# EXPLANATORY STATEMENT

***Therapeutic Goods Act 1989***

***Therapeutic Goods (Information relating to Shortages and Discontinuations of Supply of Medicines) Specification 2018***

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in, or exported from, Australia. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health, is responsible for administering the Act.

Section 61 of the Act lists a number of circumstances in which the Secretary of the Department of Health (the Secretary) may release specified kinds of therapeutic goods information, to both specified bodies (such as the World Health Organisation) and the public. Section 61 also allows the Minister for Health to make a legislative instrument setting out circumstances in which the Secretary may release therapeutic goods information to the public under that section.

The *Therapeutic Goods (Information relating to Shortages and Discontinuations of Supply of Medicines) Specification 2018* (the Specification) is a legislative instrument made by the delegate of the Minister under subsection 61(5D) of the Act, and specifies the kinds of therapeutic goods information that may be released to the public by the Secretary under subsection 61(5C) of the Act, in relation to shortages and discontinuations of the supply of medicines. The Specification principally has the effect of permitting the Secretary to release therapeutic goods information of a kind mentioned in the Specification to the public.

Therapeutic goods information in this context is defined in subsection 61(1) of the Act as information in relation to therapeutic goods that is held by the Department and which relates to the performance of the Department's functions.

The Specification commences on 1 January 2019.

## BACKGROUND

### New mandatory reporting scheme for medicines shortages and discontinuations

Medicines 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. More often, different brands of the same generic medicine (i.e. different brands of medicine with the same active pharmaceutical ingredient) are being manufactured at the same facility. This can mean that even in cases where several products containing the same active ingredient are approved for marketing in Australia, they may all be made by the same manufacturer, and a manufacturing problem may simultaneously affect several Australian sponsors.

The Medicine Shortages Information Initiative (the MSII) was launched in 2014 by the TGA. This is a voluntary notification scheme where sponsors are encouraged to notify the TGA of medicines shortages, but reporting is not compulsory. Under this scheme, however, a

significant number of shortages of critical impact on patients have not been reported, despite considerable encouragement from the TGA for greater industry engagement. As such, voluntary arrangements have not provided a sufficient incentive for sponsors to report when their products will be in shortage. This has meant that the information notified under the MSII available on the TGA's website in relation to shortages, has not been a complete or current source of information about medicine shortages for health professionals and consumers.

In addition, without mandatory reporting the TGA has not always been able to alert the Australian public to shortages in advance, or to give them timely advice about steps they may have been able to take to alleviate the effects of a shortage, or institute processes for accessing substitute unapproved and appropriate medicines through section 19A of the Act (which provides a mechanism for the Secretary to allow the lawful supply in certain circumstances of therapeutic goods which are not approved for marketing in Australia).

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 the mandatory confidential reporting of all shortages by medicine sponsors to the TGA and the publication of information about all shortages that are of critical impact on patients. In addition, sponsors will be encouraged to allow the publication of information about shortages that are not of critical patient impact. For a shortage that is not of critical impact where the sponsor does not consent to publication, the Secretary may still publish. This will occur if consumer awareness of the shortage is deemed important and publication is in the interests of public health.

The *Therapeutic Goods Amendment (2018 Measures No.1) Act 2018* (the Amendment Act) recently amended the Act to introduce mandatory requirements for sponsors of medicines (mainly prescription) to report shortages and permanent discontinuations of their products to the Secretary of the Department of Health (the Secretary). These amendments commence on 1 January 2019.

The new mandatory reporting scheme applies to 'reportable medicines'. These are principally prescription medicines (including prescription medicines containing controlled drugs for which restrictions on supply and use are recommended under the current Poisons Standard in order to avoid misuse or dependence (e.g. methadone, morphine)). However, other medicines that are registered in the Australian Register of Therapeutic Goods (the Register) may also be determined by the Minister to be subject to the new scheme, if the Minister is satisfied that their inclusion would be in the interests of public health.

The *Therapeutic Goods (Reportable Medicines) Determination 2018* identifies 11 registered, over the counter medicines that will also be included in the new scheme, due to their impact on public health and on the health of consumers who need to use these products. These are medicines that are particularly important for the health of patients including, for example, salbutamol inhalers which are a vital product for asthma sufferers, and adrenaline autoinjectors (i.e. EpiPens) which are critical in the response to severe allergic reactions in many people.

Under the new scheme, sponsors of reportable medicines will be required to notify the Secretary, using the approved form, of any shortage or permanent discontinuation of their product:

- for a shortage of 'critical impact' – 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 – 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 to discontinue the medicine; and
- 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.

A reportable medicine will be in 'shortage' if its supply in Australia will not, or will not be likely to, meet the demand at any time in the next 6 months, for all patients in Australia who take it or who may need to take it (new section 30EI of the Act refers). In other words, consideration of whether there is a shortage of a medicine involves taking an overall view of the factors affecting a reportable medicine's availability for patients in Australia for that period. Instances of unavailability or short supply that only occur at particular locations in Australia, such as due to supply contract arrangements, are not considered to be shortages under the amendments introduced by the Amendment Act.

In relation to the reporting of shortages within the above timeframes, it is important to note that the requirement to do so will only apply 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 decision to permanently discontinue a reportable medicine will be of 'critical impact' (meaning the shorter notification timeframes above will apply) where either:

- the reportable medicine is included in a legislative instrument made by the Minister under subsection 30EJ(1) of the Act – the *Therapeutic Goods (Medicines Watch List) Determination 2018* (the Medicines Watch List) - signalling that the Minister is satisfied that a shortage or permanent discontinuation of the 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 reportable medicine or, if there are, it is not likely that there would be enough of such substitutes available to meet the demand for the supply of them as a result of the reportable medicine's shortage or discontinuation.

Civil penalties will apply where sponsors of reportable medicines do not notify the Secretary of a shortage or permanent discontinuation involving their product within the applicable timeframe, with a maximum civil penalty in either instance of 100 penalty units for an individual and 1,000 penalty units for a body corporate.

An exception to these civil penalties will apply where, for a reportable medicine that is not in the Medicines Watch List, a sponsor reasonably considered that their shortage or discontinuation was not of critical impact and reported it in accordance with the non-critical requirements, but the shortage or discontinuation was later identified to be of critical impact.

**The Specification – informing the public about medicines shortages**

The purpose of the Specification is to authorise the Secretary to release to the public a range of important information about shortages and discontinuations of reportable medicines under the new scheme, including for example:

- information about the reportable medicine – including the name, active ingredient (or active ingredients), strength, dosage form and registration number of the reportable medicine;
- information about the sponsor of the reportable medicine – including the name of the sponsor of the reportable medicine and their contact details for the purposes of responding to enquiries from the public seeking additional information about the reportable medicine;
- information about the shortage or discontinuation – including:
    - its status (for a shortage, whether it is anticipated, current or resolved, and for a discontinuation, whether the medicine will be or has been permanently discontinued by the sponsor);
    - the reasons for the shortage or discontinuation (e.g. commercial reasons, manufacturing problems or a product recall);
    - the commencement date of impact on supply of the reportable medicine;
    - the sponsor's advice as to the anticipated date a shortage of a reportable medicine will be resolved;
    - the reportable medicine's availability (whether it is freely available or only has limited availability, only available under Commonwealth or State and Territory programs for vaccines, for emergency supply only or is not available at all); and
    - the patient impact of the shortage or discontinuation.

In so doing, the Specification forms a critical part of the new scheme by allowing the Secretary to inform the public about shortages and discontinuations that are reported to the TGA, so that prompt action can be taken to address the needs of patients affected by the shortage or discontinuation.

This will be particularly important for higher risk medicines for which a shortage or discontinuation will be of critical impact, as under paragraphs 30EF(1)(a) and 30EG(1)(a) of the Act, tighter reporting timeframes apply for sponsors of such products than where such an event is not of critical impact.

Under paragraph 30EF(1)(a) of the Act, a sponsor of a reportable medicine must notify the Secretary about a shortage that has a critical impact within 2 working days of when they know (i.e. become aware) , or ought reasonably to have known, of the shortage. Under paragraph 30EG(1)(a) of the Act, a sponsor of a reportable medicine must notify the Secretary of a decision to permanently discontinue the supply of the medicine at least 12 months before the discontinuation is proposed to occur (or, where this is not possible, as soon as practicable after the decision is made to discontinue a product).

The effect of the Specification, in authorising the release to the public of a range of important information about a medicine shortage or discontinuation (including, for example, the commencement date of impact on supply of the reportable medicine, and the sponsor's advice as to the anticipated date a shortage of a reportable medicine will be resolved), is to complement the introduction of the new mandatory reporting requirements. The Specification ensures that the TGA will be able to alert the Australian public to a shortage or discontinuation and give them timely advice about steps they can take for alleviating the effects of such events if these are required. By supporting the publication of such information, the Specification will also enable health practitioners to be better informed about shortages and discontinuations, so that they can work with patients to minimise the impact of such events.

**CONSULTATION**

The TGA undertook public consultation between 28 March and 30 April 2018 on the management and communication of medicines shortages, including in relation to the proposed publication on the TGA's website (www.tga.gov.au) of information about those medicines shortages that are of critical impact.

This consultation also covered other important aspects of the proposed new scheme, including the definition of a medicine shortage, the medicines that should be within the scope of the new scheme, the content of the required notifications and the proposed list of medicines for which a shortage or discontinuation would be of critical impact.

The TGA received 50 responses, including 18 from industry suppliers, sponsors or manufacturers (e.g. GlaxoSmithKline Australia), 16 from healthcare professionals, medical institutions or health professional bodies (e.g. the Australian Medical Association (the AMA), 5 from industry peak bodies (e.g. Medicines Australia (MA) and the Australian Self-Medication Industry (ASMI)), and 9 from consumers or consumer organisations (e.g. Allergy & Anaphylaxis Australia). The majority of stakeholders supported the need for better management and timely communication of medicines shortages. However, industry stakeholders were not convinced that a penalty scheme for non-compliance was necessary, and unanimously stated that criminal sanctions for doing so would be too severe. Other submissions, however, emphasised that for a mandatory reporting scheme to have any impact, compliance powers were needed to be specified in law. Following this feedback the Amendment Act only introduced civil penalties for non-compliance with requirements to report medicines shortages and permanent discontinuations, and does not include criminal sanctions.

The TGA also conducted targeted consultation between 17 October and 5 November 2018 with key stakeholder groups ASMI, MA, the Generic and Biosimilar Medicines Association, the National Pharmaceutical Services Association, the AMA, the Society of Hospital Pharmacists of Australia, the Pharmacy Guild, the Pharmaceutical Society of Australia and State and Territory health authorities on proposed revised guidelines to support stakeholders under the new scheme. This consultation also included a revised approach to publishing the details of medicines shortages and discontinuations that are not of critical impact under the new scheme (noting that the TGA had already consulted on the proposal to publish the details of all shortages and discontinuations of critical impact). Under this approach, the TGA would encourage sponsors to consent to the publication of the details of those shortages and discontinuations that are not of critical impact. For a shortage that is not of critical impact

where the sponsor does not consent to publication, these may still be published by the TGA if the shortage is nevertheless an important one for consumers to be aware of and if publication would be in the interests of public health.

Written feedback in response to this targeted consultation was received from industry peak bodies, medicine sponsors, healthcare professional peak bodies and state and territory health departments, with no concerns or objections expressed regarding the proposed approach to publication. The TGA met with representatives of Medicines Australia and several medicine sponsors on 7 November 2018 as part of this targeted consultation period, to further discuss and clarify the requirements of sponsors under the new scheme. These stakeholders acknowledged that the publication of low and medium impact medicine shortages in all cases would be ideal and would provide greater transparency in relation to medicine shortages to the public.

Details of the Specification are set out in Attachment A.

The Specification is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in Attachment B.

This Specification is a disallowable legislative instrument, and commences on 1 January 2019.

**ATTACHMENT A**

**Details of *Therapeutic Goods (Information relating to Shortages and Discontinuations of Supply of Medicines) Specification 2018***

**Section 1 Name**

This section provides that the name of the Specification is the *Therapeutic Goods (Information relating to Shortages and Discontinuations of Supply of Medicines) Specification 2018.*

**Section 2 Commencement**

This section provides that the Specification commences on 1 January 2019.

**Section 3 Authority**

This section provides that the legislative authority for making the Specification is subsection 61(5D) of the *Therapeutic Goods Act 1989* (the Act).

**Section 4 Definitions**

This section provides definitions for a number of terms used in the Specification, e.g. 'anticipated shortage', 'current shortage' and 'substitute medicine'. This section also highlights that a number of terms used in the Specification have the meaning given to them in subsection 3(1) of the Act, e.g. 'medicine', 'registered goods' and 'shortage'.

**Section 5 Repeals**

This section provides that each instrument that is specified in Schedule 1 to the Specification is repealed as set out in that Schedule.

**Section 6 Therapeutic Goods Information**

This section provides that the kinds of therapeutic goods information set out in Parts 1 and 2 of Schedule 2 to the Specification are specified (under subsection 61(5D) of the Act) for the purposes of subsection 61(5C) of the Act, in relation to a shortage of a reportable medicine in Australia that arises on or after 1 January 2019, and a decision to permanently discontinue the supply of a medicine in Australia that is made on or after 1 January 2019.

This section also provides that Parts 3 and 4 of Schedule 2 to the Specification similarly specify kinds of therapeutic goods information in relation to, respectively, shortages of, and decisions to permanently discontinue the supply of, medicines in Australia that arose or were made before 1 January 2019 (i.e. under the Medicine Shortages Information Initiative (MSII)).

**Schedule 1**

This Schedule 1 repeals the *Therapeutic Goods Information (Medicine Shortages Information Initiative) Specification 2014*.

**Schedule 2**

This Schedule sets out therapeutic goods information for the purposes of section 6 of the Specification, in relation separately to each of the following:

- a shortage of a reportable medicine that arises on or after 1 January 2019;

- a decision to permanently discontinue the supply of a reportable medicine that is made on or after 1 January 2019;
- a shortage of a medicine that arose before 1 January 2019; and
- a decision to permanently discontinue the supply of a medicine that was made before 1 January 2019.

**ATTACHMENT B**

## Statement of Compatibility with Human Rights

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

***Therapeutic Goods (Information relating to Shortages and Discontinuations of Supply of Medicines) Specification 2018***

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

### Overview of the Legislative Instrument

*New mandatory reporting scheme for medicines shortages and discontinuations*

The *Therapeutic Goods Amendment (2018 Measures No.1) Act 2018* (the Amendment Act) recently amended the *Therapeutic Goods Act 1989* (the Act) to introduce mandatory reporting requirements for sponsors of mainly prescription medicines to report shortages of, and decisions by them to permanently discontinue, their products to the Secretary of the Department of Health (the Secretary). These amendments commence on 1 January 2019.

The new mandatory reporting scheme applies to 'reportable medicines'. These are principally prescription medicines (including prescription medicines containing controlled drugs for which restrictions on supply and use are recommended under the current Poisons Standard in order to avoid misuse or dependence (e.g. methadone, morphine)). However, other medicines that are registered in the Australian Register of Therapeutic Goods (the Register) may also be determined by the Minister to be subject to the new scheme, if the Minister is satisfied that their inclusion would be in the interests of public health.

11 registered, over the counter medicines are identified in the *Therapeutic Goods (Reportable Medicines) Determination 2018* for that purpose. These are medicines that are particularly important for the health of patients who need to take them, including for example salbutamol inhalers which are a vital product for asthma sufferers, and adrenaline autoinjectors (i.e. EpiPens) which are critical in the response to severe allergic reactions in many people.

Under the new scheme, sponsors of reportable medicines will be required to notify the Secretary, using the approved form, of any shortage or permanent discontinuation of their product:

- for a shortage of 'critical impact' – 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 – 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 to discontinue the medicine; and
- 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.

A reportable medicine will be in 'shortage' if its supply in Australia will not, or will not be likely to, meet the demand for it at any time in the next 6 months, for all patients in Australia who take it or who may need to take it (new section 30EI of the Act refers). In other words, consideration of whether there is a shortage of a medicine involves taking an overall view of the factors affecting a reportable medicine's availability for patients in Australia for that period. Instances of unavailability or short supply that only occur at particular locations in Australia are not shortages under the amendments introduced by the Amendment Act.

In relation to the reporting of shortages within the above timeframes, it is important to note that the requirement to do so will only apply 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 decision to permanently discontinue a reportable medicine will be of 'critical impact' (meaning the shorter notification timeframes above will apply) where either:

- the reportable medicine is included in a legislative instrument made by the Minister under subsection 30EJ(1) of the Act – the *Therapeutic Goods (Medicines Watch List) Determination 2018* (the Medicines Watch List) - signalling that the Minister is satisfied that a shortage or permanent discontinuation of the 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 reportable 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.

Civil penalties will apply where sponsors of reportable medicines do not notify the Secretary of a shortage or permanent discontinuation involving their product within the applicable timeframe, with a maximum civil penalty in either instance of 100 penalty units for an individual and 1,000 penalty units for a body corporate.

An exception to these civil penalties will apply where, for a reportable medicine that is not in the Medicines Watch List, a sponsor reasonably considered that their shortage or discontinuation was not of critical impact and reported it in accordance with the non-critical requirements, but the shortage or discontinuation was later identified to be of critical impact.

The *Therapeutic Goods (Information relating to Shortages and Discontinuations of Supply of Medicines) Specification 2018*

The purpose of the *Therapeutic Goods (Information relating to Shortages and Discontinuations of Supply of Medicines) Specification 2018* (the Specification) is to authorise the Secretary to release to the public a range of important information about shortages and discontinuations of reportable medicines under the new scheme, including for example:

- information about the reportable medicine – including for example the name, active ingredient (or active ingredients), strength, dosage form and registration number of the reportable medicine;
- information about the sponsor of the reportable medicine – including for example the name of the sponsor of the reportable medicine and their contact details for the

purposes of responding to enquiries from the public seeking additional information about the reportable medicine;

- information about the shortage or discontinuation – including:
    - its status (for a shortage, whether it is anticipated, current or resolved, and for a discontinuation, whether the medicine will be or has been permanently discontinued by the sponsor);
    - the reasons for the shortage or discontinuation (e.g. commercial reasons, manufacturing problems or a product recall);
    - the commencement date of impact on supply of the reportable medicine;
    - the sponsor's advice as to the anticipated date a shortage of a reportable medicine will be resolved;
    - the reportable medicine's availability (whether it is freely available or only has limited availability, only available under Commonwealth or State and Territory programs for vaccines, for emergency supply only or is not available at all); and
    - the patient impact of the shortage or discontinuation.

In so doing, the Specification forms a critical part of the new scheme, by allowing the Secretary to inform the public about shortages and discontinuations that are reported to the TGA, so that prompt action can be taken to address the needs of patients affected by the shortage or discontinuation.

This will be particularly important for higher risk medicines for which a shortage or discontinuation will be of critical impact, as under paragraphs 30EF(1)(a) and 30EG(1)(a) of the Act, tighter reporting timeframes apply for sponsors of such products than where such an event is not of critical impact.

**Human rights implications**

The Specification takes positive steps to promote the right to health in article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR). This right is understood as the right of everyone to enjoy the highest attainable standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right. In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

By authorising the release to the public of a range of important information about a medicine shortage or discontinuation (including, for example, the commencement date of impact on supply of the reportable medicine and the sponsor's anticipated date that a shortage will be resolved), the Specification complements the introduction of the new mandatory reporting requirements. In so doing, it will ensure that the TGA will be able to alert the Australian public to a shortage or discontinuation, and give them timely advice about steps they can take for alleviating the effects of such events. By supporting the publication of such information,

the Specification will also enable health practitioners to be better informed about shortages and discontinuations, so that they can work with patients to minimise the impact of such events on the treatment of patients' medical conditions.

Before the introduction of the new scheme by the Amendment Act, a voluntary scheme, known as the Medicine Shortages Information Initiative (MSII)), was in place for the reporting of medicines shortages by sponsors, and an earlier information specification (the *Therapeutic Goods Information (Medicine Shortages Information Initiative) Specification 2014*) authorised the release to the public of information notified to the TGA by medicines sponsors in relation to that voluntary initiative.

Under the MSII, however, a significant number of shortages of critical patient impact were not being reported, despite encouragement by the TGA for greater industry engagement. This meant that the TGA was not always able to alert the Australian public to shortages in advance, or to give them timely advice about steps they may have been able to take to alleviate the effects of a shortage, or institute processes for accessing substitute unapproved and appropriate medicines through section 19A of the Act (which provides a mechanism for the Secretary to allow the lawful supply in certain circumstances of therapeutic goods which are not approved for marketing in Australia).

The new mandatory reporting scheme, and the release to the public of information about medicines shortages and discontinuations that are reported in accordance with the new scheme, addresses these concerns and represents an important improvement in relation to both the awareness of medicines shortages and the public's capacity to access timely and appropriate alternative treatments. The Specification will allow more detailed and timely information about medicine shortages and discontinuations to be widely available for the public and health care practitioners, and so they will be in a better position to take steps to alleviate the impact of a shortage or discontinuation on patient health.

**Conclusion**

The Specification is compatible with human rights because it promotes the right to health in article 12 of the ICESCR as outlined above, and otherwise does not raise any human rights issues.

**Jane Cook, delegate of the Minister for Health**