Australian Government
Department of Health
Therapeutic Goods Administration

Black Triangle Scheme

Information for sponsors

Version 1.1, May 2018

TGA Health Safety Regulation

Contents

Inclusion in the scheme

Prescription medicines are included in the Black Triangle Scheme if they meet one or more of the following criteria:

- The product is newly registered (Type A applications, excluding biosimilar medicines and seasonal influenza vaccines)
- The product is provisionally registered, or has a provisionally registered indication
- The indications of the product have changed to include use in a significantly different:
  - Population, for example paediatric use, and/or
  - Disease or condition, for example a change from an oncology indication to a non-oncology indication

As a sponsor, you may indicate in your application that you expect your product to be included in the scheme. This can be done by adding the black triangle symbol and accompanying text to your draft Product Information (PI) and Consumer Medicine Information (CMI).

The eligibility of a product for inclusion in the scheme will be considered in the Risk Management Plan (RMP) evaluation. The RMP Evaluation report will advise you if your product will be included in the scheme. Inclusion in the Black Triangle Scheme is applied as a condition of registration.

Duration of inclusion

Fully-registered products that meet the eligibility criteria are included in the Scheme for a 5 year period. The duration of inclusion starts from the date of first supply for new medicines, or the date of approval for new indications. Sponsors are reminded of the requirement to inform TGA of the date of first supply, as stated in the conditions of registration.

Products with a provisional registration will remain in the Scheme for a minimum of 5 years. This will include the entire period of provisional registration (up to 6 years), and may continue into the period of full registration if required. Examples where the product may remain in the Scheme following full registration include a provisional registration period less than 5 years, or an extension of indications into a broader population group at the point of full registration. Consideration of inclusion in the Scheme, and the duration of inclusion, will be considered as part of the application to transition from provisional to full registration.

Sponsor actions

Products included in the Black Triangle Scheme must have the black triangle symbol and accompanying text included in the PI and CMI, as shown below. In addition, the PI should be presented in the new format. Further information on the new PI format is available on the TGA website. A PI template which includes the required black triangle symbol and statement is also available (see 'Related information'). Further information to assist sponsors in preparing PIs in the new format can be found on the *Reformatting Product Information: Frequently asked questions* page.

Each side of the triangle symbol must have a minimum length of 5 mm. If the font size of adjacent text exceeds 20 point, the triangle symbol must also be proportional to the font size of the subsequent standardised text. In addition, a standard explanatory text will accompany the

symbol to provide further information to consumers and health care practitioners. The black triangle symbol and accompanying text should appear at the top of the first page of the PI and CMI, prior to the headings for these documents. Examples are shown in Appendix 1 and 2 of the 'print version' of this page (see Related Information).

PI wording:

▼This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

Please note: for PIs included as a package insert for use in New Zealand, the 'in Australia' should be in bold font to meet Medsafe recommendations.

CMI wording:

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Use of the black triangle symbol

The black triangle symbol and accompanying text should be included in any additional risk minimisation materials. In addition, use of the symbol and text is strongly encouraged in promotional materials.

The TGA is working with external stakeholders to get the symbol displayed in other sources of medicines information, as well as prescribing and dispensing software.

Exiting the scheme

At the end of the 5 year period, or agreed period for provisionally registered products, a products inclusion in the Scheme will automatically lapse. You will be required to submit updated versions of your PI and CMI, with the black triangle symbol and accompanying text removed. Further information on the process for lodging these updated documents will be provided when it becomes available.

Appendix 1 – Mock-up of PI with black triangle

Note: the boxed outline is intended to represent the page, and does not need to be included around the text.

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

AUSTRALIAN PI – TRADENAME (Active ingredient) capsules

1. NAME OF THE MEDICINE

Active ingredient

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

PI text…

3. PHARMACEUTICAL FORM

PI text…

Appendix 2 – Mock-up of CMI with black triangle

Note: the boxed outline is intended to represent the page, and does not need to be included around the text.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Tradename dose form

Active ingredient

Consumer medicine information

What is in this leaflet	**What Tradename is used for**	etc
CMI text….	CMI text ….	

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Pharmacovigilance and Special Access Branch	10/01/2018
V1.1	Updated to clarify requirements regarding triangle size, and when the 5 year period starts for products extending their indication	Pharmacovigilance and Special Access Branch	24/05/2018

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