The Royal New Zealand
College of General Practitioners
Te Whare Tohu Rata o Aotearoa

2 February 2016 Our Ref: HMB17-16

Natural Health Products Policy Unit
Ministry of Health
PO Box 5013
WELLINGTON 6145

Email: naturalhealthproducts@moh.govt.nz

Dear Natural Health Products Policy Unit,

The Regulation of Natural Health Products

Thank you for providing the Royal New Zealand College of General Practitioners (the College) the opportunity to comment on *The Regulation of Natural Health Products*.

Overall, the College appreciates that the proposed regulation is a considerable advance on current Natural Health Product regulation. However, the College is of the view that the regulations need to be strengthened and that all ingestible products should have to meet at least the standards of the Food Act and that those claiming therapeutic benefit – including non-ingested products – should have to provide valid scientific evidence to support claims of efficacy. We have serious concerns about the standards of evidence proposed (with 'traditional evidence' providing a clear loophole) and some concern about the use of standards that are 'proportionate to the risk' where it appears a lack of evidence is treated in the regulation as low risk. We are also concerned that there are still a considerable number of 'therapeutic products' – notably homeopathy - that fall outside of legislation.

Introduction to general practice and the College

General practice is the specialty that treats patients: with the widest variety of conditions; with the greatest range of severity (from minor to terminal); from the earliest presentation to the end; and with the most inseparable intertwining of the biomedical and the psychosocial. General practitioners (GPs) treat patients of all ages, from neonates to elderly, across the course of their lives.

GPs comprise almost 40 percent of New Zealand's specialist workforce and their professional body, the Royal New Zealand College of General Practitioners (the College), is the largest medical College in the country. The College provides training and ongoing professional development for general GPs and rural hospital generalists, and sets standards for general practice. The College is committed to achieving health equity in New Zealand. To achieve health equity, we advocate for:

- A greater focus on the social determinants of health (including labour, welfare, education and housing).
- A greater focus on measures to reduce smoking and to increase healthy food options for low-income families.
- Health services that are better integrated with other community services.
- A review of the funding model for primary care to ensure that funding is targeted towards the most disadvantaged.
- Free primary health care for low-income families, because health inequities begin early and compound over the life course.

Submission

Consultation Process

There were some concerns with the consultation process: To provide complete, well-informed feedback on the proposed regulation scheme for Natural Health Products (NHP), submitters were required to review multiple, linked, lengthy, documents. It is also noted that the consultation document and various guidelines pertain to only to NHPs, and not (explicitly) 'supplementary' products which may eventually be included in the legislation.

Introduction

The proposed regulatory scheme for low-risk NHPs aims to address the risks that ingredients in a NHP may be unsafe, that products could be manufactured in an unsafe way and that consumers may delay seeking conventional medical treatment for a physical or mental health condition. As it stands, the College does not consider that the proposed regulatory scheme mitigates these risks. The College believes that all ingestible products should have to meet at least the standards of the Food Act and that those claiming therapeutic benefit – including non-ingested products – should have to provide valid scientific evidence to support claims of efficacy.

We have serious concerns about the standards of evidence proposed (with 'traditional evidence' providing a clear loophole) and some concern about the use of standards that are 'proportionate to the risk' where it appears a lack of evidence is treated in the regulation as low risk.

We are also concerned that there are still a considerable number of 'therapeutic products' that fall outside of legislation. Homeopathy is a prime example where, if not included in this scheme, is not regulated as a medicine, natural product or food yet poses the same risk as other ineffective or placebo-based products due to patients delaying seeking medical care. Homeopathy and aromatherapy should not be exempt from the scheme. The College believes that the Natural Health Products Advisory Committee (NHPAC) should have the authority to declare a product to be a NHP where it falls outside the definition as proposed (for example, because of ingredients it contains), to ensure that all products that make a therapeutic claim are captured by the system.

Undoubtedly, NHPs (including supplements) can and do provide benefits to consumers and the College does not wish to unnecessarily reduce the availability of safe NHPs to those who are genuinely benefiting from their use. However, any substance capable of providing a clinical effect is also capable of harm. There are misconceptions that 'natural' equates to safe (or 'low risk') and that historic use equates to effectiveness. It is often forgotten that many medicines are derived from (or synthesised analogues of) naturally occurring substances and that in many instances it is dosage that makes a substance safe. The key difference is that 'mainstream' medicines have had the active ingredient isolated, standardised, subjected to critical clinical assessment which allows the dose to be carefully controlled. Conversely, for clinically harmless products falsely claiming therapeutic benefit, the risk is that consumers receive false assurance that they have been treated for an illness/ailment that may not naturally resolve. Delay in seeking appropriate treatment is known to lead to poorer health outcomes and greater cost to the consumer.

An important differentiating factor between NHPs and foods or cosmetics, is that those seeking NHPs are often unwell and therefore vulnerable to messaging that purports to ease their suffering or provide a cure. The obvious example, is that of a cancer patient who is more likely to be fearful of a terminal prognosis, and possibly desperate to find a remedy no matter how obscure or extreme. The regulation of health claims, labelling, and advertising is a crucial element to ensuring vulnerable persons are not exploited.

Therapeutic products should have to meet at least the standards of the Food Act (for ingestible products) or the Cosmetic Products Group Standards[1] (for creams etc.) and if claiming efficacy, provide a sound scientific evidence base. Currently, product claims are regulated under Advertising Standards Authority[2] and the Fair Trading Act 1986 (e.g. in July 2014, the ASA upheld complaints against Health 2000 for their vague and unsupported health claims). Whilst this provides some level of safety, health claims differ from regular advertising claims in that harm may occur due to delay in effective treatment. Therefore, the College supports the additional safety net provided by the proposed permitted substances (white) list of ingredients and the web-based product notification system.

An important distinction can be made between NHPs that claim to promote health or prevent conditions and those that claim to treat conditions. In the first instance, a safe NHP product will cost the consumer money but probably do no further harm whereas in the second instance, a consumer may delay getting effective treatment and consequently suffer worse health outcomes at a greater cost. For example, fish oil capsules that claim to be a 'good source of omega 3' are unlikely to cause harm (other than financial), but fish oil capsules claiming to 'treat depression' may result in treatment for mental illness being delayed and harm to the patient.

Ingredients

Permitted Substances

The College supports the use of a white list to regulate NHP ingredients. Some concern has been expressed that this type of list may unnecessarily limit access to some safe NHPs due to the $700 (excl GST) fee. However, the College considers the one-off nature of the application fee for a permitted substance to be sufficiently non-prohibitive.

One major foreseeable issue with the permitted substances list is the frequency of its review, and the efficiency in making changes, additions, or retractions. For this process to be efficient, effective and not overly prohibitive, there must be sufficient resource of the NHPAC. Inclusion of Natural Health Practitioners / Integrative Practitioners as well as (non-NHP) medical doctors, nurses and other health practitioners are pertinent to the balance and effectiveness of this group. Furthermore, the College recommends that committee members' conflicts of interest are publically registered.

The College agrees with the criteria for adding a substance to the list, and notes that tolerance for risk to the consumer should be low unless there is clear evidence of benefit.

With regards to restrictions on permitted substances, the College strongly advocates for clear warning requirements for NHPs that interfere with regular medicines (contraindication) as well as the recommendation that patients notify their primary health carer that they are taking the product. For example, St John's wort (Hypericum perforatum) is a herbal medicine traditionally used to treat low mood. The interaction between St John's wort and contraceptives was highlighted by Medsafe in 2000[3]. In addition to potentially interacting with oral hormonal contraceptives, St John's wort has now been noted to interact with implanted hormonal contraceptives.

Another example is Horseradish root, often marketed to 'support the upper respiratory tract', which can be an irritant for those with digestive tract conditions (e.g. IBS, intestinal ulcers) and interacts with medicines used to treat low thyroid function. It is unlikely that a consumer taking a horseradish-based therapy for viral bronchitis will know these interactions or inform their primary carer about their

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[1] Under the Hazardous Substances and New Organisms Act 1996

[2] Importantly, the ASA is a voluntary industry organisation and so can only make recommendations.

[3] Medsafe. St John's wort and implanted hormonal contraceptives. Prescriber Update 25(2); June 2014. Available at: http://www.medsafe.govt.nz/profs/PUArticles/June2014StJohnsWortAndImplantedHormonalContraceptives.htm#1

consumption of the product. Simply listing these known interactions and risks online places the responsibility entirely on the consumer to find this information.

Finally, a specific white list of permitted ingredients reduces the possibility of false authentication, whereby an inactive ingredient is inadvertently (or deliberately) included in a product making a claim. Inadvertent creation of an ineffective product could occur for a number of reasons; there are often different species of herb with a similar name (e.g. Ginseng) with varying levels of active ingredient, differing preparation methods, and the ability of the body to utilise an active ingredient/ supplement changes according to the form in which it is taken.

Proprietary ingredients

The College supports the proposal that full formulation details of proprietary ingredients must be disclosed to both the Authority and consumers. Consumer safety and the right of consumers to manage their health appropriately outweighs industry concern about business competitors. As well as allowing consumers to avoid allergens, listing of all ingredients and their safe RDI on NHP pack labels helps to avoid inadvertent overdose. It is unlikely that the average consumer would otherwise know the cumulative dose they are taking and what its safe level is. Whilst this risk cannot be altogether avoided, clear and consistent labelling about NHP ingredients and the RDI, would go some way to preventing this.

Health Benefit Claim

The College suggests that some definitions of commonly used phrases are established, as part of the regulation about health claims. This would allow for clearer links between claims and supporting evidence. For example, a common, vague, health benefit claim made by NHPs is that they "boost the immune system" or "strengthen the immune system". The immune system is extremely complicated and if you are in good/normal health, you cannot make your immune-system baseline any better. Elements of it can be affected by poor lifestyle habits (e.g. insufficient sleep or exercise, nutritional deficiencies) and chronic stress and this may be what some NHPs are aiming at with this phrase, however it is otherwise misleading. The term "boosting" is used in relation to vaccinations as the immune system is being stimulated to develop an antibody memory response. This is almost certainly not the case for most NHPs that claim to boost the immune system (and nor should it be, as chronic immune system stimulation would be harmful).

Conditions about which claims can be made

The College supports the use of a list of named conditions, but it is unclear whether allowable claims pertaining to named conditions are 'free text' claims (like the Australian system) or must follow a particular format. A free text option for claims about conditions allows for creative use of words and consequently an opportunity to intentionally, or accidently, mislead consumers.

The factors that determine whether an ICD10 named condition should be included in the Ministry's list of allowable claims are sound, however it is incorrect to imply that these factors provide a safety mechanism. As demonstrated by the anaemia example in the consultation document, it is the **cause** of the named condition that alters whether or not NHP treatment is a 'safe' option. Compulsory inclusion of a clause on labels stating "if symptoms persist, see your doctor" may go some way to mitigating this risk.

Evidence

General Practice is a scientific discipline and the College consequently advocates for a quality scientific evidence base for therapeutics remedies. However, general practice also takes into account the physical, psychological, spiritual, social and cultural dimensions of health and it is well-understood that there is more to therapy than clinical effectiveness. For this reason, the College agrees that 'traditional evidence' is appropriate in some settings. Additionally, there is still a considerable amount that is not yet understood and true science, as a system, allows for rapid changes in understanding as discoveries are made.

The College considers that in order for a product to make a therapeutic claim it must be able to demonstrate an evidential and scientific basis that it improves, protects or manages the physical or mental health of individuals. Regulation of natural health products provides a certain level of legitimacy and it is important that this is matched by legitimate mechanisms of safety and protection. Therefore, the only evidence used to support claims of health benefit efficacy should be evidence that the claims are true (i.e. scientific evidence) and not evidence that a product has been used in the past (i.e. traditional evidence).

The College perceives a great risk that 'traditional evidence' may become a loophole in the legislation for ineffective products to make therapeutic claims. Evidence of use is not evidence of efficacy. In particular, we are concerned by the statement that "scientific evidence does not take precedence over traditional evidence" (p.5, Evidence Guidelines). Where there is scientific evidence that a product is ineffective, there is also a risk of patients delaying effective treatment. Where valid scientific evidence shows a NHP to be unsafe, this should always be recognised **over and above** traditional evidence. Safety must be the first priority. For products shown to be ineffective by a scientific model, but not shown to cause harm, a compromise would be the inclusion of a clear statement **on the label** that the product is not supported by scientific evidence. The suggestion that this be included in the online summary only is insufficient as most consumers will make a purchase-decision at the point of sale.

There is also some concern about the word 'traditional' itself, which implies trust and carries authority. The College suggests that a better phrase, that would be more accurate and specific, would be "Used in Rongoā Māori for..." or "Used in the past for..." For example, "Kawakawa tea is used in rongoa Māori to support circulation and as a general tonic for cleansing the blood." This does not claim the treatment is effective, just that it has been used in the past for this purpose.

The College supports the use of the 75 year (three generations) guideline as to what constitutes 'traditional' as this is in keeping with WHO guidelines. It has been suggested by a member that the criteria for what constitutes traditional be supplemented with the criteria that the product must also have been used for the specific 'health benefit' prior to 1960, when mass advertising of remedies by TV changed the way in which they were promoted to the public. This is also important as many ineffective remedies, such as asthma cigarettes, were promoted around this time.

The College strongly recommends that further criteria are established about how a person might be considered appropriate to speak with authority on a matter of a traditional remedy (i.e. how are they recognised as an 'authority').

Aside from our qualms about the use of traditional evidence, the College supports the Evidence Guidelines. However, it is also noted that these evidence standards are only worthwhile if there is a reasonable level of monitoring and sufficiently severe consequences for non-compliance to act as a deterrent.

Manufacturing

Manufacturing standards are particularly important to reduce the likelihood of product contamination or adulteration. For example, many Asian and Ayurvedic herbal remedies have been found to contain heavy metals such as lead, arsenic and mercury.[4] Regular product safety testing, as part of manufacturing standards, is an important and necessary measure to ensure patient safety – particularly for international products where the product journey is often unknown.

The College does not think it appropriate to include exemptions to the manufacturing code. Exemptions do not occur in food manufacturing which apply even to small, private cafes. Under the FHR, you "cannot manufacture, prepare, package, store or sell food from any room or stall that is not used

[4] Genius SJ, Schwalfenberg G, Sij A-KJ, Rodushkin I. Toxic Element Contamination of Natural Health Products and Pharmaceutical Preparations. Plos One 7(11), 2012. Available at: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0049676

exclusively as a commercial food premises. This means that places such as your home kitchen cannot be used by a food business." This standard should apply to all ingestible products regardless of whether they are considered a 'food' or a 'natural health product'. The College acknowledges that some smaller manufacturers may need support to meet the standards. An Environmental Health Officer, such as the officer who provides advice on food manufacturing facilities, may be able to fill this role.

It is also notable that there is a fundamental logical flaw in stating that control will be proportionate to risk if the 'risk of a product' is not yet well-understood or if the evidence-base used to assess risk is of poor quality, inappropriate, or not scientific. In the **absence of evidence**, greater caution is needed.

Fees

The College generally agrees with the proposed fees schedule. For very-low-volume products, the College agrees that some reduction or exemption for fees is appropriate to ensure consumer access to products is not unnecessarily limited.

Labelling

A stated aim of the regulatory scheme is to help consumers make choices about the products they buy. We support the concept of including further detail regarding products and their evidence base online, but note that point-of-sale information has a greater impact on consumer choice. Consequently, labelling requirements are crucial to ensuring that consumers are appropriately informed about the efficacy of a product regarding its 'health claims'.

As noted earlier, the College recommends the following for NHP product labelling;

- All products that make a health claim based solely on traditional evidence must state that they are not supported by scientific evidence.
- The phrase for 'traditional' products be "used by X for…", rather than "traditionally used for…"
- Clear, mandatory warnings are included on products where they are known to interact with common medications e.g. "St John's Wort is known to interact with some contraceptive products. Please consult your doctor before taking this medication".

Advertising claims that use evidence-based terms such as 'scientifically shown to' or 'clinically proven to', should require the company to demonstrate that the understood, scientific meaning of these words actually applies in each case. Inaccurate appropriation of scientific terms by marketers dilutes the public's understanding of the meaning of such terms when they are applied correctly. As noted by the Royal Australian College of General Practitioners, "This is particularly important in light of the ongoing struggle of the medical profession to continually 'clean up its own back yard' by debating and applying evidence to its own therapeutic interventions."[5]

Notification

The College supports the web-based nature of the proposed regulatory system and agree that pre-market notification is appropriate. It is noted in the Guidelines for NHP Evidence Requirements that the Authority will assess the product notification for a NHP post-market introduction on an audit selection basis. This regulatory scheme has followed in the footsteps of Australia and is a trust-based approach (for Natural Health Product companies) and relies on the regulatory authority to undertake reviews of recently released products at an efficient rate. The Australian Therapeutic Good's Administration's (TGA) product review rate is not considered a good example: in the last 6 months, the TGA listed 1022 new products, initiated 72 post-market reviews, and 60% of reviews found manufacturers weren't compliant. To allow appropriate levels of assessment, the Authority must have sufficient capacity to

[5] RACGP. Regulation Impact Statement: Regulating the advertising of therapeutic goods to the general public. RACGP Submission to Therapeutic Goods Administration, July 2013. Available at: http://www.racgp.org.au/support/advocacy/advocacy-topics/

review products, as well as resource and power to adequately respond to complaints and mandate corrective action (e.g. issue substantial fines).

We acknowledge that the exemption of notification of products made by natural health practitioners is necessary to allow these practitioners to work in their scope. However, the College recommends that natural health practitioners must still adhere to the permitted (i.e. safe) ingredients list.

Recognised Authorities

The College has no specific comments about recognised authorities.

Determining if your product is a permitted natural health product flowchart

A key flaw in the proposed flowchart is that the decision boxes include dual criteria e.g. "presented in therapeutic form AND has dosage instruction". Therefore a product may meet only one of the criteria and the producer is then unable to use the flowchart.

We hope you find our submission helpful. Should you require any further information or clarification please contact the College's policy team at policy@rnzcgp.org.nz.

Yours sincerely

Helen Morgan-Banda
Chief Executive Officer