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The Development of a Natural Health Products Bill; Consultation Paper

The National Council of Women of New Zealand (NCWNZ) is an umbrella organisation representing 46 nationally organised societies. NCWNZ has 26 branches throughout the country attended by representatives of those societies and some 150 other societies. The Council's function is to serve women, families and the community through research, study, discussion and action.

This submission has been prepared by the Consumer Affairs Standing Committee after the circulation of questions to NCWNZ members throughout NZ and collation of responses received on the proposals for the regulation of natural health products. The responses received reflect the level of interest of the membership about natural health products and their continuing interest in this subject. The Committee is pleased that natural health products are now being reviewed with a view to regulatory control as they are currently inadequately regulated, posing potential risks to public health and safety. Responders agree that consumers need to be reassured that natural health products are safe, true to claim, true to label and that adequate information is provided for Consumers to make an informed choice.

Question 1
Do you support the proposed scope, purpose and principles for natural health product legislation? If not, what other suggestions do you have?

Yes, natural health products are currently inadequately regulated posing potential risks to public health.

Question 2
Do you think the scope proposed for the definition of natural health product is appropriate?

Yes, the term 'natural health products' needs to be defined as proposed.

Question 3
Are there products that would fall outside the definition that you think should be included? Conversely, are there products that fall within the definition that should be excluded?

The opinions varied from "no opinion" to "not sure" or "yes". Definition as proposed accepted. It was agreed that no prescription medicines, pharmacy-only medicines, pharmacy medicine or controlled drugs to be included.

Question 4
Are there any other functions that you consider the advisory committee should have?

No further functions suggested. A few responses expressed concern about the regulatory authority being a unit within the Ministry of Health. Responses also queried the involvement with Medsafe and the role it would have in approvals. A technical advisory expert committee must be established and function efficiently as proposed.

Question 5
Do you agree with the concept of a consultative body and its possible role?

It was generally agreed that a consultative group comprising of key stakeholders (industry and consumers) should be established and consultations should be conducted on a regular basis to provide feedback and recommendations.

Question 6
Do you agree with the proposed self-certification scheme for product approval? If not, what would you like to see instead?

Yes, responses supported a self-certification scheme and comments were made regarding the importance of obtaining product approval for imported products from countries with no trusted regulatory systems e.g. some Asian countries. Many responders expressed concern about ingredients in imported products, particularly from India and China.

Question 7
Should an exemption from product approval apply to any particular types of natural health products (for example, certain homoeopathic preparations or aromatherapy products)? If so, please specify which types of products and indicate why you consider an exemption should apply.

The majority of responses expressed that no exemptions should apply however, it was agreed that the status quo position under the Medicines Act 1981 should be maintained. Products "tailor made" by a practitioner to meet the needs of specific patients was accepted e.g. Rongoa Maori, Chinese practitioners, herbalists and naturopaths. Exemptions were to be for individual patients only and should be clearly labelled or contents listed to prevent interactions occurring with prescribed medications, allergic reactions etc. There are many chemical preparations which have adverse effects when used with homeopathic and aromatherapy products.

Question 8
Are there other situations in which it should be permissible to supply natural health products without a product approval?

Some responses supported supply of natural health products without approval by herbalists and naturopaths. Most responses expressed disagreement with products being supplied without approval. Products must have approval to be marketed.

Question 9
Are there specific lists of substances used in other jurisdictions that you think should become part of New Zealand's list of permitted ingredients? If so, please specify.

Responses supported permitted ingredients only to protect consumers and that present a low risk to health and safety when natural health products are self-selected by the public. The regulator to maintain a database of permitted ingredients post-market monitoring is essential and necessary and safety assessments undertaken by the regulator for new ingredients should to be added to the list.

Question 10
Do you think there should be a list of prohibited ingredients, as well as a list of permitted ingredients?

It was agreed in the majority of responses that a list of prohibited ingredients be maintained. Ingredients monitored if used in restricted circumstances e.g. recommended daily dose levels of Vitamin C as specified.

Question 11
Are there specific claims used in other jurisdictions that you think should become part of New Zealand's list of allowable claims for natural health products? If so, please specify.

Responders were unsure of specific claims used in other jurisdictions so did not comment specifically. If other jurisdiction claims are added they should be assessed and determined to be of low risk to health and safety. A decision should to be made by the regulatory authority and technical advisory committee.

Question 12
Do you believe that the regulator should conduct audits to assess compliance with the requirement that sponsors hold evidence to support natural health product claims?

Responses considered that audits should be concluded by the regulator to assess compliance on a regular basis. A list of permitted claims about natural health products maintained should be only of a low-level and these claims should be supported with appropriate research based evidence. The intended purpose of any natural health product, it was strongly agreed, should be required to be included on the product label and additional product information.

Question 13
Do you agree with the proposed list of labelling requirements? If not, are there requirements that should/should not be included?

Yes, the proposed list of labelling requirements was considered to be comprehensive and acceptable. Generic measurements relating to the legibility and durability of the labelling of products a mandatory inclusion. Clear, readable, labels with the use of strong colours (not red, green, or blue as many consumers are colour blind) and in other languages if feasible, is recommended. The use of leaflets with product information additional to the container is also recommended.

Question 14
Do you agree that an exemption from the general labelling requirements should apply to products that are 'tailor-made' by a natural health practitioner for supply to an individual? If so, what do you think the labelling requirements for such products should be?

Responses indicated divided opinion. Many responses considered 'tailor-made' products should be labelled to indicate ingredients, dosage, expiry date, storage conditions etc by a natural health practitioner and how it is to be used safely. The interactions with other medications and safety were an expressed concern.

Question 15
Are there other situations where a labelling exemption should apply?

No response

Question 16
Do you agree with the proposed minimum requirements for advertisements? Is there any other information that should be included?

Responders agreed with the proposal to include a minimum set of mandatory information in any written advertisement or advertisement on the internet. This information must be truthful, balanced and not misleading, and provide a balanced representation of the risks and benefits of the product. This information should be subject to ongoing surveillance and checking by the regulator and Advertising Standards Authority with pre-vetting by adjudicators a preference.

Question 17
What information should be required to be provided in radio and television advertisements?

Response as for Question 16.

Advertisements should be pre-vetted by adjudicators as for Therapeutic Advertising pre-vetting system (TAPS). All promotional material and advertisements on radio or television must include a minimum set of mandatory information that is readable and contains required information and pre-vetted.

Question 18
Are there any other types of advertising for which different requirements should be set?

Yes, posters, trade-me, in store promotions and websites probably should be under umbrella of above requirements to prevent unsubstantiated claims being made.

Question 19
What impact do you envisage the proposed regulatory scheme will have on the ability or willingness of businesses to export natural health products?

Responders agreed that sponsors should be responsible for ensuring that exported products meet standards of the importing country.

Question 20
How would having to obtain product approvals for different markets affect your willingness or ability to export?

No responses.

Question 21
Do you agree that a code of practice for the manufacture of natural health products should be developed? If not, what standards do you think should apply?

Yes, to address any potential risks associated with poor manufacturing practices – this is essential for consumer protection.

Question 22
What key risk management principles do you think should be included in a code of practice for the manufacture of natural health products?

Concern was expressed that imported products may not meet equivalent standards and requirement. NZ companies must supply evidence of acceptable manufacturing standards when applying.

Question 23
Would you prefer the costs of post-market activities to be recovered through an annual product approval maintenance charge or an annual levy based on company or product turnover? Please give reasons for your preference.

No opinions offered.

Question 24
Should there be an exemption from or reduction in, the annual charge or levy for small businesses or those supplying low-turnover products? If so, who should qualify and how should 'low turnover' be defined?

A full recovery of costs is necessary. A fee for service basis should be applied if low turnover or small business for pre market approval and safety assessments on new ingredient permissions.

Question 25
What would be the impact on your business if there were to be an annual product approval maintenance charge of $500 or $1,000 or $2,000? What do you consider would be a reasonable charge?

(For each business that would need to have products entered onto the New Zealand register under these proposals, please include details of number of products supplied in New Zealand, number of products also supplied in Australia, number of products exported to other countries, annual turnover and number of low-turnover products (based on your definition of low turnover in Question 24)).

No response

Question 26
Do you agree that the costs of completing new ingredient safety assessments should be largely recovered through levies paid by all product approval holders? If not, what cost-recovery mechanism would you prefer?

Yes.

Question 27
Should there be a cap on the number of new ingredient assessments undertaken each year?

This would be dependent on the permitted ingredient list. Responses indicated that a cap on the number of new ingredient assessments annually should be decided by the regulator and is probably desirable.

Question 28
Do you agree with the range of tools suggested for inclusion in the compliance and sanctions tool box?

Yes, no further suggestions.

Question 29
Do you think the legislation should include other types of offences? Please specify.

No comments.

Question 30
Do you have any specific suggestions about how to manage appeals and dispute resolution?

Agreed on appeals and dispute mechanism necessary. No opinions given.

Question 31
Do you think the proposed transition periods for product approvals and manufacturing standards would be adequate to give suppliers and manufacturers time to achieve compliance with the legislation?

The proposed transition period appears to be adequate. There would be consumer confusion if transition period too long.

Question 32
Are there any other aspects of the proposed regulatory scheme for which transitional measures would be needed? Please specify

Clear direction and information is necessary to avoid consumers being confused when self-selecting natural health products in the transition period. Agree with a public education campaign about the new regulations before the Bill is enacted and particularly over transition period for industry and consumers.

Elizabeth Bang
National President

Jan Brown
Convener Consumer Affairs Standing Committee