for exports as exported products comply with importing countries' regulations. An Exporter register is more appropriate. Export-only must allow ingredients, dosages and claims that are not permitted in NZ but are permitted for NHPs in importing countries. Official Statements including export certificates and statements of free-sale must be available to exporters upon request and the content of such statements must be flexible to meet different importing countries' individual requirements. Overall the exporting regulations for NHPs need reworking as they place unnecessary regulation on products that are sold in the general retail trade and therefore do not require the supply chain controls that medicines do. We are also concerned about the impact of the current drafting of export regulations to online retail sales to consumers overseas.

[14] https://www.who.int/teams/integrated-health-services/traditional-complementary-and-integrative-medicine accessed 1 March 2023

Product Standards

27. Product standards are not required for NHPs or for exported NHPs because they will comply with regulations (secondary legislation) pertaining to ingredients and their specifications, and manufacturing process control. Exported NHPs will also comply with the importing countries' regulations. The Bill should not impose unnecessary regulation and should regulate NHPs in a risk proportionate manner (light-touch).

SUBMISSION POINTS

28. Following is the detail of our submission points to the Bill with recommended amendments.

OVERALL STRUCTURE AND CONTENT OF THE BILL

Structure of the Bill

Summary of position under the Bill

29. NHPs are incorporated into clauses along with medicines and medical devices and interspersed with regulation pertaining to pharmacy and practitioner functions throughout the Bill. Consequently, for NHP stakeholders the Bill is difficult to navigate and confusing.

The Bill should be structured in a way that is easy to navigate for stakeholders of each industry affected by the Bill, including for NHPs. The Bill should be designed to minimise unintended non-compliance caused by difficult, confusing and ambiguous design.

Recommended amendment

30. All content pertaining to NHPs is set out in a dedicated section of the Bill titled "Natural Health Products"

Content of the Bill pertaining to NHPs

Summary of Position under the Bill

31. The content and regulatory requirements for NHPs differ markedly from that of the Natural Health and Supplementary Products Bill (NHSPB) 324-2. The RIS, Cabinet minute and communications from MoH officials all justified not consulting on NHPs being included in the Therapeutic Products Bill on the basis that NHPs were extensively consulted on during the drafting of and through the progression of the NHSPB through the house. The RIS[15], Cabinet minute[16] and communications from MoH officials to the public and to Natural Health Products NZ expressed the intention for the content of the NHSPB to form the content for NHPs in the Bill. This has not occurred and results in the content for NHPs within the Bill to remain not consulted on to date.

32. The structure of the Bill (see section above) contributes to this situation as NHPs have been incorporated with medicines and medical devices throughout the Bill. Although subclauses have attempted to carve out specific requirements for NHPs the overall affect is that

[15] https://www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements/regulating-natural-health-products accessed 1 March 2023

[16] https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime released 17 March 2022, accessed 1 March 2023

unnecessary regulation for NHPs has been introduced. Additionally, because the clauses are attempting to capture requirements for three distinct industries (NHPs, medicines and medical devices) interpretation is more difficult and ambiguous resulting in unintended consequences for both stakeholders and the regulator.

33. This means that in the Bill NHPs are not regulated in a risk proportionate manner.

Regulation for NHPs must be risk proportionate for NHPs which are low risk products. Regulation must be light touch and low cost to industry.

Recommended amendment

34. Modify content pertaining to NHPs to align with the content and level of regulation per the NHSPB. This submission will set out specific recommendations in this regard.

MARKET AUTHORISATIONS

Market authorisations should be market notifications

Summary of position under the Bill

35. The Bill requires NHPs to gain market authorisation before they can be introduced to the market. Although cl123(2) requires the regulator to accept the applicant's declaration as prima facie evidence of compliance with the requirements of market authorisation, under cl123(c) the regulator can assess or reject applications. The definition "authorisation" includes the ability of review and permission to be granted in some way.

36. The NHSPB required NHPs to be "notified" and not "authorised". Although this appears to be a subtle difference, we submit that this difference could result in the unintended consequence of a regulator unnecessarily assessing applications for authorisation when they are compliant. This would be a waste of regulator resources and unnecessarily delay products' entry to the market, which could reduce competitive advantage and increase costs for the applicant.

37. NHPs are low risk products so regulation must be risk proportionate and light touch.

38. Clause 352 (1) and the Ministry of Health slide presentation given at the Natural Health Products Hui on 1 and 3 November 2022[17] detail that NHPs authorisation will be via an automated electronic system that could only accept compliant applications through self-declaration by the applicant. The presentation also says "No evaluation by regulator of specific product prior to issue of market authorisation." Therefore, there would not be a requirement for the regulator to assess or reject an application.

NHPs should be a simple "notification" process.

Recommended amendments

39. We recommend that NHPs be regulated within a dedicated section of the Bill that includes a "notification" process that is not an authorisation process.

[17] NATURAL HEALTH PRODUCTS and the Therapeutic Products Bill NATURAL HEALTH PRODUCTS HUI 1 & 3 NOVEMBER 2022 Presentation by the Ministry of Health – data on file at Natural Health Products NZ

40. Amend cl122 to read “Application for a market notification for NHP” and amend every reference in this clause from “authorisation” to “notification”

41. Amend cl123 to read “Issue of market authorisation for NHP” and amend every reference in this clause from “authorisation” to “notification”

42. Delete cl123 (1) (c)

43. Delete cl123 (3)

44. Remove all other references to “market authorisation” in the Bill for NHPs and replace this with “market notification”.

Criteria for market authorisation (market notification) of NHP

Summary of position under the Bill

45. An NHP meets the criteria if the regulator is satisfied on reasonable grounds that a number of criteria apply. This includes that there is reasonable and adequate evidence to demonstrate the safety and quality of the NHP.

46. The process should be a market notification process where the regulator is satisfied that an NHP meets the criteria through a self-declaration process where the sponsor declares that the NHP product conforms to requirements in the regulations and rules (secondary legislation).

47. ‘Reasonable grounds” should not be a condition because the product will be declared to meet the requirements in regulations and rules.

48. The criteria “reasonable and adequate evidence to demonstrate safety and quality of the NHP should be qualified to clarify that this is achieved by a declaration of conformity of the product to the regulations and rules.

Recommended amendments

49. Amend cl124 to read “Criteria for market notification of NHP”

50. Amend cl124 (1) to read “An NHP meets the criteria for a market notification if the sponsor declares that the product conforms to the regulations and rules pertaining to the following criteria:”

Content of a market authorisation

Summary of position under the Bill

51. Clause 126 sets out the content of a market authorisation. Among other things the content requires a description of the product and the address of each place at which the product may be manufactured.

52. For NHPs the market authorisation should be a market notification as submitted above.

53. For NHPs the description of the product should be the trade name. Many NHP ingredients are non-proprietary and requiring a description of the product could result in the unintended consequence of confusion where descriptions can be ambiguous and subjective. A more accurate representation and identifier of the product is its trade name.

54. NHPs could be manufactured at multiple sites which could vary depending on demand and for other commercial reasons and particular stages of manufacturing (for example tableting and packing) could occur at different sites. NHPs are low risk products with risk proportionate manufacturing control that permits this scenario. Requiring the address of each place of manufacture will have the unintended consequence of requiring a change to market authorisation (notification) when there is no impact to safety or quality.

55. The responsible manufacturers name and address is included in the required content which provides sufficient oversight to the regulator of who the responsible manufacturer is and their location and contact details.

Recommended amendments

56. Amend cl126 (1) (b) to read “a description of the product, if the product is an NHP this is the trade name:”

57. Amend cl126 (1) (g) to read “if the product is a medicine or medical device the address of each place at which the product may be manufactured”.

Conditions on market authorisation

Summary of position under the Bill

58. Clause 133 sets out conditions that a market authorisation may be subject to according to the rules and these may be varied by the regulator at any time.

59. NHPs should be regulated by a self-declaration market notification system (see Market Authorisation submission point) so the regulator could not impose or vary conditions when issuing an authorisation.

60. If the regulator saw fit to vary conditions on notifications for NHPs they should inform all NHP notifiers affected with adequate notice of the variation.

61. This regulatory process will streamline variations to ensure efficient use of regulator resources and minimal impact to fees and levies via cost recovery.

Recommended amendment

62. Amend cl133 to “Conditions on market authorisation for medicines and medical devices”.

Variation of market authorisation by regulator/sponsor

Summary of position under the Bill

63. Clause 134 sets out the provisions for variations of market authorisations by the sponsor. This includes the provision that the regulator is required to evaluate the product only to the extent to the proposed variation and that a market authorisation cannot be varied to change who the sponsor is or to change what product it authorises.

64. NHPs should be regulated by a self-declaration market notification process rather than a market authorisation (see submission point Market Authorisation)

65. NHPs market notifications are a self-declaration and any change that is not a major change should be permitted by self-declaration. This includes the ability to change the Sponsor (see submission point Change of Sponsor).

The market authorisation/notification process for NHPs should be risk proportionate and flexible.

Recommended amendment

66. Draft a new clause "Variation of market notification of NHPs" that permits self-declaration variations for minor changes including a change of sponsor.

CANCELLATION OF MARKET AUTHORISATIONS

Suspension and reinstatement of market authorisation

Summary of position under the Bill

67. Clauses 136 through 138 set out the grounds and provide for the regulator to cancel market authorisations.

68. There are no provisions for market authorisations to be suspended or reinstated.

69. For NHPs the NHSPB provided for notifications for NHPs to be suspended and reinstated as well as to be cancelled. This is the draft legislation that was consulted on forming the justification for including NHPs in the Bill

NHPs are low risk products therefore suspension and reinstatement of market authorisation (notification) should be permitted.

Recommended amendments

70. Amend clauses 136 through 138 to add provision for suspension and reinstatement of market authorisations (notifications) for NHPs.

71. We recommend that Section 9D of the Australian Therapeutic Goods Act 1989, and Clause 18(1) of the Canadian Natural Health Products Regulations be consulted to inform the Bill for NHPs in these regards.

Grounds to cancel market authorisations

Summary of position under the Bill

72. Clause 136 sets out the grounds upon which a market authorisation can be cancelled. "If it is an NHP, there is no longer reasonable and adequate evidence to demonstrate its safety and quality." For all products there are a number of grounds including when the sponsor or responsible manufacturer has contravened a provision of the Act, and where the likely risks associated with the product outweigh its likely benefits.

73. Demonstration of safety and quality is an ambiguous statement open to subjectivity. The grounds for cancelling an NHP should be determined by the requirements for safety and quality as defined in the regulations.

74. Likewise, the cancellation on the grounds that the likely risks associated with the product outweigh its likely benefits is also an arbitrary and subjective assessment.

75. The grounds for cancellation if a sponsor or manufacturer contravenes the Act should be limited to the situation where the contravention is pertaining to the product for which the market authorisation is proposed to be cancelled.

Cancellation of market authorisations (notifications) must be on clear and objective grounds that are related to the NHP in question.

Recommended amendments

76. Amend cl136 (c) to read "if it is an NHP, there is no longer reasonable and adequate evidence to demonstrate its safety and quality according to the regulations".

77. Amend cl136 (k) to read "the sponsor has contravened a provision of this Act for the product identified in the market authorisation (notification)".

78. Amend cl136 (l) to read "the responsible manufacturer has contravened a provision of this Act for the product identified in the market authorisation (notification)".

79. Delete cl136 (d)

PRODUCT STANDARDS

Summary of position under the Bill

80. Clause 63 describes that product standards may be set out by the rules and that they may relate to NHPs safety and quality, maximum concentration of NHP ingredients and other matters relating to their composition.

81. For NHPs these aspects will be controlled for in regulation, so product standards will not be required. Maximum concentrations of NHP ingredients will be included in the detail of recognised NHP ingredients and how they can be used. Safety and quality will be regulated by ingredients permissibility, specifications and maximum concentrations as well as the requirements for substantiation of health benefit claims and codes of manufacturing. Matters relating to composition will be adequately controlled for in the recognized NHP ingredients detail and codes of manufacturing practice.

82. Implementation of these types of product standards will unnecessarily utilise regulator resource and could have the unintended consequence of stifling innovation and exports by putting in place standards that are not required under the principles of risk proportionality.

Regulatory burden should be minimised wherever possible for NHPs which are low risk products.

Recommended amendment

83. Delete cl63 (2) (iii)

THERAPEUTIC PRODUCTS REGISTER

Summary of position under the Bill

84. Clause 363 requires the regulator to maintain a therapeutic products register that for each product, licence, permit or thing the register must include the information required by the regulations. The regulator must make the register publicly available.

85. This means that commercially sensitive and private information could be available on a publicly available register.

86. Commercially sensitive information is required by the regulations for products, licences, permits and other things regulated in the Bill. This should not be required to be made publicly available.

87. Private information such as identifying information about responsible persons is required by the regulations in the Bill. This should not be required to be made publicly available.

The therapeutic products register should be required to publicise only the minimum information that is required by the public and should not disclose commercially sensitive or private information.

Recommended amendment

88. Add a new cl363 (3) to read “The regulations must not require confidential information to be included in the register.

EXPORTS

Export authorisations

Summary of position under the Bill

89. The Bill intends to create a market authorisation process for therapeutic products, for products that are to be imported, supplied or exported in New Zealand. Clause 117 of the Bill states that there are three kinds of market authorisations. Under cl117(c) one of these authorisations is an export authorisation. The Bill states that an export authorisation "authorises a medicine, a medical device, or an NHP for export from New Zealand even though it does not meet the criteria for a standard authorisation that would allow it to be supplied in New Zealand".

90. Clauses 122-124 of the Bill relate to issuing, and applying for, market authorisations for NHPs. These provisions are general and on the current drafting would apply to all market authorisation applications, including those for export authorisations. Therefore, products that would be exported would still need to meet a significant number of New Zealand standards, despite not being supplied in New Zealand.

Export authorisations should not be required for NHPs – instead the exporter should be required to register.

91. Given this, NATURAL HEALTH PRODUCTS NZ does not support the export authorisations in the Bill, as in our view the authorisation would unnecessarily inhibit NHPs being exported from New Zealand and creates an overly burdensome regulatory regime, when the product would not even be supplied in New Zealand.

92. Sponsors may export the same product to a number of export markets, either through general trade or by sale via online platforms. The resulting complexity of the requirement for the NZ regulator to authorise this trade per product and market does not have any benefit as products must be compliant with the importing country's regulations to be in commerce. A New Zealand brand may wish to distribute product via a number of exporters. The export authorisation requirements would require multiple authorisations for the same product. This is of no regulatory benefit and will create unnecessary burden on the resources of the regulator as well as unnecessary cost to industry. Registration of exporters gives the regulator sufficient oversight of exporting activity.

Recommended amendments

93. NATURAL HEALTH PRODUCTS NZ submits that no export authorisation be required for NHPs. Instead, NATURAL HEALTH PRODUCTS NZ submits that a new clause 68 be added to the Bill that would allow NHPs to be exported without market authorisation if the exporter is a registered exporter.

94. This proposed amendment would be similar to the registered exporter requirements for food products under the Food Act 2014.

95. A subsequent amendment to cl67(1) would be required as follows:

67 Market authorisation (notification) required to import, supply, or export

(1) A person must not—

(a) import or supply a medicine or medical device unless it has a NZ authorisation ; or

(b) export a medicine or medical device unless it has a market authorisation ; or

(c) in the course of a business or undertaking, import or supply an NHP unless it has a NZ authorisation (notification)<u>.</u>~~; or~~

~~(d) in the course of a business or undertaking, export an NHP unless it has a market authorisation.~~

Exporting is a controlled activity requiring a license or permit

Summary of position under the Bill

96. Clause 69 sets out which controlled activities are required to be licensed, permitted or controlled by regulatory orders. In relation to NHPs this includes exporting in the course of business or undertaking.

97. Wholesale exporters should not need a license or permit because the products they are exporting are authorised/notified or export-only and therefore compliant with importing country's regulations.

98. New Zealand online retailers should not be required to be licensed or permitted to carry on their business which may include selling retail products to overseas customers. Such products would be authorised/notified by the sponsor of the product and declared to be compliant to the regulations.

99. Online retailers selling products to overseas customers are in many cases a distribution channel for multiple brands and many individual products as personal parcels. They are also individual brands often operating small online sales functions from their websites. All of these

types of retailers should not be burdened with the requirement of an export license to retail NHPs.

100. Exporters should be required to be listed on a register as we submit above.

Recommended amendment

101. Delete cl69 (2) (d) (ii)

Export standards

Summary of position under the Bill

102. Clause 59 provides for the Regulator to make rules setting standards for products that are exported. Export standards are minimum standards that a product must meet before an export authorisation can be issued. Once a product has an export authorisation, the sponsor must ensure that it continues to meet those standards. Export standards may also apply to products with a NZ authorisation if they are exported. Export standards may set standards for particular products, and particular markets.

103. Internationally NHPs are regulated by country-specific regulations. There is significantly less harmonisation of regulations for NHPs than for medicines and medical devices although regulations are well-developed. The divergence of regulations across export markets means that products must meet regulations for composition, labelling and health benefit claims that vary by country. NHPs must comply with an importing country's regulations and standards to be placed into commerce in that country. Importing country's regulatory regimes control for proportionate risk for NHPs.

104. NHPs could be composed of a number of many thousands of ingredients at any number of evidence-based input levels or combinations. The MoH estimate there are 20 000 products in the market in NZ. Creating and maintaining product standards for this number of products and possible products would require a significant regulatory resource, but as product standards are controlled for by the importing countries' regulations it is not only overly burdensome to the regulator, it is an unnecessary use of regulator resource. Such a scheme is likely to result in the unintended consequence of additional costs to exporters and delay in the ability of an exporter to access overseas market opportunities. This will inhibit New Zealand's competitive advantage in the global marketplace, with no consequential benefit.

Export standards should not be required for NHPs as products will meet overseas standards.

Recommended amendments

105. Amend cl59 (1) to read " The rules set our standards (export standards) for therapeutic products (except NHPs) that are exported".

106. Delete cl124 (f)

107. Amend cl126 (1) (m) to read "any conditions, product standards or other rules that are disapplied (see section 127):"

Export certificates – Official Statements

Summary of position under the Bill

108. Clause 237 allows the Regulator to issue an official statement about a therapeutic product that is to be exported certifying as to any of the matters listed in this clause. The purpose of an official statement is to provide confirmation from the Regulator to the overseas importer and relevant authorities in the importing country that the product is what it is represented to be and meets the New Zealand requirements for it to be exported.

Official statements (including statements of 'free sale") are important to facilitate overseas trade where an importing country's regulator requires an official statement in order to grant market access for a product. The regulator must correspond directly with all individual export regulatory authorities to explain the NZ system of marketing authorisations (notifications) for NHPs and to ensure that the wording used on Official Statements and licences is acceptable to those country's health authorities. Therefore, the content and format of official statements must be flexible to meet a variety of country's requirements.

109. Natural Health Products NZ supports the inclusion of Clause 237 to facilitate a workable official statement scheme to enable exports.

Recommended amendments

110. For the official statement for export of therapeutic products, the following subclause should be inserted into clause 237(2) as follows:

> (g) any other statements the Regulator deems acceptable under the regulations to facilitate the export of therapeutic products.

111. This amendment is recommended to ensure all trade requirements can be met and that the scheme is future-proofed.

112. We also recommend that a team be established within the new NZ Regulator whose purpose is to assist exporters of NHPs (e.g. similar to MPI's Export Regulatory Advice Service (ERAS)).

Personal Export

Summary of position under the Bill

113. Clause 107 sets out the provisions for personal export of a medicine or medical device but does not include any provision for personal export of an NHP.

114. Personal export of NHPs must be permitted so that people can take their personal supplies with them when they leave New Zealand. 6 months standard supply is risk proportionate for and aligns with international best practice for NHPs.

Recommended amendments

115. Amend cl107 to read "Personal export of a medicine, medical device or NHP".

116. Amend cl107 (2) to read "An individual (person A) is allowed to export a medicine, medical device or NHP (whether or not it has a market authorisation) if they comply with the personal export conditions."

117. Amend cl107 (3) To read "The personal export conditions are that –

(a) Person A acquired the medicine, medical device or NHP lawfully; and

(b) In exporting the medicine, medical device or NHP; person A is not acting in the course of a business or undertaking; and

(c) In the case of a medicine or NHP, the amount exported by person A at any one time does not exceed –

(i) If the medicine or NHP was prescribed by a recognised prescriber or an overseas health professional or a veterinarian, the amount prescribed; or

(ii) Otherwise, 3 months' standard supply for a medicine or medical device and 6 months' standard supply for an NHP."

118. Amend cl107 (4) to read "A reference to 3 months' standard supply of a medicine or NHP means the amount of the medicine or NHP that a notional average patient (or for an NHP, person) with the same condition as the patient or person would require for 3 months calculated on the basis of the recommended daily dose specified by the medicine's responsible manufacturer, or for an NHP the sponsor.

Natural Health Products Position on Exports

119. The Bill does not adequately address the needs of NHP exporters. The overall structure and content of the Bill is problematic as NHPs are subject to many of the regulatory controls that are appropriate for medicines. NHPs are low risk products that are sold through general retail trade channels. The Bill imposes regulation for the export (and import) of NHPs that may be appropriate for medicines but is not appropriate for NHPs because NHPs are sold via general trade retail channels. This includes multiple distributors and exporters of an NHP product. This includes online retail channels selling NHP products directly to consumers in overseas markets. Medicines are not sold in this manner.

120. We submit that the committee reconsider the regulations pertaining to exporting (and also to domestic retail trade) to ensure that the Bill meets the needs of NHPs sold through general retail trade channels. And that the committee ensure that retail trade and export growth are not impeded by the Bill as it is currently drafted to best serve medicines exporting and trade.

121. We submit that the Bill as drafted could result in unintended consequences for exporters.

122. A register of exporters of NHPs is sufficient.

123. NHPs for export-only are market notified as an export-only category to ensure that they are clearly differentiated from market notifications for NHPs that comply with regulations and rules for the New Zealand market.

124. Exporters of NHPs are not required to be licensed or permitted.

HEALTH BENEFIT CLAIMS

Summary of position under the Bill

125. NHPs are included in the Bill which is recognition that NHPs can be therapeutic products. Clause 15 "Therapeutic purpose" outlines the range of therapeutic purposes under the Bill. NHPs do not appear to be restricted from making any of these claims.

126. Natural Health Products NZ supports this.

127. In secondary legislation NHPs must continue to be permitted to make all of the types of health benefit claims permitted by international regulatory practice for equivalent classes of product.

128. We submit that NHPs must be permitted to make all health benefit claims that are permitted for Natural Health Products by Health Canada as follows:

129. "natural health product means a substance set out in Schedule 1or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; (b) restoring or correcting organic functions in humans; or (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health. However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2. A natural health product is exempt from subsection 3(1) of the Act with respect to its advertisement to the general public as a preventative, but not as a treatment or cure, for any of the diseases, disorders or abnormal physical states referred to in Schedule A.1 to the Act."

130. We submit that NHPs must be permitted to make all health benefit claims that are permitted for Listed Complementary Medicines by the Therapeutic Goods Administration of Australia as follows:

131. "Non specific indications refer to general health and wellbeing, such as: health maintenance, relief of symptoms not related to a named condition; and general vitamin, mineral or nutritional supplementation. Specific indications refer to health benefits beyond general health and wellbeing, such as: health enhancement, reduction of risk or frequency of a named condition or symptoms, management or relief of symptoms linked to a named condition; and nutritional supplementation claims linked to a specific therapeutic benefit."

132. *We submit that ensuring that all such health benefit claims are enabled in regulation is commensurate with the concept of risk proportionality for NHPs which are low risk products.*

Natural Health Products NZ position on health benefit claims

133. Natural Health Products NZ and the wider industry remain concerned that not all such health benefit claims will be enabled under secondary legislation. As already discussed in our submission, the Bill does not include the content and level of regulation for NHPs that was extensively consulted on as draft legislation for the NHSPB or as per consultation between Natural Health Products NZ and Ministry of Health officials since 2017 when the NHSPB was not progressed through the House.

134. *We request that the Minister confirm that this is the intention of secondary legislation under this Bill*.

STANDARD HEALTH BENEFIT CLAIMS

Summary of position under the Bill

135. Clause 62 says that rules may set out health benefit claims that may be made about NHPs

136. The clause is unclear as it states “NHPs” “the NHP” and “an NHP”.

Recommended amendment

137. Amend cl62 (2) to read “A standard health benefit claim for NHPs is one that the rules say may be made about NHPs.”

138. Amend cl62 (3) to read “The Regulator must not make rules about a health benefit claim for NHPs unless satisfied on reasonable grounds that the claim can be substantiated in accordance with section 61(4) and (5).

SUBSTANTIATION OF HEALTH BENEFIT CLAIM

Summary of position under the Bill

139. Clause 61 (5) sets out that information about the traditional use of a product or ingredient that is in a pharmacopeia listed in the regulations is prima facie evidence of that use.

All international best-practice sources of traditional use evidence must be accepted as prima facie evidence of that use.

140. There are a number of sources of traditional use evidence that are internationally accepted best-practice sources of traditional use evidence that are not categorised as pharmacopeia. For example, (but not limited to) literature published in peer-reviewed journals, recognised texts and material medica, oral traditions of use.

Recommended amendment

141. Amend Clause 62 (5) to “Information about the traditional use of a product or ingredient that is in a pharmacopeia and **other texts and sources** listed in the regulations is prima facie evidence of that use.”

NEW REGULATOR

Therapeutic Products Regulator

Summary of position under the Bill

142. The Bill establishes a Therapeutic Products Regulator. Clause 333 sets out the performance of functions and exercise of powers of the regulator. Clauses 330 – 334 set out objectives, functions and strategy and exercise of powers of the regulator.

143. The Bill does not require separate business units within the regulator for the different classes of products (medicines, medical devices and NHPs) that the regulator will regulate.

144. Dedicated regulatory resource and expertise is required to effectively regulate NHPs in a risk-proportionate, fit for purpose and efficient manner. The MoH estimates there are

currently 20 000 NHPs in the NZ market. Previous work undertaken during the drafting of the NHSPB and the proposed permitted ingredients list established more than 7000 unique ingredients for NHPs. The evidential basis for substantiation of health benefit claims for NHPs relies on scientific and traditional use evidence that is distinct from the requirements for pharmaceutical medicines and medical devices. Effective regulation will require a significantly resourced regulator with relevant NHP expertise.

145. The NHSPB established an NHP regulator. The NHSPB is the draft legislation that was consulted on for NHPs under the Bill. The consultation made it clear that a dedicated regulator is required.

NHPs are regulated by a dedicated business unit of the Therapeutic Products Regulator.

Recommended amendment

146. Amend cl333 to add a new cl333 (2) to read "The regulator must establish dedicated and separate business units for medicines, medical devices and NHPs".

REGULATORY STEWARDSHIP

Summary of position under the Bill

147. Clause 334 requires the regulator to have a regulatory strategy and review the strategy once every 3 years.

The Bill must require the regulator to comply with the requirements of regulatory stewardship in section 12 of the Public Services Act

148. Requiring the regulator to undertake a regulatory stewardship program will ensure continuous improvement of the performance of the Bill and secondary legislation. Even with best efforts and intentions an omnibus Bill will in practice present with issues and unintended consequences for stakeholders and the regulator. The Bill must clearly ensure that the regulator is required to act when issues are identified and institute a reform program without delay.

Recommended amendment

149. Amend Clauses 333 and 334 to include requirements for regulatory stewardship as per section 12 of the Public Services Act.

EXPERTISE

Summary of position under the Bill

150. Clause 347 Advisory Committees sets out that the regulator may establish advisory committees.

The regulator must seek advice from NHP experts in order to properly carry out its regulatory activities.

151. Ensuring that advisory committees are required is a fundamental part of regulatory best practice. Advisory committees must be composed of NHP subject matter experts with

sufficient representation so that committees can provide best practice advice on matters pertaining to the regulation of NHPs.

Recommended amendments

152. Amend Clause 347 (1) to edit “may” to “must” so that the Regulator is required to establish advisory committees.

153. Amend Clause 347 (2) Advisory committees must be established separately for Medicines, Medical Devices and NHPs. Each advisory committee must have >50% composition of experts in the respective product class (medicines, medical devices, NHPs) and include representation from Natural Health Products NZ.

154. The rationale for mandating representation on an advisory committee is The Medicines Act 1981 cl(9) (3).

MINISTER MUST REVIEW ACT

Summary of position under the Bill

155. Clause 382 requires the Minister to review the policy and operation of the Act 5 years from the commencement of the Act.

156. This is an omnibus Bill replacing multiple pieces of legislation and attempts to address decades long issues with NHPs. It incorporates regulations for NHPs alongside medicines, medical devices and APIs. It is a markedly significant change in the regulation of NHPs.

157. Once the scheme is in place, unintended consequences may become apparent which may negatively impact consumers and industry. The Minister must be required to review the Act in a timely manner to minimise any of these impacts. 5 years post commencement is too long for an initial review of the performance of the Act.

Recommended amendment

158. Amend cl382 (1) (a) to read “2 years from the commencement of this Act”

COSTS

Cost Recovery

Summary of position under the Bill

159. The Bill sets out the principles and requirements for cost recovery in Subpart 2 cl335-342.

160. Clause 336 does not make it clear that NHPs should be subject to lower fees because they are lower risk products and consequently will have a lower cost burden on the regulatory system.

Recommended amendment

161. Amend cl336 to add a guidance note or example below the clause to read “For example, apply the equitable principle that NHPs should be subject to lower fees or levies because they bear a lower cost burden to the regulator and regulatory system”.

Methods of setting fees and levies

Summary of position under the Bill

162. Clause 338 (3) permits the regulator to adjust costs in respect of a financial year to make up any shortfall or over-recovery of costs.

Fees and levies must not increase in a way that negatively impacts stakeholders' ability to financially manage their businesses.

163. The regulator, could with relatively short notice, increase fees and levies. This would negatively impact the ability of businesses to effectively forecast and budget for fees and levies. Effective financial forecasting and budgeting is critical to business success particularly for new product launches and market expansions. There should be a 12-month notice period for any increase in fees and levies. Increases should be capped at CPI.

Recommended amendments

164. Delete cl338 (3).

165. Add cl338 (4) to read "Fee or levy increases for a financial year are capped at the CPI of the preceding 12-month period. If a cost recovery increase above CPI is required, the difference is funded out of appropriations."

Annual Fees and levies

Summary of position under the Bill

166. Clause 339 sets out permissions for the regulator to set annual fees and levies.

NHPs should not be subject to annual fees and levies

167. Fees and levies should only be imposed in a risk-proportionate manner for the regulatory activity for which it is incurred. For example, issuing of market authorisations (notifications) is not an annual activity so there should not be an annual fee.

Recommended amendment

168. Exclude NHPs from Clause 339. Add cl339 (3) NHPs are excluded from annual fees and levies

NHP INGREDIENTS

NHP ingredient, recognised NHP ingredient

Summary of position under the Bill

169. Clause 30 sets out the requirements for NHP ingredients. These include "a substance or mixture of substances that is obtained by the expression, extraction, distillation, purification or a traditional preparation of a plant, plant material, an alga, a fungus or a non-human animal material and is not subject to any other process involving chemical transformation other than hydrolysis or electrolysis."

170. This places limits on the types of NHP ingredient that may be permitted or 'recognised'. Methods of chemical transformation other than hydrolysis or electrolysis are deployed in the manufacture of ingredients commonly used in dietary supplements in New Zealand and equivalent classes of NHPs globally. Limiting the methods of chemical transformation will result in commonly used ingredients being unavailable for use in New Zealand negatively impacting consumer choice and inhibiting exports.

171. The permitted types of chemical modification in the Bill must future proof NHPs innovation to allow for processing during manufacture that may not exist currently. Research and development to develop innovative products will benefit New Zealanders and enable export growth of IP rich product offerings to global export markets.

Natural Health Products NZ position on NHP ingredient

172. Natural Health Products NZ and the wider industry remain concerned about the range of ingredients that will be recognised NHP ingredients under secondary legislation. As already discussed in our submission, the Bill does not include the content and level of regulation for NHPs that was extensively consulted on as draft legislation for the NHSPB or as per consultation between Natural Health Products NZ and Ministry of Health officials since 2017 when the NHSPB was not progressed through the House.

We request that the Minister confirm the intention of the Bill is to use the previous draft Permitted Ingredient List that was informed by consultation during the drafting and progression of the NHSPB as the provisional draft NHP ingredient list for secondary legislation under the Bill.

The Bill should not unnecessarily limit NHP ingredients that are well accepted globally and should not stifle future innovation opportunities.

Recommended amendments

173. Amend cl30 1 (b) to "a substance or mixture of substances that is obtained by any method permitted in the regulations"

174. Add to 30 (2) "A person may apply to the Regulator to have the rules amended to add or amend a recognised NHP ingredient"

Manufacture of an NHP ingredient

Summary of position under the Bill

175. Clause 48 "Manufacture of NHP" includes manufacturing of an NHP ingredient and this includes procurement, preparation and processing.

176. Clause 20 does not include NHP ingredient in the list of types of therapeutic product. Therefore, cl48 is at odds with cl20.

177. It is not global best practice to include the manufacturing of NHP ingredients within the requirements for manufacturing of an NHP. Manufacture of an NHP is a controlled activity. Global best practice accepts that manufacturing of NHP ingredients is to the standards and requirements of foods (for orally consumed NHPs) and cosmetics (for topically applied NHPs). Requiring the manufacture of NHP ingredients to be within the scope of manufacture of NHPs will result in the unintended consequence of ingredients manufacturing being captured by the requirements for controlled activities. This will result in ingredients

that would globally be available for the manufacture of NHPs being unavailable for the manufacture of NHPs in New Zealand or exported from New Zealand. New Zealand would diverge significantly from global regulatory best practice for NHPs. Many NHPs would not be available in the New Zealand market.

178. Globally the quality of NHP ingredients is generally controlled by supplier qualification and specifications set out or referenced to. This is risk proportionate for NHPs which are low risk products.

Recommended amendment

179. Amend cl48 to delete 48 (c) (i), (ii), (iii)

Naturally occurring thing may be a product

Summary of position under the Bill

180. Clause 18 sets out that a naturally occurring thing that might not otherwise be considered to be a product may become a product if it is changed from its naturally occurring state.

181. This means that under the Bill an NHP ingredient non-finished good that is made from a naturally occurring thing by a transformative process (for example by a method permitted in cl30 of extraction, purification or traditional preparation etc) could be interpreted to be a "product".

182. The unintended consequence of this is that such an ingredient could be interpreted to be required to adhere to all regulations pertaining to an NHP product when it is an NHP ingredient.

183. Clause 18 should make it clear that a product is only a product when it is presented in the form of a finished good for retail sale.

Recommended amendment

184. Amend cl18 to add cl18 (b) A product is a thing that is presented in the form of a finished good for retail sale.

INTELLECTUAL PROPERTY

Protection of proprietary ingredient information

Summary of position under the Bill

185. The Bill does not provide for any intellectual property information protection for proprietary ingredients for NHPs. Subpart 3 Clauses 148-150 provide for the protection of intellectual property of active pharmaceutical ingredients APIs.

Proprietary NHP ingredients (active and non-active) must have intellectual property information protection.

186. Protection of intellectual property information is important to competitive advantage in the marketplace both locally and internationally. The current draft of the Bill will mean that New Zealand businesses will be discouraged from innovating and conducting research and development to bring novel ingredients to the market. International proprietary ingredients

suppliers may remove products from the market and be discouraged from launching new and innovative products into the New Zealand market. New Zealand consumers and businesses will be detrimentally impacted as new and innovative products will be unavailable, and innovation and research and development will be inhibited.

Recommended amendment

187. Drafting clauses that afford proprietary NHP ingredients the same protections that are afforded to protected active ingredients in clauses 148-150 and anywhere else in the Bill.

ADVERTISING

Summary of position under the Bill

188. Clause 193 sets out that an advertisement for a therapeutic product means a communication that is made in any way whatsoever (with limited exclusions) for the purpose of promoting the product.

189. Clause 194 sets out the requirements for advertising to comply with the Act and regulations and rules and that distribution of advertisements is limited to authorised products and complies with regulations. The Bill provides for regulations without limitation to the form, distribution and to whom an advertisement is distributed.

190. For NHPs the unintended consequences of the Bill include situations where other legislation carves out provisions that address real-life situations where advertising would be otherwise captured. For example, section 24(b) of the Smokefree Environments and Regulated Products Act 1990 states that restrictions on advertising do not apply to:

(a) any advertisement included in any book, magazine, or newspaper printed outside New Zealand, or in any radio or television transmission originating outside New Zealand, or in any film or video recording made outside New Zealand, unless—

(i) the main purpose of the book, magazine, newspaper, transmission, film, or video recording is the promotion of the use of regulated products; or

(ii) the book, magazine, newspaper, film, or video recording is intended for sale, distribution, or exhibition primarily in New Zealand; or

(iii) in the case of an advertisement in any radio or television transmission, the advertisement is targeted primarily at a New Zealand audience.

191. The Smokefree Environments and Regulated Products Act 1990 also sets out provisions for other specified publications exempt from advertising prohibitions including:

(a) any regulated product advertisement published by a regulated products manufacturer in a magazine intended for distribution only to the manufacturer's employees:

(b) the exhibition, in any museum or art gallery, of any work or artifact:

192. The Bill does not permit trade show and exhibitions to present information about NHP products (including product samples) that sponsors may wish to bring to the market (notify) in New Zealand.

193. The Bill must also ensure that advertising that occurs in export markets is not the responsibility of the sponsor, responsible manufacturer or exporter because exported product is required to comply with the regulations of the importing country and these may differ from those in the Bill.

The regulations for the advertising of NHPs must be fit-for-purpose to account for all possible scenarios where an NHP which is a general retail trade product may be advertised so that advertising is regulated in a risk proportionate manner.

Recommended amendments

194. Amend cl194 to delete "without limitation" so that cl194 (3) reads only "regulations for this section may relate to the following:"

195. Amend clauses 193 and 194 to incorporate carve-out provisions as per the Smokefree Environments and Regulated Products Act 1990 and any other legislation that addresses advertising in this manner.

196. Amend clauses 193 and 194 to permit trade show and B2B advertising of NHP products (including the importation of product samples for these purposes) to ensure trade and innovation is not restricted.

197. Amend clauses 193 and 194 and any other clauses in the Bill to ensure sponsors, responsible manufacturers', exporters and any other persons are not responsible for advertising of exported products in importing countries' markets.

198. If further amendment of the Bill is required to permit the importation of NHP product samples for trade shows and B2B advertising, we submit that these amendments are made.

SPONSORS OBLIGATIONS

Sponsors must ensure compliance with market authorisation/notification

Summary of position under the Bill

199. Clause 139 requires that sponsors of NHPs must if the market authorisation (notification) requires any other person to do or not do, something, ensure that the other person complies with the requirement.

200. This requirement is unnecessarily onerous and unworkable for sponsors of NHPs. As NHPs are general trade products there can be a number of persons involved in the distribution and sale of NHPs domestically and in export markets. A sponsor cannot be held responsible for the actions of persons involved in general trade. A sponsor should not be held responsible for a retailer selling an NHP for use in a way that is not permitted in a market authorisation/notification. For example, if a product that was market authorised/notified for children aged 3 – 14 years was sold for use by an adult.

Sponsors' obligations for compliance with market authorisation/notification of NHPs should be limited to only those with which the sponsor can reasonably be expected to be responsible for.

Recommended amendment

201. Delete cl139 (c)

Sponsor must ensure product meets export standards

Summary of position under the Bill

202. Clauses 140 and 141 require the sponsor to ensure NHPs meet any applicable product standards.

203. We submit that product standards are not required for NHPs as they will be sufficiently controlled by the regulations. See our submission "Product Standards" above. However, should this amendment not be accepted, we submit the following:

204. These clauses do not qualify that this requirement is when the product is released for supply. The sponsor of NHPs cannot be reasonably expected to ensure that an NHP supplied domestically and exported into general trade conforms to any applicable product standards at any other time than at "release for supply". This is proportionate to risk for NHPs which are low risk products.

Sponsor's obligations for NHPs should be limited to only those which the sponsor can reasonably be expected to be responsible for.

We also recommend review of all NHPs sponsors' obligations under the Bill to ensure they are risk proportionate and fit for purpose for NHPs which are low risk products sold in general trade.

Recommended amendments

205. Amend clause 140 (1) to read "The sponsor of a therapeutic product must ensure that the product meets the product standards that apply to it at release for supply"

206. Amend clause 141 (1) to read "The sponsor of a therapeutic product with an export standard must ensure that the product meets the export standards that apply to it at release for supply"

207. Amend clause 141 (2) to read "The sponsor of a therapeutic product with a NZ authorisation or notification must ensure that if the product is exported it meets the export standards that apply to it at release for supply"

COSMETICS AND FRAGRANCE – NHP INTERFACE

Summary of position under the Bill

208. The Bill does not define the cosmetic and fragrance – NHP interface or set out a clear determination of a product being a cosmetic or an NHP.

209. Topical products that are not medicines or medical devices could be NHPs or cosmetics (regulated by the Cosmetic Products Group Standard 2020) under the Bill because the ingredients could be recognized NHP ingredients and health benefit claims could be interpreted to be therapeutic purpose claims under cl15 Therapeutic purpose.

210. Examples of products that could be unintentionally captured by these provisions include skin creams containing vitamin C or Vitamin E or CoEnzyme Q10 that make claims that are globally accepted as being appropriate for cosmetic products.

211. Re-categorisation of these products as NHPs or medicines will have unintended consequences of limiting the ability of internationally accepted cosmetics to remain on the market or enter the market or be exported as cosmetics manufacturers will not accept the additional regulation that is required as an NHP or medicine for a product that is globally accepted as being a cosmetic.

212. This also applies to products that are regulated Food Additives and Fragrance Materials (Flammable) Group Standard 2020 by the EPA some of which may have an intended therapeutic purpose via the principles of aromatherapy.

213. However, under the Bill topical and fragrance products that are currently prohibited from making health benefit claims as an NHP will be permitted to make such evidence-based claims provided claims can be sufficiently substantiated.

214. Clearly defining the interface between cosmetics and topical NHPs and medicines is critically important. One way to do this is to define topical and fragrance products that make health benefit claims for Named Conditions to be NHPs or medicines.

The interface between cosmetics and fragrances and therapeutic products must be clear so that products currently sold as cosmetics and fragrances are not inadvertently captured as therapeutic products. Such products that are intended to be therapeutic products must also be adequately and clearly provided for within the Bill in a risk-proportionate manner.

Recommended amendment

215. Amend cl16 Therapeutic Product to read 16 (1) (d) a topical or fragrance product is only a therapeutic product if (i) it contains an API or (ii) a sponsor makes a therapeutic product application for the product or (iii) it contains recognized NHP ingredients and (iii) it makes health benefit claims for a Named Condition (International Statistical Classification of Diseases and Related Health Problems (ICD))

MEDICINES REGULATIONS 1984 CLAUSE 58A

Summary of position under the Bill

216. The Bill repeals the Medicines Regulations 1984

217. Clause 58A of the Medicines Regulations 1984 sets out that dentifrice, anti-dandruff, anti-acne skin care, barrier cream and anti-bacterial skin products are not medicines providing a number of conditions related to composition and health benefit claims are met.

218. This enables products that are sold globally as cosmetics (not regulated as medicines) to be available for New Zealand consumers and to be imported and exported into and from New Zealand for the benefit of international trade.

219. The Bill does not set out any provisions for such products. Because they make health benefit claims that would be therapeutic purpose claims under the Bill they would be captured by the provisions of the Bill and required to be medicines, medical devices or NHPs.

220. This would result in products that are internationally regulated in non-therapeutic product classes to be regulated as therapeutic products in NZ. This will result in products currently on the market being unavailable for NZ consumers because manufacturers of such products

sold internationally as cosmetics will not be willing to operate with the increased regulatory burden required for a small market like NZ. Examples of such products are those that everyday NZ consumers buy in supermarkets such as toothpastes, non-medicated anti-dandruff shampoos, barrier cream for chafing, antibacterial soap, non-medicated pimple gels creams and cleansers.

221. We also refer to our submission points for the Bill's interface with foods, cosmetics and fragrance products.

Clause 58A products must continue to be permitted to be regulated as cosmetics.

Recommended amendment

222. See recommended amendment at COSMETICS AND FRAGRANCE - NHP INTERFACE

FOODS – NHP INTERFACE

Summary of position under the Bill

223. The Bill does not define the food – NHP interface or set out a clear determination of a product being a food or an NHP.

224. Some products that are currently sold as food could fall within the definition of NHP in Clause 29 (2). If a product falls into a category for which there is a Food Standard~~,~~ then the product should not be classified as an NHP.

The interface between foods and NHPs must be clear to prevent confusion and subsequent unintended consequences of products being brought to market ambiguously.

Recommended amendments

225. Add clause 29(3) (c) to read "there is a food standard for the product".

226. Add clause 29 (2) (c) to read "the concentration of each NHP ingredient is not more than the maximum concentration set out in the rules; and

227. Add clause 29 (2) (d) to read "the product is presented in a controlled dosage format".

COMBINATION NHP-MEDICAL DEVICE PRODUCTS

Summary of position under the Bill

228. The Bill does not address products that may be combined NHP-Medical Devices

229. Some low-risk medical devices that incorporate ingredients that will become NHP ingredients are currently notified on the WAND database as medical devices. For example, a dressing that also has manuka honey ingredients. This product would currently be notified as a medical device in WAND because of the physical therapeutic purpose of the dressing.

230. The Bill does not set out provisions for a product such as the above to be able to make evidence-based health benefit claims pertaining to the NHP ingredient(s).

231. Such a combination product would be authorised/notified as an NHP as well as regulated as a medical device.

232. The ability for the Bill to provide for such products would future-proof the Bill and enable innovation.

Combination NHP-Medical Device products that permit NHP ingredients and evidence based NHP health claims must be permitted.

Recommended amendment

233. Amend cl21 to add a new cl21 (3) to read "A therapeutic product can be a combination medical device – NHP product according to the rules".

FIT AND PROPER PERSON

Summary of position under the Bill

234. Clause 60 sets out a fit and proper person to (among other things) be of good character and for the regulator to have regard to any other matters that it thinks are relevant in its determination.

The criteria for determination of a fit and proper person by the regulator should be clear and solely objective and unambiguous.

Recommended amendment

235. Delete cl60 1 (g) and (h)

SUPPLY CHAIN

Summary of position under the Bill

236. Clauses 55 – 57 set out provisions for supply wholesale supply, supply chain activities and persons in the supply chain.

237. NHPs are sold by general retail sale. This is different to the supply chains for medicines that commonly have risk proportionate controls to all aspects of supply chain activities because medicines pose a higher risk than NHPs.

238. Other general retail products are not subject to such regulations pertaining to supply chain and persons in the supply chain.

239. We recommend that the committee give careful consideration to the supply chain regulations for NHPs under the Bill to ensure that they do not result in unintended consequences for persons that participate in a general retail trade supply chain both domestically and in export markets.

Consideration should be given to NHPs to be excluded from clauses 55 - 57 and other references to Supply Chain for activities that are not controlled activities.

RESPONSIBLE PERSON

Summary of position under the Bill

240. Clause 159 requires a responsible person to be ordinarily resident in New Zealand

241. Clause 14 Interpretation says that a responsible person in relation to a licence means an individual named in the licence as a responsible person.

242. Clause 152 Content of a licence requirements for responsible persons for controlled activities to be named on the licence.

243. The responsible person(s) for controlled activities for NHPs may reside outside of New Zealand. For example, if quality assurance functions that are undertaken overseas because either that component function for a licensee exits in an overseas jurisdiction or it is not available domestically.

Regulations for NHPs must take into account the nature of the manufacturing of NHPs which can include multiple sites for controlled activities and capability that may not be available in New Zealand

Recommended amendments

244. Delete cl159 (b) “is ordinarily resident in New Zealand”.

245. Delete cl159 (d) “is a fit and proper person to be a responsible person” See submission point FIT AND PROPER PERSON.

RESPONSIBLE MANUFACTURER

Summary of position under the Bill

246. Clause 42 sets out that the responsible manufacturer of a therapeutic product is the person who is primarily responsible for its manufacture. The clause goes on to provide detail of the considerations in determining who is the responsible manufacturer including stating that a person may be the responsible manufacturer of a product whether or not they do anything that is part of its manufacture.

247. The Bill does not set out who determines who the responsible manufacturer is. This is problematic as the regulator could make a determination that the responsible manufacturer is a party outlined in cl42 (2) and (3) that differs from the determination that has been made by those parties.

248. There should be a provision for the responsible manufacturer nominated on the market authorisation (notification) to be the only determined responsible manufacturer.

249. For NHPs a number of manufacturers may be involved in the manufacture of a product. In this case the Sponsor or another party that is not one of the manufacturers should be able to determine with certainty that they are the responsible manufacturer on the product authorisation (notification).

Recommended amendment

250. Amend cl42 (1) to read “The responsible manufacturer of a therapeutic product is the person who has determined that they are primarily responsible for its manufacture and the notified manufacturer on the product authorisation”.

CONTRACTURAL RELATIONSHIP – REVIEW BY THE REGULATOR

Summary of position under the Bill

251. Clause 125 sets out the requirements for sponsorship of NHP which includes that a sponsor must have a contractual relationship with the responsible manufacture that the satisfies the regulator.

252. This clause permits the regulator to review contracts between sponsors and responsible manufacturers.

253. cl125 (2) is not required because cl123 (2) sets out that the regulator must accept the applicant’s declaration referred to in section 122 as prima facie evidence of the matters declared in an application for market authorisation/notification.

254. This appears to be an infringement on the freedom of contract.

Recommended amendment

255. Delete cl125 (2) (a) and (b)

MAJOR CHANGE

Summary of position under the Bill

256. Clause 129 states “Major change results in different product”. It goes on to set out that a major change in relation to an NHP with a market authorisation means a change to the product itself or to any matter of information relating to the product that may have a significant impact on its quality or safety.

257. For NHPs the use of the terms “significant impact” on “quality and safety” could be ambiguous and subjectively interpreted.

258. For example, interpretation that a change to a manufacturer, or a change to a source of a raw material is a major change is unwarranted, because for NHPs the quality and safety will be controlled for in regulations pertaining to manufacturing and raw material specifications.

259. The intention of the clause is for a major change to be one that results in a different product. For an NHP this is limited to a change in the quantity or proportions of recognized NHP ingredients.

260. Other changes should be permitted by cl134 variation of authorisation (notification)

For NHPs a major change should only be one that results in a different product

Recommended amendment

261. Amend cl129 (1) (a) (iii) to read "if it is an NHP, the quantities or proportions of recognized NHP ingredients".

CHANGE OF SPONSOR

Summary of position under the Bill

262. Clause 130 sets out that a market authorisation cannot be transferred from the sponsor to another person unless the regulator is satisfied on reasonable ground that the proposed new sponsor meets the criteria for being a sponsor. Clause 134 (2) sets out that a market authorisation variation cannot change who the sponsor is.

263. This level of review is not required for a change of sponsor for NHPs which are low risk products. Compliance with the requirements of cl125 should be sufficient.

264. Variations to market authorisations (notifications) should permit a change in sponsor if the new sponsor meets the criteria for being a sponsor.

Recommended amendments

265. Add a new cl130 (1) to read "A market authorisation (notification) for an NHP can be transferred from the sponsor to a new sponsor if the proposed new sponsor meets the criteria for being a sponsor in section 125.

266. Amend cl134 (2) to read "for a medicine or medical device to change who the sponsor is"

LICENCES

Content of a Licence

Summary of position under the Bill

267. Clause 152 details what a licence must set out including cl152 (1) (e) "the therapeutic products covered by the licence".

268. NHP manufacturers often manufacture many products, this is particularly true for contract manufacturers. Requiring individual products to be detailed on a licence is impractical as the NHPs being manufactured may change as contracts to manufacture are undertaken and completed.

269. The manufacturer and place of manufacture of individual NHPs is commercially sensitive information and should not be disclosed on a licence. Contract manufacturers in particular will be required by sponsors to maintain commercial confidentiality about the individual NHP products they manufacture.

270. More practically the "types" or "formats" of NHPs should be listed on the licence. This is how licencing for manufacture is conducted in similar jurisdictions such as in Australia by the TGA for Listed Complementary Medicines which are the equivalent class of product to NHPs under the Bill.

271. The “types” or “formats” of NHPs to be listed on a licence can be defined in secondary legislation.

272. This would require a licence to only be updated when a new “type” or “format” of NHP is undertaken or removed from manufacturing capability by a manufacturer.

Licencing should be managed in a risk-proportionate manner for NHPs which are low risk products. Commercial confidentiality should also be accounted for. Therapeutic product “type” or “format” is an appropriate listing on a licence for NHPs.

Recommended amendment

273. Amend cl152 (1) (e) to read “the therapeutic products covered by the licence or for NHPs the therapeutic product type as defined in the regulations (other than for a pharmacy licence).

Effect of a Licence

Summary of position under the Bill

274. Clause 153 sets out what a licence allows including things to be done in relation to a therapeutic product covered by the licence.

275. See submission point above Content of a Licence

Licencing should be managed in a risk-proportionate manner for NHPs which are low risk products. Commercial confidentiality should also be accounted for. Therapeutic product “type” or “format” is an appropriate listing on a licence for NHPs.

Recommended amendment

276. Amend cl153 (2) (a) to read “in relation to a therapeutic product or for NHPs a therapeutic product type as defined in the regulations, covered by the licence; and

POST MARKET SURVEILLANCE AND RESPONSE SYSTEM

Summary of position under the Bill

277. The Bill requires sponsors to have in place a post-market surveillance and response system for NHP products that conducts surveillance of the safety and quality of NHPs.

The post market response system for NHPs should be limited to the requirement for sponsors to have in place a product complaint handling system, a serious adverse event reporting system and product recall system.

278. Surveillance of the quality and safety of NHPs in the market is not defined and subjectivity or ambiguity could be introduced into the system as an unintended consequence. For NHPs which are low-risk products surveillance of NHP products in the market is not required because the regulations will set out product safety and quality requirements. The Bill confirms these using statements such as “maximum concentrations of NHP ingredients” and requiring NHP ingredients to be “recognised NHP ingredients”. Such ingredients will be determined to be risk proportionately safe for use in NHPs according to the regulations.

279. Such a system requiring post market surveillance for safety and quality could place a requirement for unnecessary activities of post market sampling and testing on the sponsor at

significant additional cost. Under the Bill exports appear to be included in this and whilst it is not practical for such a system to be implemented domestically, it would be impossible for a sponsor to carry out in multiple export markets where distributors may be engaged. In any case the importing country's regulations for serious adverse event notification and recall would apply to products in that market.

280. The NHSPB (which was the draft legislation for NHPs consulted on to inform this Bill) included an adverse event reporting requirement and did not include any requirement for post market surveillance of safety and quality by the sponsor. This should be the position within the Bill.

Recommended amendments

281. Amend cl142 (1) to "The sponsor of a therapeutic product that is not an NHP must have in place a system for post market surveillance and response for the product".

282. Delete cl142 (2) (iii) "if the product is an NHP, it's safety and quality; and"

283. Add new clause 143 "The sponsor of an NHP must have in place a system for product complaints handling serious adverse event reporting and product recall".

284. We submit that Clause 17 of the Natural Health and Supplementary Products Bill 324-2 (Product notifier must notify Authority of any serious adverse reaction to natural health and supplementary product) inform re-drafting of the Bill for NHPs

285. We submit that the Australian TGA pharmacovigilance requirements for Listed Complementary Medicines be used to inform re-drafting of the Bill for NHPs

286. We submit that the FDA 21 CFR 111 Subpart O Product Complaints be used to inform re-drafting of the Bill for NHPs

287. We submit that the Food Act 2014 part 3A Tracing and Recall be used to inform re-drafting of the Bill for NHPs

COMPLIANCE MONITORING BY REGULATOR

Summary of position under the Bill

288. Clause 203 requires the regulator to have in place a post-market surveillance and response system to conduct surveillance of the quality and safety of NHPs.

289. The use of the phrase "quality and safety can be ambiguous and subjective and should be further qualified.

The regulator's post market surveillance of the quality and safety of NHPs should be qualified to refer to compliance with the regulations for quality and safety of NHPs.

Recommended amendment

290. Amend cl203 (2) (a) (iii) to read "the safety and quality of NHPs according to the regulations".

INVESTIGATIVE POWERS

Summary of position under the Bill

291. Part 7, Subpart 2 – Regulatory Powers sets out extensive powers for the regulator to enter premises, require samples and testing, examine any supply chain activities, test any equipment or process including those in the supply chain, test any products, take samples, make records and recordings, copy documents, take samples and use any equipment at the premise among other things.

292. Part 8, Subpart 1 – Investigative Powers sets out extensive powers for the regulator to enter premises, search, seize and require persons to do things among other things.

293. According to the Legislation Design and Advisory Committee Legislation Guidelines 2021, Chapter 21, new search powers should be granted only if the policy objective cannot be achieved by other means. If the information or evidence concerned can be obtained by means other than by granting new search powers (for example, by recourse to the common law, consent, or existing powers), those alternatives should be used. If new search powers are required, the approach that results in the least limitation on privacy rights should be adopted. Search powers should not be granted for the convenience of the agency or ease of prosecution. Each search power must have a separate justification for why it is necessary. A general justification that search powers are required is not sufficient.

294. The regulatory powers in the Bill are invasive powers and have not been justified as necessary for low-risk products such as NHPs.

Recommended amendment

295. Part 7, Subpart 2 and Part 8, Subpart 1 are redrafted to ensure that any of these powers that the regulator may have are risk proportionate for NHPs which are low risk products. Serious consideration is given to the impacts of carrying on business should the regulator exercise such powers where they are not warranted as the policy objective can be achieved by other means.

SHARING OF INFORMATION

Summary of position under the Bill

296. Clause 356 sets out the power of the regulator to act on requests of overseas regulators and overseas organisations. Clause 343 sets out the provisions of sharing of information with regulatory entities, overseas regulatory entities, and overseas organisations by the regulator. Clause 346 sets out the provisions by which the regulator may rely on decisions of recognised entities and that the regulator may, by regulator's notice designate overseas entities, overseas organisations and any other person or body (that the regulator is satisfied about) as a recognised entity.

297. We submit that sharing of information with overseas regulators be limited to regulators in those countries with which New Zealand has a cooperation agreement as per the Commerce Act 1986. The Commerce Act 1986 limits the sharing of information with an overseas regulator to countries that New Zealand has a cooperation agreement with.

298. This includes the provisions under Sections 99A-99P of the Commerce Act 1986 relating to the assistance that may be provided to overseas regulators.

299. A regulatory cooperation agreement must meet the requirements of the Commerce Act 1986 Section 99E for Government-to-government co-operation arrangements which includes obligations of the Minister of Business, Innovation, and Employment.

300. The Commerce Act states that the Commerce Commission must not provide compulsorily acquired information or investigative assistance to an overseas regulator unless the information or assistance is provided—

(a) to a recognised overseas regulator in accordance with a co-operation arrangement; and

(b) in accordance with sections 99I to 99K.

301. Furthermore, Section 99I (2) provides criteria that the Commission must be satisfied of and states:

Before providing compulsorily acquired information or investigative assistance under subsection (1), the Commission must be satisfied that—

(a) providing the information or assistance will, or is likely to, assist the recognised overseas regulator in performing its functions or exercising its powers in relation to competition law; and

(b) the provision of the information or assistance will not be inconsistent with the co-operation arrangement; and

(c) the provision of the information or assistance will not significantly prejudice New Zealand's international trade interests.

Recommended amendments

302. Amend clauses 343, 346, 356 to align with the provisions of the Commerce Act 1986 regarding assistance provided to overseas regulators

303. Delete reference to "overseas organisations" in clauses 343, 346, 356.

LOW CONCENTRATION

Summary of position under the Bill

304. Clause 31 sets out the requirements for low concentration NHPs

305. The clause does not make it clear that a low concentration NHP is a homeopathic NHP. The unintended consequence of this is that NHPs that contain low concentrations of ingredients that is not a product manufactured to and adhering to globally accepted principles of homeopathy could come to market as unauthorised products.

The definition and setting out of low concentration products should clarify that these are homeopathic products

Recommended amendment

306. Amend cl31 to add 31 (1) (f) "it is prepared according to homeopathic principles according to the rules"

VETERINARIAN

Summary of position under the Bill

307. Clauses 93 through 101 do not include mention of NHPs.

Veterinarians should be permitted to use and handle NHPs for their patients as they see fit according to their professional expertise.

Recommended amendments

308. Amend cl93 (2) to read “A veterinarian is allowed to supply a medicine, medical device or NHP by non-wholesale supply (whether or not is has a market authorisation/notification).

309. Add cl93 (3) (d) to read “if it is an NHP that requires compounding it is lawfully compounded for that patient”.

310. Amend cl95 (2) to read “A veterinarian is allowed to administer a prescription medicine or NHP (whether or not is has market authorisation/notification)

311. Amend all clauses 95-101 pertaining to veterinarians in a similar fashion to permit veterinarians to use NHP products.

OFF-LABEL USE & SPECIAL CASE REQUIREMENT

Off-label use

Summary of position under the Bill

312. Clause 49 sets out provisions for persons carrying on controlled activities for authorised medicines and medical devices for purposes or indications that are not authorised indications that is an off-label supply, administration or use purpose.

313. The clause does not include provisions for off-label use for NHPs.

We submit that persons carrying on controlled activities should be able to use NHPs for purposes or indications that are not authorised indications that is an off-label supply, administration or use purpose.

Recommended amendment

314. Amend cl49 to read “A person carrying on a controlled activity with a medicine, medical device or NHP that has a NZ authorisation or notification for 1 or more authorised or notified indications carries on the activity for an off-label use if,-“

(a) In carrying on the activity, they supply, administer or use the medicine, device or NHP for a purpose or an indication that is not an authorised or notified indication; or”

Special case requirement

Summary of position under the Bill

315. Clause 65 sets out the provisions for special case requirements where a health practitioner or a veterinarian can carry on a controlled activity with a medicine or medical device that does not have a NZ authorisation in relation to a patient for special case requirements.

316. The clause does not include special case provisions for NHPs.

We submit that health practitioners and veterinarians should be able to use NHPs for special case requirements.

Recommended amendments

317. Amend cl65 to read:

318. "(1) This section applies for the purposes of a provision of this Act that allows a health practitioner or veterinarian to carry on a controlled activity with a medicine, medical device or NHP that does not have a NZ authorisation or notification in relation to a patient if the special case requirement is met.

319. (2) The special case requirement is met if the health practitioner or veterinarian, exercising their professional judgement, is satisfied that—

(a) there is no available medicine, medical device or NHP with a NZ authorisation or notification that is suitable to meet the clinical needs of the patient (whether as an authorised or notified indication or an off-label use); and

(b) it is appropriate to carry on the activity with the medicine, device or NHP that does not have a NZ authorisation or notification.

320. (3) For the purposes of subsection (2)(b), the health practitioner or veterinarian must have regard to any criteria or requirements in the regulations."

TRANSITIONAL

NHPs temporary market authorisation

Summary of position under the Bill

321. Schedule 1 cl12 provides upon commencement of the Act for a temporary market authorisation for NHPs of 2 years.

322. The MoH estimates that there are 20 000 NHPs on the market in New Zealand. It is not practical to require such a large number of NHPs to become authorised (notified) in such a short space of time. It is unlikely that the resources of the regulator or of industry can cope with this timeframe due to capacity and capability requirements that are likely to be required to be introduced to the supply chain. It is possible that a manufacturer may be required to implement process control that requires capex sourced plant and machinery and IQ/OQ. These processes take significant capital and time to source, implement and sign off for commercial manufacturing. There could be a bottleneck within industry of capability across multiple functions due to the scheme being introduced across the entire NHP industry at one time.

Transitional requirements must set realistic timeframes to enable the regulator and industry to transition into the scheme so that consumer choice, exports and economic growth are not negatively impacted.

Recommended amendment

323. Amend Schedule 1 cl12 (d) to “expires 5 years after commencement”.

Unregulated product now a medicine or medical device

Summary of position under the Bill

324. Schedule 1 clause 11 sets out a 6-month expiry date for temporary market authorisation for a product that was in the market and was not a medicine or medical device but becomes a medicine under the Act.

325. 6 months is an unreasonably short time to transition to a medicine classification. This transition could require manufacturers to make substantial product and manufacturing changes, prior to preparing an application.

Recommended amendment

326. Amend Schedule 1 cl11 (3) (d) to 2 years.

OFFENCES AND PENALTIES

Summary of position under the Bill

327. Clauses 247-476 and other clauses under the Bill set out offences and penalties for all therapeutic products. Despite NHPs being low risk products, the regulation regarding offences and penalties is the same for medicines, medical devices. APIs and NHPs.

328. This places an unnecessary burden of regulatory risk on industry participants. The unintended consequences of not taking a risk-proportionate approach to these parts of the Bill will be to negatively impact New Zealand NHP businesses both domestically, for export and for importers into our market. Consumer choice will be impacted as will economic growth. This is because the majority of our businesses are small and medium sized enterprises who will choose not to enter or remain in a market that has such a level of offence and penalty provisions. The ability and costs for businesses to obtain sufficient business insurance will be impacted as they will be viewed by insurers with the same lens as a pharmaceutical company.

Offences and penalties pertaining to NHP activities must be commensurate with the low risk profile of NHPs.

Recommended amendment

329. We submit that all clauses pertaining to offences and penalties for NHPs including but not limited to cl247 – 276 be reviewed and amended to a low risk profile. The benchmark for this is the relevant clauses in the NHSPB which is the only draft legislation and proposed regulation that was extensively consulted on for NHPs.

REVIEW OF DECISIONS BY THE REGULATOR

Summary of position under the Bill

330. Clause 357 sets out how a person may apply to have a regulator's decision reviewed. It includes a requirement that application for review is made within 30 working days after the notice of decision has been served.

331. However, there is no similar obligation upon the review panel. Most of the reviewable decisions would have financial implications, therefore a drawn-out review process could have significant impacts to persons and businesses impacted by the regulator's decision.

Service delivery requirements for regulator activities will ensure efficient regulatory function and minimise preventable impacts to stakeholders.

Recommended amendment

332. Amend cl357 to add 357 (3) "The regulator must undertake review and report the review decision to the applicant within 30 working days of receiving the application for review".

COMMENCEMENT

Summary of position under the Bill

333. Clause 2 does not confirm that all secondary legislation – all regulations and rules will be law prior to the commencement of the Act.

334. If all of the secondary legislation (regulations and rules) is not law prior to the commencement of the Act, NHP products cannot be adequately regulated in a risk proportionate manner. This could impact consumers and industry by limiting product availability and constraining exports and imports.

The entire scheme for NHPs which includes all secondary legislation must be in place before the Act commences.

Recommended amendments

335. Amend cl2 to add new (1) This Act may only come into force when all secondary legislation has been enacted.

336. Delete current cl(2)

CLOSING SUMMARY

337. Natural Health Products NZ would like to reiterate that we are encouraged that a Bill that is intended to address much needed regulatory reform for NHPs is again before the House.

338. Our support for the Bill is conditional because there are a number of significant clauses and details in the Bill, (as well as the way it is structured for NHPs) that we submit do not achieve the intention of the Bill to regulate NHPs in a risk proportionate manner.

339. We are concerned that regulation for NHPs in the Bill has not been consulted on under the justification that extensive consultation was undertaken previously to inform the NHSPB.

However, the content of the Bill for NHPs is a material and significant departure from that of the NHSPB. We submit that this justification cannot hold up and that NHPs in the Bill have effectively not been consulted on to date.

340. Therefore, we urge the committee to adopt our recommended amendments which will bring regulation for NHPs into the form and content that has been consulted on and ensure that regulation for NHPs is modern and risk proportionate.

341. Effective, efficient and flexible regulation for NHPs will benefit New Zealand consumers providing them with information (that they are currently prohibited from knowing) about the evidence-based health benefits of NHPs available in the New Zealand market. It will minimise product and participant non-compliances. Significantly, all these benefits extend to the wider economy through enabling innovation and export growth.

342. The natural health sector is a rising star of the New Zealand economy significantly contributing to our GDP, local employment and manufacturing capability, global export trade and the transformation of New Zealand's primary produce from volume to value.

APPENDIX – NATURAL HEALTH PRODUCTS NZ MEMBERS

Company	Region	Category
A S Harrison	Auckland	Ingredients
Absolute Essential Ltd	Auckland	Branded Goods
ADM	Auckland	Ingredients
Advanced Wellness Regulatory Solutions	Australia	Services
aibGROUP Insurance	Auckland	Services
AJ Park	Wellington	Services
Aker Biomarine New Zealand Limited	Otago	Manufacturing
Alaron Products Ltd	Nelson/Marlborough/Tasman	Manufacturing
Alchemy Agencies	Auckland	Ingredients
Anagenix Ltd	Auckland	Ingredients
ApiHealth NZ Ltd	Auckland	Branded Goods
Artemis Ltd	Otago	Branded Goods
AsureQuality Ltd	Auckland	Services
Atomic Regs Pty Ltd	Australia	Services
BioBalance Ltd	Nelson/Marlborough/Tasman	Branded Goods
BioEquitas Ltd	Auckland	Services
BioPacific Partners	Auckland	Services
Biotec Solutions Ltd	Auckland	Services
Biovit GMP Laboratories Ltd	Auckland	Manufacturing
Blackmores Ltd	Auckland	Branded Goods
Blis Technologies Ltd	Otago	Ingredients
Blue Star Group (NZ) Ltd	Auckland	Services
Botanic Healthcare	Auckland	Ingredients
Brenntag New Zealand Ltd	Auckland	Ingredients
Bronson & Jacobs NZ	Auckland	Ingredients
Callaghan Innovation	Wellington	Services
Capsugel NZ Ltd / Lonza	Australia	Services
Cawthron Institute	Nelson/Marlborough/Tasman	Services
Chemiplas (NZ) Ltd	Auckland	Ingredients
Chr Hansen Pty Ltd	Australia	Ingredients
Ciprian Consulting Ltd	Auckland	Services
Cosmed Group Industrial Ltd	Auckland	Manufacturing
Cospak Ltd	Auckland	Services
DKSH Performance Materials NZ Ltd (formerally Axieo)	Auckland	Ingredients
Douglas Pharmaceuticals (Natural Health Laboratories / Clinicians)	Auckland	Branded Goods
DSM Nutritional Products NZ Ltd	Auckland	Ingredients
Endeavour Consumer Health Limited (formerly Red Seal Natural Health Ltd)	Auckland	Branded Goods
ENZO Nutraceuticals Ltd	Waikato	Ingredients
ESR	Wellington	Services
Essentially New Zealand Ltd	Auckland	Ingredients
Euromed SA	Australia	Ingredients
Fine Aromatics Ltd	Canterbury	Branded Goods
Forbes Packaging	Auckland	Services
Forest Herbs Research Ltd	Nelson/Marlborough/Tasman	Branded Goods
GC Rieber Oils AS	Australia	Ingredients
GMP Pharmaceuticals Ltd	Auckland	Manufacturing
GO Healthy NZ Ltd (The Better Health Company)	Auckland	Branded Goods
Good Health Products Ltd	Auckland	Branded Goods
Grin Natural Products	Auckland	Branded Goods
Hally Labels Ltd	Auckland	Services
Harker Herbal Products Ltd	Northland	Branded Goods
Harvest Natural Health Ltd	Auckland	Services
Hawkins Watts	Auckland	Ingredients
Health 2000+	Waikato	Retail
HealthPost Limited	Nelson/Marlborough/Tasman	Retail
Hi Well Healthcare Limited	Auckland	Manufacturing
Hibiscus Solutions	Auckland	Ingredients
IMCD NZ Ltd	Auckland	Ingredients
Ingredients Plus NZ Ltd	Auckland	Ingredients
InsightReg Consultancy	Auckland	Services
Institute for Innovation in Biotechnology	Auckland	Services
Integria Healthcare	Auckland	Branded Goods
Invita NZ Ltd	Auckland	Ingredients
IPPC	Auckland	Services
IQVIA Solutions (NZ) Ltd	Auckland	Services
IRI (NZ) Ltd	Auckland	Services
Ironside McDonald Intellectual Property	Auckland	Services
James & Wells	Auckland	Services
Keene Manufacturing Solutions	Auckland	Services
Keraplast Manufacturing	Canterbury	Ingredients
Label & Litho Ltd	Wellington	Services
Lifestream Ltd	Auckland	Branded Goods

Manuka Bioscience Ltd	Auckland	Branded Goods
Metagenics	Auckland	Branded Goods
MeToday	Auckland	Branded Goods
MitoQ	Auckland	Branded Goods
Nelson Honey Ltd	Nelson/Marlborough/Tasman	Branded Goods
New Wayz Consulting Ltd	Auckland	Services
New Zealand Extracts Ltd	Nelson/Marlborough/Tasman	Ingredients
New Zealand Health Manufacturing	Auckland	Manufacturing
New Zealand Trade & Enterprise	Auckland	Services
Nutriomics Ltd (TRU MK7)	Auckland	Branded Goods
Nutrizone Limited	Auckland	Manufacturing
NZ Bio Pharma Ltd	Bay of Plenty	Branded Goods
OneOne Health	Auckland	Branded Goods
Oranutrition Ltd	Auckland	Manufacturing
Pacific Flavours & Ingredients Ltd	Auckland	Ingredients
Pathways	Australia	Ingredients
Pharmaceutical Solutions Ltd	Auckland	Services
PharmaNZ	Waikato	Manufacturing
Pharmapac Ltd	Auckland	Services
Phytomed Medicinal Herbs Ltd	Auckland	Branded Goods
Plant & Food Research	Auckland	Services
ProHerb	Canterbury	Services
Pure Ingredients Ltd	Auckland	Ingredients
Pure Vitality Limited	West Coast	Branded Goods
Quantec Ltd	Waikato	Ingredients
RMF Nutraceuticals	Canterbury	Ingredients
School of Product Design, UC	Canterbury	Services
Scitex Consulting Group	Auckland	Services
SeaDragon Marine Oils Ltd	Nelson/Marlborough/Tasman	Ingredients
Sensient Technologies	Auckland	Ingredients
Seperex Nutritionals Ltd	Otago	Ingredients
Shanghai Freemen Australia Pty Ltd	Australia	Ingredients
SleepDrops	Auckland	Manufacturing
Smart Regulatory Solutions	Bay of Plenty	Services
Solgar NZ Ltd	Auckland	Branded Goods
SRW Laboratories Limited	Auckland	Branded Goods
Sun Life Nutritionals	Auckland	Branded Goods
The Cosmetic Company Ltd	Auckland	Manufacturing
The Health Lab Ltd	Auckland	Manufacturing
TSI Group Ltd	Australia	Ingredients
Tui Balms	Nelson/Marlborough/Tasman	Branded Goods
United Fisheries Ltd	Canterbury	Branded Goods
Verital Innovations Ltd	Auckland	Ingredients
Vitaco Health NZ Ltd	Auckland	Branded Goods
Wadding Solutions Ltd	Auckland	Services
Wakatu Incorporation	Nelson/Marlborough/Tasman	Branded Goods
Weleda NZ Ltd	Hawkes Bay	Branded Goods
Wholesale Aroma Supplies	Bay of Plenty	Services