Natural Health Products Regulations

Natural Products NZ Summit 2016

Haley Ataera, Senior Advisor, Ministry of Health

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MINISTRY OF HEALTH
MANATŪ HAUORA

Content

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Post-market surveillance

- There will be some!
- BUT this is still a **light touch**, low cost regime
- We need you to help us with this
- We can and will audit notifications
- We will have an adverse reactions monitoring system in place
- But we will be relying heavily on complaints to help us focus compliance activities

Manufacturing - to GMP or gmp?

- Thank you!
- GMP gives the regime a high level of credibility
  - BUT does the level of risk posed by NHPs justify GMP being the minimum requirement?
  - Worthy goal for the future
- Food standards might be acceptable if raw ingredient suppliers are qualified
  - Would decrease the number of audits some manufacturers would need
- Have compared the CoMP, GMP, US FDA, and FSANZ Food Standards
- Would like to get feedback from you to further develop our thinking
- Compromise - Export certificates will distinguish between products meeting GMP and products meeting the CoMP standard

Manufacturer registration

- All NZ based manufacturers require a licence
  - includes products containing less than 20 ppm of **natural substance** actives
  - excludes products **made by a natural health practitioner** for:
    - an individual following a consultation after being requested by the individual to use their discretion to treat their condition
    - another natural health practitioner
- All manufacturers need to meet the Code of Manufacturing Practice
  - Lower risk manufacturers may only be subject to a desk audit whereas higher risk manufacturers will need to be audited
  - Medsafe vs third party audits and recognition of existing audits where reasonable

Manufacturer registration continued

- All NZ based manufacturers need to be fit and proper – declaration
- All NZ based manufacturers will pay a fee to be licensed.
  - Some exemptions may apply for smaller manufacturers who are also low risk

Product notification exemptions

- Products containing less than 20 ppm of natural substances
  - But these do need a licence to manufacture if the manufacturer is NZ based
- Products **made by a natural health practitioner** for:
  - an individual following a consultation after being requested by the individual to use their discretion to treat their condition
  - another natural health practitioner
- Other - To be determined following the analysis of the consultation documents

Permitted substances

- Substances allowed in Australia, Canada and the EU will not automatically be included on the NZ permitted substances list
    - This is because we need to consider NZ specific requirements such as the Medicines schedule and the Misuse of Drugs schedules
- Inclusion on the NZ list will be determined by the NHP Authority and may require a recommendation from the Advisory Committee
- The Bill requires that the Advisory Committee **must consider** whether a recognised authority permits the use of the substance in a similar product
- We intend to automatically refer any substance included on the TGA or Health Canada lists in the future without the need for an application from industry

Proprietary ingredients

- Thank you!
  - We've had a lot of feedback during the consultation period.
- We've done a lot of work in this area since the consultation period started
- Nothing is impossible but everything will require compromise by someone
- We want your input
  - We have identified 9 options for you to rank and comment on
  - Survey to go out tomorrow (hopefully)

Proprietary ingredients

- Guiding principles
  - Low cost, light touch regime
  - The regulation of NHPs should be proportionate to the risks associated with their use
  - Consumers should have access to as much information as is **reasonably** possible at the point of sale to help them choose the correct product for them based on their individual needs
  - This regime should be at least as robust as the current Dietary Supplements Regulations (eg the particulars of the active ingredient(s) must be disclosed)

Proprietary ingredients

- Concerns
  - Consumers need to know:
    - if the product contains known allergens
    - how much of an ingredient with a restriction is present.
  - Product notifiers need to know that the PI contains only permitted ingredients
  - How will this happen if the PI is made by a third party?
  - Unlikely to be able to access medicine PI records without written consent from the PI owners…

Proprietary ingredients

- Other considerations
  - Should PIs manufactured by the product owner be treated differently to PIs manufactured by a third party?
  - Should active ingredient PIs be treated differently to excipient PIs?
  - Should PIs containing ingredients that have a maximum daily amount be treated differently to those that don't (but how would you know if it's manufactured by a third party)?
  - Should PIs for different dosage forms be treated differently? Eg it's unlikely that an individual would overdose from a substance when given topically…
  - The more complicated the system, the more expensive the database build, the more likely costs will need to be recovered from industry…

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Proprietary ingredients

Option	Comparison of disclosure requirements with the status quo[1]	Additional work for or cost to the Authority	Additional notification cost	Impact on Industry[2]	Risk of overdose?	Risk of allergic reaction?
1) No PIs allowed	Less permissive	No	No	Significant	Low	Low
2) PIs allowed. Name of PI notified. Name and amount of active ingredient stated on labels. No declarations required[3].	Similar	Negligible	No	Low	Low	Medium
3) PIs allowed. No details notified. Name and amount of active ingredient stated on labels. Declarations required.	Equivalent	None	No	Low	Low	Low
4) PIs allowed. No details notified or disclosed on labels. No declarations required.	More permissive	None	No	Low	High	High
5) PIs allowed. All details notified and disclosed on database and labels. No declarations required.	More permissive	Negligible	No	Significant	Low	Low
6) PIs allowed. All details notified but not disclosed on database or labels. (This is the TGA approach). No declarations required.	Less permissive	Significant	Yes	Medium	Medium	Low
7) PIs allowed. All details notified. Only details of ingredients with restrictions disclosed on database and labels. No declarations required.	Less permissive	Significant	Yes	Medium	Low	Low
8) PIs allowed. All details notified. Details of active ingredients and ingredients with restrictions disclosed on database and labels. No declarations required.	More permissive	Significant	Yes	Medium	Low	Low
9) PIs allowed. All details notified. Name and amount of active ingredient disclosed on database and on labels. No declarations required.	Equivalent	Significant	Yes	Low	Medium	Medium

1) The status quo means the particulars (name and amount) of the active ingredient must be disclosed to the Authority and the public.
2) As assessed by the Ministry of Health after discussions with industry. The Ministry accepts that industry may have other views on this assessment and welcomes comment on it.
3) Declarations from the PI manufacturer are required stating that the PI contains only permitted substances and that the product notifier has been informed of all restrictions on ingredients in the PI. A separate declaration from the product notifier is required that the restrictions on ingredients have been observed.