



Australian Government
Department of Health
Therapeutic Goods Administration

Review of Medicines and Medical Devices Regulation - Options for the advertising of OTC and complementary medicines Regulation Review – an update

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WSMI Regulators Forum, 20 October 2017

TGA Health Safety
Regulation

Review of Medicines & Medical Devices Regulation

- **Expert Panel** commenced late 2014 after most of 2014 in pre-work
- **Review process** included discussion papers, submissions and interviews by the panel
- **Two reports** on medicines and devices and complementary medicines and advertising released during 2015 with 58 recommendations
- Following release of the reports, workshops held with key stakeholders by the Department to get **feedback on recommendations**
- Health Minister took preferred position to Cabinet
- **Government response** was publicly released on 15 September 2016



Reminder



Seven bundles of work agreed and costed

1. Increasing Flexibility for Registration and Post-Market Processes for Medicines
2. Increasing Flexibility for Approval and Enhanced Post-Market Monitoring of **Medical Devices**
3. Increasing Flexibility for Pre-Market Approval and Increased Evidence of Efficacy of **Complementary Medicines** for Consumers
4. Simplified and More Effective Regulation of **Advertising** of Therapeutic Products
5. Streamlined Regulation of **Patient-Specific Access** to Therapeutic Products
6. **Further Reviews**
7. Rationalisation of **TGA Statutory Advisory Committees**

Overarching principles for regulation as endorsed by Government

- **Australia maintain the capacity to undertake assessments** of therapeutic goods for safety, quality and efficacy
- The Australian Government **retain responsibility for approving the inclusion of therapeutic goods** in the ARTG
 - Rather than automatically accepting international approvals
 - However need to make much greater use of overseas evaluations
- Need to introduce **greater flexibility in approval pathways** for both medicines and medical devices
- TGA could **more appropriately align level regulation with the actual risk posed by the products** in certain areas

The Scheduling Policy Framework - background

- The SUSMP is the basis by which public access to medicines and chemicals is controlled
- Substances are placed into a schedule based on the risk associated with their use
- Progression through the schedules signifies increasing restrictions
- For medicines: S2, S3, S4 and S8
- For chemicals: S5, S6 and S7
- S9: only available for teaching, research etc
- Decision making powers contained in the *Therapeutic Goods Act 1989*, i.e. delegates of the Secretary of the Department of Health make the actual scheduling decisions
- The SPF provides the risk based decision making principles to be used by the decision maker – the scheduling decision is captured by the SUSMP
- Implementation of the SUSMP is through relevant State and Territory legislation

Advertising Reforms



Advertising of therapeutic goods

- 1. Advertising of therapeutic goods to the public continues to be regulated by TGA** (Therapeutic Goods Advertising Code under s42BAA of the Act)
- 2. Abolish mandatory pre-approvals of advertising**
- 3. Requirements for advertising to the public to be made consistent** for all medicines and medical devices
- 4. Advertising to the public continues to be prohibited** for prescription medicines
- 5. TGA to take on the role of the single body** responsible for handling direct-to-consumer (DTC) **advertising complaints** from 1 July 2018
- 6. Investigation and enforcement powers** broadened
- 7. Sponsor education programs** to assist in compliance

Advertising of Complementary medicines

- The object of the Code is to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer
- Direct-to-consumer advertising of prescription medicines (Schedules 4 and 8 of the *Poisons Standard*) and certain pharmacist-only (Schedule 3) medicines is banned
- Non-prescription medicines and medical devices can be advertised directly to the public
- Advertisements must comply with the Code and other advertising requirements set out in the Act and Regulations
- Since 2007 there has been significant **broadening of the types of therapeutic goods** being promoted and sold directly to the public. Including the range and presentation of complementary medicines

Advertising of Complementary medicines

The Code will also be required to be **consistent with the proposed complementary medicine reforms that may impact on advertising** such as the permitted indications list and the new “Assessed Listed Medicine” pathway

Required revisions to the Code may also include changes consequent to allowing certain complementary (and potentially OTC) medicine products to include a “claimer” of efficacy on their labels and promotional materials

Review of Pharmacist Only (S3) Medicines Advertising

- Currently **only a limited number of S3 medicines can be advertised**
- **Diverse views** on possible change
- **Government** has asked for more specific consultation to be conducted
- Options included:
 - make no change to the current system
 - move instead to having a small list of substances forbidden from advertising
 - move to a self-regulatory approach
 - allow “information provision” by industry but not advertising
- There was strong support to increase advertising of Schedule 3 substances, with a particular emphasis on public health awareness.
- Current work is focused on developing a mechanism, utilising existing framework to allow more S3 substances to be advertised

Pharmacist Only Medicine Advertising Reforms

Possible options from recent consultation

- Alter the policy intent to allow advertising of Pharmacist Only medicines to the public, unless it is determined that advertising is not appropriate for a particular substance
- Substances that are permitted to be advertised will be included in Appendix H of the Poisons Standard
- The following additional information is proposed for Pharmacist Only product advertisements:
 - **“Your pharmacist *must decide* if this product is suitable for you”**
 - **“Ask your pharmacist about side effects relevant to you”**

Pharmacist Only Medicine Advertising Reforms

Proposed factors for determining appropriateness for advertising

In making a decision whether a substance is appropriate to be advertised, the Delegate may consider a range of matters including:

- The potential public health benefits and health risks
- Available Consumer Medicine Information and consumer education
- The likelihood of advertising of the substance leading to inappropriate patterns of medication use
- The provisions of the Code and any prohibited and restricted representations relevant to the substance
- Available Risk Management Plan
- Any other information that is relevant to the decision making

Pharmacist Only Medicine Advertising Reforms

Substances unsuitable for inclusion in Appendix H

As a guide, the following categories may not be appropriate for direct-to-consumer advertising:

- Injectable
- Substance for use in emergency situations
- Where safer analogues or therapeutically equivalent medicines are available
- Where there is potential for inappropriate use, abuse or diversion
- Where the substances form part of surgical procedure
- Medicine for treatment of chronic condition that requires a doctor as part of the treatment

Pharmacist Only Medicines Advertising Reforms

- **Proposed next steps**

- Consultation closed on 13 October. Currently analysing the submissions received
- Prepare the guidelines for Pharmacist Only Advertising based on the feedback from consultation
- Seek Ministerial approval for the proposed new guidelines
- Advertising Code also to be revised based on consultation feedback, with further consultation planned following Ministerial approval
- Intention to implement revised advertising framework in mid 2018



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