



Australian Government

Department of Health

Therapeutic Goods Administration

Guidance for the deletion of commercially confidential and personal information in an AusPAR

For prescription medicines

Version 1.0, July 2021

TGA Health Safety
Regulation

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About this guidance

This guidance applies to sponsors of [prescription medicines](#) in Australia and outlines how TGA identifies and treats commercially confidential information (CCI) and personal information in drafting an Australian Public Assessment Report (AusPAR).

This guidance 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.

CCI and personal information in an AusPAR

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

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

Commercially confidential information (CCI)

Information on what is CCI and our approach to the release of CCI to the public is available at [TGA Approach to disclosure of commercial in confidence information \(CCI\)](#).

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and trade secrets (for example formulas, programs, process or information contained or embodied in a product, unpublished aspects of trademarks, patents and similar);
- commercial confidences (for example details of commercial arrangements, development plans of a company).



Information that is already in the public domain, or comes into the public domain prior to the publication of an 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.

If information has been in the public domain through a breach of the law, it could still be considered confidential. However, the onus is on an owner of the information to inform the TGA in writing of the breach.

Unless there is an overriding public interest in disclosure, the TGA will refrain from disclosing CCI or personal information.

Information on the quality and manufacturing of medicines

In general, detailed information in relation to the matters described below may be CCI.

More general information should be disclosed. However, in certain circumstances even a general description of a specific aspect could be regarded as CCI, if justified.

Composition and product development

Pharmaceutical development information for new products is generally considered 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 (as it is for some biological products, for example).

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

Active substances

The principles contained in the diagram below apply to pharmaceutical and [biological](#) products and to novel [excipients](#).

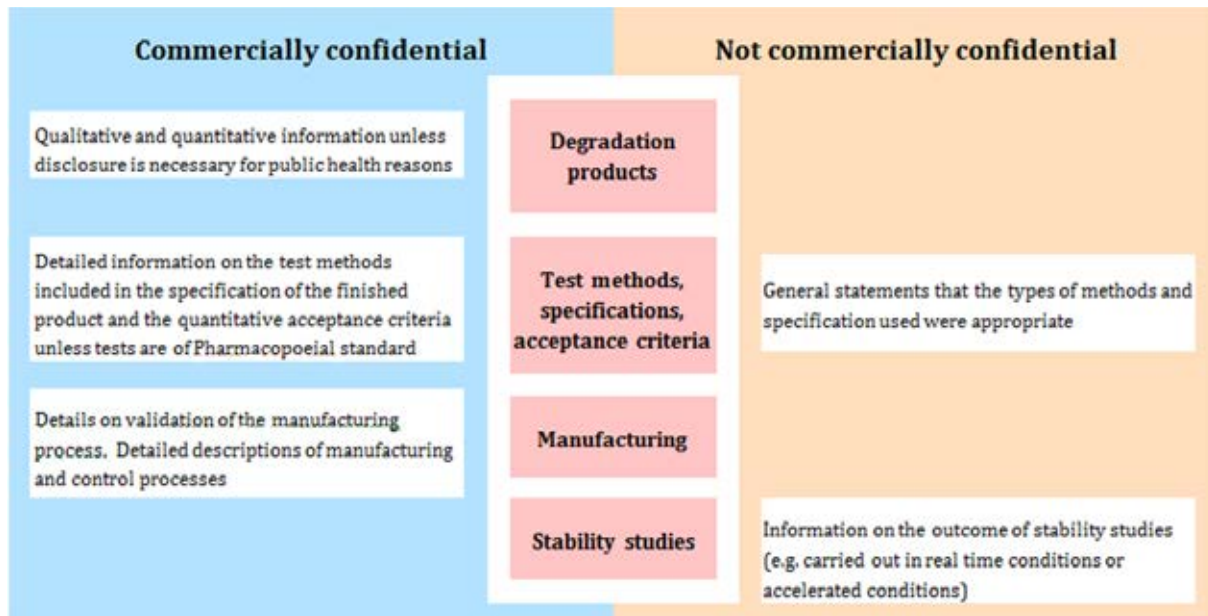
Classification of commercially confidential information for active substances

Commercially confidential		Not commercially confidential
Detailed information on synthesis/manufacture, including details on by-products and validation of synthesis/manufacturing process	Structure	Information on the structure of the active substance
Detailed information concerning the particulars of studies	Synthesis	
Qualitative and quantitative information unless disclosure is necessary for public health reasons	Polymorphism and particle size	A general statement on the results of studies
Detailed information on the test methods used and specification and quantitative acceptance criteria established for the active substance (unless the tests meet specific monographs in the European Pharmacopoeia)	Impurities and degradation products	
Operating parameters and specific material requirements	Test methods, specifications, acceptance criteria	A general description of the types of test methods used and the appropriateness of the specification
Details on the validation of the active substance manufacturing process	Fermentation and purification	General information
Details of characterisation methods	Manufacturing	Statements confirming that the manufacturing and control processes have been validated
	Characterisation	General information on the characterisation of active substance and statements confirming that molecule is appropriately characterised
	Biotechnology products	A general description of the active ingredient for biotechnology products, including type of molecule and its general structural features (e.g. number of amino acids, general glycosylation details) or of the type of producer cell (e.g. E.Coli, S. Cerevisiae, Chinese Hamster Ovary cells, Madin Darby Kidney cells)
	Cell banks	A general statement on the establishment of the Master Cell Bank (MCB) or Working Cell Bank (WCB) and on the stability of the cell banks

Finished product

The principles contained in the diagram below 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.

Classification of commercially confidential information for finished products



Nonclinical and clinical information

Information encompassing nonclinical and clinical development and its subsequent assessment by TGA is generally not CCI. Examples include:

- Data generated by the sponsor using another sponsor's product, for example 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.
- Information related to environmental risk assessments and risk management plans.

Examples of nonclinical and clinical information that is 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, for example 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 the results and timelines of such studies are part of the conditions for ARTG approval, they are not regarded as CCI.

Information on inspections

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

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.

Scientific advice

All information about new developments and formulations are CCI.

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.

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.

Personal Information

Personal information is defined in Subsection 6(1) of the [Privacy Act 1988](#).

As the [TGA is bound by the Privacy Act 1988](#) in relation to the collection, use and disclosure of personal information, personal information is not normally included in an AusPAR.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication Existing content – appendix from AusPAR guidance published as a separate guidance.	Regulatory Guidance	May 2021

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