Natural Health Products

Workshops on regulatory detail

June/July 2015

Status

- Reconsidered options now ANZTPA not proceeding
- Going ahead with separate NHSP scheme
- Re-establishing a team
- Enactment this year
- Commencement 2016

Why Regulate?

To protect consumers

To promote trade

Why Regulate?

Safe

True to claim

True to label

Engagement

Today is about:

- testing some ideas
- getting your views
- helping us put together a workable scheme

Today is not about:

- fully-formed proposals
- imposing our ideas on you

We will be consulting formally on proposals later this year.

Engagement last year

Broad agreement on most detail:

- Ingredients – *Permitted ingredients list review to 2021 requirements*
- Claims – *including Named Conditions review to any changes in ICD 11*
- Labelling – *"NHP XXXX number on label"*
- Database – *NHP notified products*

Engagement last year

Not covered in detail:

- Evidence Risk-based Code of Manufacturing Practice Fees

Schedule for today

- Evidence – *Appropriate Scientific and Traditional Evidence Guidelines*
- Manufacturing standards – *review to latest PIC/S per 2021*
- Fees – *low and user friendly with turn-around-times for activities, authority to be adequately resourced to cope*
- Anything else

Evidence

- What is evidence?
- Traditional
- Scientific

Requirements for evidence

- the evidence must be able to be replicated
- the method of administration used in the evidence must be the same as the recommended administration of the product
- the evidence must be relevant to the target population *(requiring studies to be undertaken in the NZ population is impractical)*
- the evidence must directly measure the health benefit
- the evidence must be reasonably applicable to NZ self-care
- the evidence must not conflict with a wider body of evidence.

Traditional evidence

- Evidence of traditional use - *how many generations (3?)*
- Claim is “traditionally used for X”
- Evidence from approved pharmacopeia
- Evidence from other traditional sources
- *Evidence must relate to form (e.g root, extract etc)*
- *Oral history of use must be permitted to enable Māori traditional medicines/Rongoā Māori*
- *Oral history can be developed using interview process by suitable ethno-botanist.*

Scientific evidence

Claim is: “does X”

1. Systematic reviews
2. Critically appraised topics
3. Critically appraised individual articles
4. Randomised controlled trials
5. Cohort studies
6. Case-controlled studies, case series, time series
7. *Unpublished studies*
8. Background information, expert opinion

- *Allow in-vitro and animal data to support claims appropriately*

Manufacturing standards

Legislative requirements:

- A manufacturer will need to be compliant with the Code of Manufacturing Practice within 3 years of commencement of the Act
- Manufacturing facilities will need to be registered and licenced. Licences last 5 years
- Overseas facilities must meet equivalent standards – *need list of recognised authorities*

Elements of Code

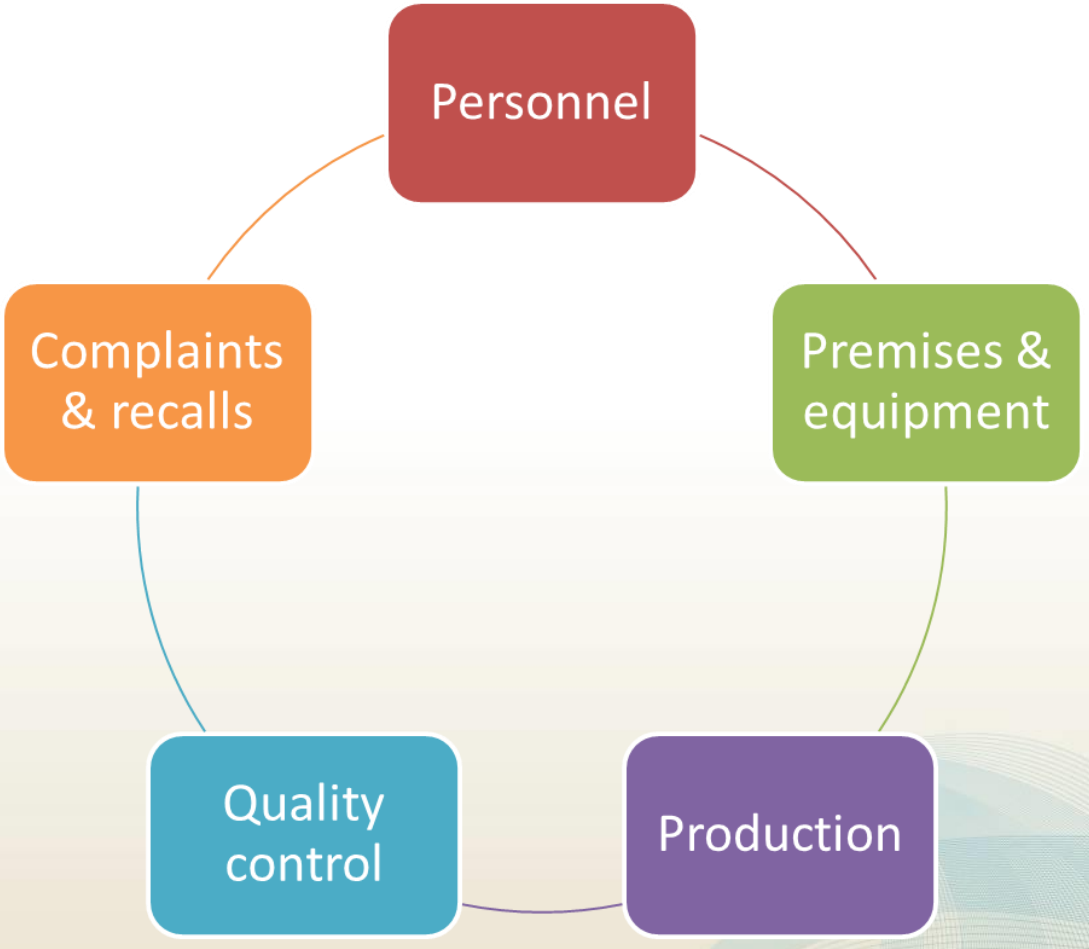
- Risk-based tiered system - requirements proportionate to risk
- Likely that Authority will recognise some other Codes - *need list of recognised authorities*
- Audit requirements depending on risk level

Manufacturing standards

This year:

- How the Code might work
- Assessing risk

What a Code of Manufacturing Practice is made of



How much is necessary?

- As much as is necessary to address the risks.
- Detailed guidance in risk assessment framework
- We'll work through 5 examples
- *Note: a multi ingredient product manufactured in a facility with in-process controls may be a lower risk product than a single ingredient product manufactured without any in-process control. Review Risk Matrix with input from industry.*
- *Note: an ingredient sourced and grown in NZ may also require quality control measures to affirm identity. Quality and traceability. This equally applies to locally sourced and imported ingredient.*

Case Study 1

A Nelson lavender farmer grows lavender and produces her own hand-cream to sell locally at the weekend farmers' market. The hand-cream is the only product produced and all of the lavender used in the cream is grown by the farmer. Approximately 15 units of the cream are sold per week.

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Low Risk

As the manufacturer is very small and is producing a low-risk, low volume product the same systems as a larger manufacturer would not generally be applicable.

All attributes lead to lowest risk on the spectrum –

- topical cream for unbroken skin
- low quantities produced
- the only product produced
- certainty about the source ingredient.

Case Study 2

A small manufacturer , employing 5 people, makes capsules of Echinacea powdered extract. The New Zealand manufacturer is using extract powder from an overseas supplier and encapsulating it, then packing and labelling the final product. The product is sold at health shops in the Waikato and the company hopes to expand distribution throughout New Zealand.

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Medium Risk

The higher risk attributes for this product are the source of the raw materials and the identification of the raw materials. Overseas sources can be higher risk as there may be little information available regarding how the raw materials are made or the quality standards of supplier. Identification of the powder as Echinacea extract can be difficult as many powders have similar properties.

Case Study 3

A manufacturer is producing and selling Gripe Water. Gripe Water is produced for infants with colic, gastrointestinal discomfort, teething pain, reflux and other minor stomach ailments. It is ingested and generally contains herbs (such as dill and fennel) as well as bicarbonate of soda and water.

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Medium Risk

Gripe water can be a fairly straightforward and potentially a low-risk product, but it is an oral product marketed for babies.

Case Study 4

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High risk

The high risk of this product comes from the multi-step processing using live micro-organisms.

Case Study 5

Tablets manufactured using a complex mixture of various minerals and herbs as well as Vitamin D. The tablet is produced by a large manufacturing company that produces a broad range of supplements and sports nutrition products, exported around the world.

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High Risk

Features of this case study place it at the high-risk end of the risk matrix:

- Raw materials are sourced from various suppliers
- Vitamin D at high volumes poses serious risk so dosage is very important
- Cross-contamination risk from multiple products being manufactured
- High number of consumers due to size of manufacturer.

Manufacturing – comments in previous workshops

- Link to health claim – if depends on certain levels of ingredients, must be able to verify level of ingredient
- Also links to general claims – integrity of products
- Important to separate safety from integrity – need both
- Trusted suppliers – certificates of analysis – but how do we know whether to trust certificates – *analytical testing and supplier qualification*
- Testing important – both safety and composition
- Recognised GMP essential for credibility and export promotion – *review draft guidelines for any relevant changes to most recent PIC/s guidelines*

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Fees

- Low fees
- Fees can only recover costs
- Annual budget reduced by half from original estimates

Fees

- Cost recovery
- Third-party audit
- General costs recovered via notification fee
- Very sensitive to number of products
- *Fee based activities must have a time frame for action and completion from the Authority with measured KPIs*

Fees

Notification

Our preliminary estimates range from $110-170

Depends on assumptions about:

- Location of regulator
- Whether work is internal or outsourced
- Heavily dependent on number of products.
- *There needs to be an ability for a changed product notification with an appropriate fee*

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Fees

Activity	Approximate fee	*Turn around time Measured KPI*
New Permitted Substance	$700	
New Named Condition	$2,050	
New Allowable Claim	$4,800	
Export Certificate - Electronic	$65	
Export Certificate - Printed	$135	
Manufacturing Licence	$600	
Appeal	$200	

Website

- Key cost saving measure
- All interactions on-line
- Cost recovered over time

Anything else you want to tell us?

Definition of a Natural Health and Supplementary Product

"A product that has nutritive, preventive, or treatment properties applicable to enhancing health or overcoming illness, that consists largely or completely of permitted ingredients that are derived directly from nature or made to be similar or the same as those found in nature"

that is manufactured, sold or represented for use in

- ***(a)*** *the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;*
- ***(b)*** *restoring or correcting organic functions in humans; or*
- ***(c)*** *modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.*

Thank you

We will send you:

- Ingredients list
- Conditions list
- Draft Code of Manufacturing Practice and Guidelines