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KEY ISSUES	**COMMENTARY/UNINTENDED CONSEQUENCES**	
1. The change from a notification to a mixed notification/ pre-approval regime	***1.1 The changes*** The proposed regime has been changed from a notification regime to a part notification part pre-approval regime. This is in response to a perceived problem of defining the exclusion of serious conditions. Clause 12 has been has been changed so that in effect three different categories of health benefit claim are treated in different ways; 1. health benefit claims that fall within the definition of a health benefit claim but do not refer to a condition or symptom: these claims may be 'notified' without approval; 2. health benefit claims about certain pre-approved named conditions: provided the condition has been "pre-approved by the Authority, these claims may be notified without further approval: and 3. any other health benefit claim which needs to be formally approved by the Authority. ***1.2 The changes are un-necessary and disproportionate when considered against the approach taken to medicines*** The change to include a pre-approval aspect to the regulatory regime (categories 2 and 3 above) is unnecessary. In his letter to NZHT dated 6 November 2012 (ref 12001501) the Minister says: *"The change in the provisions about named conditions was in response to concerns raised about the original prohibition of claims about serious conditions. Officials were unable to come up with a definition of serious condition that did not exclude claims that*	Recognising the principle of low cost risk proportionate regulation, we propose that (as per the previous draft of the Bill) any health benefit claim for a natural and supplementary health product be notified and evidence to support that claim must be held by the notifier and provided to the Authority on request. Possible concerns about health benefit claims about serious conditions are implicitly dealt with by the mechanisms in clause 16 which allow the Authority to suspend notification for products that it has reasonable grounds to believe are likely to cause harm or are products for which misleading information has been provided. If it were considered necessary to explicitly deal with serious conditions (which we say it isn't), a short list of particular conditions could be identified. Claims in relation to those conditions could be made on a pre-approval basis. We suggest using the list in Part 1 of the Medicines Act 1981 as a template (minus those conditions the Ministry have identified as being suitable for health benefit claims to be made without approval). This list should be included in the NH&SP Bill as a Schedule. Alcoholism. Appendicitis. Arteriosclerosis. Arthritis. Baldness. Blood pressure, disorders of. Bust, underdevelopment of. Cancer. Cataract. Central nervous system, disorders of. Diabetes.

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	are reasonable to make, such as iron tablets helping anaemia. The notification regime would require a list of serious conditions to include everything possible. Even if it were done by category rather than individually listing conditions, there would need to be exclusion, which would amount to an approved list." There are two issues – whether a list of excluded conditions could be drafted and if so what it would need to encompass. The examples we have previously provided show that such a list <u>can</u> be drafted (and see below for a further example). The real objection appears to be a policy objection. The Minister's letter says that a list of serious conditions would *"require a list of serious conditions to include everything possible"* essentially because *"The other regulations you refer to operate pre-approval regimes, which allow them to consider any particular claim in detail, so they do not need a complete list of excluded conditions"*. The starting point drafting the NH&SP Bill was that NH&SPs require risk proportionate regulation. A notification regime was accepted as appropriate because of the low risk nature of NH&SPs. The intent of regulation was primarily to identify who and what was in the market and to make sure that any claims made about products were supported by appropriate evidence. In that sense, and unlike medicines, a detailed analysis and approval of a product and its effects is not necessary. Drawing a distinction between a notification regime and a pre-approval regime on the basis that the notification regime does not allow claims to be considered in any detail ignores the fact that pre-approval was never considered necessary in the context of NH&SPs. It also ignores the fact that the notification regime as originally proposed provides ample opportunity for any problematic claim to be considered in detail and dealt with appropriately. Claims must be notified with supporting evidence available to the	Diphtheria. Dropsy. Epilepsy. Gallstones, kidney stones, bladder stones. Gangrene. Glaucoma. Goitre. Heart disease. Infertility. Leukaemia. Menopause, disorders of.* Menstrual flow, disorders of.* Mental disorders.* Nephritis. Pernicious anaemia. Pleurisy. Pneumonia. Poliomyelitis. Prostate gland, disorders of. Septicaemia. Sexual impotence. Smallpox. Tetanus. Thrombosis. Trachoma. Tuberculosis. Tumours. Typhoid Fever. Ulcers of the gastro-intestinal tract. Venereal diseases. * These conditions have been identified by the Ministry as conditions for which health benefit claims ought to be able to be made without pre-approval. The reference to menopause and menstrual flow disorders could be deleted. The reference to mental disorders could be amended to mental disorders except anxiety, stress and depression (because

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	Authority. Clause 16 provides the Authority with powers to suspend or cancel product notifications in circumstances where there is reasonable grounds to believe a product *"has caused, is causing, or is likely to cause any harm to any person"* or *"the Authority has reasonable grounds to believe the product notifier has provided false, misleading, or incomplete information in the product notification"*. Any health benefit claim could be scrutinised to the extent considered necessary by the Authority and any concerns could be dealt with through the clause 16 powers. Against that background, identifying a short negative list of serious conditions and requiring health benefit claims about these conditions to be approved, is the appropriate regulatory response (and is more administratively efficient than having the regulator establish a long positive list of approved conditions). We say that the negative list of serious conditions should be restricted to conditions that are particularly serious. The Medicines Act places restrictions on advertising medicines that make certain claims about particular named conditions. These are listed in a schedule to the Act (see section 58 Medicines Act and Schedule 1, Part 1 (set out in the suggested amendments column) and Part 2. The conditions covered include serious conditions and conditions that may be prone to "crank" remedies and among the restrictions imposed include claims medicines will *"prevent, alleviate or cure any disease or prevent reduce or terminate any physiological condition specified".* An analogy can be drawn between a "claim" about a medicine that may be made (without "pre-approval" of that claim but subject to regulation) in the form of an advertisement and a health benefit claim made about a NH&SP (which under the proposed Bill could also be subject to regulations imposing restrictions and/or particular requirements). The major difference is that NH&SPs are inherently lower risk products than medicines and therefore should be subject to significantly less control.	there other mental disorders within this category).

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	We note that while it is clear from the lists in Schedule 1 of the Medicines Act that some of the conditions targeted in those lists are clearly conditions prone to "crank" remedies as well as serious conditions we think the (part 1 list in particular) could be used as a starting point for a list of "serious conditions" under the NH&SP Bill with those conditions the Ministry has already identified as being conditions for which formal approval would not be required, removed from the list. ***1.3 Not what was promised to the industry*** The introduction of an approval aspect to the regime flies in the face of assurances to the industry that the regulatory regime would be a notification regime: an assurance that was made recognising that a notification regime would be a risk proportionate regulatory response to need for regulation of natural and supplementary health products. This change is **not** a risk proportionate regulatory response and will significantly increase administrative and compliance costs for the industry. ***1.4 Will create a black list of health benefit claims for which approval would be required*** The ability to make category 2 health benefit claims is predicated on the Authority "pre-approving" a list of named conditions. As re-drafted a named condition would be defined by reference to the World Health Organisation ICD Codes which are designed to capture every condition or symptom. In effect this would create a negative/black list of all named conditions/symptoms for which health benefit claims could not be notified without the Authority's approval. There is no statutory requirement for the Authority to produce or maintain such a list. And there would be an additional cost associated with the Authority pre-approving that list and any updates. Category 3 health benefit claims would encompass any claim that relates to any condition or any symptom that is not on the pre-	

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	approved list. These claims would require specific and individual approval by the Authority which would be significantly more costly than simply notifying a claim. ***1.5 Will be significantly more costly – at the expense of the industry and ultimately the consumer*** Current Ministry of Health cost recovery fees for approving a new related product are $5,500. To change a name costs $720 and to add a flavour or type of sweetening costs $1,440. It is reasonable to assume that pre-approval costs under this Bill would be similar. In addition to fees for approval applications, there will be administrative overheads associated with putting in place the infrastructure to deal with pre-approval applications. The Government's intention (as set out in the Cabinet Social Policy Committee paper seeking approval to develop the Bill (SOC(10) 141) notes that the Crown will fund only the costs of regulatory policy advice and post-market activities. All pre-approval costs will therefore be a cost to the industry. There are many small to medium sized enterprises in the natural products industry who are just keeping their heads above water. Additional administrative and compliance costs will have a significant effect. ***1.6 The obligation to provide a summary of evidence with notification will impose significant indirect compliance costs and be unworkable*** Sub-clause (13(2A)) requires a product notifier (when notifying a product) to publish on the internet a summary of the evidence supporting a health benefit claim. This clause will result in a notifier incurring significant compliance costs – particularly when considered in the context of new offence provisions. The bill now provides that it is an offence to knowingly provide information in the 13(2A) summary that contains any health benefit claim that relates to a named condition unless it is an "allowable" claim (see clause 40A(2)). This	

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	means that any evidence intended to be posted in order to comply with 13(2A) will need to be edited to ensure that it contains only claims in "allowable" form (ie in the wording approved by the Authority). It is not difficult to foresee a situation where, for example, a scientific paper could not be posted as evidence because the claims in the paper are not limited to the wording of the "allowable claim". This obligation is unworkable and will not achieve the object of allowing the public to make informed decisions. It should be deleted from the bill. ***1.7 The changes would incentivise generalised claims making it less likely consumers will be able to make informed decisions about products*** It is inevitable that category 3 (and possibly category 2) health benefit claims will attract a higher notification /pre-approval fee. This will incentivise the industry to stick to more general structure and function claims (ie the type of claims that may be made under the existing law) to the cost of consumers who will miss out on the opportunity to receive more detailed and accurate information about products. We note the intention is that the process for approving category 2 and category 3 claims contemplates approval of classes of conditions and classes of products. Prospective notifiers will think twice about applying for such an approval if there is a prospect of their competitors benefiting from their application.	
2. Definition of health benefit too narrow	***2.1 The definition of health benefit must include the concept of "restoration"*** The definition as currently drafted does not cover all the characteristics of a NH&SP. Many NH&SPs do more than maintain or promote health or wellness and relieve symptoms; they actively assist in treating conditions and restoring health or wellness. Therapeutic claims that fall outside the definition as drafted will only be able to be made with Medicines Act approval. Given that the Bill has evidential	Amend paragraph (a) to read "(a) the restoration, maintenance, or promotion of health or wellness"

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	processes designed for NH&SPs, and in particular to ensure that any claim made is evidence based, it makes no sense to have products diverted to the Medicines regime because of the type of claim made. The significant cost of Medicines Act approval will essentially ensure no such claims are made.	
3. The re-draft gives the Authority too much power	***3.1 Allowable claims – no obligation on the Authority to come up with a pre-approved list of named conditions*** A key aspect of the re-draft is that the Authority would pre-approve a list of named conditions. Products that make health benefit claims that relate to any of those named conditions would be "pre-approved" and could be notified without further approval by the Authority (category 2 claims set out above). The power to approve a list of named conditions is set out in clauses 12B(1)(b) and 12B(4). There is no obligation on the Authority to come up with this list or to periodically revise it. Individual parties may apply to have a condition put on the list but that would be subject to a fee. This creates a financial incentive for the Authority to recover the costs of populating this list via a more direct fee structure (for an individual application for approval) rather than indirectly through administrative budget. ***3.2 Consultation obligations have been watered down considerably*** In a number of key areas the re-draft waters down obligations on the Authority to consult. The commentary provides no reason for this. Whereas previously the obligation was to consult persons likely to be affected, the obligation is now to consult persons or organisations *"that the Authority considers to be representative"* of various interests likely to be affected. Parts of the Bill that include this more limited consultation obligation include:	See above. This problem will resolve itself when the pre-approval process is removed. The obligations to consult in clauses 27, 35 and 47 must revert to the previous drafting so that the Authority and the Minister have obligations to consult parties likely to be affected.

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	• Development of the Code of Manufacture (clause 27); and • The prescription of fees (clause 35); The Minister's obligation to consult in respect of some of the regulation making powers (clause 47) has been similarly narrowed from an obligation to consult *"any person or organisation that the Minister considers has an interest in, or will be substantially affected by the regulations"* to an obligation to consult *"any person or organisation that the Minister considers to be representative of the interests of persons likely to be substantially affected by the regulations"*. The natural health products industry is a diverse industry. Participants in the industry vary widely in terms of size of operation and philosophy. Consultation with "representatives" chosen by the Authority or the Minister will inevitably mean that not all interested parties will have a voice. ***3.3 The Bill does not provide a process for the policy/operational review, in particular there is no requirement to consult the industry*** Clause 48 of the Bill provided for a review of the policy of the Act, to be conducted no later than five years after the commencement of the Act. The re-draft extends this to include the "operation" of the Act. Consideration does not appear to have been given to the transitional provisions - which will mean that the Act will not be in full operation until three years after the commencement date. We believe that to conduct a review within just two years of the Act coming out of transition is too soon. This legislation has had a long and politically contentious journey with the Ministry of Health supporting a joint agency with Australia's TGA	This review must be conducted by the Minister. This clause must include an obligation to consult interested parties. The clause must also include and obligation that the review consider whether the existing regulatory framework and operation and administration of that framework under the NH&SP Act is the most effective and efficient means to: • provide for risk proportionate, transparent and stable regulation; • promote the legitimate commercial interests of notifiers suppliers and manufacturers of NH&SPs; and • support innovation in the NH&SP market.

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	in preference to New Zealand developing its own regulatory framework. There are many in the industry who believe that this stance has not changed and that this review is intended to provide an opportunity for the proposed regime to be abandoned in favour of adding natural products to the Australian New Zealand Therapeutic Products Agency. Against that background, we say that any review should be conducted by the Minister, not the Ministry of Health. Industry have invested considerably in the development of this regulatory framework and will invest further once the Act is in place – in developing programmes to ensure that operations comply with the Act. To carry out that investment with the threat of an unspecified review in five years time – that could result in a complete change of regulation and therefore compliance obligations – is unfair to the industry. Given that background, there must be clear direction in the Bill setting out a detailed review process including specific matters to be considered and obligations to consult with interested parties.	For the avoidance of doubt, consideration of efficiency and effectiveness should include consideration of the benefits of the natural health products industry in the context of health spending as a whole.
4. Disproportionate and unworkable restrictions on advertising NH&SPs)	***4.1 New clause 40C is onerous and unworkable*** Clause 40C is ill thought out and will have a severe impact on the industry by inhibiting the flow of information about products to natural health practitioners in particular. Clause 40C targets advertisements that directly or by implication suggest that a NH&SP is able to *"treat or assist in the treatment of a named condition"*. It creates an offence for any such advertisement to be published unless the claim is an "allowable claim" – ie the claim has been approved by the Authority. In essence this will mean that the ability to advertise products and make claims that relate to a 'named condition' will be severely limited because notifiers will be limited to advertising their product in the words approved by the Authority as an "allowable claim".	Clause 40C should be deleted.

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	The most problematic aspect of this clause is that there is no exemption for the publication of information about products provided to natural health practitioners. This will impose an unreasonable limit on information about products. Currently many manufacturers provide manuals detailing product ingredients and excerpts of scientific evidence relating to particular ingredients. Many of those manuals would be in breach of this clause. The effect will be to unreasonably limit information available to practitioners. The cost of having every such publication approved would be prohibitive. This approach is inconsistent with the approach taken to medicines in New Zealand. The Medicines Act 1981 provides exceptions for medical advertisements distributed to certain types of health practitioners and advertisements in publications that are ordinarily circulated to such practitioners. Another inconsistency with the approach take to medicines is that the Medicines Act provides a specific defence of truth in respect of advertisements that breach that Act, yet there is no such provision in the Bill. In its current form the clause will arguably capture the news media. Any public interest story broadcast about a NH&SP that reported the promotion of a claim that a NH&SP assisted in the treatment of a named condition (that has not been approved as an allowable claim by the Authority), could be prosecuted under clause 40C. This clause is an unreasonable limit on the right to freedom of expression. We think it is un-necessary. Any false or misleading claims would be a breach of the Fair Trading Act 1986 and could be dealt with under that legislation.	

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5. Onerous re-notification provisions	***5.1 Re-notification provisions do not recognise practical realities*** As re-drafted clause 18 imposes unrealistic obligations to withdraw and re-notify a product where there has been a change of manufacturer. This is un-workable. There is a positive obligation to withdraw the notification if the manufacturer is changed but this ignores the fact that there may be a significant amount of product still available for sale under that notification. Withdrawal of the notification would result in that product not being able to be sold. The sensible and practical approach is to allow for an amendment to a notification for a change of manufacturer identified by dates of manufacture or batch dates. Notifications must be able to accommodate different manufacturers at the same time or overlapping times because notifiers may be using more than one contract manufacturer at any given time.	A change of manufacturer should not trigger withdrawal and re-notification of a product. The clause must be amended to allow for notification of more than one manufacturer for a particular product and for amendments to be made to a notification to reflect changes in manufacture.
6. Onerous obligations to report serious adverse events	***6.1 Obligation to report allergic reactions as serious adverse events is disproportionate to risk*** As re-drafted clause 17 imposes an obligation on notifiers to advise the Authority of any "serious adverse reaction" which includes an allergic reaction. "Allergic reaction" encompasses a wide-range of symptoms and would place very onerous reporting obligations on notifiers. The all encompassing nature of the term would make it very easy for competitors to promote a flood of complaints which a notifier would then be obliged to report. The inclusion of an "allergic reaction" is inconsistent with the approach taken by the World Health Organisation (see http://www.who-umc.org/graphics/27400.pdf). We could not find an overseas jurisdiction that included "allergic reaction" in the definition of a serious adverse reaction in a similar context. It is also inconsistent with the current approach taken to the monitoring of adverse events in New Zealand. CARM (Centre for Adverse	Delete clause 17(2)(e).

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	Reactions Monitoring) collects and evaluates reports of adverse reactions in medicines, vaccines and complementary and alternative medicines (NH&SPs) and provides this to Medsafe. See http://www.medsafe.govt.nz/profs/puarticles/mar2013adversereactionreporting.htm for the most recent adverse reaction report. This notes that CARM determine what is a "serious adverse reaction" in regard to internationally agreed criteria (see below Figure 1 in the report) and describes a serious adverse reaction as a reaction "resulting in hospitalisation, is life-threatening, fatal, results in a disability or requires intervention to prevent permanent disability, or results in a congenital abnormality" – ie the WHO definition. It makes no sense to apply a different (and more stringent) standard to NH&SPs than the standard applied to medicines and vaccines – particularly given the relative risk of an adverse events (in 2012 medicines account for around 67% or adverse reactions reported, vaccines 30% and complementary and alternative medicines a negligible amount – see the above adverse reaction report).	
	Please note that this table is a summary of key issues only and is not intended to be comprehensive. A comprehensive list of concerns is set out in separate document.	