Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Increasing transparency of Good Manufacturing Practice (GMP) inspection outcomes

Consultation Paper

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Purpose

The Therapeutic Goods Administration (TGA) is seeking feedback on a proposal to increase transparency of the Good Manufacturing Practice (GMP) compliance of manufacturers of pharmaceutical products on the TGA website.

Specifically, the proposal is to publish:

- the GMP Certificates issued following TGA GMP inspections of international manufacturing sites supplying pharmaceutical products to Australia, and
- the final regulatory outcome of GMP inspections performed by the TGA of pharmaceutical products manufacturing sites both in Australia and internationally.

The purpose of publishing this information is to:

- improve the transparency of regulatory oversight of the manufacture of pharmaceutical products supplied in Australia
- help the public to better understand the safeguards in place to ensure quality of pharmaceutical products, and
- provide clearer and more accessible regulatory information for industry and other stakeholders.

For the purposes of this consultation paper, the term 'pharmaceutical products' refers to medicines, blood, biologicals and hematopoietic progenitor cells. The proposal applies to manufacturers involved in any stage of production, from full product manufacture to individual steps such as testing, sterilisation, storage, and release for supply.

Background

The TGA is the Australian Government regulator responsible for the safety, quality and efficacy of therapeutic goods in Australia. The TGA's regulatory functions include conducting inspections of manufacturing facilities, in Australia and internationally, to assess compliance with relevant manufacturing principles.

Good Manufacturing Practice Principles

The TGA applies manufacturing principles based on internationally harmonised GMP standards, including:

- the **Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP Guide,** which sets the mandatory manufacturing principles for all steps in the manufacture of medicines, and
- the **Australian Code of GMP for human blood and blood components, human tissues and human cellular therapy products,** which sets out the mandatory manufacturing principles for the collection, processing, testing, storage, release for supply and quality assurance of these products.

These principles help to ensure pharmaceutical products are manufactured consistently and meet the required quality standards for their intended use. These principles cover areas such as:

- quality management systems
- personnel and training
- premises and equipment
- documentation and record keeping
- production and process controls
- quality control testing
- packaging and labelling, and
- release of products to the market.

GMP inspections

To assess compliance with GMP requirements, qualified TGA officers conduct inspections of manufacturing sites in Australia and internationally. Depending on risk and circumstances, inspections may be conducted at the manufacturing site, remotely, or using a hybrid approach.

Where non-compliance with GMP is identified during an inspection, manufacturers are required to address the findings through corrective and preventative action (CAPA) plans. Once all non-compliances are resolved and the TGA accepts the CAPA plans, the TGA issues a final inspection report with a compliance rating for the manufacturing site.

GMP inspections result in either an acceptable or unacceptable compliance rating. Where an unacceptable compliance rating is determined, the TGA may take additional regulatory actions.

For international manufacturing sites, the TGA will issue a **GMP Certificate** where an inspection confirms compliance with the same GMP requirements applicable to Australian sites. This certificate confirms compliance with GMP principles for a defined scope of manufacturing activities and for a specified period. GMP certificates are distinct from the manufacturing licence issued to manufacturing sites in Australia.

Transparency of GMP inspection outcomes

Providing information about regulatory activities is an important part of the TGA's commitment to transparency. Making information about GMP compliance publicly available helps the public to understand how manufacturers are regulated, and supports confidence in the quality of medicines supplied in Australia.

The TGA currently publishes a list of domestic manufacturers that hold a GMP licence. The list on the TGA website includes the name and address of the manufacturer, and the approved manufacturing steps. Historically, unlike comparable international regulators, the TGA has not published lists of international manufacturers that it has inspected. This information has been treated as confidential regulatory information and used primarily for regulatory purposes rather than public release. Similarly, the TGA has not published the outcomes of the inspections it conducts either within Australia or internationally.

The TGA is now proposing to publish the outcomes of all GMP inspections, as well as the GMP certificates for international manufacturing sites. This recognises increased public interest in transparency and aims to strengthen public confidence in the oversight of domestic and international manufacturing sites. The peoposal is consistent with international regulatory practice. Publishing GMP certificates for international manufacturing sites would provide equivalent visibility to that currently available for Australian manufacturers.

International practice

Publishing information about manufacturing inspection outcomes is common practice for comparable international regulators.

In the European Union, the European Medicines Agency maintains the public EudraGMDP database. This database provides access to non-confidential information about manufacturing and distribution authorisations, as well as GMP certificates. It also includes statements of non-compliance issued following inspections. This allows regulators, industry and the public to check a manufacturer's compliance status and supports confidence in the global supply chains for therapeutic goods.

Health Canada publishes inspection information for both domestic and international manufacturing sites through its Drug and Health Products Inspections Database. The database provides public access to inspection outcomes and compliance ratings, supporting greater regulatory transparency.

In the United States, the Food and Drug Administration (US FDA) publishes inspection outcomes for manufacturing sites through public inspection databases and dashboards. These include final inspection classifications that describe whether a site has met regulatory requirements. The US FDA does not issue GMP certificates, but publishes inspection classifications to promote transparency and encourage compliance.

The proposal

Your views are sought on the proposed options to improve transparency of the TGA's inspection program. This consultation seeks feedback on the proposal to publish:

- GMP certificates issued by the TGA following the inspection of international pharmaceutical products manufacturers, and
- final compliance outcomes of GMP inspections of pharmaceutical products manufacturers conducted by the TGA both in Australia and internationally.

For inspection outcomes, the published information would be limited to the:

- manufacturer name
- manufacturing site address
- inspection date
- type of inspection
- scope of manufacturing activities inspected
- whether the site was assessed as **acceptable** or **unacceptable**, and
- licence or certificate number.

The TGA is not proposing to publish confidential or commercially sensitive information. This means that inspection reports or information about individual companies' supply chains will not be published as part of this proposal.

The TGA is also seeking feedback on whether inspection outcomes should be published:

- on a **prospective basis only** (that is, for inspections completed after implementation), or
- on a prospective basis and include a **limited retrospective period of 12 months**, (that is, including outcomes from inspections completed in the 12 months prior to implementation).

If the proposal proceeds, publication of the final regulatory outcome of an inspection as well as GMP certificates issued following international GMP inspections would form part of routine regulatory communication with manufacturers. Manufacturers would be informed of the TGA's intention to publish inspection outcomes once the final compliance has been determined. The TGA is not proposing to seek further or additional approval from manufacturers before publishing this information.

To enable publication, the TGA proposes to make a legislative instrument under section 61(5D) of the *Therapeutic Goods Act 1989*. The instrument would provide the legal basis for publishing GMP certificates issued to international manufacturers and the outcomes of both domestic and international inspections.

Timeframes for implementation

The TGA expects to finalise and register the proposed legislative instrument on the Federal Register of Legislation by **October 2026**.

Publication of GMP certificates and inspection outcomes is proposed to commence shortly after the registration of the instrument on the Federal Register.

How to respond

The TGA invites comments on the proposal outlined in this consultation paper.

You may respond to any or all questions. Responses do not need to address every question.

Feedback can be provided by:

- completing the online consultation form, or
- uploading a written submission using the file upload option on the consultation page.

Consultation questions

Question 1

Do you support the proposal to publish **GMP Certificates** for international manufacturing sites on the TGA website?

☐ Yes
☐ No

If no, please explain your reasons.

Question 2

Do you support the proposal to publish **GMP inspection outcomes** for both Australian and international manufacturing sites on the TGA website?

☐ Yes
☐ No

If no, please explain your reasons.

Question 3

Noting that only final compliance ratings, determined once all corrective actions and remedial actions have been agreed with manufacturers are proposed to be published, do you agree with the **type of information** proposed to be published for each manufacturing site, including:

- manufacturer name
- manufacturer address
- date of inspection
- type of inspection (initial, routine, targeted)
- scope of manufacturing activities inspected
- inspection outcome (acceptable, unacceptable), and
- licence or certificate number.

☐ Yes
☐ No

If no, please explain your reasons.

Question 4

The TGA is seeking views on whether published inspection data should be prospective only or include a limited retrospective period.

☐ **Option A – Publish prospective inspection data only**

Publish inspection outcomes for inspections conducted after commencement of the proposed publication arrangements.

☐ **Option B – Publish prospective and limited retrospective inspection data**

Publish inspection outcomes for inspections conducted in the 12 months prior to commencement, in addition to all inspections conducted after commencement of the proposed publication arrangements.

Question 5

Do you agree that following communications between the TGA and manufacturers throughout the inspection process, and once a final compliance outcome is determined, **GMP inspection outcomes** should be published as a standard process?

☐ Yes
☐ No

If no, please explain your reasons.

Question 6

Do you agree that, following communications between the TGA and manufacturers throughout the inspection process, and once all corrective and preventative action plans are agreed, **GMP certificates** for overseas manufacturers should be published as a standard process once they are issued, without further consultation?

☐ Yes
☐ No

If no, please explain your reasons.

Question 7

Do you think publishing GMP inspection outcomes will **help to improve public confidence** in the quality of medicines supplied in Australia?

☐ Yes
☐ No

If no, please explain your reasons.

Question 8

Is there additional information that you think the TGA should make publicly available to **help improve public confidence** in the quality of medicines supplied in Australia?

☐ Yes
☐ No

If yes, what additional information would help provide confidence in the quality of medicines.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Licencing Certification and Engagement Section	May 2026

OFFICIAL

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