Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Medicine Shortages in Australia

Reporting obligations and the TGA's compliance framework

Version 1.1, March 2023

Contents

Medicine Shortages – Reporting Obligations and Compliance Framework

Purpose

This publication sets out:

1. the mandatory reporting scheme for shortages or permanent discontinuation of medicines under the *Therapeutic Goods Act 1989*; and
2. the compliance framework in relation to the reporting obligations under the reporting scheme; and
3. the TGA's approach to non-compliance with that scheme.

Background

Medicine shortages have become an increasing problem in recent years for a number of reasons, including a decrease in the local manufacture of prescription medicines, and the increasingly globalised nature of supply chains.

A Medicine Shortages Information Initiative (MSII) and website was launched in 2014 by the TGA. This was a voluntary notification scheme where sponsors were encouraged to notify the TGA of medicine shortages, but reporting was not compulsory. Under that scheme, however, a significant number of medicine shortages of critical impact on patients had not been reported, notwithstanding considerable encouragement from the TGA for greater industry engagement.

As such, the voluntary arrangements did not provide a sufficient incentive for sponsors to report when their product would be in shortage, meaning that the information available on the TGA's website in relation to shortages, notified under the MSII, was not a complete or current source of information about medicine shortages.

In response to the issues experienced with the voluntary scheme, a Medicine Shortages Working Party comprised of the Medicines Partnership of Australia, the Australian Medical Association and the Society of Hospital Pharmacists of Australia, and chaired by the Department of Health, developed a revised protocol for the management and communication of shortages. This involved mandatory confidential reporting of all shortages to the TGA, the publication of those shortages that are of particular impact on patients and the development of a more transparent and action-oriented approach to the management of confirmed and serious medicines shortages.

Introduction of mandatory reporting scheme for medicine shortages and discontinuation of supply of medicine

The *Therapeutic Goods Act 1989* ("**the Act**") was amended effective 1 January 2019 to introduce a **mandatory reporting scheme** for medicine shortages and permanent discontinuations of supply of mostly prescription medicines The Act was further amended effective 22 September 2023 to clarify the requirement to notify changes to the duration or end date, and confirm the resolution of, a previously notified shortage. The scheme makes the timely reporting of all medicine shortages in Australia mandatory, in order to enable public communication to those impacted, alternative supplies to be accessed and timely discussion by the TGA with the affected sponsor and, separately, other potential suppliers, regarding suitable therapeutic alternatives.

The new scheme applies to **reportable medicines**; that is, registered goods that are principally prescription medicines, and other medicines that are registered in the Australian Register of

Therapeutic Goods for which the Minister determines, in a legislative instrument, that they should be covered by the scheme in the interests of public health.[1]

The **reporting requirements** require sponsors of reportable medicines to notify the Secretary, using the approved form, of any shortage or permanent discontinuation of their product as:

- for a shortage of 'critical impact' or changes to the duration or end date of such a shortage - as soon as possible, but no later than 2 working days after they know or ought to have reasonably known of the shortage;
- for any other shortage or changes to the duration or end date of such a shortage - within 10 working days after they know or ought to have reasonably known of the shortage;
- for a discontinuation of 'critical impact' - at least 12 months before the discontinuation would occur or, if this is not possible, as soon as practicable after the sponsor's decision;
- for any other discontinuation - at least 6 months before the discontinuation would occur or, if this is not possible, as soon as practicable after the decision.[2]

The **period of shortage** starts on the day the supply of that medicine in Australia will not, or will not be likely to, meet the demand for the medicine for all of the patients in Australia. The period of shortage ends the day before the day the supply of that medicine in Australia will (or will likely) meet demand.

A medicine is in '**shortage**' if its supply in Australia will not, or will not likely, meet the demand for it at any time in the next 6 months, for all the patients in Australia who take it or who may need to take it.[3] A shortage is determined at a national level, and instances of unavailability or short supply that only occur at particular locations are not shortages under the Act.

In relation to the reporting of shortages within the above timeframes, the requirement to do so only applies after the sponsor has considered all the information that it needs to take account of for the purposes of identifying if its medicine will, or will likely, be in shortage.

A shortage or a decision to permanently discontinue a reportable medicine is of '**critical impact**' (meaning that the shorter notification timeframes outlined above would apply) where either:

- the reportable medicine is included in a legislative instrument made by the Minister, known as the **Medicines Watch List**, signalling that the Minister is satisfied that a shortage or permanent discontinuation of that product could cause significant morbidity or death for patients in Australia; or
- there are no other registered medicines that could reasonably be used as a substitute for the medicine or, if there are, it is not likely that there would be enough of such substitutes to meet the demand for the supply of them as a result of the reportable medicine's shortage or discontinuation.[4]

The **Medicines Watch List** is designed to provide certainty for sponsors and the public in relation to the reporting obligations for shortages and discontinuations of medicines included on the list, while also providing the appropriate level of flexibility to ensure the list continues to reflect medicines for which a shortage or permanent discontinuation is appropriately deemed to be critical.

Further information on medicine shortage reporting requirements and obligations of sponsors can be viewed on the TGA website at https://apps.tga.gov.au/prod/MSI/search-externalsite

[1] *Therapeutic Goods Act 1989* (Cth) s 30EH.
[2] *Therapeutic Goods Act 1989* (Cth) ss 30EF(1) and 30EG(1)
[3] *Therapeutic Goods Act 1989* (Cth) s 30EI.
[4] *Therapeutic Goods Act 1989* (Cth) ss 30EF(2), (3) and 30EG(2), (3) and 30EJ

Medicine shortage reporting compliance framework

Civil penalty provisions

Civil penalties apply where sponsors do not notify the Secretary of a shortage or permanent discontinuation of a reportable medicine within the applicable timeframes set out in the Act, with a maximum civil penalty in either instance of 100 penalty units for an individual and 1,000 penalty units for a body corporate.[5]

Exceptions to the above civil penalties applies where, for a medicine that is not in the Medicines Watch List, it was reasonable for a sponsor to assume that their shortage or permanent discontinuation was not of critical impact and the sponsor reported it in accordance with the non-critical requirements, but the shortage or discontinuation was later identified to be of critical impact. Sponsors who have already notified a shortage are not required to re-notify that shortage if duration and end date remain unchanged (subsection 30EF(8)). However, sponsors are required to notify that a shortage has been resolved or if the duration or end date of the shortage change (subsection 30EFA (1) and (2).

Section 42YCA of the Act provides for daily penalties for **continuing contraventions** of civil penalty provisions and applies to subsection 30EF(6). This has the effect that the obligation of the sponsor to report a medicine shortage will continue until a report has been made, and is not discharged upon expiration of the deadline. A separate contravention of the civil penalty provision will be incurred for every day the obligation is not met.

Section 42YK empowers the Secretary to issue an **infringement notice** where the Secretary has reasonable grounds to believe a person has contravened a provision of the Act or the regulations that is an offence of strict liability or a civil penalty provision. Where an infringement notice is issued by the Secretary for breach of the reporting obligation in subsection 30EF(1), a sponsor is able to choose to pay an infringement notice amount as an alternative to having court proceedings brought against them for the contravention.

Subsection 42YKA(2) limits the amount payable under an infringement notice that relates to a single alleged contravention to the lesser of:

- one-fifth of the penalty that a court could impose on the person for that contravention; and
- 12 penalty units where the person is an individual, or 60 penalty units where the person is a body corporate.

Section 42YKA(3) provides an equivalent limit on the amount payable under an infringement notice that relates to multiple contraventions.

Information gathering powers

The Secretary has the power to require a person in relation to whom a reportable medicine is registered to provide information or documents in relation to:

- whether or not there is a shortage of the medicine in Australia;
- if there is a shortage of the medicine in Australia - the shortage, or
- any decision of the person to permanently discontinue the supply of the medicine in Australia.[6]

[5] *Therapeutic Goods Act 1989* (Cth) ss 30EF(6) and 30EFA(5) and 30EG(6); the amount of a “penalty unit” is set by section 4AA of the *Crimes Act 1914* (Cth)
[6] *Therapeutic Goods Act 1989* (Cth) s 31(1)(ja).

The TGA's approach to medicine shortage reporting non-compliance

Compliance measures in relation to the new reporting obligations are in accordance with the TGA's Regulatory Compliance Framework. The TGA takes a graduated, risk-management approach to compliance that attempts to identify persons at risk of unintentional or deliberate non-compliance and enable the development of appropriate strategies to prevent non-compliance. A graduated approach in this regard, including activities to raise awareness and understanding of the new scheme, allows the TGA to respond appropriately to the full range of non-compliant behaviours. In that regard, the TGA is engaged in an education programme targeted at sponsors of likely reportable medicines including those on the Medicines Watch List, to raise awareness of the new scheme and to help sponsors prevent non-compliance with their reporting obligations.

The TGA's response to non-compliance will likely be guided by two factors;

- whether there is a potential for detriment to the health of consumers, and
- the sponsor's behaviour prior to and in relation to the non-compliance with their reporting obligations.

If there is disagreement with a sponsor as to whether there is a 'shortage' within the meaning of the Act, the TGA may consider whether it is appropriate to settle the issue by pursuing court proceedings for a relevant court ruling.

The TGA's risk-based approach to non-compliance means its response is tailored to the risk posed by the non-compliant reporting or the attitude toward compliance by the sponsor. Further escalation of regulatory action may be considered against risk factors associated with additional or continued non-compliance. An example of escalated regulatory action is where the sponsor is aware of their reporting obligations but is not willing to comply, or the alleged reporting non-compliance is such that there is an impact on the ability of the consumer to access a medicine to their detriment due to the non-reporting of the medicine shortage by the sponsor.

The TGA may provide assistance through the form of legal obligations letters or formal warning letters. However, it may be that the use of compliance or enforcement action under the Act is more appropriate and proportionate for the purpose it serves.[7] Civil penalty proceedings in the Federal Court are more likely to be pursued where there is a history of repeated non-compliance with reporting obligations or where actual or potential public health risk may result from that non-compliance.

As set out in the TGA's public consultation paper, compliance obligations and penalties will commence 6 months after the amendment to the Act to allow sponsor to adjust to the new framework. On this basis, sponsors will become liable to penalties and sanctions commencing on 1 July 2019.

Medicine Shortages Compliance and Risk Framework

Table 1: TGA’s approach to reporting non-compliance.

Compliance risk			
Low	Medium	High	Extreme
TGA's approach to managing compliance risk			

[7] *Minister for Immigration v Li* (2013) 249 CLR 332 [30] French CJ.

Compliance risk			
Help and support • Make ongoing compliance easy through clear education and guidance material	**Inform and advise** • Direct education and guidance in a legal obligations letter to help the sponsor become and stay compliant	**Correct non-compliant behaviour** • Send a formal warning letter and giving notice of available compliance and enforcement options available to the TGA • Publish names of non-compliant sponsor	**Enforce penalties** • Civil penalties • Infringement Notices • Enforceable Undertakings
Sponsor's approach to compliance with medicine shortage reporting obligations			
Voluntary compliance • Effective compliance systems in place • Management is compliance oriented	**Accidental or opportunistic non-compliance** • Ineffective compliance and/or developing compliance systems • Management is compliance oriented but lacks capability	**Regular non-compliance** • Resistant to compliance • Limited or poor compliance systems • Management is not compliance oriented	**Intentional non-compliance** • Deliberate non-compliance • No or ineffective compliance systems • Reckless attitude towards reporting obligations
"Committed to doing the right thing"	*"Try to comply but don't always succeed"*	*"Don't want to comply but will if made to"*	*"Conscious decision to be non-compliant"*

Table 2: Medicine shortages Compliance Risk Framework

Nature of alleged breach	Risk level	Available regulatory action/s can include
Extensive non-compliance to reporting obligations that raises public health concerns or undermines the TGA's mandatory reporting scheme for medicine shortages with possible poor public health implications. Action: Contact person responsible as soon as possible. Use of the most appropriate and proportionate regulatory tools to address the non-compliance in a timely manner.	**EXTREME**	• Investigate with a view to instigating civil penalty action in the Federal Court against the non-compliant sponsor. • Issue an infringement notice as an alternative to Court action where appropriate. • Enter into an enforceable undertaking with the sponsor as an alternative to Court action where appropriate. • TGA may publish details of non-compliant sponsors.

Nature of alleged breach	Risk level	Available regulatory action/s can include
Continued alleged reporting breaches and/or breaches that are more serious in nature such as for critical medicine shortages. Action: Formal email or phone contact requiring immediate action and follow up with a formal warning letter or a compliance action.	**HIGH**	• Send a formal warning letter to sponsor requiring response within 14 business days as to what, if any, remedial action they intend to undertake to remedy their non-compliance with their reporting obligations. • Give the sponsor an infringement notice or enter into an enforceable undertaking with the sponsor where appropriate and often where the sponsor has a previous history of non-compliance and is aware of their reporting obligations. • TGA may publish details of non-compliant sponsors.
Alleged ongoing breaches where the sponsor has been made aware of their obligations and has continued non-compliance with reporting obligations. Action: Formal warning letter advising of the breach and the regulatory tools available to address further noncompliance. The letter requires a response within 14 business days. No response may lead to an escalation of action by the TGA.	**MEDIUM**	• Send a formal warning letter to the sponsor requiring response within 14 days as to what if any remedial action they intend to undertake to remedy their non-compliance with reporting obligations. The letter will contain access to: – Guidance material – Education and training • TGA may publish details of non-compliant sponsors
One off or isolated alleged breach of mandatory reporting obligations Action: Sponsor is sent a legal obligations letter advising of the alleged breach and how to address their current non-compliance and to prevent further non-compliance. The letter will contain information and guidance to assist with future compliance but a response is not required. Sponsor can contact the TGA to dispute or discuss the alleged breach of reporting obligations.	**LOW**	• Legal obligations letter putting the sponsor on notice about their failure to comply with their mandatory reporting obligations. The letter will contain access to: – Guidance material – Education and training material

Regulatory compliance and enforcement tools

A **legal obligations letter** informs a sponsor that their reporting may not be compliant and advises them of their obligations. The letter also provides educational and guidance material to assist the sponsor with reviewing their reporting framework to ensure future compliance. The letter does not seek a response but a sponsor can dispute or discuss the alleged reporting non-compliance with the TGA.

A **formal warning letter** informs a sponsor that their reporting is non-compliant. A formal warning letter will generally be sent when the TGA knows the sponsor is aware of their reporting obligations but have not met them. The formal warning letter sets out the alleged non-compliance and requires the sponsor to respond to the TGA outlining the steps they will carry out and the timeframe required to achieve compliance. As detailed in the public consultation paper, the TGA will publish the names of sponsors who do not comply with their mandatory reporting obligations without additional sanction. Failure to respond to a formal warning letter may result in an escalation of further regulatory action by the TGA.

An **infringement notice** may be given where a sponsor has, within 12 months, contravened a civil penalty provision of the Act for non-compliance with their reporting obligations relating to medicine shortages or discontinuations. The person can choose to pay an amount to the Commonwealth as an alternative to having court proceedings brought against them in relation to the alleged contravention. If the sponsor chooses not to pay the amount, they may be pursued in the Federal Court for civil penalties relating to the original alleged reporting non-compliance.

A sponsor may choose to offer the TGA an **enforceable undertaking**, a promise able to be enforced by a court. An example includes where the sponsor undertakes to establish, review and improve their reporting processes to be compliant with the requirements in the Act and to make regular reports to the TGA for the period of the undertaking.

The TGA may commence **civil penalty** litigation in the Federal Court which can result in large fines being imposed on the alleged wrongdoer (the sponsor).

Publication of compliance outcomes

The TGA's compliance handling policy includes the power to publish information about alleged non-compliance with statutory provisions in the Act.[8] Details about the sponsor and action undertaken by the TGA in response to the non-compliance with their reporting obligations may be published on the TGA website in the following instances;

- Confirmed non-compliance following the issue of a formal warning letter may result in the publication of the details of the sponsor and their non-compliance with their reporting obligations.
- The TGA publishes information about infringement notices if they are paid.
- If the TGA enters into an enforceable undertaking with a sponsor as an alternative to litigation, the Act requires the TGA to publish the undertaking.
- If the TGA pursues a sponsor in the federal court and the court imposes civil penalties, those matters will also be published by the TGA or may be referred to in media or social media releases when the case is finalised.

The TGA considers that the publication of information about such matters is central to the transparency of the TGA's compliance handling processes.

[8] *Therapeutic Goods Act 1989* (Cth) s 61(5D).

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	RLSB	April 2019
V1.1	Updates to accommodate clarification of reporting requirement introduced to the *Therapeutic Goods Act*	Pharmacovigilance Branch	March 2023

Therapeutic Goods Administration

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