Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Pharmacovigilance Inspection Program

Information on TGA's biennial Pharmacovigilance Inspection Program (PVIP) Risk Assessment Survey

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On this page

The TGA's Pharmacovigilance Inspection Program Risk Assessment Survey (https://immunisationhandbook.health.gov.au/news/news/pharmacovigilance-inspection-program-risk-assessment-survey) is now open for medicine sponsors to complete. The survey will remain open until 18 December 2022.

About the Pharmacovigilance Inspection Program

Following a successful pilot program conducted in 2015-16, the TGA's Pharmacovigilance Inspection Program (PVIP) was implemented as an initiative to help sponsors of medicines meet their pharmacovigilance obligations.

The TGA applies a risk management approach to ensuring that medicines included on the Australian Register of Therapeutic Goods (ARTG) (https://immunisationhandbook.health.gov.au/node/287250) meet acceptable standards of quality, safety and efficacy, and are subject to ongoing

monitoring to ensure that these standards are maintained.

Pharmacovigilance is defined by the World Health Organization (http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/) as the science and activity related to detecting, assessing, understanding and preventing adverse effects and other medicine-related problems.

The aim of therapeutic product vigilance is to continually monitor and evaluate the safety and efficacy (performance) profile of therapeutic products and to manage any risks associated with individual products.

The PVIP is a product vigilance program designed to facilitate the collection and evaluation of safety information relating to all medicines on the ARTG. It involves TGA representatives interviewing sponsors and reviewing documents in order to assess the sponsor's compliance with pharmacovigilance requirements set out in:

- the *Therapeutic Goods Act 1989* (https://www.legislation.gov.au/Series/C2004A03952)
- the *Therapeutic Goods Regulations 1990* (https://www.legislation.gov.au/Series/F1996B00406)
- the '*Pharmacovigilance responsibilities of medicine sponsors - Australian recommendations and requirements* (https://immunisationhandbook.health.gov.au/node/289370)'.

Sponsors have the primary responsibility for the safety of any therapeutic products they import, supply or export from Australia, and there are penalties for not meeting these obligations.

Inspections benefit sponsors by identifying areas within their existing pharmacovigilance practices where there may be gaps or where improvements could be made. This will help them to improve their pharmacovigilance systems and quality processes as a whole - ultimately ensuring the ongoing safety of medicines available to the Australian public.

Further information about Australia's therapeutic product vigilance system (https://immunisationhandbook.health.gov.au/node/282893) is available on the TGA website.

Inspection information for sponsors

Sponsors will be notified six to eight weeks prior to an inspection.

The announcement of the inspection will be in writing and may include, for example, the objectives, nature/type of the inspection, the dates and if known the address of the proposed inspection site(s).

In exceptional circumstances, an inspection may be performed without prior notice.

Inspection guidelines are based on the UK Medicines and Healthcare products Regulatory Agency (MHRA) guidelines, but also address relevant Australian issues and requirements.

Further information on the inspection process can be found in the PVIP Inspection guidelines (https://immunisationhandbook.health.gov.au/node/285158).

Resources

- PVIP Inspection Guidelines (https://immunisationhandbook.health.gov.au/node/285158)
- Pharmacovigilance responsibilities of medicine sponsors - Australian recommendations and requirements (https://immunisationhandbook.health.gov.au/node/289370) (Pharmacovigilance Guidelines)
- Pharmacovigilance obligations of medicine sponsors - Frequently asked questions (https://immunisationhandbook.health.gov.au/node/289600)

Reports

The TGA publishes annual inspection program metrics reports containing de-identified information on the number of inspections held, the type of inspections, the type of findings and whether they have been resolved.

A summary of conclusions, in relations to comparisons over time, is included in these reports.

- Pharmacovigilance Inspection Program metrics report: January - December 2021 (https://immunisationhandbook.health.gov.au/node/337269)
- Pharmacovigilance Inspection Program metrics report: January - December 2020 (https://immunisationhandbook.health.gov.au/node/285518)
- Pharmacovigilance Inspection Program metrics report: January - December 2019 (https://immunisationhandbook.health.gov.au/node/285494)
- Pharmacovigilance Inspection Program metrics report: September 2017 - December 2018 (https://immunisationhandbook.health.gov.au/node/285457)

Presentations

Any TGA presentations relating to pharmacovigilance and the PVIP made in the past 12 months can be found on the TGA's presentations (https://immunisationhandbook.health.gov.au/node/282893) web page.

Contacts

For any PVIP-related enquiries, please email Pharmacovigilance.Inspections@health.gov.au (https://immunisationhandbook.health.gov.aumailto:Pharmacovigilance.Inspections@health.gov.au).

Topics:

Medicines safety (https://immunisationhandbook.health.gov.au/topics/medicines-safety)

Therapeutic goods regulation (https://immunisationhandbook.health.gov.au/topics/therapeutic-goods-regulation)

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