PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

5 March 2016

Natural Health Products
Ministry of Health
PO Box 5013
Wellington 6145.
via email: naturalhealthproducts@moh.govt.nz

To whom it may concern,

RE: The Regulation of Natural Health Products Consultation document.

Thank you for the opportunity to submit comments to the Regulation of Natural Health Products Consultation document.

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 3,000 pharmacists, from all sectors of pharmacy practice. We provide to pharmacists professional support and representation, training for continuing professional development, and assistance to enable them to deliver to all New Zealanders the best pharmaceutical practice and professional services in relation to medicines. The Society focuses on the important role pharmacists have in medicines management and in the safe and quality use of medicines.

The Society supports the Natural Health and Supplementary Products Bill and the regulation of natural health products to provide assurances of evidence and quality to New Zealand consumers.

Regarding the consultation document, we would like to make the following specific comments:

Ingredients
We note that a Natural Health Products Advisory Committee will consider the following factors when determining whether to add a substance to the permitted substances list:

- the toxicity of the ingredient (in the quantities likely to be used)
- the risk of inadvertent overdose
- the risk of adverse effects from prolonged or inappropriate use
- the need for advice from a health practitioner
- known side effects
- whether any concerns can be managed by a condition of use.

The Society believes that consideration should be given to risks associated from intentional as well as unintentional overdoses. This will relate to the inherent toxicity of the ingredient, dose presented in a "usual" dose form, and the number of doses presented in common products. This can influence pack size restrictions, warnings, or whether the substance is appropriate to be approved as "permitted".

We also believe the Committee should consider any evidence available to indicate a pharmacodynamic or pharmacokinetic interaction with medicines. This will examine the pharmacological activity together with any influence on drug metabolising enzymes such as the Cytochrome P450 system, or drug transport systems such as Organic Anion Transporters (OAT), Organic Cation Transporters (OCT) or p-glycoprotein. For a number of natural health products this evidence exists, and knowledge of this provides valuable guidance to the potential risks and/or safety of using a substance in combination with others or with medicines.

When noting the approval for permitted substances, The Society recommends that the Authority publish a summary of the information for the factors described above, including standard or "permitted" dosing information, and an indication of the level of evidence available for the claims, risks, doses etc as approved. This may include the adoption of an evidence rating scale similar to that used in evidence-based medicine – albeit modified as appropriate to the purposes of the Act and Regulations.

The Society supports the requirement to use scientific names of ingredients in the permitted list, which would provide greater clarity to the specific substance in question and remove any ambiguity around common names.

The Society fully supports the proposal to require the full formulation details of proprietary ingredients to be disclosed to both the Authority and consumers, and that proprietary ingredients and products must ONLY contain permitted substances. This provides clarity and assurance to consumers that the product will be safe and appropriate for use under the intent of the Act and Regulations.

We agree that the Committee should consider weighting the criteria for approving substances and that this should place greater significance on the level of evidence provided for each factor. For instance where very limited evidence is provided for a consideration factor, this alone could be grounds for not approving a substance. Similarly, when strong evidence is provided, this can provide greater reassurance of safety.

The Society believes the Committee should compose of a medical practitioner and/or pharmacist with appropriate knowledge or expertise in pharmacology to consider the evidence presented on ingredients.

Health Benefit Claims

The Society understands that only those named conditions where appropriate evidence can be produced to support a health benefit claim can be made. However we have concerns where a condition cannot be self-diagnosed or self-monitored and a consumer may decide to use a substance inappropriately. The conditions listed could be considered non-serious or self-limiting, however this may not be so when the consumer has been experiencing the condition for some time and/or it may have progressed to a state of medical concern – for example prolonged iron or other nutritional deficiencies if not managed may become serious, as can prolonged scabies infestations, diarrhoea or prolonged high fever.

The risks of complicated presentations of the approved conditions must be considered when approving health benefit claims for a substance. Therefore we believe the factors should be weighted to permit the Authority/Committee to appropriately consider risks against claimed benefits, while acknowledging the potential for warnings that can be applied to a substance or product.

Evidence

The Society strongly supports the requirement that all claims for natural health products must be supported by appropriate evidence. However we have concerns around how the requirements for evidence are proposed to be managed.

We acknowledge that the evidence related to natural health products and their use varies markedly, both in the "therapeutic use" as well as evidence of risks, harms, and pharmacological activity. However we are concerned that the evidence will not be

evaluated by the Authority prior to a product entering the market. This relies on the proposed "proactive" regulatory audit or a retrospective audit following receipt of a complaint. The Society is concerned that products will be released to market with inadequate proof of evidence. Should the Authority decide that such a process is deemed acceptable, The Society strongly recommends that all evidence and relevant supporting information related to a product or substance is made publically available. This would permit the public, natural health practitioners and regulated health professionals to determine some level of risk and appropriateness when considering use of a natural health product. Products that had been assessed as meeting regulatory requirements either through audit or approval could have this indicated to highlight those products meeting the required standard and those that had not yet been assessed.

The Society strongly supports the use of scientific evidence in regulating natural health products, and recommends that a grading scheme is adopted to illustrate the degree of evidence that is available for a product or substance. Such a grading scheme, if designed could illustrate to all the "level" of evidence available for a product or substance and can recognise this in their decision making. The Society encourages the use of peer-reviewed scientific evidence to guide use of natural health products. A scheme that recognises level of evidence for health benefit claims and use of natural health products – such as the Oxford Centre for Evidence-based Medicine Levels of Evidence, or variations thereof could be adopted to illustrate evidence levels. This would provide a clear indication of the significance of the available evidence from randomised-controlled trials through to case studies. The Society considers that "scientific evidence" should be published, peer-reviewed studies.

The Society acknowledges the role of traditional claims for natural health products and the limitations in available evidence around such use. We note the proposal that the time required for something to be considered traditional use is "three generations (75 years, 25 years per generation)" and agree with this as a proposed minimum period of use. We support the recognition of approved pharmacopoeia in documenting information and experience guiding traditional use of natural health products. However, many of the pharmacopoeia listed in Schedule 2 of the Bill are not publically available. We would recommend relevant information from approved references that are not publically available be made so to provide assistance to practitioners (both regulated health professionals and natural health practitioners) monitoring and treating consumers.

There are a number of high quality herbal/natural medicine references that could be considered appropriate, including Herbal Medicines, 4th Edition. Edited by Pharmaceutical Press Editorial. Published by Pharmaceutical Press, London, UK, 2013. ISBN 978-0-85711-035-0. The Society would suggest that the schedule of approved pharmacopoeia be able to be reviewed and modified by Gazette notice.

Notification Exemptions

We are concerned at the exemptions to the natural health products scheme provided for products that are made by a natural health practitioner for sale to an individual, following a consultation with that individual. Assuming that substances and claims are permitted, permitting exemptions to products made by natural health practitioners presents the same issues as the consultation describes requiring full disclosure of proprietary ingredients. For consumers, natural health practitioners and regulated health professionals, the full list of ingredients of a product must be noted on that product in order for effects to be monitored and potential interactions with medicines able to be checked.

The consultation document states that practitioner-made products are not limited to permitted ingredients, but cannot contain substances included in Schedule 1 of the Medicines Regulations 1984 (prescription or pharmacy medicines). This prohibition of using medicines does not encompass general sale medicines and the Pharmaceutical Society would strongly oppose any permission for natural health practitioners to adulterate natural health products with any medicine including general sale medicines. Monitoring and assessment of risks and benefits of natural health products should not be complicated by the repurposing of registered medicines into these products.

Labelling
The Society supports the minimum information requirements for labelling as described. Labelling is important for communicating the ingredients contained and any safety information related to these. The Society reiterates our support stated previously that all ingredients must appear on the product label.

In addition to the described labelling requirements, the Society strongly recommends that labels for natural health products be prohibited from references to pharmacy, pharmaceuticals or registered medicines. We are currently aware of a product in the market that refers to "Pharmacy Strength" dietary supplements which we strongly oppose, as this suggests a level of strength, or quality that is equivalent to pharmacy-medicines. Natural health products must not be able to draw comparisons to medicines in their claims.

Manufacturing
The Society supports the requirement for products to be manufactured in facilities that meet the Code of Manufacturing Practice. We also support site audits as a necessity in approving manufacture of natural health products to ensure quality assurance requirements are met.

Recognised Authorities
The Society supports the proposal to recognise Medsafe and the authorities recognised by Medsafe for the purposes of good manufacturing practice auditing.

Thank you for consideration of this submission. I would be happy to discuss any aspect of this submission further, if required.

Yours sincerely,

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