MINISTRY OF HEALTH
MANATŪ HAUORA

Natural Health & Supplementary Products

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The Natural Health and Supplementary Products Bill

Low risk natural health products

Light touch regime

Inexpensive

Easy to use

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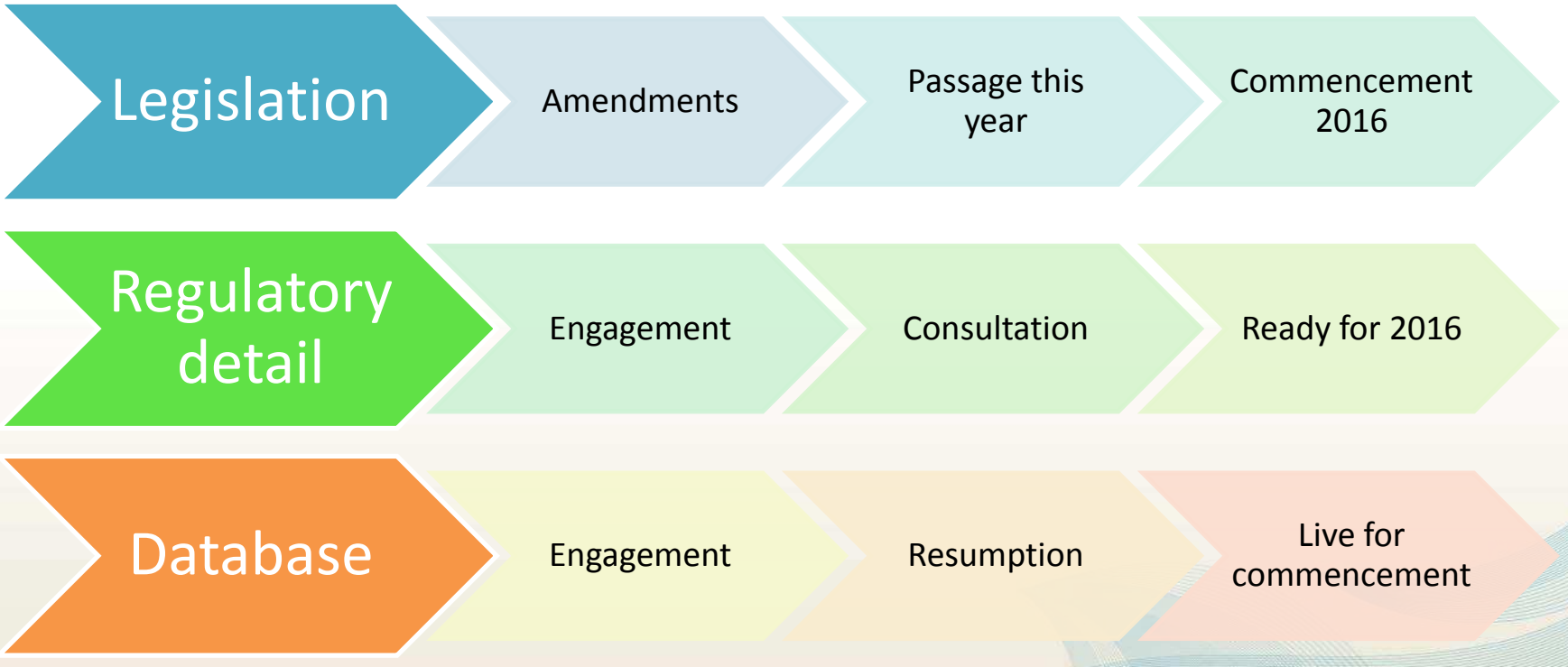
Controls in the Bill

Product must consist only of permitted ingredients	**Product must be manufactured by a NHSPRA licensed manufacturer or equivalent**	**Allowable claims made for the product with summary of evidence**	**The product notifier must be a resident of NZ**

Status

- Reconsidered options now ANZTPA not proceeding
- Going ahead with separate NHSP scheme
- Extensive sector engagement June/July assisted greatly in the further development of the regime
- 2nd draft of PIL released for comment.

Progress


Legislation
Amendments
Passage this year
Commencement 2016
Regulatory detail
Engagement
Consultation
Ready for 2016
Database
Engagement
Resumption
Live for commencement

Permitted Ingredient List

Send requests for ingredients to be added and feedback to naturalhealthproducts@moh.govt.nz

Some of the ingredients submitted require more analysis due to their complexity and are still in the process of being considered.

If possible include taxonomic and common names, an international non-proprietary name and a pharmacopoeia name citing the pharmacopoeia or a chemical registry number citing the registry.

Provide safety information on the ingredient - part or parts used, how it is used or processed, how much is used, method of administration and any quality specification or references to uses in material medica.

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Fees

- Fees to be kept as low as practical - notification fee likely to be $120 - $170 per product
- Cost recovery – fee based on cost of regulator
- Institutional arrangements affect cost

What you need to remember

- The Government wants the scheme to go ahead
  - must be palatable to industry
  - export-supporting
  - low costs
- Formal public consultation Oct/Nov this year
- Pre consultation engagement encouraged especially on the PIL
- Exemptions – practitioners, low risk/volume

Questions

I see the NZ model is looking to provide a summary of the evidence table at the time of listing, which is not done in an AU context as the TGA took that this may be construed at the regulator having reviewed and endorsed the summary table if they held it on file.

Do the MOH intend having GMP standards for natural health products?

Will further guidance be given to GMP auditors to assist them to assess a manufacturer's risk level, will it be publicly available and will this guidance always return the auditor to the real risk to the consumer? In other words, are any additional communications envisaged to prevent the inadvertent application of full pharmaceutical GMP to very low risk products?

Questions

1. Many companies manufacture product in NZ to TGA standard for export to Australia and other markets. These products generally have good label claims with a listing number. Will these products be able to be sold " as is" in NZ so that the manufacturer and the consumer do not have to pay extra in costs for products especially labelled for the NZ market.

2. Will Australian manufactured product be able to be imported and sold in NZ " AS IS" again so as the manufacturer and the consumers do not have extra costs.

3. Will products approved by the European union and the USA made under GMP be allowed to be imported as is .

4. If bulk capsules or tablets as an example are made overseas or in NZ but not in a GMP facility can they be sold in the market as long as the packer has a GMP licence and is satisfied with the testing and manufacturing methods and hold relevant documentation.

5. Will the regulator supply Free Sales Certificates for exporters.

6. Will the MOH be encouraging the Minister of Health to obtain a mutual undertaking with Australia on NZ manufactured goods that are made under the notification system. Under the new system product will be made under a GMP licence issued by Medsafe there should be no reason the Australian Govt would not let natural products or dietary supplements to be imported into Australia as is. Especially if the plan is to have lower level claims. This certainly will assist NZ companies into the Australian market .

7. To what " level" of evidence will be needed to be supplied for the "evidence summary" on the web site for all people to be able to see. This is a case of where intellectual property may be breached. Or one companies hard work is copied by a competitor.

Questions

1. Will Australian listed medicines sold into NZ need to be notified to the NZ regulating body?
2. Will Australian listed medicines with compliant labels be accepted in NZ without change? What is the likelihood of label changes required? Can we over-stick labels? Will the excipient information still be required on NZ labels?
3. What will NZ accept, TGA allows 90% Label Claim at Expiry…… Stability studies should be conducted to demonstrate that the product remains within specification for the length of its shelf-life – is there a range that is considered acceptable as per the TGA
4. Can you use in-vitro & animal studies to support indications?
5. The requirement to attached a hyperlink to evidence that is already publicly available: Considering evidence requirement similar to AU and assuming there would be a similar provision (as in AU while listing) of submitting a declaration for maintaining evidence for claims, attaching a hyperlink to evidence (publicly available) would be extremely time consuming and unnecessary. Also, any evidence on public websites can become obsolete over a period of time and the content many a times get removed from the link., and doesn't seem to be very practical
6. Will any claims applied for by a company, be available for other companies to use? Or will they be for exclusive use.
7. What will the requirements be for overseas manufacturers for NZ products? Will TGA licenced facilities be accepted?
8. Is there a NHP number required to be displayed on the label?
9. Manufacturing licences are renewed after 5 years, how is this done?
10. Is there to be post-market surveillance of NHPs? If so what will this involve?

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Thank You