Australian Government
Department of Health
Therapeutic Goods Administration

Australian Public Assessment Report (AusPAR) guidance document

For prescription medicines

Version 1.5, March 2015

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <http://www.tga.gov.au>.

About AusPARs

- An Australian Public Assessment Record (AusPAR) provides information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve a prescription medicine submission.
- AusPARs are prepared and published by the TGA.
- An AusPAR is a static document, in that it will provide information that relates to a submission at a particular point in time.
- A new AusPAR will be developed to reflect changes to indications and/or major variations to a prescription medicine subject to evaluation by the TGA

Version history

Version	Description of change	Author	Effective date
V1.2	Published on TGA website	Office of Medicines Authorisation	October 2010
V1.3	Minor edits to links and reformatted	Medicines Authorisation Branch	March 2015

Contents

1. Introduction

The Therapeutic Goods Administration (TGA) evaluates applications for the registration of prescription medicines for entry on the Australian Register of Therapeutic Goods (ARTG).

The Australian Public Assessment Report (AusPAR) includes information on the outcome of the evaluation process and the rationale for the decision to register or to reject registration. The AusPAR is published on the TGA website. The publication of an AusPAR is an important part of the transparency of the TGA's decision-making processes.

The TGA currently publishes an AusPAR for the majority of applications under the category of "major submission" for the inclusion of a prescription medicine on the ARTG. This includes submissions for new chemical and biological entities, extension of indication/s, and significant variations to already registered prescription medicines. More details on the submission types in relation to which AusPARs are published are listed under *Section 4.1- AusPARs by application type*.

The AusPAR is a static document that is submission specific. It records TGA's consideration of a submission for that prescription medicine at a specific point in time of the regulatory process. The AusPAR is not intended to be updated to reflect variations to a prescription medicine after it has been registered. A new AusPAR will be published where an application is subsequently made for an additional indication and may be published where an application is later made for major variation.

The first AusPAR was published in November 2009 as part of TGA's implementation of the increased transparency strategy under the Business Process Reforms for Prescription Medicines. The TGA's approach to AusPARs is consistent with similar transparency measures introduced within the European Union and United States.

2. Legislative framework

Under 61 of the *Therapeutic Goods Act 1989* (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 can release to the public 'therapeutic goods information'[1] 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 can, by legislative instrument, specify kinds of therapeutic goods information for the purpose of subsection 61(5C).

The *Therapeutic Goods Information Specification 2015* (the 2015 Specification) is a legislative instrument made by a delegate of the Minister under subsection 61(5D) and replaces the *Therapeutic Goods Information Specification 2009*. The 2015 Specification sets out various kinds of therapeutic goods information that can be released to the public by the Secretary under subsection 61(5C) and refers to the kind of information included in an AusPAR. A copy of the instrument is at Appendix 1.

[1] 'Therapeutic goods information' means information in relation to therapeutic goods that is held by the Department of Health and relates to the performance of the Department's functions (see subsection 61(1) of the Act).

3. AusPAR description

3.1 AusPAR structure

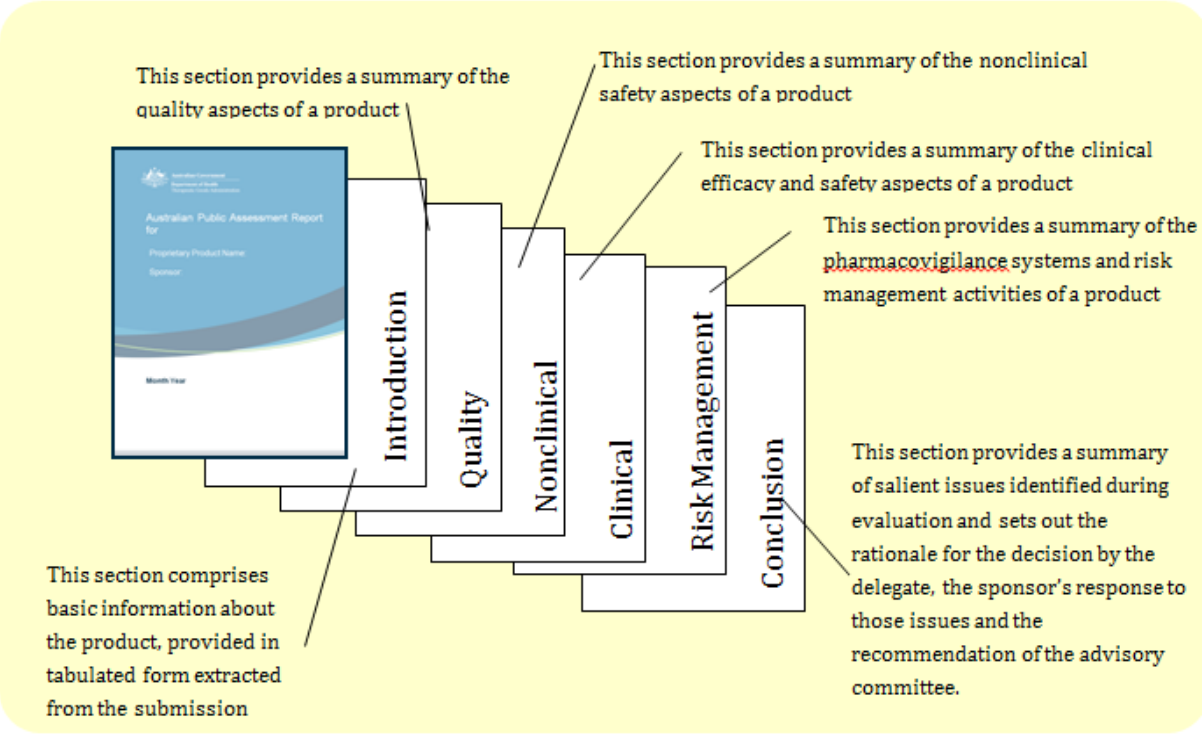
An AusPAR records the steps undertaken by the TGA in the evaluation of the application to register a prescription medicine, the outcomes of each step and describes the reasons for any decision on the application by the TGA.

The structure and content of an AusPAR may vary according to a range of factors such as:

- **the submission / product type** – this is the matter to which the submission relates (as described in **Table 1**)
- **the process** – the submission may have been referred to an expert advisory committee, for example the Advisory Committee on Prescription Medicines (ACPM) and/or the Pharmaceutical Subcommittee of ACPM
- **the substance type** – whether the submission relates to a radiological agent, radiopharmaceutical, certain vaccines, or a range of other substances
- **the nature of the process** – if the decision or other information relating to the evaluation changes as a result of a review or appeal.

The component sections of an AusPAR for submissions such as new chemical entities are described in **Figure 1** below.

Figure 1. Typical AusPAR components



The AusPAR also has two attachments:

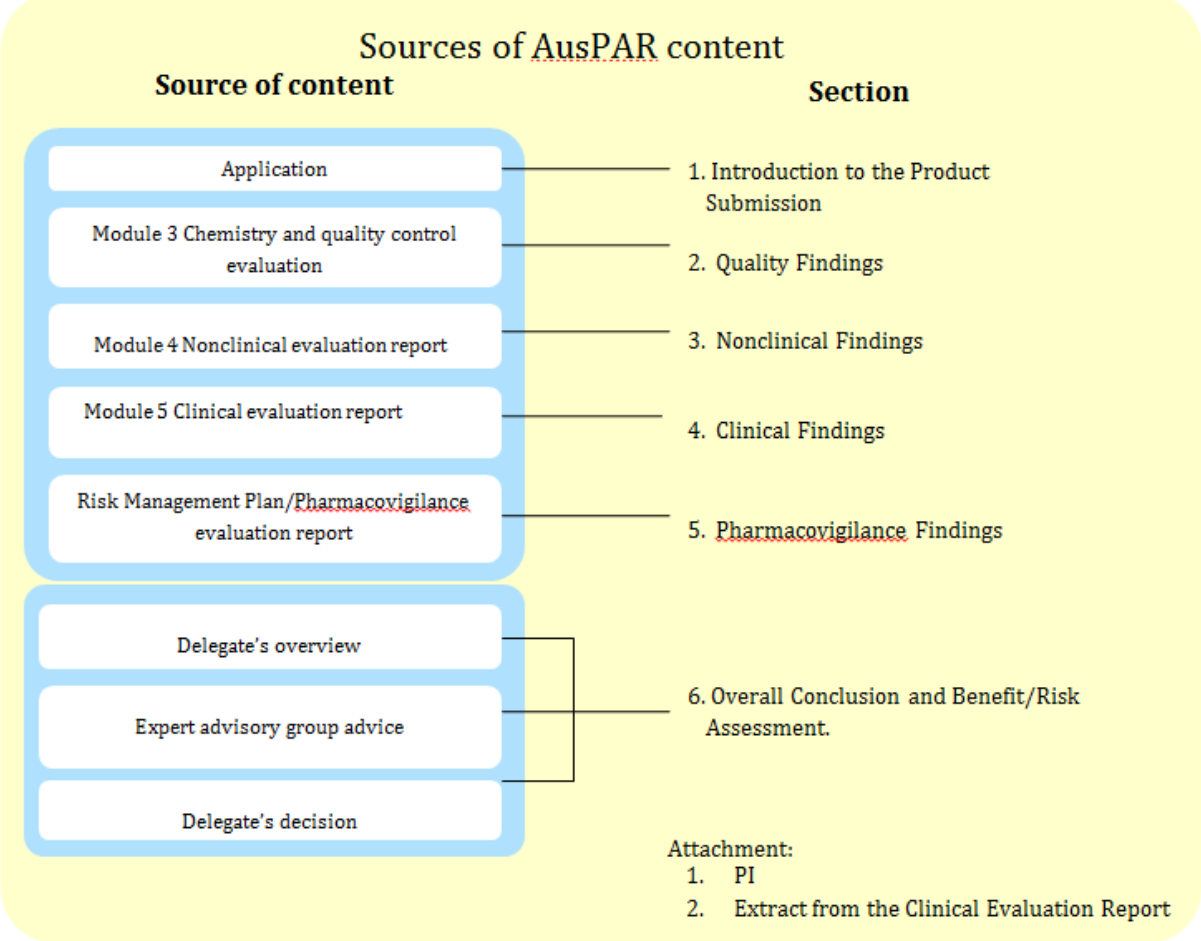
- Attachment 1: The approved Product Information as at the time the AusPAR was prepared and first published.

- Attachment 2: Extract from the clinical evaluation report containing more details of the clinical findings.

3.2 AusPAR content

Depending on the submission type, an AusPAR is compiled by the TGA using key components and stages of the evaluation and assessment process as shown below in **Figure 2**.

Figure 2. AusPAR sources of content



3.3 Commercially confidential information and personal information

Guidance on the classification of commercially confidential information is provided at Appendix 2 - Principles to be applied for the deletion of commercially confidential information and personal information in an AusPAR.

It provides guiding principles and procedural direction to assist the TGA and a sponsor to identify what information may be considered for removal by the TGA from a draft AusPAR. See also *Section 5 – Sponsor consultation*.

4. AusPAR business rules

4.1 AusPARs by application type

The regulatory framework for prescription medicines describes applications in accordance with the category and type groupings as set out in **Table 1**.

Not all prescription medicine applications require an AusPAR as in many cases the significance of the change to a medicine previously approved by the TGA is low and therefore does not warrant the development of an AusPAR to detail the regulatory decision. The approved Product Information (PI) will accurately reflect the outcome of such decisions.[2]

The following table sets out the business rules the TGA applies to ensure a consistent approach to the AusPAR development by application type. The TGA retains discretion to decide on certain applications and this is indicated in the table.

AusPARs will not normally be published for applications that are not considered by ACPM. Thus an AusPAR will not normally be published for a generic medicine application. Other than in relation to Type A, Type B and Type C applications, the TGA will exercise a discretion as to whether an AusPAR is published, even if an application was considered by ACPM.

Table 1. Summary of AusPAR required by application category and types

Application categories and types		**AusPAR**		
		Yes	No	TGA discretion
Category 1 and 2 applications[3]				
Type A	New chemical or biological entity	✓		
Type A	New salt/ester of previously approved active ingredients	✓		
Type A	Biosimilar medicine	✓		
Type B	New combination of previously approved active ingredients	✓		
Type C	Extension of indications	✓		
Type D	Generic medicines			✓
Type E	Major Variation - Additional trade name		✓	

[2] Under the Act, the Secretary is required, when approving product information, to be satisfied that it reflects the basis on which the Secretary decided to register the medicine: subsection 25AA(1).
[3] Applications are made under section 23 of the Act (for a new entry in the ARTG) or a request made under subsection 9D(3) of the Act (for a variation to the entry of a registered prescription medicine which requires the evaluation).

Application categories and types		AusPAR		
		Yes	No	TGA discretion
Type F	Major Variation - New medicinal product strength			✓
Type F	Major Variation - New dosage form			✓
Type F	Major Variation - New route of administration			✓
Type F	Major Variation - Change/increase in patient group			✓
Type F	Major Variation -Change in dosage			✓
Type J	Change to ARTG entry - Change to Product Information requiring the evaluation of clinical, non-clinical or bioequivalence data		✓	
Category 3 applications				
Type G	Minor Variation - Change of formulation (excipients)		✓	
Type G	Minor Variation -Change in trade name		✓	
Type G	Minor Variation -change of container		✓	
Type H	Change to ARTG entry – minor editorial change to Product Information NOT requiring evaluation		✓	

4.2 AusPARs for approved, rejected and withdrawn submissions

Where approval is given for a prescription medicine to be supplied in Australia (whether or not all proposals in the submission were approved), the TGA will aim to publish the AusPAR **within 12 weeks** from the date the approved product is included on the ARTG. This period includes the 14 day sponsor review period of the draft AusPAR.

An AusPAR will be published where a submission is approved in any aspect.

The mechanism by which a sponsor can seek a review of a TGA decision made under section 25 of the Act is described in the document *Australian Regulatory Guidelines for Prescription Medicines.* A sponsor has 90 days from notification of a decision in which to request a review of the decision by the Minister (a section 60 review). This applies to all decisions (approval and rejection decisions) made by a Delegate. The sponsor can also seek such a review of a TGA decision made under section 25AA in relation to product information.

Where a request for a section 60 review of the Delegate's decision under section 25 or 25AA is made by a sponsor, the AusPAR will **not** be withheld from publication pending the outcome. The Minister's delegate has 60 days to make a decision on the review.

As indicated above, the TGA will aim to publish the AusPAR within 12 weeks from the time the product was included on the ARTG. In this situation, full details of the approved aspect(s) will be published. For any aspect(s) of the submission that were not approved (for instance, an indication was not approved), only the nature of that decision will be mentioned. Where relevant, appropriate notation will be made on the AusPAR and on the TGA website indicating that the decision is under review.

At the conclusion of the section 60 review the published AusPAR will be updated to include information about the outcome (e.g. whether the initial decision was upheld or not). The sponsor will also be given an opportunity to review the updated AusPAR before publication in accordance with the sponsor consultation process (see *Section 5 – Sponsor consultation*).

If the sponsor then seeks a review by the Administrative Appeals Tribunal (AAT) of the decision of the Minister's delegate the updated AusPAR will **not** normally be withheld from publication. However an appropriate notation will be made on the AusPAR and on the TGA website 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. However, as the AAT decision is not made under the Therapeutic Goods Act, the AusPAR will not include an explanation of, or reasons for, that decision. Decisions of the AAT are published at http://www.austlii.edu.au/au/cases/cth/AATA/.

4.2.1 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 submission type.

The publication of the AusPAR will however be withheld pending the expiration of the 90 day appeal period for a section 60 review 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 consultation and published as soon as practicable.

A summary of the outcome of any section 60 review will be included in the AusPAR before it is forwarded to the sponsor in accordance with the sponsor consultation process (see *Section 5 – Sponsor consultation*). For this purpose, publication of the AusPAR will follow the same process as for an approved submission.

If the sponsor then seeks a review by the AAT of the decision of the Minister's delegate the updated AusPAR will **not** normally be withheld from publication. However an appropriate notation will be made on the AusPAR and on the TGA website indicating that the section 60 decision is under AAT review.

Following the outcome of the AAT review, the AusPAR will be updated to indicate the AAT outcome. However, as the AAT decision is not made under the Therapeutic Goods Act, the AusPAR will not include an explanation of, or reasons for, that decision. Decisions of the AAT are published at http://www.austlii.edu.au/au/cases/cth/AATA/.

4.2.2 Withdrawn submissions

An applicant for registration of therapeutic goods can withdraw a submission at any time. The TGA will publish an AusPAR for the withdrawn submission depending on when the withdrawal letter is received from the sponsor as outlined below in **Table 2**.

Table 2. AusPAR publication indicators where a submission is withdrawn

Time of withdrawal	AusPAR	
	Yes	No
Submission withdrawn before acceptance of the submission by the TGA		✓
Withdrawal letter is received by the TGA after acceptance but: • where any part of the submission is reviewed by ACPM - before any response to the Request for ACPM advice is received by the TGA from the applicant sponsor • where the submission is not reviewed by ACPM - before the end of the 14 day period for evaluation report review by the applicant sponsor		✓
Withdrawal letter is received by the TGA at any time after: • where any part of the submission is reviewed by ACPM - after the applicant sponsor's Pre-ACPM response to the Request for ACPM review is received by the TGA • where the submission is not reviewed ACPM - the end of the 14 day period for evaluation report review by the applicant sponsor	✓	

4.3 Content considerations for specific application types

4.3.1 For new chemical or biological entity

The AusPAR for a new chemical or biological entity (Type A in **Table 1** above) will generally contain all of the sections of content listed in **Figure 2** (above) reflecting the TGA's assessment of all aspects of a new product.

4.3.2 For new indications for a registered medicine

Indications for therapeutic goods are defined in the Act as 'the specific therapeutic uses of the goods'.[4] The content of AusPARs for new indications (Type C in **Table 1** above) is dependent on the complexity and range of data submitted by the sponsor to support the change in indications.

4.3.3 For major variation to a registered medicine

Examples of Type F in **Table 1** above (major variations to registered goods) would include an application to delete a contraindication or precaution and some changes to the clinical trials section of the product information (PI). The content of AusPARs for these submissions is dependent on the complexity and range of data submitted by the sponsor to support the major variation. The TGA will exercise a discretion as to whether an AusPAR is published for Type F applications even if the application was considered by ACPM (see **Table 1**).

4.3.4 For literature based submissions

Applications to register a prescription medicine can under some circumstances be 'literature-based submissions' (LBS) or partially literature-based (so called 'hybrid' applications). The content of the AusPARs for these submissions may contain published literature references submitted by the sponsor as they are not considered to be commercially confidential

[4] See subsection 3(1) of the Act.

information because the references are already in the public domain. The published information is considered to form part of drug development and the Delegate's decision and there is a public interest in making this information available.

Details of methodology and literature search strategy, the analysis of the literature search output will however not be published in an AusPAR as these could be considered as confidential intellectual property.

See further at *Section 3.3*, *Section 5* and Appendix 2 in relation to commercially confidential information.

4.3.5 For 'generic' biological products or similar biological medicinal products

'Generic' biological products are referred to as 'similar biological medicinal products' (SBMPs) or 'biosimilars' in recognition of the fact that due to the complexity of their molecular structure and manufacturing it is not possible to produce true generic versions (Type A in **Table 1** above).

Unlike for small molecule drugs (where a generic manufacturer is usually required to demonstrate bioequivalence between the generic and innovator products using pharmacokinetic criteria), the sponsor of an SBMP is also required to provide data to demonstrate equivalent efficacy and safety. The AusPAR document for an SBMP will therefore reflect the difference in the number and nature of studies and evaluations that are required for an SBMP to be approved for registration compared to a true generic.

5. Sponsor consultation

5.1 Scope

Once an AusPAR for a product is drafted by the TGA, the sponsor is given the opportunity to review the document prior to it being published so that any information that may be commercially confidential information (CCI) or personal information can be identified. Although permitted to be released under subsections 61(5C) and 61(5D) of the Act, the TGA may decide not to include this information in the document to be published. See Appendix 2 of this Guidance document for further clarification of the management of CCI and personal information.

A sponsor must justify any assertion that information is CCI or personal information which it seeks to be excluded from the 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 of evaluators, the Delegate or the advisory committee to be edited because they are an integral part of the evaluation and decision process.

Completion of an AusPAR is independent from other regulatory processes - the Delegate's decision, marketing approval, and related regulatory processes are not dependent on finalisation of an AusPAR.

5.2 Outcome of review of 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. Should there be disagreement about the proposed removal of CCI content, an internal review process will be applied by the TGA. The sponsor will be asked to provide a request/justification in writing for the removal of the content which will be referred 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. More details about publishing timeframes for an AusPAR, based on whether the AusPAR is approved, not approved or the submission is withdrawn are in the *Section 4.2 - AusPARs for approved, rejected and withdrawn submissions* and *Section 6 – AusPAR publishing*.

5.3 Review period

The TGA provides a sponsor with 14 calendar days to undertake a review of the draft AusPAR and identify any information that it believes is CCI that it does not want published in an AusPAR. If the review identifies significant issues which require resolution, the TGA will respond and provide the sponsor with an additional 3-7 calendar days to review the TGA response.

5.4 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.

6. AusPAR publishing

The timeframe for the publication of an AusPAR for a prescription medicine by the TGA depends on whether the submission is approved or not approved by the Delegate under section 25 of the Act or whether and when the submission is withdrawn by the sponsor prior to a decision by the Delegate. The circumstances for publishing an AusPAR and applicable timeframes are provided in the relevant sections above.

6.1 TGA website location and search functionality

AusPARs published by the TGA are located at https://www.tga.gov.au/australian-public-assessment-reports-prescription-medicines-auspars

They can be searched by the following fields:

- active ingredient
- product name
- sponsor.

6.2 Product Information

To ensure the AusPAR can be read in conjunction with the relevant approved Product Information (PI), a copy of the approved PI is included in 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 PI/CMI publishing facility at https://www.ebs.tga.gov.au/.

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.

6.3 Release of AusPAR to NPS MedicineWise

The Secretary can, by reason of the *Therapeutic Goods Information (Sharing of Information about Prescription Medicines) Specification 2015* provide information set out in an AusPAR to NPS MedicineWise prior to the publication of the AusPAR on the TGA website for the purpose of assisting in the preparation of comments on newly registered medicines for publication in the *Australian Prescriber*.

The information will only be provided after the consultation process with the sponsor has been completed and extracts from the AusPAR will not be published in Australian Prescriber before the AusPAR is published on the TGA website. Sponsors will be informed that the AusPAR will be provided to NPS MedicineWise following its finalisation.

The Specification can be found at https://www.tga.gov.au/therapeutic-goods-information-specifications.

Appendix 1

Therapeutic Goods Information Specification 2015

Therapeutic Goods Act 1989

I, JOHN SKERRITT, a delegate of the Minister for Health make this Specification, under subsection 61(5D) of the *Therapeutic Goods Act 1989*.

Dated 23 January 2015

(Signed by)

JOHN SKERRITT

Delegate of the Minister for Health

1 Name of Specification

This Specification is the *Therapeutic Goods Information Specification 2015.*

2 Commencement

This Specification commences on the day after it is registered.

3 Definitions

In this Specification:

Act means the *Therapeutic Goods Act 1989*.

Register means the Australian Register of Therapeutic Goods.

Regulations means the Therapeutic Goods Regulations 1990.

TGA means the Therapeutic Goods Administration which is part of the Department of Health.

4 Therapeutic goods information

The kinds of therapeutic goods information in Schedule 1 are specified under subsection 61(5D) of the Act for the purposes of subsection 61(5C) of the Act.

Schedule 1 Specified kinds of therapeutic goods information
(section 4)

The following kinds of therapeutic goods information:

Note: The following specified kinds of therapeutic goods information may be released by the Secretary to the public under subsection 61(5C) of the Act.

1 Product information approved by the Secretary under subsection 25AA(1) or 25AA(4) of the Act in relation to therapeutic goods.

2 Information required by regulation 9A or 9B of the Regulations to be supplied with certain therapeutic goods.

3 Information in documents prepared for the purpose of evaluating therapeutic goods under subsection 25(1) or subsection 9D(3) of the Act.

4 Information in relation to post-market pharmacovigilance requirements imposed by the Secretary under section 28 of the Act as a condition of registration on therapeutic goods or by a regulation made for the purposes of paragraph 28(5)(e) of the Act.

5 Information in documents relating to assessments made of the pharmacovigilance system, quality and non-clinical and clinical data in relation to therapeutic goods for the purpose of evaluating those goods under subsection 25(1) or subsection 9D(3) of the Act.

6 Information in documents included in a request of the Secretary to:

- the Advisory Committee on Prescription Medicine (ACPM) or its sub-committees (including the Pharmaceutical Subcommittee) or
- the Advisory Committee on the Safety of Medicine (ACSOM) or its sub-committees, or
- the Advisory Committee on the Safety of Vaccines (ACSOV),

seeking advice in relation to the evaluation of therapeutic goods under subsection 25(1) of the Act or subsection 9D(3) of the Act, including in relation to post-market pharmacovigilance requirements and the continued suitability for registration of therapeutic goods.

7 Information in the minutes or outcomes of ACPM or its subcommittees, ACSOM or its sub-committees or ACSOV, about the evaluation of therapeutic goods under subsection 25(1) or subsection 9D(3) of the Act, including in relation to post-market pharmacovigilance requirements.

8 Information in the minutes or outcomes of any other expert committee established by the Regulations about the suitability for inclusion in the Australian Register of Therapeutic Goods of therapeutic goods the subject of an application for approval.

9 Information in any written decision made under subsection 25(3) of the Act in relation to the registration of therapeutic goods, including the reasons for the decision.

10 Information in any written decision under section 60 of the Act on a review of a decision under subsection 25(3), subsection 9D(3), or subsection 25AA(1) or 25AA(4), of the Act, in relation to therapeutic goods.

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislation kept under the *Legislation Act 2003*. See https://www.legislation.gov.au/.

Appendix 2

Principles to be applied for the deletion of commercially confidential information and personal information in an AusPAR

1 Introduction

Content for an AusPAR is derived from various outputs of the assessment and decision-making processes. Given that 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.

This document provides general principles to confirm the approach by TGA to the identification and treatment of CCI and personal information in the drafting of the AusPAR. While the sponsor is afforded the opportunity to review the draft AusPAR, the TGA expects the sponsor to only raise concerns about AusPAR content from a CCI or personal information perspective, if it believes there is a justification for an exception to the general principles provided in this guide.

This guide and the approach of the TGA reflect compliance with the considerations that give rise to the commercial exemptions in the *Freedom of Information Act 1982* and relevant privacy principles.

Openness and transparency of the regulatory process is important in the promotion of public health. However, unless there is an overriding public interest in disclosure, the TGA will refrain from disclosing CCI or personal information.

2 General principles – commercially confidential information (CCI)

The TGA's approach to the release of information is set out in the *TGA Approach to disclosure of commercial in confidence information (CCI)* (https://www.tga.gov.au/publication/tga-approach-disclosure-commercially-confidential-information-cci).

'Commercially confidential information' means any information which:

- is not in the public domain or legally publicly available; and
- where disclosure may undermine or prejudice the economic interest or competitive interests of the owner of the information.

These principles will be applied so that CCI can be deleted prior to publication of an AusPAR.

It should be noted that CCI is not determined by a sponsor marking information as CCI when provided to the TGA as part of a submission dossier or otherwise as part of the assessment or related process. In all instances the above definition will apply.

Information that is already in the public domain, or comes into the public domain prior to the publication of the AusPAR, is not considered commercially confidential. This includes published references or compiled searches for information submitted in support of an application to register a prescription medicine.[5] If information has been in the public domain through a breach of the law, it could still be considered confidential in accordance with the principles of this document. However, the onus is on an owner of the information to inform the TGA (in writing) of the breach.

[5] See also material at *Section 4.3.4 – For literature based submissions*.

For the purposes of AusPARs, the TGA has adopted the EMA approach which broadly defines the following two categories of information considered CCI:

- confidential intellectual property, "know-how" and trade secrets (including for example formulas, programs, process or information contained or embodied in a product, unpublished aspects of trademarks, patents etc.); and
- commercial confidences (e.g. details of commercial arrangements, development plans of a company).

3 Information on the quality and manufacturing of medicines

In general, detailed information in relation to the matters described below may be CCI but more general information should be disclosed. It may be however that in certain circumstances, even a general description of a specific aspect could be regarded as CCI, if justified.

4 Composition and product development

In general, pharmaceutical development information for new products is CCI. This includes detailed data concerning active substances, formulation and manufacturing and test procedures and validation.

In general, the names of manufacturers or suppliers of the active substance or the excipients are CCI unless disclosure is necessary for public health reasons (e.g. for some biological products).

The final qualitative formulation (composition) of the authorised product is not CCI.

5 Active substances

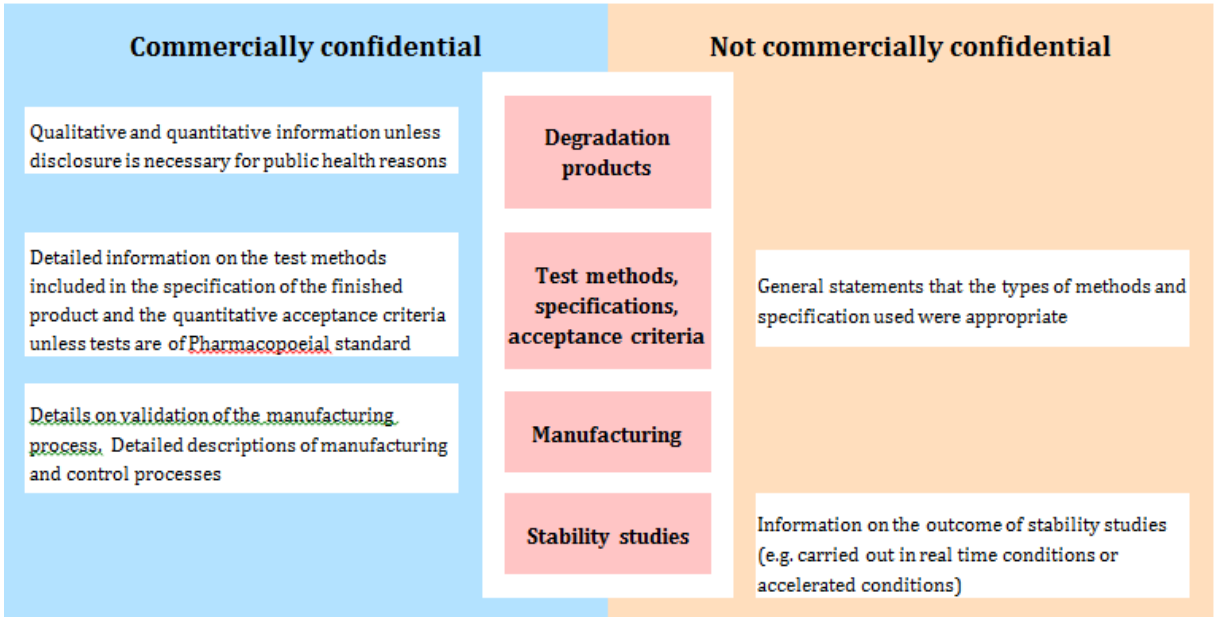
The principles contained in the diagram below (**Figure 3**) apply to pharmaceutical and biological products and also to novel excipients.

Figure 3. Classification of commercially confidential information for active substances

6 Finished product

The principles contained in the diagram below (**Figure 4**) apply to pharmaceutical and biological products. Any confidentiality issue regarding novel packaging or medical device aspects should be justified by the sponsor and will be assessed according to the below principles.

Figure 4. Classification of commercially confidential information for finished product



7 Nonclinical and clinical information

As a general rule, information encompassing nonclinical and clinical development and its subsequent assessment by TGA is not CCI, examples include:

- data generated by the sponsor using another sponsor's product, e.g. comparative studies against the reference medicinal product are not CCI by virtue of this is fact only. However the commercial confidentiality of such data shall be assessed in accordance with the principles set out in this document
- published references submitted in support of an application to register a prescription medicine are also not CCI
- information related to environmental risk assessments and risk management plans.

Examples of CCI include:

- specific details on a method used in a study, which, upon justification from the sponsor, could be regarded as trade secret
- development plan from the company, e.g. for a different indication, when it is neither requested by TGA nor related to the safety of the product would also be CCI.

However, when such studies, their results and their timelines are part of the conditions for ARTG approval, they are not regarded as CCI.

8 Information on inspections

Information on the outcome of inspections is not CCI, however specific a detail regarding facilities and equipment is considered to be CCI.

9 Contractual agreements

Contractual agreements between individuals or organisations are generally considered CCI. Where contracts exist between companies and contract research organisations that have

contributed to or are responsible for important information included in the dossier, they are generally not CCI.

10 Scientific advice

All information about new developments and formulations are CCI.

11 Pharmacovigilance information

Generally, a quantitative description of the sponsor's proposed pharmacovigilance activities is not considered to be CCI. However, detailed descriptions of the pharmacovigilance system can at times be considered confidential if they contain individual patient data or business strategies such as planned studies or commercial agreements involving other companies or organisations.

12 List of references and original manuscripts

The list of references of the publications included in the dossier, or subsequent assessment processes is not CCI. An exception is if the actual manuscripts are included and they are subject to copyright.

13 Personal information

"Personal information" refers to information or an opinion about an identified individual, or an individual who is reasonably identifiable:

a. whether the information or opinion is true or not; and

b. whether the information or opinion is recorded in a material form or not.[6]

Personal information is not normally included in an AusPAR.

[6] See definition in subsection 6(1) of the *Privacy Act 1988*.

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Reference/Publication #