Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Black Triangle Scheme information for sponsors

Information about what to include in the PI and CMI for products included in the Black Triangle Scheme.

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On this page

The black triangle is a reminder to health professionals and consumers to report suspected adverse events related to new medicines. It also applies to those being used in significantly different ways (for additional diseases, conditions or patient groups). Products included in the scheme feature the black triangle symbol and accompanying text on:

- Product Information (PI) documents
- Consumer Medicines Information (CMI) documents
- other TGA material and literature such as Australian Public Assessment Reports for prescription medicines (AusPARs).

Products included in the Black Triangle Scheme

You can find medicines included in the Black Triangle Scheme in the Australian Register of Therapeutic Goods (ARTG) using the advanced search option.

Registered prescription medicines

All new prescription medicines are included in the scheme when they are registered, except:

- biosimilar medicines
- generic versions of already-approved prescription medicines not included in the Black Triangle Scheme
- seasonal influenza (flu) vaccines.

Generic versions of medicines that are included in the Black Triangle Scheme must also be included in the scheme.

We don't include flu vaccines as the Australian Government Department of Health and Aged Care's AusVaxSafety program provides additional monitoring of flu vaccine safety.

Provisionally registered medicines

We include all provisionally registered medicines in the scheme, including those with a provisionally approved indication. Other medicines may be included after approval for an extension of indication that is either:

- for a significantly different condition
- for use in a significantly different patient population.

Our decision to include these medicines in the scheme will consider international evidence. We may not include medicines where international evidence shows that the safety profile for the new indication is consistent with the current indications.

When you apply to register a provisionally approved medicine you can expect your product to be in the Black Triangle Scheme. You should add the Black triangle symbol and accompanying text to your draft Product Information (PI) and Consumer Medicine Information (CMI). Inclusion in the Black Triangle Scheme is applied as a condition of registration.

More information

Black Triangle Scheme format and examples

Use the black triangle for 5 years

Fully registered products meeting the eligibility criteria belong to the scheme for a 5-year period. The 5 years starts from either:

- the date of first supply for new medicines
- the date of approval for new indications.

You must inform us of the date of first supply, as stated in the conditions of registration.

Provisional 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)
- 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
- an extension of indications into a broader population group at the point of full registration.

Inclusion in the scheme, and the duration of inclusion, will be considered as part of the application to transition from provisional to full registration.

Exiting the Black Triangle Scheme

At the end of the 5-year period (or the agreed period for provisionally registered products) your product's inclusion in the scheme will automatically lapse. There is no need to apply to us to leave the scheme. You will need to submit updated PI and CMI documents to us with the black triangle symbol and text removed.

More information

- The Black Triangle Scheme
- Reporting adverse events
- Black Triangle Scheme - Information for Sponsors

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