



Consultation Paper: *Regulation of Homoeopathic and Related Medicines*

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Current regulation of homoeopathic medicines

- **In New Zealand, homoeopathic medicines:**
 - without therapeutic claims - are regulated as 'dietary supplements'
 - with therapeutic claims – are regulated under the *Medicines Act*
 - the term 'homoeopathic' is not defined



Current regulation of homoeopathic medicines

- **In Australia, homoeopathic preparations:**
 - definition does apply
 - are considered to be therapeutic goods
 - are required to be Listed in the ARTG, unless exempt
 - most are exempt



Exemptions applying to homoeopathic medicines in Australia

- **Exemption from product inclusion in the ARTG, where:**
 - **all** ingredients are more dilute than 1000 fold dilution of a mother tincture;
 - the preparation is **not** required to be sterile;
 - the preparation is **not** of human or specified animal origin; *and*
 - claims do not contravene the *TG Advertising Code*.



Exemptions applying to homoeopathic medicines in Australia

- **Exemption from TGA manufacturing approval where:**
 - the homoeopathic preparation is more dilute than a 1000 fold dilution of a mother tincture;
 - the preparation is not required to be sterile.



Exemptions applying to homoeopathic medicines in Australia

- Although a homoeopathic medicine may be exempt from certain requirements, other requirements of the *Therapeutic Goods Act* apply
- Exemptions do not apply to products where the definition of a homoeopathic preparation is not met:
 - eg. flower essences, etc.
 - eg. ‘dilute’ preparations



Issues to be considered

- **Responses to questions raised in the Consultation Paper will inform the development of an appropriate system of regulation for homoeopathic and related medicines, which:**
 - is consistent with international best practice
 - helps ensure supply of safe, quality, efficacious medicines
 - meets the needs of consumers, practitioners and industry



Definitions

- **Necessary to properly identify what is being regulated, and in what way**
- **Wording has been proposed for the term ‘homoeopathic medicine’**
- **Other definitions may be required**
 - eg. anthroposophical medicines
 - eg. ‘vibrational’ essences



Quality

- **Currently very little regulatory jurisdiction**
- **Are appropriate homoeopathic standards being applied and met?**
- **Safety?**
- **Accountability?**
- **What other principles or guidelines should apply?**



Safety

- **These products are low risk, providing certain conditions are met**
- **Any direct or indirect risks should be identified, so they can be managed appropriately**
- **How can we be assured that these requirements are met if products are not subject to appropriate scrutiny?**



Efficacy

- **Levels and kinds of evidence to support indications and claims will be dealt with elsewhere**
- **Consider issues relating to efficacy ‘within the paradigm’**
 - combination remedies
 - concomitant ingestion eg. coffee, toothpaste
- **How are these issues best managed?**



Naming, quantification and labelling to reflect the homoeopathic paradigm

- **Should there be specific names for these types of medicines?**
 - Current system in Australia has sometimes led to consumer misconception
 - Appropriate for the remedy
 - Consistent with appropriate pharmacopoeia
 - Meaningful to consumers



Naming, quantification and labelling to reflect the homoeopathic paradigm

- **How should homoeopathic and related medicines be expressed and quantified?**
 - Does quantification on the label mean anything?
 - May be necessary in applications where ingredient restrictions apply
 - How should excipients be quantified?
 - How should potencies be expressed, and what standard should apply?



Naming, quantification and labelling to reflect the homoeopathic paradigm

- **Labelling for consumers**
 - What is meaningful information for consumers, to prevent misunderstanding?
 - How should these medicines be differentiated from other paradigms?
 - How should homoeopathic indications be expressed, if at all?
 - How should should indications for other ‘vibrational’ remedies be expressed?



Other issues

- **Adverse event reporting for homoeopathic and related medicines**
- **Practitioner access to remedies**
- **Any other matters**



Conclusion

- **This consultation paper provides an opportunity for all stakeholders to have input into the development of appropriate regulation for homeopathic and related medicines under the joint Agency**
- **We welcome your responses to the issues proposed in the Consultation Paper, and any other matters related to the development of appropriate regulation for these types of medicines**