

Update on Natural Health Products Legislation

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The Natural Health Products Bill

- The Bill is awaiting House time to consider its final stages
 - The Government has put in a Supplementary Order Paper (SOP) to revise minor technical issues, and a few things that were strongly asked for from stakeholders
 - Main changes are:
 - Revising the definition of natural health product
 - Revising the structure of the Bill
 - NZ manufacturers require a licence for a wider group of products due to the definition change, including all exporters
 - All exports need to be notified
 - Making the practitioner exemption clearer
 - SOP is publicly available on www.legislation.govt.nz (search for the Natural Health and Supplementary Products Bill and click on the tab titled Versions and SOPs)
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The Regulations and Notices under the Act

Where my team comes in

- Given the framework of the Bill/Act, the regime needs to be workable
 - Provide the detail of the scheme – labelling, advertising rules, notification details, manufacturing requirements, database for notification
 - Consultation has just finished – thank you for your submissions!
 - 500 submissions – quite a number comment only on the Bill
 - Highlights areas of concern that we can look at and work with industry on
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Intellectual Property

Concern about IP

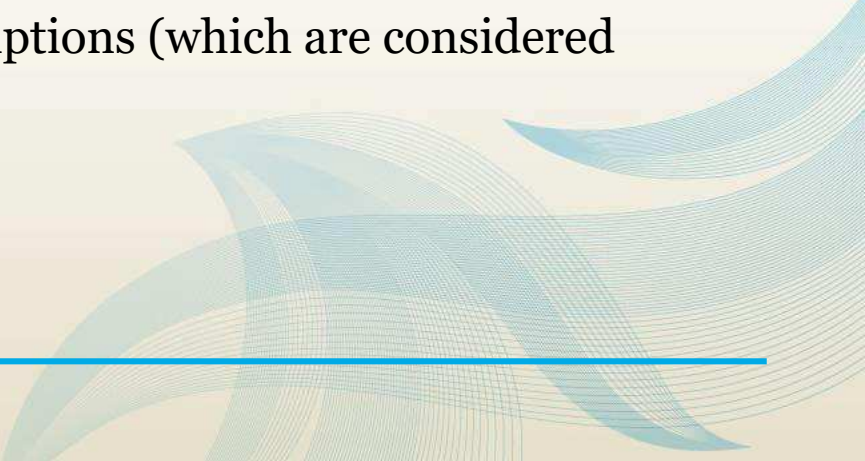
- You have asked for certain information to be held confidentially
 - You will provide information in a secure way on the notification database, only seen by yourself and the Authority
 - Consumers and competitors will only see a public view of information – mainly for consumers to be reassured that the product is manufactured well and has evidence for claims
 - Authority will expect you to hold information for immediate release to the Authority if requested (as in Australia)
 - The Official Information Act 1982 allows commercially sensitive information to be withheld from requestors
 - Will do further work on IP issues – any volunteers to work with us?
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Summary of Evidence

The Bill requires a summary of evidence for consumers.

- What is the actual concern?
 - Writing the summary?
 - Having the evidence behind the summary?
 - You will have to hold the evidence behind the scenes
 - The summary can be on your website
 - The Authority does not charge for it so it has no effect on the fees
 - Depending on the nature of the concern, we can work with industry on this
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Fees

- The Consultation document set out the indicative fees
 - Most of the scheme is cost recovered from fees, but some establishment costs will be met by govt
 - Reiterate that the notification fee will depend on the number of notifications – more notifications, less fee.
 - Current modelling shows the notification fee at \$170 excl GST
 - Main costs are the notification database
 - There is an ability to review fees if assumptions (which are considered conservative) are incorrect
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Further Engagement

- We are very keen to keep talking to industry regarding the regulations and notices
 - Visits to sites of different sizes has been invaluable
 - Testing of the notification database will be required
 - Want to make it workable, and to gather information on what isn't working so well. My team will also review the Act and therefore monitor how it is going
 - It's a new scheme so there will be situations where discussion and problem solving will be required, and is encouraged
 - Feel free to email on naturalhealthproducts@moh.govt.nz and also sign up for our updates at <http://www.health.govt.nz/our-work/regulation-health-and-disability-system/natural-health-and-supplementary-products>
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