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TGA public consultation on 'low risk' product regulation

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TGA consultation on 'low risk' product regulation

MMDR review released (2015)[1]

TGA review of 'low risk' product regulation (2016-2017)[2]

- Ear candles and homeopathic products selected for analysis
- Public consultation held (> 1000 submissions received)

Government decided on regulatory reform (June 2018)[2]


Submissions received: Options for the future regulation of 'low risk' products

Related information

Submissions

Submissions submitted by multiple organisations/individuals separately using similar wording or a template

References
1. Australian Government Department of Health. Expert Review of Medicines and Medical Devices Regulation [Internet]. Canberra ACT: Australian Government Department of Health; [date unknown] [updated 2017 March 16; cited 2018 Oct 19]. Available from: http://www.health.gov.au/internet/main/publishing.nsf/content/expert-review-of-medicines-and-medical-devices-regulation
2. Therapeutic Goods Administration. The future regulation of low risk products [Internet]. Symonston ACT: Therapeutic Goods Administration; 2018 June 21 [updated 2018 Oct 16, cited 2018 Oct 16]. Available from: http://www.tga.gov.au/future-regulation-low-risk-products

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TGA consultation on 'low risk' product regulation

Ear candles[1]
Option 1: Status quo regulation
Option 2: Exemption
Option 3: Exclusion

Homeopathic products[1]
Option 1: Status quo regulation
Option 2: More scientific evidence
Option 3: Exemption
Option 4: Exclusion

References
1.Therapeutic Goods Administration. Consultation: Options for the future regulation of "low risk" products [Internet]. Symonston ACT: Therapeutic Goods Administration; March 2017 [cited 2018 Oct 06]. 68 p. Available from: http://www.tga.gov.au/sites/default/files/consultation-options-future-regulation-low-risk-products.pdf

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Research aims and hypothesis

Aims:

1. Assess consultation submissions addressing ear candles and homeopathic products
2. Determine their impact on TGA/Government decision-making about regulatory reform

Hypothesis:
Consultation submissions were not taken into account in decision-making

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Methods: Document analysis

1. Downloaded published submissions
2. Quantified them according to product(s) addressed, Option(s) supported and author identity
3. Extracted themes and illustrative quotations
4. Determined consensus regulatory actions based on submissions
5. Compared these to TGA/Government decisions and determined impact of submissions on decision-making

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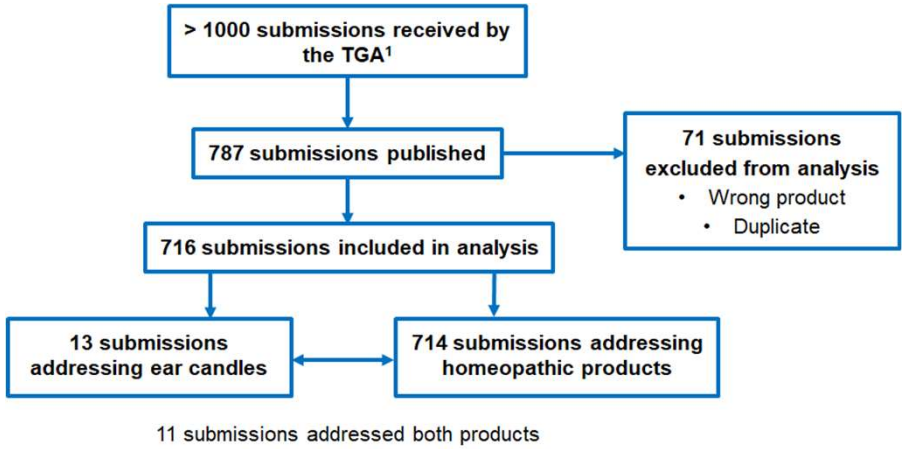
Overview of submissions



References
1. Therapeutic Goods Administration. The future regulation of low risk products [Internet]. Symonston ACT: Therapeutic Goods Administration; 2018 June 21 [updated 2018 Oct 16, cited 2018 Oct 16]. Available from: http://www.tga.gov.au/future-regulation-low-risk-products

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Submissions addressing ear candles

- **Consensus regulatory action:** Option 1 (maintain status quo)
  - Supported by 7 of 13 (54%) authors
    - Including ACCC, NICM, FSM
    - Argued that continued specialist regulation by TGA is ideal
- **TGA/Government decision:** Option 3 (exclusion)[1]
  - Concerns in submissions not addressed
  - 'Cutting red tape' agenda prioritised

References
1. Therapeutic Goods Administration. The future regulation of low risk products [Internet]. Symonston ACT: Therapeutic Goods Administration; 2018 June 21 [updated 2018 Oct 16, cited 2018 Oct 16]. Available from: http://www.tga.gov.au/future-regulation-low-risk-products

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Submissions addressing homeopathic products

- **Consensus regulatory action:** Option 1 (maintain status quo)
  - Supported by 686 of 714 (81%) authors
    - Including ACCC, ARoH, AHA, FSM
    - Argued that continued specialist regulation by TGA is ideal
- **TGA/Government decision:** No decision made[1]
  - Concerns in submissions not addressed
  - Regulatory paralysis

References
1. Therapeutic Goods Administration. The future regulation of low risk products [Internet]. Symonston ACT: Therapeutic Goods Administration; 2018 June 21 [updated 2018 Oct 16, cited 2018 Oct 16]. Available from: http://www.tga.gov.au/future-regulation-low-risk-products

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Limitations and future directions

- **Limitations:**
  - Not all submissions published
  - Unclear whether organisations should be given more weight than individuals
- **Future directions:**
  - Analysis of other TGA consultations
    - Similar results found for consultation on pre-approval of advertisements

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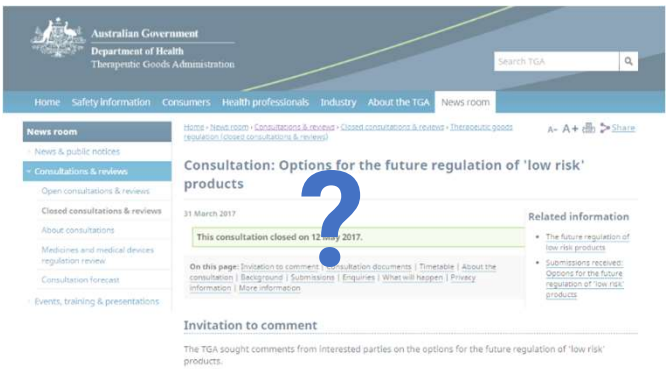
Conclusions

- Appears that consultation submissions **not** taken into account
- Implications for consumer protection and value of the consultation



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