Australian Government
Department of Health
Therapeutic Goods Administration

The Prescription Medicine Authorisation Branch updates

Discussion of further reforms

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TGA Health Safety Regulation

Government reform process – A summary

Change is methodical and with many steps

- Internal proposal and internal consultation
- Executive agreement to a proposal (RIS?)
- Drafting of external consultation document
- Ministerial Submission for Agreement
- Consultation and gathering of responses
- Collation and consideration of responses and amendment (RIS?)
- Executive agreement on revised proposal
- Ministerial submission with update and proposal for change
- Instrument, regulation or Act change.

Companion diagnostics

Consultation

Between 23 October 2018 and 14 December 2018, the TGA sought comments from interested parties

- Twenty-three written responses were received.
- Submissions received in response to the consultation showed that the majority of stakeholders support the implementation of a regulatory framework for IVD companion diagnostics which is aligned with comparable overseas regulators such as the European Union (EU) and the United States Food and Drug Administration (USFDA).

Most of the submissions have supported the various elements of the proposed framework including:

- A regulatory definition of IVD companion diagnostic;
- Confirmation they are class 3 IVDs;
- Compulsory audit of all with the proviso that abridged assessments and reduced fees will be utilised whenever suitable evidence of prior assessment is available;
- The need for the TGA to recover the costs of audit assessments
- Clear identification of all IVD companion diagnostics on the ARTG;
- Provisions for transition of IVD companion diagnostics which are included on the ARTG at the commencement date of the new regulations and a transition timeframe that is aligned with the transition period for the EU Regulations;
- Regulatory requirements to apply to both commercially supplied IVDs and in-house IVD.

Companion diagnostics

Ministerial approval to proceed to regulations

- Drafting of amendments to the Therapeutic Goods (Medical Devices) Regulations 2002
- For an IVD medical device or an in-house IVD medical device
- Definitions include wording to cover:
  - whether the patient would be likely to benefit from the use of a corresponding medicine or biological; or
  - whether a patient would be likely to be at an increased risk of a serious adverse reaction as a result of use of the corresponding medicine or biological; or
  - monitor a patient's response to the corresponding medicine or biological

Reforms to Schedule 3 advertising

- Advertising of medicines containing Pharmacist Only (Schedule 3) substances direct to consumers (DTC) should be permitted unless actually deemed unsuitable by the Scheduling Delegate
- Factors the Delegate will consider when deciding if a substance is not suitable for advertising:

1. The potential impact on public health
   a) Is there potential for inappropriate use, abuse, diversion that may be exacerbated by advertising?
   b) Are there potential interactions with the substances (drug-drug, drug-food) that require increased patient education to ensure safe use?
   c) Are there additional risks associated with the dosage form that may impact on safe use?
   d) Any other information that may be relevant, for example the substance has sedating properties, or there are safer alternatives available

Mandatory Requirements

- Advertisements for therapeutic goods must comply with the Therapeutic Goods Advertising Code (the Code)
- The revised Code took effect on January 2019
- There is a specific requirement in the revised Code for Schedule 3 substances:

"Ask your pharmacist – they must decide if this product is right for you"

Reforms to Schedule 3 advertising

- Public consultation to determine which Schedule 3 substances should be added to Appendix H was closed on 9 July.
- The current Schedule 3 substances were classified into two lists: those that can be advertised (added to Appendix H), those that are not suitable for advertising.
- Following consideration of the consultation feedback, together with feedback from stakeholder meetings, the Delegate will do one or more of the following for each substance:

1. Make a decision to add a substance to Appendix H
2. Decide not to add a substance to Appendix H
3. Reconsider the initial proposal and seek further comment on an alternative proposal
4. Refer the substance to the ACMS for further advice.

- 20 submissions were received as part of the public consultation.
- There are some substances that will be referred to the ACMS for further advice.

Advertising Code

Changes to the Therapeutic Goods Advertising Code (No.2) 2018

- The Therapeutic Goods Advertising Code (No.2) 2018 (the Code) came into effect on 1 January 2019.
- minor corrections and clarifications to the Code effective from 30 July 2019.

Key corrections and clarifications

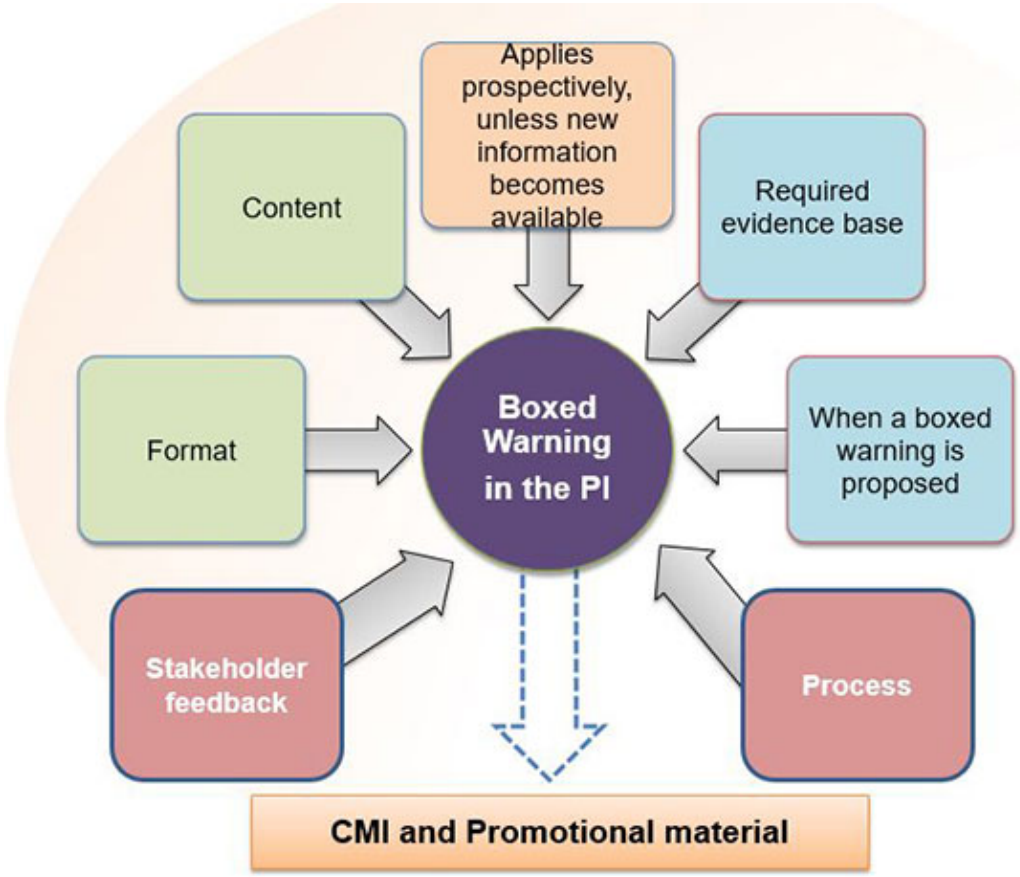
The amendment instrument contains a full list of the changes made to the Code. Key amendments include:

- *clarification that the section 11 mandatory statement applies to advertising of any therapeutic good that includes a Schedule 3 substance when the advertising is permitted by inclusion of the substance in Appendix H of the Poisons Standard;*
- *Etc.*

Boxed warning guidance

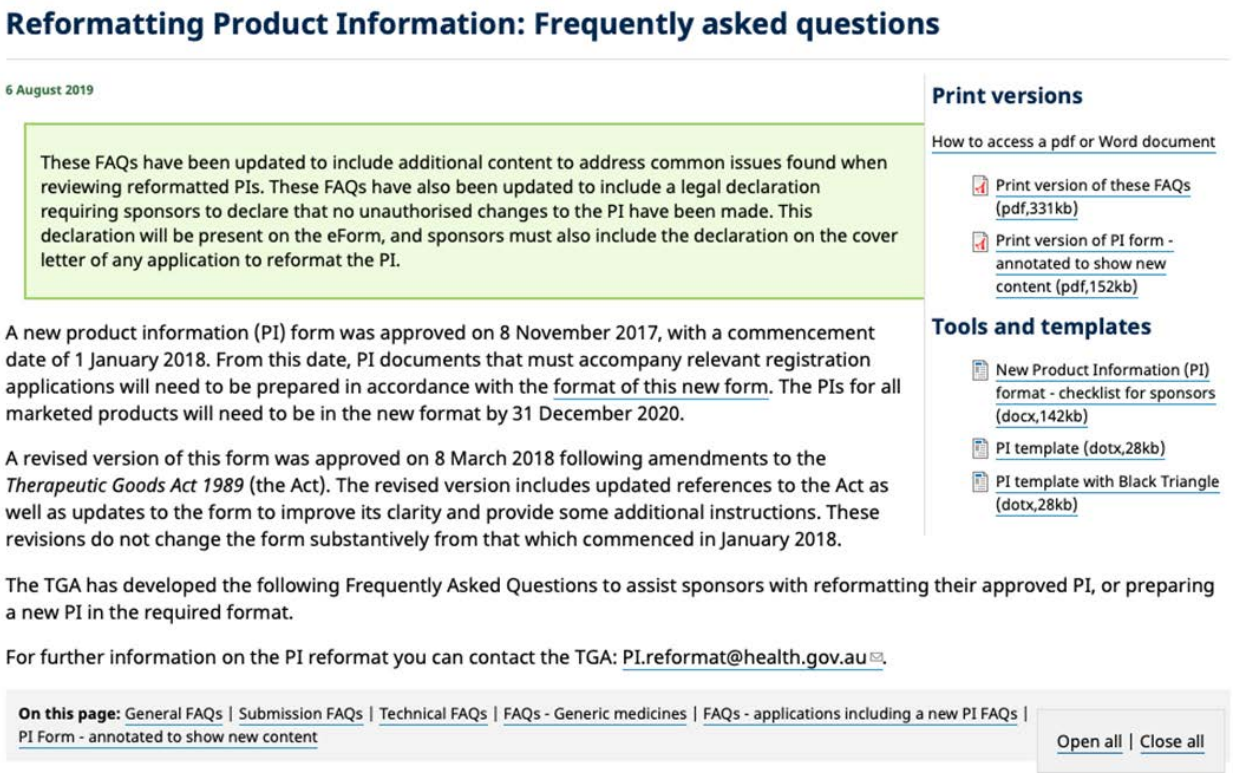
- A mechanism used to **highlight** special **warning statements** in the Product Information to the prescriber.
- **Concerns prominent safety issues** with a potential for major impact on public health.
- Have been **used for more than 25 years** in Australia and are **also used in other jurisdictions**.
- Previously **no TGA guidance**, we are seeking to standardise the approach.

Boxed warning guidance



Product information reformats

Many more are required



Reformatting Product Information: Frequently asked questions

6 August 2019

These FAQs have been updated to include additional content to address common issues found when reviewing reformatted PIs. These FAQs have also been updated to include a legal declaration requiring sponsors to declare that no unauthorised changes to the PI have been made. This declaration will be present on the eForm, and sponsors must also include the declaration on the cover letter of any application to reformat the PI.

A new product information (PI) form was approved on 8 November 2017, with a commencement date of 1 January 2018. From this date, PI documents that must accompany relevant registration applications will need to be prepared in accordance with the format of this new form. The PIs for all marketed products will need to be in the new format by 31 December 2020.

A revised version of this form was approved on 8 March 2018 following amendments to the *Therapeutic Goods Act 1989* (the Act). The revised version includes updated references to the Act as well as updates to the form to improve its clarity and provide some additional instructions. These revisions do not change the form substantively from that which commenced in January 2018.

The TGA has developed the following Frequently Asked Questions to assist sponsors with reformatting their approved PI, or preparing a new PI in the required format.

For further information on the PI reformat you can contact the TGA: PI.reformat@health.gov.au.

On this page: General FAQs | Submission FAQs | Technical FAQs | FAQs - Generic medicines | FAQs - applications including a new PI FAQs | PI Form - annotated to show new content

Open all | Close all

Print versions

How to access a pdf or Word document

- Print version of these FAQs (pdf,331kb)
- Print version of PI form - annotated to show new content (pdf,152kb)

Tools and templates

- New Product Information (PI) format - checklist for sponsors (docx,142kb)
- PI template (dotx,28kb)
- PI template with Black Triangle (dotx,28kb)

Additional reforms impacting prescription medicines

- New CMI Format
- Opioid consultation outcomes
- New export guidance
- Early ACM advice
- Transparency of Applications Under Evaluation

Compliance with conditions of registration

Standard and special

- A review of these conditions including tracking of compliance is pending

PMAB 2019

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