



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Increasing transparency of Good Manufacturing Practice (GMP) inspection outcomes

Consultation Outcomes Paper

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Purpose

This paper summarises the submissions and outcomes from the public consultation on the proposal for increasing transparency of Good Manufacturing Practice (GMP) inspection outcomes.

All submissions that gave permission to be published on our website are available through the 'View submitted responses' on our consultation hub.

Background

The Therapeutic Goods Administration (TGA) is responsible for regulating therapeutic goods in Australia, including overseeing the manufacture of medicines, blood and biologicals to ensure they meet appropriate standards of quality, safety and efficacy. As part of this role, the TGA conducts inspections of manufacturing facilities in Australia and overseas to assess compliance with GMP requirements.

Transparency is an important part of the TGA's regulatory role and commitment to open government. Providing information about regulatory activities helps the public, healthcare professionals and industry better understand how manufacturers are regulated and how the TGA oversees compliance with GMP requirements. Greater visibility of regulatory activities can also support confidence in the quality of medicines supplied in Australia.

The TGA currently publishes information about Australian manufacturers that hold a GMP licence, including details of approved manufacturing activities. However, unlike comparable international regulators, the TGA has not routinely published GMP inspection outcomes or GMP certificates for international manufacturing sites. To increase transparency and provide greater insight into its regulatory oversight of manufacturing activities, the TGA proposed publishing GMP inspection outcomes for both domestic and international manufacturing sites, together with GMP certificates issued for international manufacturers. The proposal was intended to improve public understanding of how manufacturers are regulated, provide greater visibility of manufacturing oversight, and align the TGA's approach with international regulatory practice.

The TGA conducted a public consultation to allow Australian manufacturers, overseas manufacturers, sponsors, organisations and members of the public the opportunity to comment and provide feedback on the proposed publication of GMP inspection outcomes and GMP certificates.

Public Consultation

The public consultation on increasing GMP inspection transparency inspection outcomes was conducted between 10 June and 13 July 2026. A total of 67 submissions were received from Australian and overseas manufacturers, sponsors, organisations and members of the public. The consultation asked eight questions and provided an opportunity for respondents to submit additional comments in relation to the proposal of publishing GMP inspection outcomes and overseas GMP certificates.

The consultation confirmed there was overwhelming support for publishing both GMP inspection outcomes and overseas GMP certificates. Key themes raised by respondents included:

- The need for clear explanatory material, publication criteria and guidance to support interpretation of published information.
- Support for publishing overseas GMP certificate information in a format clearly differentiated from official GMP certificates.
- Differing views on the appropriate scope of publication, with some respondents supporting a more limited approach and others seeking more extensive compliance information.
- Concerns regarding the potential for misinterpretation, protection of commercially confidential information, inappropriate reliance on published GMP certificate information, and procedural fairness considerations relating to retrospective publication.

Respondents

The public consultation on increasing the transparency of GMP inspection outcomes provided interested stakeholders with an opportunity to comment on the proposal to publish GMP inspection outcomes and overseas GMP certificates, including the type of information that would be published for each final inspection outcome.

Responses were received from a broad range of stakeholders, with organisations (30%) and sponsors (24%) accounting for more than half of all submissions. Australian manufacturers represented 19% of respondents, followed by members of the public (15%) and overseas manufacturers (12%). The 'organisation' category encompassed a range of stakeholders, including healthcare practitioners, testing laboratories, government and academic bodies, industry associations, and GMP consulting firms. As respondents did not consistently identify organisation subcategories, these responses have been reported as a single stakeholder group.

The responses were received from a variety of Australian and international locations. Not all States and Territories were represented in the responses with the largest number of responses received from New South Wales and Victoria. This may be reflective a concentration of manufacturing activities within these states.

Table 1 summarises the stakeholder groups that provided submissions.

Table 1: Interested stakeholder groups

Stakeholder group	Total	Percentage
Member of the public	10	15%
Australian Manufacturer	13	19%
Overseas Manufacturer	8	12%
Sponsor	16	24%
Organisation	20	30%

Table 2 below details the locations of respondents.

Table 2: Location of respondents

Location	Total	Percentage
Domestic		
ACT	4	6%
NSW	24	36%
NT	0	0%
QLD	7	10%
SA	0	0%
TAS	0	0%
VIC	14	20%
WA	2	4%
Overseas		
China	3	5%
France	2	4%
Germany	1	1%
Greece	1	1%
India	2	4%
New Zealand	1	1%
Spain	1	1%
Switzerland	1	1%
United Kingdom	3	5%
Unanswered	1	1%

Consultation questions

Question 1. Do you support the proposal to publish GMP Certificates for international manufacturing sites on the TGA website? If no, please explain your reasons.

There were 66 responses to this question:

- 64 answered 'Yes' to the proposal to publish GMP certificates for international manufacturing sites.
- 2 answered 'No' to the proposal to publishing GMP certificates for international manufacturing sites.

The 2 respondents who did not support the proposal raised concerns regarding the scope and format of the information proposed for publication, including the potential for published certificate information to be misinterpreted or used outside its intended regulatory context. They also highlighted the need for appropriate safeguards, disclaimers and protection of commercially sensitive information.

Outcome

After considering all the submissions, the TGA will proceed with publishing relevant GMP certification information for international manufacturing sites. To support transparency while minimising the potential for misinterpretation, the TGA will provide contextual information and guidance alongside published information. The information published will be clearly differentiated from the format of official GMP certificates and be limited to the content of the certificates and will not include commercially sensitive information. Relevant GMP certification information will be published as part of a routine monthly publication cycle to ensure information remains current and is published in a consistent and timely manner.

Question 2. Do you support the proposal to publish GMP inspection outcomes for both Australian and international manufacturing sites on the TGA website? If no, please explain your reasons.

There were 66 responses to this question:

- 57 answered 'Yes' to the proposal to publish GMP inspection outcomes for both Australian and international manufacturing sites.
- 9 answered 'No' to the proposal to publish GMP inspection outcomes for both Australian and international manufacturing sites.

Of the 9 responses that did not support publication there were differing views on the appropriate scope of publication, with some respondents supporting a more limited approach and others seeking more extensive compliance information.

Some concerns relate to the potential for inspection outcomes to be misinterpreted without appropriate regulatory and technical context, particularly by members of the public. Respondents also sought greater clarity regarding the scope, format and level of detail to be

published, and highlighted the need to protect commercially sensitive information. Some respondents considered that publication could result in unintended reputational or commercial impacts for manufacturers and sponsors, particularly where inspection outcomes may not accurately reflect a manufacturer's current compliance status following corrective actions.

Outcome

The TGA will proceed with publishing GMP inspection outcomes for both Australian and international manufacturing sites, noting the strong support expressed by respondents and the variable reasons for not supporting the publication. Publishing GMP inspection outcomes is also consistent with the approach taken by comparable international regulators. Consultation feedback highlighted the importance of ensuring published information is accompanied by appropriate context and explanatory material to support its interpretation and use. Inspection outcomes will be published as part of a routine monthly publication cycle to ensure information remains current and is published in a consistent and timely manner.

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.

If no, please explain your reasons.

There were 63 responses to this question:

- 51 answered 'Yes' they agree with the type of information proposed to be published for each manufacturing site.
- 12 answered 'No' they do not agree with the type of information proposed to be published for each manufacturing site.

The 12 respondents who did not support the proposed information for publication raised concerns that a simple inspection outcome of either acceptable/unacceptable may not provide sufficient context to accurately reflect the range and complexity of GMP inspection findings. Several respondents supported the publication of additional information, including more detailed compliance classifications, inspection findings or explanatory information to assist interpretation and risk assessment. Other concerns related to the potential for published outcomes to be misinterpreted, the risk of reputational or commercial impacts, and the need to ensure information is presented with appropriate context.

Outcome

The TGA will proceed with publishing the proposed information for each manufacturing site inspected, noting the strong support expressed by respondents and consistent with the approach taken by comparable international regulators. While some respondents sought the publication of additional inspection information and more detailed compliance classifications, others highlighted the importance of ensuring published information is accompanied by appropriate context to support interpretation. The TGA considers that the proposed information provides an appropriate balance between transparency, clarity and accessibility for stakeholders whilst protecting commercially sensitive information from release. Information will be published as part of a routine monthly publication cycle.

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.

There were 61 responses to this question:

- 26 were in favour of publishing prospective inspection data only.
- 35 were in favour of publishing prospective inspection data and limited retrospective data.

Respondents were divided on whether publication should be prospective only or include a limited period of retrospective inspection data. While a slight majority supported the publication of prospective inspection data together with a limited retrospective period, several respondents supported prospective publication only.

Outcome

The TGA will commence publication of GMP certificates and inspection outcomes on a prospective basis. The TGA considers that commencing with the publication of prospective outcomes only will support the timely and consistent implementation of the publication framework.

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? If no, please explain your reasons.

There were 65 responses to this question:

- 57 answered 'Yes' they agreed that GMP inspection outcomes should be routinely published once the inspection process is complete and a final compliance outcome has been determined.
- 8 answered 'No' they do not agree that GMP inspection outcomes should be routinely published once the inspection process is complete and a final compliance outcome has been determined.

The 8 respondents who did not support the proposal raised concerns about the interpretation and value of publishing GMP inspection outcomes. Concerns focused on the potential for inspection outcomes to be misunderstood without appropriate technical context, the risk of reputational impacts arising from publicly available compliance information, and the need for clarity regarding the process for determining final compliance outcomes. While some respondents did not support publication of inspection outcomes, others advocated for greater transparency through publication of more detailed inspection findings and compliance information.

Outcome

The strong support expressed by respondents indicates broad stakeholder support for increased transparency of regulatory oversight. The TGA will proceed with the routine publication of GMP inspection outcomes only once the inspection process has been completed and a final compliance outcome has been determined. Feedback received through consultation highlighted the importance of ensuring that published information is supported by appropriate context and explanatory material to assist interpretation.

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? If no, please explain your reasons.

There were 64 responses to this question:

- 59 answered 'Yes' they agreed that GMP certificates for overseas manufacturers should be routinely published once the inspection process is complete and all corrective and preventative actions are agreed.
- 5 answered 'No' they did not agree that GMP certificates for overseas manufacturers should be routinely published once the inspection process is complete and all corrective and preventative actions are agreed.

The 5 respondents who did not support the proposal raised concerns regarding the scope and presentation of published overseas GMP certificate information. Concerns focused on the potential for information to be misinterpreted without appropriate context, the need to protect commercially sensitive information, and the importance of ensuring published information accurately reflects the purpose and limitations of overseas GMP certification. Some respondents supported publication of basic certification information only, while others considered that additional context would be required if publication were to proceed.

Outcome

The strong support expressed by respondents indicates broad stakeholder support for increased transparency of overseas GMP certification information. The TGA will proceed with the routine publication of GMP certificates once the inspection process has been completed and all corrective and preventative actions have been agreed. Feedback received through consultation highlighted the importance of providing appropriate context and explanatory material to support interpretation of published information.

Question 7. Do you think publishing GMP inspection outcomes will help improve public confidence in the quality of medicines supplied in Australia? If no, please explain your reasons.

There were 63 responses to this question:

- 48 answered 'Yes' they agreed that publishing GMP inspection outcomes will help improve public confidence in the quality of medicines supplied in Australia.
- 15 answered 'No' they did not agree that publishing GMP inspection outcomes will help improve public confidence in the quality of medicines supplied in Australia.

The 15 respondents who did not agree that publishing GMP inspection outcomes would improve public confidence generally considered that the information may be difficult for consumers to understand without appropriate technical context. Respondents noted that public confidence in medicines is influenced by a range of factors beyond GMP compliance and expressed concern that published inspection outcomes could be misinterpreted, resulting in confusion or disproportionate concern. Some respondents also questioned the practical value of the information to consumers, particularly where manufacturing arrangements are not visible to the public and highlighted the importance of accompanying published information with clear explanations and contextual material.

Outcome

The TGA considers that publishing GMP inspection outcome information will support public confidence by increasing transparency of regulatory oversight and providing greater visibility of manufacturing compliance. While some respondents questioned the extent to which publication alone would influence public confidence, feedback consistently highlighted the importance of providing appropriate context and explanatory information to support public understanding. The TGA will incorporate explanatory material alongside published

information to assist stakeholders in understanding the role of GMP inspections and the significance of published outcomes.

Other issues raised

In addition to the issues addressed through the consultation questions, respondents raised the following matters:

- The need for explanatory and educational material to help stakeholders understand GMP inspections, published inspection outcomes and the broader regulatory framework that supports the quality, safety and efficacy of medicines supplied in Australia.
- Suggestions to publish additional compliance information, including inspection reports, deficiencies raised at inspections, deficiency ratings, corrective actions, statements of non-compliance and other information used by comparable overseas regulators.
- Requests for greater transparency regarding manufacturing arrangements and regulatory oversight, including clearer links between products and manufacturers, inspection activity, certification status and manufacturers operating under mutual recognition arrangements.
- Recommendations to provide sponsors with access to more detailed site-specific compliance information through secure or controlled access arrangements, where appropriate.
- Suggestions to publish additional operational information, such as inspection schedules, inspection coverage metrics, certificate expiry dates and certificate renewal information.

Outcome

The TGA has considered all additional issues raised through the consultation. Feedback relating to the need for explanatory material, contextual information and clear publication practices has informed the design of the publication framework. The TGA will provide supporting guidance to assist stakeholders in understanding published overseas GMP certificates and inspection outcomes and their role within the broader regulatory system. Published information will be limited to non-sensitive information contained within overseas GMP certificates, ensuring transparency objectives are met while protecting commercially sensitive information.

Next steps

The TGA intends to register a legislative instrument to enable publication of prospective GMP inspection outcomes and overseas GMP certificates on the TGA website. Publication is expected to commence following registration of the instrument.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Manufacturing Quality Branch Medical Devices and Product Quality Division Health Products Regulation Group	September 2026

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