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REGULATORY AFFAIRS

Australian Complementary Listed Medicines

Regulatory Reforms

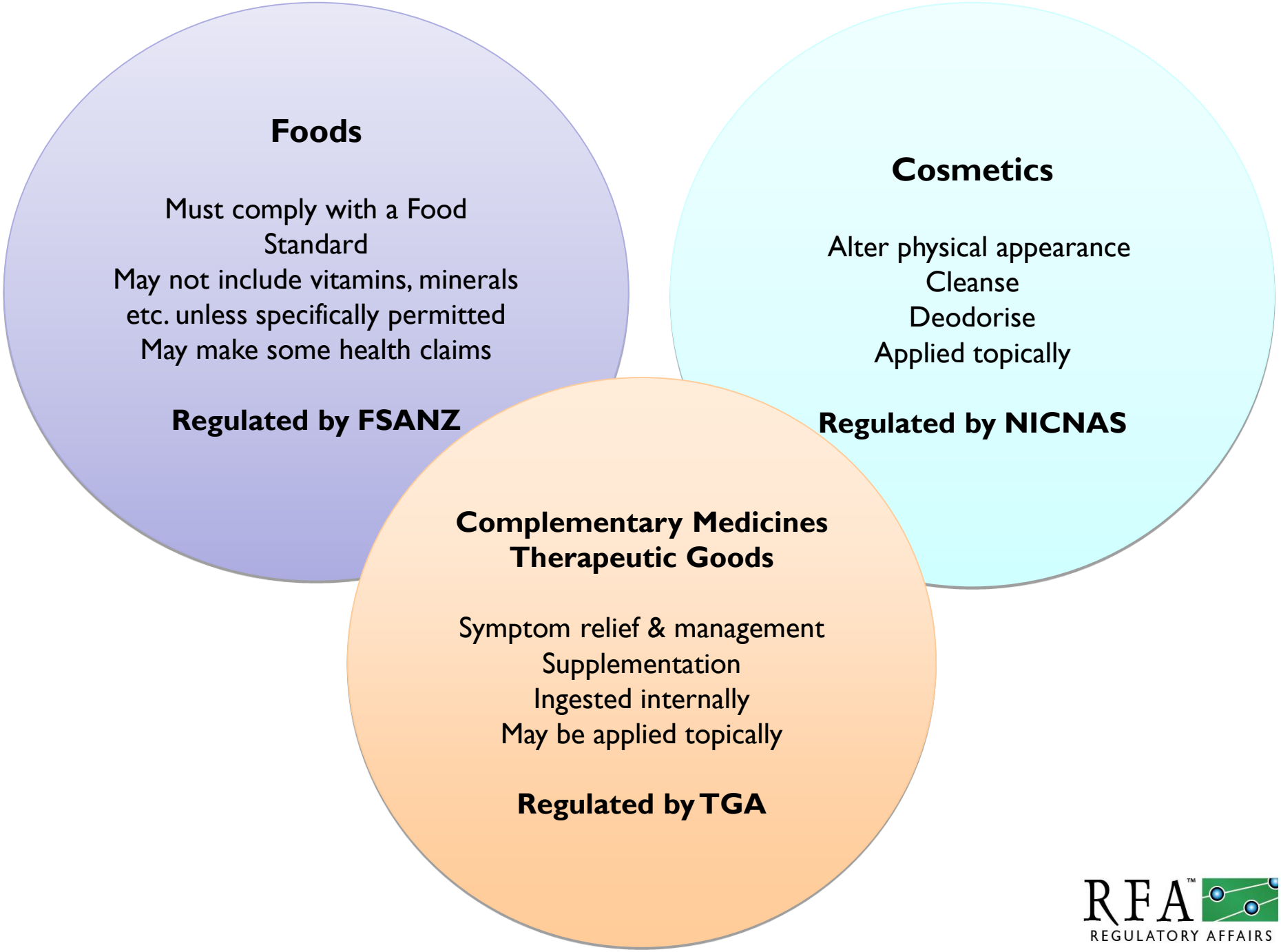
Robert Forbes

Natural Health Products NZ – Suppliers' Day

23 August 2018

Agenda

- Regulation of complementary medicines in Australia
- Permitted ingredients
- New ingredient evaluation
- Permitted indications
- Advertising framework
- Future reforms



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Regulation of Complementary Medicines in Australia

1. Listed Medicines – AUST L

No pre-market evaluation

1. Pre-approved GMP
2. Pre-approved ingredients
3. Permitted indications

2. Assessed Listed Medicines – AUST L (A)

Pre-market evaluation for:

- Efficacy – intermediate and permitted level indications
- Optional 'claimer' (under review)
  1. Pre-approved GMP
  2. Pre-approved ingredients
  3. Permitted indications

Regulation of Complementary Medicines in Australia

3. Registered Medicines – AUST R

Pre-market evaluation for

- Quality
- Safety
- Efficacy
- Optional ‘claimer’ (under review)

Permitted ingredients

- Contained in Therapeutic Goods (Permissible Ingredients) Determination (No. 2 of 2018)
- Meet all requirements set out in the Determination
- Can apply for new ingredients to be evaluated and added to the Determination
- Need to demonstrate quality and safety of new ingredient, as outlined in the ARGCM

New ingredient evaluation

- Once approved added to the Therapeutic Goods (Permissible Ingredients) Determination

- Exclusive use for 2 years by:
  - the ingredient applicant
  - others authorised by the applicant

New ingredient evaluation

4 application categories:

Category	Quality evaluation	Safety evaluation
IN1	Based on evaluation reports from a comparable overseas regulator (COR).	Based on evaluation reports from a COR.
IN2	Independent evaluation by the TGA.	Based on evaluation reports from a COR.
IN3	Based on: - Evaluation reports from a COR; or - A monograph contained in a default standard (BP/USP/EP).	Independent evaluation by the TGA.
IN4	Full independent evaluation by the TGA.	Full independent evaluation by the TGA.

Permitted Indications

- Therapeutic Goods (Permissible Indications) Determination
- Only indications from permitted list can be claimed for the product (AUST L)
- You can apply for new indications to be added. An application fee applies
- Evidence guideline – Guidelines on the evidence required to support indications for listed complementary medicines
- 3 year transition period for sponsors of existing listed medicines

Advertising

NEW

New code

Therapeutic Goods Advertising Code 2015

Therapeutic Goods Advertising Code 2018 (In effect 1 January 2019)

Single complaints body

- TGA handling and managing complaints for advertising of therapeutic goods to the public

New 4 tier complaint handling model

- Critical, High, Medium and Low
- Applicable to corporations and individuals

Advertising

NEW

Education development

- NEW online portal Advertising hub
- New consumer specific educational materials

Pre-approval required of specified media advertisements until 30 June 2020

New and enhanced sanctions and penalties

Future reforms

- Use of comparable overseas regulator (COR) reports

- Efficacy assessment 'claimer'

Further information

Further information on presentation topics including new ingredient evaluations contact Robert@rfareg.com

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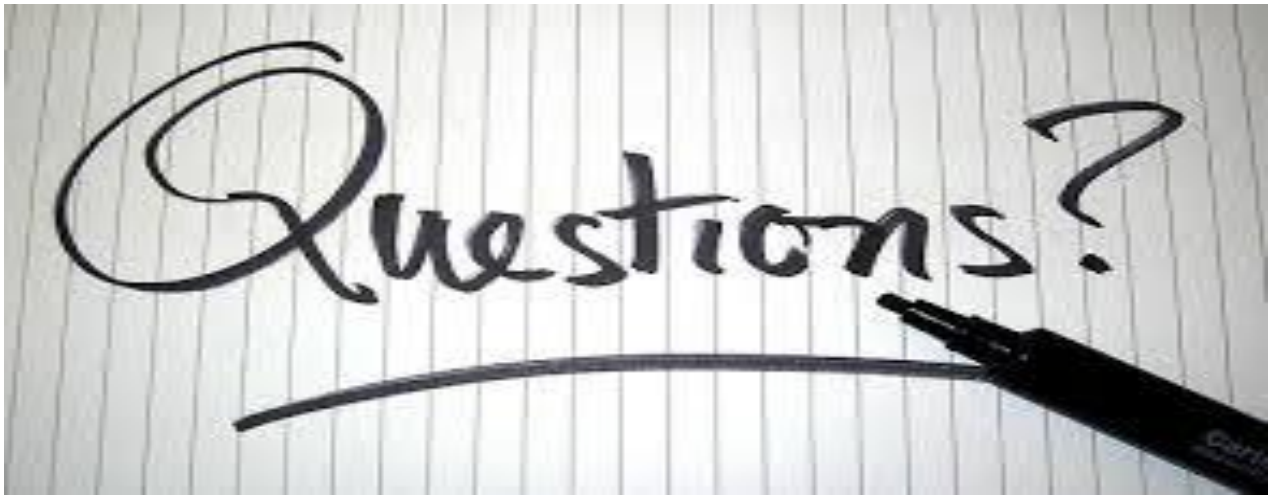
Any Questions?



Thank you

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Regulatory Affairs Consultants

complementary medicines, foods & personal care products

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