

# Update on Natural Health Products Legislation

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# The Natural Health Products Bill


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- 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](http://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

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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

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## 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

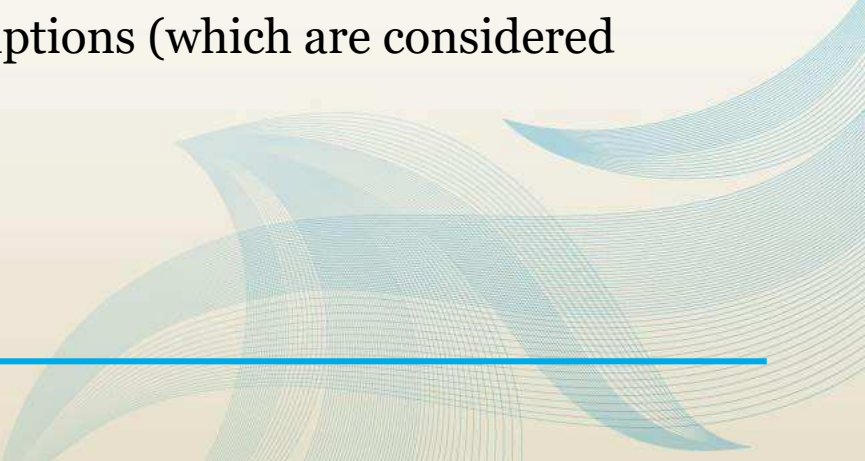
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The Bill requires a summary of evidence for consumers.

- 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

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- 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

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- 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](mailto: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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