NZ Health Trust

Protecting your Future

1 November 2013

The Honourable Tony Ryall
Minister of Health
Parliament Buildings

Dear Minister,

Natural Health & Supplementary Products Bill

1. By way of update, we have been working closely with officials on the various issues we raised with you when we last met. Given a commencement date of May 2014, we are mindful of the short amount of time left to get this regulation right. We are writing now because the Trust has significant concerns and wants to help you to achieve the best outcome and avoid unintended consequences.

Progress on drafting issues

2. For your information, we enclose a copy of a letter dated 5 June 2013 setting out our understanding of where officials have got to in considering various minor amendments/changes to the Bill. (We have since been advised that the two items in italics (paragraphs 3 and 5) will not require amendment because the issues raised are encompassed in current drafting).

No progress on the important issues

3. One issue officials have not been prepared to consider further is the approach taken in the Bill to "serious conditions" (notwithstanding that at our meeting in April, we understood you asked officials to reconsider this). The 5 June 2013 letter (attached) sets out the Trust's position in regard to that issue at paragraph 19ff. Other issues of key concern for the Trust include the ingredients list, the approach to be taken to fees and the manufacturing code.

Delays in consultation on ingredients list, conditions list, fees and Manufacturing Code

4. Since June, we have understood that consultation papers on ingredients lists, conditions lists, the Manufacturing Code and the fee structure were in the process of being prepared. Initially we understood these would be sent out for consultation in around mid-August. In July we were advised that these papers would be released in the next couple of months. In August, we were advised it would be early to mid-September (after the Advisory Group had seen the lists) and in early September we were advised that the draft lists would be released after a meeting with you to sign-off time-lines. At a meeting on 20 September we were told that we would be advised the following week when the lists would be released. That didn't happen but on 1 October the Trust was eventually provided with a copy of the draft ingredients list[1] but asked to keep it confidential.

[1] The draft list is essentially the Australian database with some Canadian additions.

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Officials and Industry Group meeting on 10 October

5. The industry group met with officials on 10 October. Again, officials were unable to provide a specific time-frame for release of the lists for consultation or formally advise when consultation would take place other than to say that it was intended that the first phase of consultation (on the Manufacturing Code, the lists and fees) would be undertaken before the end of the year.

Industry has strong concerns that meaningful consultation will not occur

6. At the meeting industry representatives (including the Trust) expressed a strong concern that the consultation period may occur over the Christmas break which would make it very difficult for interested parties to participate in a meaningful way. An assurance was given that this would not occur but we remain concerned, particularly given the delays to date and the intended commencement date of May 2014.

Officials are replicating the rejected TGA model <u>NOT</u> what was promised: a risk proportionate notification based regulatory regime

7. The Trust has spent a considerable amount of time and money trying to help government get the regulatory approach right. As you know NZHT has been working with you since 2007 to achieve a risk-proportionate low cost notification regime. Since the Bill has been drafted the Trust has had concerns that the Bill provides the Authority with too much discretion, and that the Ministry/Authority would be unable to approach this other than with a fixed TGA/pharmaceutical mindset.

Officials have created a TGA style "approval" regime

8. Those concerns have been realised. Simple notification of ingredients has gone out the window. Officials have created a proposed ingredient list from the Australian (and Canadian) lists and have advised that it will only consider other ingredients if they are on other jurisdictions' ingredient lists that have been created through an "approval" process equivalent to the Australian process or the ingredient meets certain criteria (designed to replicate the Australian approval process). One of the problems with that approach is that our research shows that there is no other jurisdiction with a process equivalent to the TGA approach. The suggestion that it would be easy for industry to add to the list is misleading. It is clear that it will only be easy if the particular ingredient is already on the Australian list or capable of being added to the Australian list.

9. At the 10 October meeting officials provided industry representatives with what appear to be arbitrary draft "decision criteria" for creating the permitted ingredients list. There was widespread concern from industry representatives to the requirement for "criteria" to be met before an ingredient would be permitted (and concerns about the level of evidence that would be required to meet those criteria and the cost of doing so).

10. In essence officials are adopting an approach to the draft legislation that is not risk proportionate, requiring "approval" of ingredients that have been used for hundreds if not thousands of years across the globe. This approach ignores wider considerations such as the fact that ingredients have a recognised history of safe use or are recognised in traditional medicine or pharmacopoeias (the latter factors are **required** to be taken into account under clause 20 of the Bill but do not figure in the officials current approach).

A substance in Schedule 1 must be permitted unless there is a good reason not to

11. We say that the starting point should be that any ingredient that belongs to the class of substance in Schedule 1 of the Bill should be declared a "permitted" ingredient (and therefore able to be notified) unless there is good reason not to and that the approach taken to an ingredient by a recognised authority and/or traditional medicine or pharmacopeia should be a means to flag any potential problems. This is an entirely different (and more risk-proportionate) approach than picking one "recognised authority" – Australia and using the Australian process as a proxy regulatory process for approval of ingredients.

12. Adopting our approach (suggested above) will provide a cost effective and risk-proportionate regulatory outcome. Under current proposals any ingredient not on the Australian/Canadian list will require a lengthy and costly approval process. Even a small number of such ingredients will likely mean that the list will not be completed before enactment.

"Serious conditions" process flawed and not risk-proportionate

13. We have been told that a list of conditions would be created to enable "notification" of claims about those conditions, thereby limiting the number of claims that would require "approval". This proposition is obviously predicated on a list that contains a large number of conditions (requiring significant regulator input which in turn will increase costs to the industry).

14. A preliminary list of conditions has been prepared by persons with medical background and no apparent natural health or supplementary product experience or qualifications. The industry has been told that the government is committed to an extensive list before enactment but despite promises we have not seen this list.

15. At the 10 October 2013 meeting officials only provided industry representatives with the criteria for adding a condition to the list. In discussions it became obvious that the list has been put together first and the criteria drafted as an afterthought in an effort to capture the approach taken. It was acknowledged by officials that the criteria were not particularly transparent. There are only two criteria: *a) the condition is non-serious, and self-limiting* and *b) the condition presents only minimal risk from delayed contact with a health practitioner*. It became apparent to all at the meeting that it was not possible to have a useful discussion about the list of conditions without seeing the list. We were promised the list would be circulated the week after the meeting but have still not seen it.

A black list of serious conditions (for which approval is required) would be a better approach

16. Notwithstanding our understanding that at our last meeting you asked officials to consider our alternative approach, officials have refused to do so. We firmly believe that a black list of "serious conditions" taken from the ICD list would be a more risk-proportionate approach than requiring approval of conditions (whether by means of this pre-approved list or through approval by the Authority), and significantly less costly to administer.

The Establishment Unit does not employ anyone with natural health and supplementary products experience and has a strong bias to a "medical" approach

17. In our discussions with officials it is apparent that the approach taken to setting up the Authority has a strong medical influence and bias. There does not appear to be anyone working for the Ministry on the establishment of the Authority with experience in, or understanding of the natural health products industry. The "conditions" criteria provide a good example of the medical approach being taken. Criteria b) (set out above in paragraph 15) assumes a consumer would choose between a natural health and supplementary product or conventional medical treatment whereas in fact often people try both.

There is a vacuum of information about the approach to fees

18. To date, and despite repeated promises that a consultation document will be released the industry has received no further information about proposals to recover the costs of the Authority. Consultation on this topic is particularly important because a fee per ingredient/product/claim will incentivise manufacturers to minimise the number of ingredients/products/claims available to consumers, dis-incentivise innovation and increase costs.

19. We also note with some concern that at the meeting with officials, there is clearly some concern within the establishment unit that more ingredients and claims listed before enactment will result in less revenue for the Authority. It was very clear that officials have decided on a fee per approval approach and are placing reliance on that approach to fund the Authority. We are concerned that this approach to revenue gathering has been pre-determined. We have been adamant throughout the development of the Bill that a turnover based fee would be a much fairer solution that would incentivise innovation and dramatically reduce costs. Such an approach is provided for in the Bill but officials appear to be closed to that option.

The solution

20. In order to progress this Bill, and to meet the timetable for enactment with industry-wide support we suggest the following:

- The adoption of a "notification" process for ingredients (as outlined in paragraph 11 above);
- Dealing with "serious conditions" by means of a black list of conditions extracted from the ICD (with approval required for anything on the black list) as set out above in paragraph 16;
- A commitment to and the carrying out of meaningful consultation in a timely fashion (not over the Christmas period);
- A commitment to not simply replicate the Australian/TGA regulatory system.

Yours sincerely

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5 June 2013

Ministry of Health
Wellington

Attention: Oliver Poppelwell

NZHT – our meetings re amendments to the NH&SP Bill

1. Further to our meeting on 29 May 2013, I have set out below an updated list of amendments discussed to date. For ease of reference, the additions to the list following our meeting on 29 May are added in italics.

Clause 5 - interpretation

2. You advise you will seek confirmation from PCO that the definition of "health benefit" as drafted encompasses the concept of "restoration" and will provide something in writing to that effect. As you know NZHT's preferred position is that "restoration" be included in the definition.

3. *We discussed a possible definition of "practitioner". You are going to pursue drafting a definition that reflects the approach taken in clause 13A referencing a practitioner to a request for treatment.*

Clause 12B

4. Clause 12B (and where necessary elsewhere in the Bill) will be amended to clarify that an "allowable claim" does not incorporate the concept of a particular health benefit claim but rather identifies conditions for which any health benefit claim may be made (clause 12(1)(b) in particular). Your suggestion is to amend references to a health benefit claim (in for example, 12B(1)(a) and (b)) to "health benefit claims".

Clause 13A NH&SPs that do not require product notification

5. *You are going to draft an exemption for small batch manufacture by a practitioner for supply to patients/clients of that practitioner.*

Clause 16 – Suspension & cancellation of product notification

6. Adding flexibility to the period of suspension (rather than 21 days) will be looked into.

Clause 16A – Effect of suspension

7. Clause 16A(a) to be looked at. Given that the clause contains no provision for notice of suspension this should be "take all reasonable steps to ensure" [product is not sold].

Clause 17 – serious adverse reaction

8. The reference to "allergic reaction" to be amended to "serious allergic reaction".

Clause 18 – When a new product notification is needed

9. The phrase "as soon as practicable" in clause 18 will be re-worded to take account of the practical realities of manufacturing (in particular to allow of the run-out of products on the market for sale when a change of manufacturer has been effected).

Clause 27 – Code of practice for manufacture

10. The obligation to consult will be re-drafted so that the obligation to consult is to consult "persons likely to be affected" or there will be an obligation on the Authority to consult via publication of proposals on a web-site.

Clause 34 - revocation/suspension of licence

11. Consideration will be given to a limiting the period of suspension to three months.

Clause 35 – fees

12. The consultation obligation in this clause will be re-drafted consistent with changes to clause 27 (as noted above).

Clause 40C

13. Clause 40C is to include a practitioner exclusion for the restrictions on advertising (modelled on section 50(b) of the Medicines Act).

Clause 46 – Transitional provisions

14. Clause 46 is to include obligations on the Authority to populate a list of ingredients and a list of named conditions during the transitional period. *NZHT's view is that 2 years is an appropriate transitional period.*

Clause 47 – Regulations

15. The consultation obligation in this clause will be re-drafted consistent with changes to clause 27 (as noted above).

Clause 48 – Policy & operational review

16. This clause will be amended so that the review is undertaken by the Minister (rather than the Ministry of Health).

Schedule 1 – suitable substances

17. Consideration will be given to amending Item 8 so that it refers generally to "an amino acid" rather than providing a list.

    a. Clause 12B (and where necessary elsewhere in the Bill) will be amended to clarify that an "allowable claim" does not incorporate the concept of a particular health benefit claim but rather identifies conditions for which any health benefit claim may be made (clause 12(1)(b) in particular), provided it meets the definition of a health benefit claim. Your suggestion is to amend 12B(1)(a) & (b) (and elsewhere necessary for consistency and clarity) to refer to "health benefit claims" rather than "a health benefit claim";

    b. Clause 40C is to include a practitioner exclusion for the restrictions on advertising modelled on section 60(b) of the Medicines Act.

18. Please let me know if this record does not align with your understanding of where we got to.

Serious conditions

19. The significant remaining issue is the Trust's concern that the regulatory framework revert to the original approach of notification for all products bar those that make claims about serious conditions. As previously discussed this could be achieved by a black list of "serious conditions" identified by the ICD list. Approval to make claims about those conditions would be necessary.

20. As you have previously noted, the MOH's primary concerns in adopting this approach are that:

    a. A "serious condition" may be inadvertently left off the black-list; and

    b. There would be an ongoing and additional cost because the Authority would have to check every claim to ensure that it did not relate to an un-listed serious condition.

21. The Trust's view is that the risk of omitting a particular serious condition from the black-list is low. Given (under the currently proposed framework) there is an intention to carry out a detailed review of the ICD list to determine "named conditions", it should equally be possible to accurately determine a black-list of serious conditions. Whichever approach is adopted carries the risk that a condition will be sorted into the wrong list.

22. The Trust is also not persuaded that checking every health benefit claim notified would be an proportionate regulatory response to the risk that a serious condition may not have been listed. As with any other product, the Authority will have powers to suspend if the product is likely to cause harm, the Authority has been provided with misleading information or the product is unsafe.

23. A risk proportionate response to the possibility of serious conditions being left off the black-list is to have procedures in place so that a serious condition may be added to the list. The Trust's firm position is that the risk of possibly over-looking initially including a serious condition on a black-list does not justify an ongoing quasi-approval system for an unknown number of conditions (with all of the additional expense that this will involve).

24. As always, I would be happy to discuss.

Yours sincerely

Nicola Wills

cc Dave Sloan, NZHT