Providing reliable and effective natural product solutions

Dr Mandy Suddes

R+D Head

Manuka Health New Zealand Ltd

Given by Nature, Proven by Science.

manuka health NEW ZEALAND

The Challenge

- Data for market differentiation

  … at a reasonable cost

  – Bioactive properties, Health claims
  – Pre-clinical (lab) research, clinical trials, publications

- Is the product protected?
  – Intellectual property (IP)
    - Composition or Use patent?
  – By ‘black box’ manufacturing process?

The Challenge

Need to Understand Regulations

- Regulations vary by market :
  - Food or dietary/ food supplement
  - Regulations are evolving
  - Health conditions / permissible claims
    - Non-serious conditions
    - Pre-clinical states e,g, metabolic syndrome/ glucose control rather than diabetes
- Advertising regulations

Permissible Claims depend on Regulations - examples

US 'Dietary Supplement'	EU 'Food supplement'	Canada 'Natural Health Product'	Australia 'Listed medicine'	NZ (in draft)
• Structure/ function Health Claims • Nutrient Content Claims	• Structure/ function Health Claims • Nutrient Content Claims	• Structure/ function • Therapeutic Claims • Risk-Reduction Claims • Foods: Nutrient Content Claims • Health claims	• Health maintenance Claims • Health enhancement Claims • In non-serious, self-limiting conditions	• Health Claims • Nutrient Content Claims • ???
Self-substantiated	Pre-approval by EFSA	Pre-approval by HC	Self-substantiated	?Self sub-stantiation

Data to support claims and safety: expensive, takes time

- Can I use data published by others?
- Will others be able to use my data?
- What do I need to do?
  - Lab/ in vitro work
    - Mode of action of bioactives
  - At least 1 clinical trial typically required
    - Trial design is key – use experienced statistician
    - Randomised, controlled trial (RCT) = gold standard
    - Efficacy end points and number of subjects
    - Health condition to be studied
    - Safety data
- Be careful not to unintentionally classify product as a medicine

Other Requirements

- Good Manufacturing Practice (GMP) standards
  - Even if contracted out, sponsor is ultimately responsible for GMP compliance
  - Batch records and traceability
- Safety Monitoring
  - Product complaint/ adverse event report collection
  - Serious Adverse Event reporting
  - Product Recall processes

Thank you