Australian Government
Department of Health
Therapeutic Goods Administration

Review of "low risk therapeutic goods"
Broad options consulted upon for each product type

- Maintain the **status quo regulation** for each product type
- Review the **eligibility of active ingredients to become listable**
- **Modify requirements** for regulatory processes – GMP, ingredients etc if there is not a direct impact on safety, performance and quality
- Make **greater use of standardised requirements** – e.g. use monographs
- **Issues identified by stakeholders** with some of current approaches:
  - Regulatory requirements are confusing
  - Timeframes for application processing can be very long
  - Safety evaluations for different formulations are expensive

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Used a risk framework to assess products

- **Parameters** such as:
  - safety of the ingredients
  - route of administration
  - risk associated with the claims
  - nature of the condition being treated/ prevented
  - Nature/size of population using the product
  - impact of poor manufacturing quality on safety
- **Regulatory "familiarity"**
- Ability of sponsors to **self-assess** the product ?
- **International regulatory approaches**

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Product types in scope

- Water-soluble vitamins and minerals
- Homeopathic products
- Primary and secondary sunscreens
- Throat Lozenges, antacids, chest rubs
- Disinfectants, OTC antiseptics, medicated soaps and toothpastes, nappy rash treatments
- Antiseptic mouth washes, rubefacient preparations, Antiperspirants
- Sanitary tampons and menstrual cups
- Ear candles

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