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Natural Health Products
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Ministry of Health - Natural Health Products Bill Submission

Complementary Medicines Australia (CMA) is pleased to respond to the New Zealand Ministry of Health on the Natural Health Products Bill consultation. The following comments are provided in the context of the *Regulation of Natural Health Products Consultation Draft* and related documents, published online 18, November 2015.

CMA is the peak trade association representing companies involved across the complementary medicine supply chain. We represent approximately 96% of the major Australian companies in the natural health products space.

Australian complementary medicine exports are booming. Over the last two years exports of Australian complementary medicines have grown 36%, with New Zealand being one of the top export markets. With a continued healthy demand for Australian products, driven by the industry's reputation for safe, high quality products, now is an opportune time to look for a level of regulatory harmonisation that is risk appropriate and meets consumer demand.

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Introduction

Complementary medicines play a significant role in allowing individuals to maintain a high level of physical and psychological wellness, and have the potential to assist in the reduction of the ever-increasing healthcare costs associated with preventable chronic diseases. Increasingly, complementary medicines are being found to contribute to improved health outcomes, through increased effectiveness, safety and cost-effectiveness, and integration with conventional medical care.

Executive Summary

CMA applauds the Ministry on establishing a light handed regime to address this lower risk sector of goods. The proposed regulatory scheme aligns with international best practice in providing controls for:

Manufacturing through GMP and audits
A permitted ingredients list
A list of conditions allowed for use
Levels of evidence guidelines; and
A central register for all natural health products.

However, there are a number of areas that CMA will address in this submission including:

- The proposal that evidence held by the sponsor be made publically available. The publication of evidence, even in summary form, is not supported by CMA. This would not necessarily add any meaningful context for the average consumer and could create additional confusion over the way in which natural health products are regulated via a lower risk based scheme. It would also require resources of the Authority to ensure the content of the publications were correct.
- CMA does not support the public disclosure of the following sources of information, manufacturer's details on product labels, full formulation details, testing facilities and importer information, mainly for alignment with the Australian regulatory environment.
- Strong arguments are made for the protection of a range of information that is considered proprietary for both the sponsors and the manufacturers of the raw material(s). A possible solution has been put forward where, similar to the Australian system, the Authority takes ownership of reviewing the proposed PI by conducting a review of ingredient safety and applicability after an application has been lodged.
- We support the development of a labelling guideline, similar in approach to how the current guideline applies to listed complementary medicines in Australia.
- CMA suggests the Ministry review the list of conditions being proposed for NHPs. For some conditions that do not pose a significant health risk, such as Irritable Bowel Syndrome (IBS), a qualifying statement such as 'Medically diagnosed" prefixing the condition could be used.
- Enforcement and compliance - We are concerned about the apparent lack of information with regard to enforcement of the Bill and the relevant penalties that will apply should the Act be breached. Additionally post market surveillance regarding product compliance has not been adequately addressed.

- CMA supports the scheme continues to be developed cognisant of regulatory innovation and investment into the NHP sector.

Natural Health Products Bill

The Natural Health and Supplementary Products Bill seeks to establish a new regulatory regime for low risk products, separate from those in place for food and medicines.

The regime is intended to ensure the natural health products consumers use to support their health and wellbeing:

- are safe to use;
- that the health claims are true; and
- that the products contain what their label says they do.

The regulations are in place to protect consumers and to promote trade.

CMA supports that the aim of the Bill is to achieve an appropriate level of risk management and assist consumers in making informed, safe choices about the products they buy.

Ingredients

Permitted Substances

Under the new regulatory scheme, natural health products (NHPs) sold over the counter may only contain permitted substances. In deciding to add a substance, the Authority must take into account whether a 'trusted' regulator allows it, if it is recognised as an ingredient in a traditional medicine system as well as other relevant information.

The list of permitted substances will be compiled from a combination of the lists of substances allowed by the Australian regulator, the Therapeutic Goods Administration as well as Canadian regulators of similar products.

1. Are there other criteria that the Committee should consider when adding a substance to the permitted substance list?

In seeking views on what other relevant information the Authority should consider, CMA suggests the following points be considered by the Authority/Advisory Committee:

1. Is the substance controlled by other regulatory schemes in New Zealand?
2. Considering item 1, could the substance be made available in natural health products at a lower dosage level for use in a natural health context and managed by conditions of use?
3. Previous expert opinion on the substance, if available, should be considered in light of any new body of evidence.

After the draft list takes effect, substances may continue to be added at any time but notifiers will need to apply for the substance to be added and pay a fee. Predictable and target timeframes for the addition of substances would need to be outlined.
CMA also suggests that it may be appropriate for the Authority to add to the list of permitted

ingredients as new ingredients become available for use in Australia and Canada as part of National Regulatory Authorities working together and information sharing.

The Bill requires the Authority to establish a Natural Health Products Advisory Committee. CMA is supportive of the implementation of an Advisory Committee to provide advice to the Authority on the suitability of active substances to be used in NHPs. The committee should include a diverse and appropriate spread of expertise in the fields of toxicology, pharmacology, herbal medicine, nutritional medicine, natural health product practice, research and manufacturing.

CMA is supportive of the consultative process used by the Authority, including an online searchable list of substances and the ability to make suggestions for inclusion of new ingredients directly to the Authority for consideration.

Names of permitted substances

The names of permitted substances in NHPs should meet internationally recognised naming conventions to allow a product to be recognised in overseas markets. CMA suggests that labels should contain the international naming convention/scientific name and the common name for the consumer to understand. The World Health Organization's International Non-proprietary Name (INN) system is maintained by member states, including Australia and adopting such a system would meet global naming conventions.

Proprietary Ingredients

The Authority proposes that full formulation details must be disclosed, including to consumers. CMA suggests that full disclosure be made to the Authority only and a risk appropriate approach is taken by the Authority on behalf of the public. This would allow IP security to the PI owner, a system similar to that used in Australia. As such we do not support the inclusion of the last paragraph on page 5 of the consultation document.

The term proprietary ingredient could apply to a blend of active ingredients or the colours and flavours for example. In Australia, an excipient ingredient need not be nominated on a medicine label, unless it is a restricted ingredient, for example: included in the Poisons Standard; or included in the First Schedule of the Therapeutic Goods Order No. 69 - *General requirements for labels for medicines (*which lists excipient ingredients required to be mandatorily declared on medicine labels). If elected to disclose a *non-mandatory* excipient on a medicine label, then all excipients must be disclosed, that is: declaration of excipients on a medicine label cannot be selective[1].

A risk appropriate approach is taken as an excipient ingredient is not therapeutically active and does not contribute to the physiological or pharmacological action within the medicine's final formulation. Types of excipient ingredients include: a fragrance, flavour, preservative, printing ink, antioxidant, coating, binding agent, filler or anticaking agents. To allow for a level of

[1] there are additional restrictions and requirements for ingredients that are of animal or human origin or that are genetically modified organisms or genetically modified products. See the Australian Regulatory Guidelines for Complementary Medicines (ARGCM) for more details.

harmonisation of regulatory requirements between Australia and New Zealand, a similar approach should be adopted by New Zealand.

In addition, another option would be for PIs to be added to the approved ingredient list for the Authority to assess safety on behalf of the public. The cost to the Authority would be recovered with a cost recovery system, whereby the manufacturer of the PI pays a submission fee for each PI ingredient, which the Authority is required to assess. Once the PI has been assessed for risk, the Authority may issue a unique PI number to the submitter. When a sponsor uses the PI in a NHP, the PI number is used in the list of ingredients. If there are any potential allergens within the PI, the Notification system and label would contain the allergen. Mandatory labelling requirements for applicable PIs would allow consumers to make decisions based on safety or otherwise suitability.

We believe that maintaining the propriety information of PIs will help protect the unique research and development that the manufacturers allocate to develop a PI. It will also benefit the notifier, in order to adequately market the product that utilises PIs.

CMA is supportive of the implementation of an Advisory Committee to provide advice to the Authority on the suitability of active substances to be used in NHPs.

We note the consultation on the permitted substance list is open through to May 2016, after which substances may be proposed along with a yet to be determined fee. We also note the latest source of ingredients can be located on the 'database for permitted substances' found on the website. CMA supports that where label advisory statements are proposed, words of a similar meaning to the advisory statement may be used.

We note the list covers items on the Australian 'list of permissible ingredients', however, the approach proposed by the Authority with regard to proprietary ingredients would be unworkable, largely due to the intellectual property issues that arise.

2. Of the criteria proposed, are there any that you think should not be considered by the committee when adding a substance to the permitted substance list, and why?

The criteria proposed covers considerations around the quality and safety of the proposed active substance and should take into account its availability in the natural health products environment. Inactive substances should not be assessed against the six criteria points outlined in the consultation document on page 4.

The committee should also have scope to consider other relevant matters as the Authority deems suitable in providing its advice. This could include submissions made by the applicant of a new substance for consideration by the Committee.

3. Should the criteria to be considered by the Committee be weighted or ranked in some way?

All criteria should be considered equally and the final assessment to be based on the risk inherent in each criterion.

CMA supports a risk appropriate approach to the regulation of NHPs. The Authority should have a streamlined process for the inclusion of ingredients that have been approved by reputable regulatory authorities such as Australia (TGA, FSANZ), Canada and the UK, including ingredients that have been approved under food legislation. For example, the FDA's GRAS system should be viewed as being acceptable for assessing ingredients for NHPs.

The Committee should provide its advice on the safety and quality criteria on a case by case basis, noting the majority of there ingredients are of a lower risk.

4. Do you agree that full formulation details of proprietary ingredients should be disclosed? If not, what alternatives do you suggest?

CMA does not agree that full formulation details of proprietary ingredients be disclosed to the public. We are strongly opposed to this suggestion and have detailed some alternative options for the Authorities consideration, including a model where confidential disclosure to the Authority can occur.

5. Are there substances that could be added to or should be removed from the draft permitted substance list?

CMA suggests that all traditional herbal medicines documented in the national pharmacopoeias: Chinese, Japanese, Indian and German Compendiums be included in the list of substances before the end of May 2016 close off. Grandfathering of all existing ingredients in the market should also occur.

Health Benefit Claims

The term 'health benefit' is defined in clause 5 of the Bill to mean any one of the following benefits:

- The maintenance or promotion of health or wellness
- nutritional support
- vitamin or mineral supplementation
- affecting or maintaining the structure or function of the body
- relief of symptoms.

CMA supports that any health benefit claim must be supported by evidence of a suitable standard.

Named Conditions

CMA suggests that the below factors, if considered in context of one another, are suitable in determining if claims can be made about named conditions:

- Non-serious
- Self-limiting
- Suitable for self-management
- *un*likely to cause serious consequences without health practitioner involvement

It is noted that a named condition is any disease, disorder, condition, ailment or defect that is listed or described in the most current version of the *International Classification of Diseases* (ICD 10). As such the terminology contained in the conditions list is medically termed.

The draft 'proposed list of conditions about which claims can be made' adapts terminology from ICD10 and as such does not appear to have covered a range of allowable lower level health benefit claims. Additional claims should be added to the list to support the maintenance and promotion of health and wellness, nutritional and supplemental support and traditional claims etc. CMA seeks clarification that lower level health benefit claims are permitted in addition to those outlined in the named conditions list.

6. Should other factors be considered?

In addition, CMA suggests there should be a process to propose or amended entries on the list of conditions about which claims can be made. For example, *H93.1-Tinnitus* does not appear on the list and could be proposed to the Authority for inclusion. There should also be a process where the Authority are able to endorse food legislation claims as safety considerations have been assessed, thus further evidence would not need to be provided but the Authority could seek the required assurances.

In proposing additional entries, such factors as emerging evidence, evidence already considered by other regulatory authorities (including food legislation), the use of the proposed substance within a NHP and with mitigating label warnings etc. could be submitted to the Authority for consideration. The Authority could seek advice from the Committee, where required.

As with the Australian regulatory regime, interface issues may require consideration and further guidance should be available. The NHP-cosmetic interface and those products dealing with 'weight management' and 'energy products' may require further consideration as to appropriate parameters and guidance.

7. Are there conditions you think should be added to or removed from the draft list of conditions about which health claims may be made?

As mentioned above, other conditions about which health claims can be made should be added to the list. A cross comparison with the TGA's draft permitted Indications list and that of Health Canada should be conducted to identify any omissions.

It is suggested that the following 'conditions' be added to the list

- Anxiety, mild anxiety, nervous restlessness, stress or conditions to the effect of
- Macular degeneration
- Edema
- Muscle building
- Tinnitus

CMA suggests that consideration should be given to including a range of conditions that may require an initial diagnosis/intervention by a healthcare professional. For example, hypertension

due to an underlying cause would require investigation and would not be suitable for a consumer to differentiate between primary or secondary hypertension due to a potential undiagnosed serious condition. The inclusion of the term 'medically diagnosed' or similar to relevant named conditions would assist in risk mitigation in this regard. There may also be instances where the degree of a named condition maybe applicable. For example, pain from rheumatoid arthritis maybe classified as 'mild' or 'moderate'.

A set of definitions is required to define the action or effect terms used in claims. Providing definitions for these terms allows the applicant to determine the strength of the claims being made and thus the level of evidence required to support it. CMA suggests the following terms could be defined:

- Support
- Maintain
- Improve
- Enhance
- Manage
- Help
- Assist

Evidence

CMA supports that health claims for NHPs, as for complementary medicines, be supported by appropriate scientific and or traditional evidence. However, we do not support the proposed mandatory requirement for product notifiers to include a reference to a website with a summary of the evidence supporting the health claims for a product.

Relevance and Representativeness of Evidence

Evidence is continually evolving and it would be expected that a review of the evidence is required to be undertaken to assure stakeholders that the evidence remains accurate for the product. This would mean updating the evidence summary for each product on the website, requiring a significant investment in resources.

CMA suggests that a summary of the evidence available to the public should include only a summary of the

- claims that the notifier has made in respect to the product (traditional/scientific).

Noting that section 13(3)(b)(ii) of the Natural Health and Supplementary Products Bill states the product notifier is able to provide, at the Authorities request, evidence to support the health benefit claims made for the product.

It is proposed that the source of the evidence, including the objective, method, key findings and conclusions be published. This would be beyond the scope of the average consumer to make adequate and reasonable decisions about the level of scientific evidence and therapeutic relevance of the product. A public summary of scientific evidence may also encourage other notifiers to use evidence made available by others without independently and adequately assessing the suitability of the evidence in the scope of their individual product.

The Authority could, after calling in evidence, make a statement on its website to the effect that evidence has been reviewed and found suitable/not suitable in relation to the claims made for the product etc. This would instigate a similar post-market listing compliance review process to what is conducted in Australia for listed complementary medicines. It is acknowledged that cost recovery considerations would need to be considered for this approach however, the benefit would be a single source of truth for the consumer. This option would also allow regulatory/administration protections to industry that are vital to encouraging businesses to invest in research and development.

8. Are there other criteria that should be included, or should any of the listed criteria be excluded, and if so, why?

Claims should be permissible based on individual ingredients and ingredient combinations where supported by scientific and or traditional evidence. It should not be a requirement for the supporting evidence of a claim to relate to the whole formulation of a product, unless a claim is made specifically about the therapeutic benefits of the actual product.

CMA queries how existing products will be handled?

Traditional Evidence

The Bill establishes that health claims may be made based on evidence of traditional use. These claims are required to take the form of 'traditionally used for X' or words to that effect.

CMA supports the approach with regards to traditional claims that may be used as it is aligned to the approach taken by the Therapeutic Goods Administration (TGA). With regards to possible sources of traditional evidence, CMA supports schedule 2 of the Bill that lists approved pharmacopoeias, including the additions made earlier. There should also be recognition of other forms of traditional evidence such as the Commission E Monographs and Health Canada Monographs.

Scientific Evidence

CMA suggests that a summary of scientific evidence available to the public include a summary of the claims that the notifier has made in respect to the product only. No other information is required to be made publically available.

CMA seeks further clarity around the statement that 'the minimum level of study that (the Authority) currently consider acceptable – should not be beyond the reach of the average product notifier'. This seems to be in contrast to an earlier recommendation for summaries of evidence to be made publically available.

As mentioned earlier we support that section 13(3)(b)(ii) of the Natural Health and Supplementary Products Bill allows the product notifier to provide, at the Authorities request, evidence to support the health benefit claims made for the product. This information, once provided to the Authority should be held in confidence.

Manufacturing

The Code of Manufacturing Practice

The Bill provides that the Authority must issue a Code of Manufacturing Practice, to come into force no later than one year after the legislation.

CMA supports NHPs be manufactured to meet the requirements of the Code of Manufacturing Practice. Compliance with the Code will be monitored by regular on-site audits, either by the Authority or other recognised Authorities. For imported products, the Authority would generally look for evidence that the facility is audited by a local trusted regulator.

The Authority has prepared a draft Code that details minimum standards for personnel, premises and equipment, production, quality control, and complaints and recalls.

9. Do you agree with the proposed Code of Manufacturing Practice?

CMA supports NHPs be manufactured to meet the requirements of the Code of Manufacturing Practice. However, there are some areas that require clarification through required protocols or guidance documents, such as stability, process validation and testing protocols. There appears from the consultation document various forms of GMP will be acceptable. This may cause issues concerning various degrees of quality and interpretations which may have a detrimental effect on the quality of the product.

With respect to products manufactured in Australia under TGA licence, clarity around mutual recognition should confirm complementary regulatory arrangements across the Tasman. Mutual recognition of the reputed overseas GMP certification should also include cGMP, Health Canada NHP GMP, ASEAN GMP i.e. TGA GMP license is already recognised. Appropriate GMP should include ISO Standards for both Nutritional Supplements (ISO 22000) and for Topical products (ISO 22716:2007 Cosmetics GMP) or cGMP or equivalent.

If third party auditors are to be accepted by the Authority, then a clear set of guidelines would be required that explain the minimum the Authority would accept for GMP.

10. How frequently should audits be required? Should this differ for different levels of risk?

CMA suggests that audits conducted on a 5 year frequency would be adequate and is inline with the renewal for manufacturing licences. The frequency of audits should abide by the notion of ‘proportionate to risk” as low risk medicines.

11. Do you think there should be exemptions from manufacturing licensing?

Given the proportionate to risk as low risk medicines notion, CMA believes there should not be a process for exemptions from manufacturing licensing. Aspects around extemporaneous compounding of complementary medicines and practitioner only products however should be aligned with Australia.

Fees

The Bill provides that the cost of the Authority is to be recovered from the industry through fees. This is inline with the framework for the regulation of complementary medicines in Australia.

CMA supports that the fees and fee structure be reviewed within the first three years of the Bill coming into effect.

Types of Fees

Annual Product Notification Fees

It is proposed that the product notification fee be an annual amount charged at the time of the initial notification and annual renewal. For products already on the market when the Bill takes effect, there will be a transition period of one year before notification is required and that no notification fee will be required for this implementation period.

Types of Fees and Fee Structure

We note that the proposed fees include a surcharge to recover the establishment costs over five years. As mentioned, CMA supports that the fees and fee structure be reviewed within the first three years of the Bill coming into effect and suggest another review after the five year time frame to establish a longer term framework for fees.

12. Are there any additional issues relating to fees and charges that you would like us to consider?

- CMA suggests that further clarity could be provided around export certificates.
- A provision for a change of notification and further clarity on what would trigger a new notification should be provided. E.g. excipient or raw material changes or product name changes.
- CMA suggests that changes that do not impact upon the active formulation be allowed. For example, criteria where certain changes to excipient ingredients are allowed via a notification process.

Very Low-volume Products

CMA considers that a policy should be in place for very low-volume products, such that NHPs are encouraged to enter into and remain in the market. A scheme should be devised that reduces the financial and administrative burden on providers of products that might otherwise not be viable in the market. We appreciate that this raises concerns about cross-subsidy and suggest that a policy be put in place for the first three years prior to the review of the fees and fee structure, at which point its impact and extent of cross-subsidy could be further assessed.

Up until 2015, Australia had a low value turnover (LVT) policy in place. CMA supported the retention of this policy for the benefit of a number of smaller manufacturers and companies in the market and or those providers of products that might otherwise not be viable in the Australian market. In our case, complementary medicines being regulated under the same scheme as prescription and OTC medicines, big business were seen as the large portion of users claiming the LVT exemption and thus a new annual charges scheme was introduced. CMA believes that the NHP Bill, being set up distinct to other regimes, would therefore not fall into the same issues as experienced here.

13. Do you see a case for reducing fees for very low-volume products?

Yes. However, consideration would be required on ways the scheme could operate without undue administrative burden for applicants complying with the scheme. For example, the exemption could operate on the basis of self declaration of low turnover and an audit program to detect incorrect declaration could be implemented.

14. How would you define very low-volume products?

The Australian policy, in place between 1990 to 1 July 2015, used a threshold of sales that equated to 15 times that of the Annual Charge.

Labelling

The Ministry is cognisant of the fact that many products are sold in multiple countries, where requirements differ. The labelling requirements set out in the Regulations are intended to minimise the need for relabelling products.

Product notifiers will have two years from when the Bill comes into effect to comply with the labelling requirements in the regulations.

The regulations will require that the label be:

- Clearly visible
- In English
- In lettering that is clear, distinct and legible
- Durable and not readily damaged by normal handling

Minimum Information Requirements for Labelling

The majority of the minimum labelling requirements appear acceptable. Again clear guidelines would need to be established. The requirement to have all ingredients on the label is considered unnecessary and excipient ingredients have been mentioned above.

In determining what will be minimum label requirements for outer packaging, the ministry has proposed that:

The name and address of the manufacturer (if it is different from the product notifier) be included.

The notification on the label of the manufacturer and importer are not acceptable. There may be multiple manufacturers of the same product for example. The Importer of the product on the label is of no benefit for the consumer as it is the Notifier who takes the responsibility for the product being notified to the Authority. The Notifier would be the main point of contact for the consumer desiring any additional product information and thus the name and address of the product notifier is important for contact purposes.

CMA suggests that at a minimum labels of NHPs should include:

- the product name
- intended purpose of the product (linked to the health benefit claimed)
- the scientific names of all active ingredients (common names can be used as well but not instead of).
- the quantity of all active ingredients
- applicable warning statements
- batch number
- storage conditions
- expiry date
- statement of the net weight/volume
- description of dosage form (tablet, capsule) and presentation (oral)
- directions for use, including the dose and frequency of the dose to the maximum daily does (for adult or children)

CMA suggests that labelling requirements be detailed in a guidance document to industry, including definitions and acceptable limits for legible lettering etc. In addition further guidance may be required on the expression of quantity or proportion of herbal ingredients. The current proposal is unclear around the requirements for input amount of dry/fresh equivalent, and whether or not the plant part and or common name of the herb are to be included.
CMA suggests alignment to the current TGO 69 General requirements for labels of medicines. Further information may also be sought from the "Guidance to the Expression of Herbal Ingredients in ARTG Applications and on Labels".

CMA agrees that product labels include a unique identifier. Unique identifiers are considered important in differentiating a NHP from a food or other product. However, an example of where greater alignment could be made is with regards to identifiers. There should be consideration of an option for Australian imported products to use a pathway where the AUST L number could be used and accepted as the identifier in the NZ system. This would avoid label re-work and minimise costs. CMA proposes there be an option to use the Australian listing (AUST L) number as an accepted identifier in the NZ system.

For business there would still be the requirement of maintaining the NZ registration with the current AUST L however, if the onus was on the sponsor to keep this current then responsibility comes down to change systems within individual organisations.

Notification

A publically available Notification system is acceptable except for the ability of the consumer to cite the manufacturers of products. As stated previously, multiple manufacturers may be used and some maybe classified as primary or secondary in instances where the primary may not be able to deliver by a specific date. There is no benefit in listing the manufacturer(s) of the product as the assurance is that the product is manufactured under GMP as the minimum standard.

15. Is there information that you think should be included or excluded from the notification process?

CMA suggests the following should also be excluded from the notification process:

- Retailers – keeping this information current would be an unnecessary administrative burden. Notifiers, as required under the code of manufacturing practice, would have batch tracking capabilities in the case of quality or safety recalls.
- Manufacturing licence status - the system developed should automatically be able to identify from the list of pre-approved sites.
- The importers name and address is considered unnecessary. There may be multiple importers of NHPs involved which are not always used as they could be considered primary or secondary.
- Quantity of excipients – the input quantity can vary slightly from batch to batch due to the complexity of NHP formulations. Excluding this requirement for specific examples would align with the Australian system for complementary medicines.

16. What information that we are proposing be notified that you think should not be made publically available and why?

CMA suggests that the following <u>not</u> be made publically available:

- Name and quantity of all non-active ingredients
- PI information
- Manufacturers details
- Testing facilities
- Summary of the evidence
- Importer details
- Manufacturing licence details (details of grant or expiry)

Some of the above information is considered proprietary information e.g. full formulation details, evidence and manufacturer details. Having an extended list of manufacturers and or testers would provide limited value and could cause consumer confusion. The Authority could seek to obtain such information provided that it is held in confidence.

Recognised Authorities

17. Are there any additional purposes for which you think the Authority should consider recognising other authorities?

No further suggestions made.

18. Are there any purposes for which you think the Authority should **not** consider recognising other authorities?

CMA refers to the following as not being recognised by the Authority:

- part 4 of the Medsafe document - Guideline on the Regulation of Therapeutic Products in New Zealand (GRPTNZ): manufacturer of medicines.
- The FDA document - Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food (CGMPS) regulations (21 CFR Part 110) should not be accepted for NHPs.

Other

Enforcement

We are concerned about the apparent lack of information with regard to enforcement of the Bill and the relevant penalties that will apply when the Act is breached. Additionally post market surveillance regarding product compliance has not been adequately addressed.

ENDS