Australian Government
Department of Health
Therapeutic Goods Administration

Pharmacovigilance inspection program

Guidance for medicine sponsors

Version 1.0, September 2017

TGA Health Safety Regulation

Contents

Introduction

Pharmacovigilance is defined by the World Health Organization as the science and activity related to detecting, assessing, understanding and preventing adverse effects and other medicine-related problems. The Therapeutic Goods Administration (TGA) conducts a range of pharmacovigilance activities to monitor the safety and efficacy of medicines in Australia and, where necessary, take appropriate action.

The pharmacovigilance responsibilities of sponsors of medicines included on the Australian Register of Therapeutic Goods (ARTG) and regulated by the TGA are set out in the Pharmacovigilance responsibilities of medicine sponsors—Australian recommendations and requirements.

The TGA inspects Australian sponsors to assess whether they are meeting their pharmacovigilance responsibilities.

This guidance will help you understand our pharmacovigilance inspection program (PVIP). It outlines how we prepare, conduct, report and follow up pharmacovigilance inspections and lists the criteria we use when scheduling inspections.

In this guidance, we use 'must' or 'required' to describe something you are **legally obliged** to do. We use 'should' to **recommend** an action that will assist you to meet your legal requirements. We refer to the TGA as 'we' or 'us', and to sponsors as 'you'.

This guidance describes:

- how we prioritise and schedule pharmacovigilance inspections
- the kinds of inspections we might make and the inspection process
- the legal basis for pharmacovigilance inspections of all sponsors of medicines on the ARTG

Responsibilities

All sponsors of medicines on the ARTG are subject to the Pharmacovigilance Inspection Program.

Sponsors of medicines approved for supply in Australia are legally responsible for meeting pharmacovigilance reporting requirements for their medicine (in accordance to subsection 28(5)(e) of the *Therapeutic Goods Act 1989* and Regulation 15A of the Therapeutic Goods Regulations 1990).

We expect you to have an effective pharmacovigilance system in place to monitor and take appropriate action on the safety of your medicine, as outlined in the Pharmacovigilance responsibilities of medicine sponsors—Australian recommendations and requirements.

Your inspection-related responsibilities include, but are not limited to:

- ensuring your pharmacovigilance system adheres to Australian pharmacovigilance legislation and guidelines
- maintaining your readiness for inspection, as inspections may be unannounced

- ensuring any sites to be inspected, and any firms contracted by you to perform pharmacovigilance activities, agree to be inspected prior to inspection
- providing the inspectors, within the given deadline, with any information or documentation they need to prepare or conduct the inspection
- ensuring staff involved in pharmacovigilance or related activities are available (in person or remotely), where possible, during the inspection for interview or to clarify issues
- preparation and implementation of appropriate and timely corrective and preventative action (CAPA) plans to address the inspection's findings that prioritise any critical or major findings
- completion of a biennial report (once every two years) on your pharmacovigilance system via the electronic form provided, to assist in prioritisation of inspections.

Our inspection-related responsibilities include, but are not limited to:

- provision and review of the submitted biennial report on your pharmacovigilance system and prioritisation of inspections
- coordinating the inspection and personnel—including scheduling dates, times, venues—and providing the agenda
- conducting the inspection
- preparing the inspection report
- reviewing your CAPA plan(s) and finalising the inspection.

Objectives of the pharmacovigilance inspection program

The pharmacovigilance inspection program aims to strengthen and broaden the TGA's post-market monitoring activities and protect public health by ensuring the continued safety of medicines.

Pharmacovigilance inspections allow us to:

- verify you are compliant with your pharmacovigilance responsibilities
- ensure you have robust pharmacovigilance systems in place to:
  - collect and collate current information on the safety and efficacy of your medicines(s)
  - assess the benefit-risk balance of your medicine(s)
  - meet the mandatory reporting requirements
  - take action to mitigate any identified safety issue(s)
- work with and educate you or, if necessary, compel your compliance to ensure you have effective pharmacovigilance systems in place in alignment with Australian pharmacovigilance guidance and legislation.

Scope of the pharmacovigilance inspection program

All Australian sponsors of listed and registered medicines on the ARTG are subject to the pharmacovigilance inspection program. The program will only include sponsors of medicines included on the ARTG.

Inspections will examine your compliance with the applicable Australian legislation and guidelines:

- *Therapeutic Goods Act 1989*, referred to as 'the Act' (section 28(5e), 29A and 29AA)
- Therapeutic Goods Regulations 1990 (Regulation 15A)
- *Pharmacovigilance responsibilities of medicine sponsors—Australian recommendations and requirements* (the Pharmacovigilance guidelines)
- Conditions - standard and specific (Applying to registered or listed therapeutic goods under Section 28 of the *Therapeutic Goods Act 1989*).

Inspections assess the appropriateness and compliance of your pharmacovigilance system in line with the Pharmacovigilance guidelines. At a minimum (for routine inspections), we will review the following aspects of your system during an inspection:

- the collection, collation, processing, timely and appropriate reporting and follow-up of adverse reaction reports
- where relevant, the preparation of Periodic Safety Update Reports (PSURs) and your adherence to risk management plans (RMPs)
- the ongoing analysis of the benefit-risk profile of your medicine(s) during the post-authorisation period, including analysis of global data where relevant
- the reporting of significant safety issues
- how you maintain any reference safety information to ensure product information is up-to-date and in line with current scientific knowledge
- whether your qualified person responsible for pharmacovigilance in Australia (QPPVA) is suitable and available, and what activities they undertake
- whether there are appropriate safety agreements in place and being adhered to with any company contracted to perform pharmacovigilance activities on your behalf
- clinical trials involving medicines on the ARTG where the medicine is used in line with the product information or label indications.

Inspection process

Inspection prioritisation

We take a risk-based approach to the scheduling of pharmacovigilance inspections and prioritise routine inspections based on the risk we have assigned to you or your pharmacovigilance system. Systems with lower risk products or good compliance history are less likely to be inspected regularly. However, random inspections as well as 'for cause' inspections may also occur.

The elements we **consider** when assigning you risk and consequently determining whether and when we inspect include, but are not limited to:

- product-related factors such as:
  - uncertainty about a medicine's risk profile (including new classes of medicines and provisionally registered medicines)
  - whether the product has additional pharmacovigilance or risk-minimisation activities
  - whether the medicine had specific condition(s) of registration applied due to safety concerns
  - if the product has significant Australian sales volume (that is, if a large number of patients are exposed to the medicine)
  - product(s) with limited alternatives in the market place
  - products with known or emerging important safety concerns
  - the type of medicine—complementary, over the counter or prescription medicines.
- sponsor-related factors such as:
  - evidence that you have failed to comply with other TGA regulatory requirements such as good manufacturing practice, RMP activities or the submission of PSURs
  - data analysis that indicates you may have failed to comply with legislative pharmacovigilance requirements, such as:
    - evidence that you have failed to submit adverse drug reaction reports within required timeframes, or
    - your adverse drug reaction reports are erroneous, or
    - information from prior inspections in Australia or overseas
  - whether you supply many products to the Australian market
  - changes to, or suspected lack of, resources for pharmacovigilance activities
  - experience as an Australian sponsor of medicines included in the ARTG
  - organisational changes such as mergers and acquisitions.

- pharmacovigilance system-related factors such as:
  - whether you have subcontracted your pharmacovigilance activities, or have employed multiple firms to undertake pharmacovigilance activities
  - whether your QPPVA has changed
  - changes to your pharmacovigilance safety database(s). These could include changes to the database or to associated databases; the database's validation status and the transfer or migration of data
  - changes to your contractual arrangements with pharmacovigilance service providers or to the sites where pharmacovigilance is conducted.
- inspection-related factors such as:
  - your compliance history, including previous Australian pharmacovigilance or other inspection findings
  - whether you have been subject to a pharmacovigilance inspection previously
  - whether re-inspection was recommended by previous inspector(s)
  - how long it has been since your last pharmacovigilance inspection

To help us prioritise inspections, we will ask you to complete a biennial report (once every two years) on your pharmacovigilance system via an electronic form made available to all nominated contact persons for pharmacovigilance on the TGA website. The form will ask for information pertaining to the elements we consider when assigning you risk as listed above. Completing the requested fields helps us assign your risk based on predetermined risk scores and prioritise you for inspection. Sufficient time will be given for this survey to be completed. Your risk score obtained from this report will be combined with other risk information known to the TGA in order to prioritise inspections. Your assigned risk score will not be made available to you. If you do not complete the report, we will assign you the highest risk. We may also ask you to complete this form on an ad hoc basis.

Sites to be inspected

We choose the type and number of sites to inspect to ensure we meet the key objectives within the scope of the inspection. In most cases, we limit inspections to Australian affiliate sites; however, we may also inspect overseas sites if appropriate. We will liaise with international regulators in preparation of any international inspections, as appropriate.

Any party or organisation contracted to carry out some or all pharmacovigilance activities in conjunction with, or on behalf of, the sponsor may be inspected to confirm they are capable of supporting the sponsor's compliance with Australian pharmacovigilance obligations. Such inspections will generally be arranged through the sponsor as part of an overall pharmacovigilance inspection.

Types of inspections

Routine inspections

Routine pharmacovigilance inspections are scheduled as part of the inspection program. There is no specific trigger for these inspections, although we take a risk-based approach to prioritising them. These inspections are usually system-related inspections, but one or more products may be selected as examples to verify the implementation of the system and provide practical evidence of its functioning and compliance.

'For cause' inspections

'For cause' inspections are undertaken in response to specific triggers where a pharmacovigilance inspection is the appropriate way to examine the issues. 'For cause' inspections generally focus on specific aspects of your pharmacovigilance system or examine identified compliance issues and their impact on a specific product. However, we may also inspect your entire pharmacovigilance system as a result of a trigger. Significant public health concerns or identified noncompliance are expected to be the most common triggers. Some (but not all) of the elements listed under Inspection prioritisation are also triggers.

System-related inspections

Pharmacovigilance system-related inspections review the procedures, systems, personnel and facilities in place and determine whether your system meets your regulatory pharmacovigilance obligations. As part of this review, product-specific examples may be used to determine how the pharmacovigilance system operates and whether it complies with requirements.

Product-related inspections

Product-related pharmacovigilance inspections primarily focus on product-related pharmacovigilance issues, including product-specific activities and documentation, rather than reviewing the system overall. They are likely to be 'for cause' inspections to investigate a specific product issue. Some aspects of the wider system may be examined during a product-related inspection (that is, the system used for that product).

Announced and unannounced inspections

We anticipate the majority of inspections will be announced—that is, we will notify you of them in advance to ensure the relevant personnel will be available for the inspection. However, it may sometimes be appropriate to conduct unannounced inspections or to perform an inspection at short notice (for example, when an announcement could compromise the objectives of the inspection or when prompt inspection is required due to urgent public health concerns).

Reinspections

We may reinspect your pharmacovigilance system as part of our routine inspection program. We prioritise re-inspections by assessing risk factors. If a previous inspection identified a high level of compliance this may increase the time between reinspections. More frequent reinspections may occur:

- where we have identified significant noncompliance
- to verify you have taken action to address inspection findings

- to evaluate your ongoing compliance with your obligations and evaluate changes to your pharmacovigilance system
- when a previous inspection found you had failed to take appropriate corrective and preventative action in response to prior inspections.

Remote inspections

These are pharmacovigilance inspections of your premises (or the premises of a firm you have contracted to help fulfil your pharmacovigilance activities) that we perform remotely using communication technology such as the internet or video/tele conferencing. For example, where key sites for pharmacovigilance activities are located outside Australia or a third-party service provider is not available at the inspection site, it may be feasible to interview relevant staff and review documentation via remote access. If the remote inspection reveals issues that require on-site inspection, or the inspection objectives could not be met remotely, we may visit the inspection site.

Inspection notification

We have the right to perform a pharmacovigilance inspection at any time (see Legal basis for pharmacovigilance inspections). In exceptional circumstances, we can perform an inspection without notice. However, we would normally give you advance notice of our intention to conduct a pharmacovigilance inspection.

The period of notice served should be sufficient for you to make logistic arrangements, and ensure key personnel are available and have access to relevant data. As a guide, we consider six to eight weeks' notice to be sufficient for a routine inspection.

Notice of the inspection could include, for example, the inspector's name(s), the inspection's objectives and nature, the inspection date and, if known, the address(es) to be inspected. We will also request information about your pharmacovigilance system so we can plan the inspection.

We will notify you of the pharmacovigilance inspection in writing, unless an unannounced inspection is required. We will issue the inspection notification to your *Australian pharmacovigilance contact person's* nominated email address. We will request confirmation of your availability, ask you to ensure the cooperation of all parties and to confirm in writing that you agree to the inspection of all relevant sites and will make all required documents and databases directly accessible to our inspectors. If the nominated *Australian pharmacovigilance contact person* is not the QPPVA, the contact person should inform the QPPVA of the notification.

We may also request supporting data demonstrating how your pharmacovigilance system operates, for example your global Pharmacovigilance System Master File (where available), a description of the Australian pharmacovigilance system or further information on specific issues of interest. We will give you clear advice on when and how to submit these.

Preparing for inspection

Once you have been selected for, and notified of, a pharmacovigilance inspection, you need to prepare for it.

We will consider avoiding duplicating inspections conducted as part of another country's pharmacovigilance inspection program when feasible. There may be circumstances where we can perform a more detailed inspection of specific aspects or limit the scope of the inspection. For example, when appropriate, the inspection may focus on reviewing local Australian processes where global processes have recently been subject to a positive international inspection.

We will prepare an inspection plan, which will identify:

- the objectives and scope of the inspection
- our inspection team member(s) and their respective role(s)
- the inspection date and site(s) to be inspected
- the specific documents, electronic tools and systems to be reviewed and which we require access to, insofar as possible
- the expected time and duration of each major inspection activity (premises, processes et cetera)

We will share the inspection plan with you in advance to ensure the relevant personnel, meeting rooms, databases and/or documents are available.

We may also request specific electronic documents prior to the inspection to allow sufficient pre-inspection analysis and inspection planning and will specify a timeframe for their delivery. You may provide such documentation to the TGA by various means in adherence with your data privacy processes; including via secure email, provision of access to secure file hosting service or provision of USB or CD or other means.

Conducting the inspection

The inspection will proceed according to the details set out in the inspection plan. This will be negotiated prior to the inspection and can be amended during the inspection to ensure we achieve the inspection objectives. Any amendment to the plan will be documented. The inspection will take place over several days depending on the complexity of the system.

We may collect relevant information to support the inspection and verify compliance with guidance and the mandated reporting requirements set out in the *Pharmacovigilance responsibilities of medicine sponsors—Australian recommendations and requirements* by, for example:

- interviewing appropriate staff members regarding pharmacovigilance activities
- reviewing applicable company or contracted organisation policies and procedures regarding pharmacovigilance activities
- examination or demonstration of computers, electronic systems and databases, where required, to obtain data on adverse event cases, product safety and pharmacovigilance activities
- reviewing adverse event case documentation
- reviewing internal and external communication relevant to adverse event cases, product safety and pharmacovigilance activities
- reviewing product-related documentation relevant to adverse event cases, product safety and pharmacovigilance activities
- reviewing staff training records in relation pharmacovigilance activities

If you refuse us access to any relevant record or documentation that our inspectors have a legal right to access, this will be documented in the inspection report so we can decide on further action and consequences.

Opening meeting

Our inspection team will have an opening meeting with your representatives before the inspection begins. The lead inspector will chair the meeting.

The purpose of the opening meeting is to:

- introduce the inspection team
- explain the regulatory framework for conducting the inspection
- provide information about the inspection's scope and objectives
- clarify logistics, timeframes and other matters referred to in the inspection plan
- allow you to introduce your representatives attending the inspection
- allow you to present an overview of your pharmacovigilance system
- clarify with you whether there are any anticipated difficulties relating to the conduct of the inspection

Collecting and verifying information

Pharmacovigilance inspections examine your compliance with the relevant Australian legislation and guidelines. The scope of inspections includes, but is not limited to, the following elements as appropriate to the system being reviewed:

- adverse reaction reports
  - collection and collation of reports from all sources and sites, including but not limited to cases reported via medical information enquiries, international literature, social media and the internet, market research programs, patient support programs, voluntary patient registries, post-registration studies and partners
  - assessment (validation, seriousness, expectedness and causality), coding and processing
  - follow-up and outcome recording
  - reporting within the specified timeframes to the TGA, where required
  - record keeping and archiving.
- periodic safety update reports (PSURs)
  - completeness and accuracy of the data included, appropriateness of decisions concerning data that are not included
  - addressing safety topics, providing relevant analyses and actions
  - formatting according to requirements
  - timeliness of submissions.
- ongoing safety evaluation
  - use of relevant information sources for signal detection (including global data where relevant)
  - appropriately applied analytical methodology

- appropriateness of investigations and follow-up actions such as the implementation of recommendations following data review, including updating reference safety information
- notification to the TGA of significant safety issues that are identified internationally within the specified timeframes
- implementation and ongoing review of the Risk Management Plan and other safety commitments (this may include registries, enhanced surveillance or traceability systems)
- timely identification and provision of complete and accurate data, in particular in response to specific requests for data from us
- implementation of new/updated reference safety information, including internal distribution and external publication
- examination of processes, decision-making, communications and actions relating to a specific trigger and/or product

· pharmacovigilance system

- the integration of pharmacovigilance activities within your quality management system and your adherence to it, including quality control and quality assurance processes
- up-to-date and comprehensive policies and procedures in place regarding your role and responsibilities in relation to your pharmacovigilance system, with appropriate document control
- accuracy, completeness and maintenance of records
- quality and adequacy of training, qualifications and experience of your pharmacovigilance staff
- the fitness for purpose of computerised systems
- your contracts and agreements with all relevant parties reflect their pharmacovigilance responsibilities and activities, and are adhered to
- defined roles and responsibilities for your pharmacovigilance personnel including the QPPVA, including access to the quality system, performance metrics, audit and inspection reports, availability and their ability to take action to improve compliance.
- The QPPVA's involvement and awareness of product-specific issues.

· previous Australian pharmacovigilance inspection findings

- review of the status of the system and/or CAPA plan(s) resulting from previous pharmacovigilance inspections(s)
- review of any significant changes to the pharmacovigilance system since the last pharmacovigilance inspection (such as a change in the pharmacovigilance database, company mergers or acquisitions, significant changes in contracted activities or change of the QPPVA)
- review of process and/or product-specific issues from the assessment of information you provide, or not covered in a prior inspection.

Closing meeting

At the end of the inspection, our inspector(s) will conduct a closing meeting with your representatives. The QPPVA should ensure their team attends the meeting. The purpose of the meeting is to:

- summarise the inspection findings to ensure you clearly understand the inspection outcomes
- define the grading deficiencies, if any have been identified
- explain the procedures and timelines for distribution of our inspection report, your response and any follow-up measures
- provide you an opportunity to correct any misconceptions and misunderstandings in the findings.

An inspection may consist of visits to more than one location. If appropriate, a closing meeting may be held at each location inspected.

If the inspection is prematurely terminated due to exceptional circumstances, we will document the reason for the early termination and any deviations from the inspection plan in the inspection report.

Inspection reporting

Preparing inspection reports

Our inspection team will prepare an inspection report and associated close-out record for each pharmacovigilance system inspected.

Reporting an inspection

1. Our inspectors will issue you the pharmacovigilance inspection report and cover letter in a timely manner—normally within 30 days of completing the inspection.
2. If required, you will then be requested to prepare a corrective and preventative actions (CAPA) plan in the form of a close-out record on the template provided with the inspection report. You should provide the inspectors with the close-out record within 30 days of receiving the inspection report. On submission of the close-out record, you should also provide the inspector with comments on any major factual errors in the inspection report, as necessary. If we do not receive a response within the agreed time frame, this will be recorded in the inspection report.
3. Our inspectors will assess the close-out record and any major factual errors identified in the inspection report will be noted and corrected in the final inspection report. An assessment will be made on the impact of any comments on the inspection findings and the adequacy of the proposed CAPA and proposed time frames.
4. The assessment of the CAPA will be documented in the close-out record. If we do not accept the proposed CAPA or the proposed time frames of actions, additional follow-up and negotiation procedures will occur, until an agreement is reached.
5. We will close the inspection when we have agreed on an acceptable CAPA plan. At this point, the lead inspector will sign the final inspection report and associated close-out record and issue these to you.
6. Our inspectors may ask you for ongoing evidence of completion or updates on your CAPA activities.

Inspection report contents

The inspection report consists of five sections:

1. Inspection-related data, including
   - details of the inspected site(s) and the main site contact(s)
   - inspection details including inspection type, scope, date and the names and roles of the inspectors
2. Introduction to and summary of the inspection activities including the inspection's purpose, and background information on the sponsor and product range
3. Inspection observations and findings
4. List of any deficiencies observed during the inspection
5. Name and signature of the person authorising the report on behalf of the TGA.

Content of the close-out record

We issue a close-out record with the inspection report to incorporate your CAPA commitments and our assessment of your CAPA.

The close-out record documents:

- any deficiencies identified
- the root cause of the deficiencies
- the proposed corrective and preventative actions to the root cause
- corrections to observed examples (if relevant)
- objective evidence provided (if relevant)
- proposed completion dates of CAPAs
- any comments by the inspector
- the final response acceptance.

Inspection follow-up

When non-compliance with Australian pharmacovigilance legislation and guidelines is identified during an inspection, follow-up will be required until a CAPA plan **that appropriately addresses the non-compliance** is completed. The following follow-up actions may be initiated, as appropriate:

- meeting with you to discuss the deficiencies, their impact and your action plans
- reviewing progress reports on the corrective actions
- re-inspecting to assess appropriate implementation of the CAPA plan
- asking you to provide us with data you have not yet submitted
- requesting variations to amend product information document(s)
- impact analyses, for example following a review of data that were not previously included
- asking you to issue safety communications or amend marketing and/or advertising information
- communicating the inspection findings to other regulatory authorities, where applicable under international agreements
- taking other product-related actions depending on the impact of the deficiencies and the outcome of follow-up

Compliance and enforcement

The Regulatory Compliance Framework sets out the TGA's overall approach to compliance.

Where the pharmacovigilance inspection process identifies deficiencies we will generally, in the first instance, work with you to address the deficiencies, for example by providing you with guidance and examples of best practice where available.

If we identify significant or critical deviations where you fail to comply with pharmacovigilance requirements we can:

- cancel or suspend medicines from the ARTG for refusing or failing to comply with a condition of registration or listing, under subsections 29D(1)(b) and 30(2)(c) of the Act
- prosecute offences related to not complying with conditions of registration or listing, under Section 21A of the Act
- prosecute offences related to not complying with requirements to notify TGA of adverse effects, under Section 29A of the Act.

We publish information about regulatory compliance decisions and actions on our website.

Records management

You should ensure you have appropriate processes in place to allow for the identification, retrieval and management of all documentation relating to pharmacovigilance activities. Documentation relating to adverse events and signal management should include any measures taken to investigate the issue, the timelines for those investigations and decisions on safety concerns. Our inspectors may ask to evaluate this documentation during the inspection process.

You are required to record all pharmacovigilance information and ensure it is handled and stored in a way that allows the information to be accurately reported, interpreted and verified. This includes information related to pharmacovigilance inspections—particularly inspection reports, close-out records and records related to implementing CAPAs.

We record pharmacovigilance inspection data, including inspection plans, finalised inspection reports and close-out records, as well as any evidence of confirmed deficiencies. We handle and store this information in a way that allows it to be accurately reported, interpreted and verified. Our records management system for documents related to pharmacovigilance inspection planning and reporting ensures the documents can be retrieved, and that measures taken to investigate deviations from regulatory compliance or safety concerns can be traced.

Publishing pharmacovigilance inspection data

Reported information

We publish de-identified information on completed pharmacovigilance inspections on the pharmacovigilance inspections TGA web page; the information published will not identify individual medicine sponsor names. However, if an inspection leads to regulatory actions being taken under the Act, this information will be published in line with TGA compliance and enforcement procedures, which can include identification of the sponsor and offences for more serious contraventions of the Act and/or Regulations. The de-identified inspection information published on the PVIP pages of the TGA website may include, but is not limited to:

- the number of inspections conducted in the previous 12 months and how many were scheduled as part of the risk-based approach or were for cause inspections
- aggregate information on
  - critical findings and whether they have been resolved
  - major findings and whether they have been resolved
  - other findings and whether they have been resolved

We may include a short summary of conclusions based on the information above, particularly comparisons over time.

Reporting frequency

We expect to publish a report on our website approximately every 12 months, commencing 12 months after the implementation of our Pharmacovigilance Inspection Program.

Legal basis for pharmacovigilance inspections

You must have suitable pharmacovigilance systems in place to fulfil your pharmacovigilance responsibilities as outlined in *Pharmacovigilance responsibilities of medicine sponsors—Australian recommendations and requirements*.

We undertake pharmacovigilance inspections on the basis of the conditions in s28(5) of the *Therapeutic Goods Act 1989* and the related powers in s.46A of the Act to ensure you comply with the legislation. This legislation allows an authorised person to enter premises where pharmacovigilance documents are kept and to inspect and make copies of any documents relating to pharmacovigilance activities, for the purpose of determining whether you are complying with the Act and regulations.

In addition, under s.47 of the Act, if an authorised person has reasonable grounds for suspecting that there is evidence of an offence under the Act on the premises (for instance, material that suggests noncompliance with regulation 15A resulting in a breach of reporting requirements), they can enter the premises with consent or a warrant, seize the evidence, and require answers to any questions they put.

Grading deficiencies

Critical deficiency

A deficiency in pharmacovigilance systems, practices or processes that adversely affects the rights, safety or well-being of patients or that poses a potential risk to public health or that represents a serious violation of applicable legislation and guidelines.

Deficiencies classified as critical may include a pattern of deviations classified as major.

A critical deficiency also occurs when a sponsor is observed to have engaged in fraud, misrepresentation or falsification of data.

Major deficiency

A deficiency in pharmacovigilance systems, practices or processes that could potentially adversely affect the rights, safety or well-being of patients or that could potentially pose a risk to public health or that represents a violation of applicable legislation and guidelines.

Deficiencies classified as major may include a pattern of deviations classified as minor.

Minor deficiency

A deficiency in pharmacovigilance systems, practices or processes that would not be expected to adversely affect the rights, safety or well-being of patients.

A deficiency may be minor either because it is judged as minor or because there is insufficient information to classify it as major or critical.

Comment

The observations might lead to suggestions on how to improve quality or reduce the potential for a deviation to occur in the future.

Note:

- Deficiencies are classified by the assessed risk level and may vary depending on the nature of medicine. In some circumstances an otherwise major deficiency may be categorised as critical.
- A deficiency reported after a previous inspection and not corrected may be given higher classification.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Pharmacovigilance and Special Access Branch	September 2017

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Reference/Publication #