Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Australian Public Assessment Report (AusPAR) guidance

For prescription medicines

Version 3.0, October 2023

Contents

About this guidance

This guidance describes the information included in an Australian Public Assessment Report (AusPAR) and the circumstances under which the Therapeutic Goods Administration (TGA) publishes them.

Australian Public Assessment Reports (AusPARs)

The TGA evaluates submissions for the registration of therapeutic goods on the Australian Register of Therapeutic Goods (ARTG). An AusPAR provides information on the steps undertaken in the submission evaluation, the outcomes of each major evaluation and the reasons for any decisions.

AusPARs are prepared by the TGA and published on the TGA website (under section 61 of the *Therapeutic Goods Act 1989* (the Act)). The publication of an AusPAR is an important part of the TGA's commitment to transparency of the decision-making process.

Each AusPAR is generally a static document that provides evaluation information related to a submission at a particular point in time. The AusPAR will not be updated to reflect variations to a prescription medicine after it has been registered by the TGA, except for relevant submissions where a reconsideration of the initial decision is requested, through a section 60 review or appeal to the Australian Appeals Tribunal (AAT). A new AusPAR will be published for certain subsequent applications.

The first AusPAR was published in November 2009.

Under section 61 of the Act, the TGA can publish information about therapeutic goods. The following provisions are relevant:

- subsection 61(5A), which provides that the Secretary of the Department of Health and Aged Care can release to the public 'therapeutic goods information' relating to any decision or action taken under the Act or the regulations made under the Act.
- subsection 61(5C), which provides that the Secretary can release to the public 'therapeutic goods information' of a kind specified under Subsection 61(5D).
- subsection 61(5D), which provides that the Minister for Health and Aged Care can, by legislative instrument, specify kinds of therapeutic goods information for the purpose of subsection 61(5C).

See Specification Therapeutic Goods Information Specification 2017 for more information.

When is an AusPAR required

AusPARs are published for submissions where the significance to the public is considered to be high. An AusPAR is not published for every prescription medicine submission.

AusPARs by application type

The following table sets out the business rules we apply when deciding which submissions will receive an AusPAR by major application type. However, as highlighted above an AusPAR can be published for any submission (regardless of application type) for which the significance to the public is considered to be high.

Other than in relation to Category 1 Type A and Type B applications, the TGA will exercise discretion as to whether an AusPAR is published. For example, submissions that are considered by the Advisory Committee on Medicines (ACM) or Advisory Committee on Vaccines (ACV) are likely to get an AusPAR.

Summary of AusPAR requirements by application types

Application types		AusPAR published?
Type A	New chemical/biological entity, new salt/ester/isomer/complex/derivative of an existing active ingredient, a similar biological medicinal product	Yes
Type B	New fixed combination medicine	Yes
Type C	Extension of indications	TGA discretion
Type D	Generic medicine	TGA discretion
Type F	Major variation (new dosage form, change/increase in patient group, change in dosage, new strength, new route of administration)	TGA discretion
Type J	Variation to Register entry resulting in a change of product information requiring evaluation of clinical, nonclinical, or bioequivalence data	TGA discretion
Type S	Transition from provisional to full registration	TGA discretion
Type T	Extension of provisional registration	TGA discretion

AusPARs for approved, rejected and withdrawn submissions

For the relevant application types, an AusPAR will be published whether the submission is approved, rejected or withdrawn after a specific stage in the registration process. An AusPAR will also be published for relevant application types where a reconsideration of the initial decision is requested, through a section 60 review or appeal to the Australian Appeals Tribunal (AAT).

Approved submissions

Where approval is granted for a prescription medicine to be supplied in Australia, we will aim to publish the AusPAR **within 12 weeks** from the date the approved product is included in the ARTG. This period includes the period for the sponsor to review the draft AusPAR. An AusPAR will be published whether or not all proposals made by the sponsor in a submission are approved by the TGA.

Where a request for a section 60 review of the TGA decision to approve or partially approve an application is made by a sponsor, the AusPAR will **not** be withheld from publication pending the outcome. At the conclusion of the section 60 review the published AusPAR will be updated to include information about the outcome.

Rejected submissions

An AusPAR will be published for a submission that has been wholly rejected by the TGA. It will have a similar format to that of an approved application of the same application type.

However, publication of the AusPAR will be withheld until the end of the 90-day appeal period for a section 60 review of the TGA decision and finalisation of any such review.

If no request for section 60 review is made within the 90 days, the AusPAR will be sent out for sponsor review and published as soon as is practicable.

Where a section 60 review is undertaken, a summary of the outcomes will be included in the AusPAR before it is forwarded to the sponsor in accordance with the sponsor review process. For this purpose, publication of the AusPAR will follow the same process as for an approved submission.

Withdrawn submissions

Applicants can withdraw their submission for registration of a therapeutic good at any time before a decision is made by the TGA. We will publish an AusPAR for the withdrawn submission depending on when the withdrawal letter is received from the applicant sponsor, as outlined in the table below.

AusPAR publication indicators where a submission is withdrawn

Time of withdrawal	AusPAR required?
Submission withdrawn before acceptance of the submission by the TGA	No
Withdrawal letter is received by the TGA after acceptance but: • where any part of the submission is reviewed by the Advisory Committee* - before any response (or the due date) to the Request for Advisory Committee advice is received by the TGA from the applicant • where the submission is not reviewed by the Advisory Committee - before the end of the 14-day period for evaluation report review by the applicant, typically referred to as the review of the round 2 evaluation reports	No
Withdrawal letter is received by the TGA at any time after: • where any part of the submission is reviewed by the Advisory Committee* - after the applicant's Pre-Advisory Committee response to the Request for the Advisory Committee review is received by the TGA or if the due date for this request passes • where the submission is not reviewed by the Advisory Committee - the end of the 14-day period for evaluation report review by the applicant sponsor	Yes

* The 'Advisory Committee' refers to either the Advisory Committee on Medicines (ACM) or the Advisory Committee on Vaccines (ACV), depending on the nature of the medicine.

Review by the Administrative Appeals Tribunal (AAT)

If following a section 60 review of a TGA decision, the sponsor subsequently seeks a review by the Administrative Appeals Tribunal of the decision of the Minister (or the Minister's delegate), the AusPAR will **not** normally be withheld from publication.

However, an appropriate notation will be made in the AusPAR indicating that the section 60 appeal decision is under AAT review.

Following the outcome of the AAT review, the AusPAR will be updated to indicate the outcome only. The AusPAR will not include an explanation of, or reasons for AAT decisions as these decisions are not made under the Act.

Typical components

An AusPAR is divided into 5 sections:

1. List of abbreviations
    - lists abbreviations used in body text of the AusPAR

2. Product submission
   - includes submission details, product background and regulatory status
3. Registration timeline
   - details the major milestone dates reached in the application and decision process
4. Submission overview and risk/benefit assessment
   - The decision makers overview of any quality, nonclinical, clinical findings, risk management plan and a risk-benefit analysis
5. Outcome
   - The TGA's decision and any specific conditions of registration applying to these goods as well as the AAT outcome where applicable

AusPARs for approved submissions also have one or more attachments:

- the Product Information (PI) document/s approved with the submission described in the AusPAR.

Product submission

Submission details

Submission details provides an overview of the product.

This section includes application type, product name(s), active ingredient(s), decision, date of decision, date of entry onto ARTG if relevant, ARTG number(s) if relevant, black triangle scheme status for the current submission, sponsor's name and address, dose form(s), strength(s), container(s), pack size(s), approved therapeutic use for the current submission, route(s) of administration, dosage, and pregnancy category.

Product background

Product background typically include a description of the disease and its prevalence in Australia, therapies currently approved for use in Australia, clinical need, and the product's mechanism of action.

For any Australia-Canada-Singapore-Switzerland-United Kingdom (ACCESS) workshare, Project Orbis or Comparable Overseas Regulator (COR) submissions, the product background will also include names of foreign Regulatory Agencies that collaboratively reviewed the submission with the TGA or whom the TGA received evaluation reports from.

Regulatory status

Regulatory status describes the regulatory status of the product internationally.

For a product that is not considered a new chemical entity or a new biological entity, the Regulatory status may also include a summary of previous approvals of the product in Australia.

Indications of the product that received orphan drug designation will also be included if relevant.

Registration timeline

The registration timeline captures the key steps and milestone dates for the submission.

Submission overview and risk/benefit assessment

The submission overview provides a critical appraisal and summation of the quality, nonclinical and clinical data relevant to the submission, and any recommendations made by the evaluation areas. It also summarises the safety concerns and associated risk monitoring and mitigation strategies as part of the risk management plan.

Risk-benefit analysis summarises the considerations of the Delegate of the Secretary of Department of Health and Aged Care (the Delegate) when making the final decision. It also includes the action (approval or rejection) proposed by the Delegate, questions for the sponsor to address as well as any advice sought by the Delegate from an Advisory committee or independent experts.

Outcome

For approved submissions, the outcome section summarises the details of the approved product, the approved indication(s) and the specific conditions of registration that apply to the product.

For withdrawn submissions, the outcome section includes the date that the sponsor withdrew their submission.

For rejected submissions which were reviewed under section 60 of the *Therapeutics Goods Act 1989*, an excerpt from the section 60 Delegate's decision letter is included. If the sponsor has at this stage made an application to the AAT for a review of the decision this will also be indicated in this section. The outcome of AAT appeal will be added to the published AusPAR when known.

Information sources

The information sources used in an AusPAR include the approved Product Information (PI), ARTG entry, evaluation reports, Delegate's Overview, Advisory Committee advice, independent expert advice, sponsor submitted application details and sponsor's response to Delegate's questions.

Commercially confidential information and personal information

As the AusPAR is a publicly available document, it is essential that any commercially confidential information (CCI) and personal information be identified and where appropriate removed prior to publication.

How we identify and treat CCI and personal information

Information on how we identify and treat CCI and personal information when drafting an AusPAR is available at Guidance for the deletion of commercially confidential and personal information in an AusPAR.

Literature based submissions

Applications to register a prescription medicine can under some circumstances be literature-based submissions or partially literature-based ('hybrid' applications).

AusPARs for literature-based submissions may contain details of published literature references submitted by the sponsor. As published literature is already in the public domain, they are not considered to be CCI. The published information is considered to form part of the drug development process and informs the TGA's decision, and there is a public interest in making this information available.

Details relating to the literature search strategy and analysis are not published in AusPARs as these could be considered confidential intellectual property.

Sponsor review

Sponsors have 7 calendar days to undertake an initial review of the draft AusPAR and identify any information considered to be CCI or personal information. If the review identifies significant issues that require resolution, the TGA will provide the sponsor with additional time (2 to 7 calendar days) to review the TGA's response.

Sponsors must justify any claims that information is CCI or personal information which they seek to be excluded from an AusPAR. Sponsors are required to carefully consider the definitions of CCI and personal information in crafting their justification.

It is not possible however, for the comments and conclusions of evaluators, the Delegate or the Advisory Committees and the final outcome of the submission to be edited as they are an integral part of the decision process, except for correction of errors and removal of CCI or personal information.

Outcome of sponsor review of a draft AusPAR

Following a sponsor's review of a draft AusPAR, the TGA will review any proposed changes relating to the removal of CCI by a sponsor.

Where there are significant disagreements about the proposed removal of CCI content, we will apply an internal review process. The sponsor will be asked to provide a request/justification in writing for the removal of the content which will be referred internally for advice (as needed) prior to a final decision being made.

The internal review process is undertaken with the aim of publishing the completed AusPAR **within 12 weeks** from the date the product is included on the ARTG (for approved submissions).

For more information on publishing timeframes see AusPARs for approved, rejected and withdrawn submissions.

Failure to respond within AusPAR review period

If there is no response from a sponsor to a TGA request to review a draft AusPAR, the TGA reserves the right to publish the finalised AusPAR without further reference to the sponsor.

AusPAR quality assurance process

Following sponsor review, and prior to publication, the AusPAR undergoes a quality assurance (QA) process to conduct final checks for accessibility and compliance with Government requirements. This process has been in place since 2009 when AusPAR production began. Any major changes to the AusPAR that occur during the QA process are communicated to the sponsor via email prior to publication. Minor changes will not be communicated to the sponsor prior to publication.

How to access AusPARs and other relevant information

Searching AusPARs

AusPARs are published on the TGA website.

Product Information (PI)

A copy of the PI approved with the submission is included as an attachment to the AusPAR document when it is published by the TGA. This version of the PI will remain static (similar to the AusPAR) and will be 'watermarked' to ensure that this is clear to the reader that any later version of the approved PI is available via the TGA eBusiness Services system.

Publishing the approved PI with the AusPAR does not replace the requirement for the sponsor to load their PI, and Consumer Medicine Information (CMI) documents onto the TGA eBusiness Services system.

Release of AusPAR to Therapeutic Guidelines Ltd

The Therapeutic Goods (Prescription Medicines—Sharing of AusPARs) (Information) Specification 2023 allows the TGA to provide information from an AusPAR to Therapeutic Guidelines Ltd (TG Ltd) prior to its publication on the TGA website. This is to assist with the preparation of comments on newly registered medicines for publication in the Australian Prescriber.

We will only provide this information to TG Ltd after the review process with the sponsor has been completed.

Extracts from the AusPAR will not be published in Australian Prescriber before the AusPAR is published on the TGA website.

Version history

Version	Description of change	Author	Effective date
V1.0	Approved for TGA web publishing	BPR Project	October 2010
V1.1	Approved for TGA web publishing	Medicines Authorisation Branch	February 2015
V1.2	Formatting for web publishing	Medicines Authorisation Branch	March 2015
V2.0	Updates to reflect streamlined AusPAR format specifically the 7-day sponsor review timeframes, minor edits and formatting changes to increase readability and removal of the Appendices.	Prescription Medicines Authorisation Branch	July 2021
V3.0	Updates include detailed components of the AusPAR, the release of AusPARs to Therapeutic Guidelines Ltd instead of NPS MedicineWise, as well as the types of applications that receive AusPARs.	Prescription Medicines Authorisation Branch	October 2023

Therapeutic Goods Administration

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Reference/Publication #