EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Reportable Medicines) Determination 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 (Reportable Medicines) Determination 2018* (the Determination) is a determination made by the delegate of the Minister under subsection 30EH(2) of the Act. The purpose of the Determination is to identify, for the purposes of subparagraph 30EH(1)(b)(ii) of the Act, those medicines (other than medicines which contain substances included in Schedule 4 or 8 to the current Poisons Standard) that must comply with the mandatory reporting requirements relating to medicine shortages and discontinuations under sections 30EF and 30EG of the Act.

The Determination commences on 1 January 2019.

BACKGROUND

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 Therapeutic Goods Administration (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, notwithstanding considerable encouragement from the TGA for greater industry engagement. As such, those voluntary arrangements have not provided a sufficient incentive for sponsors to report when their products will be in shortage, meaning the information available on the TGA's website in relation to shortages, notified under the MSII, has not been 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 involving the mandatory confidential reporting of all shortages by medicine sponsors to the TGA, the publication of those shortages of particular impact on patients and the development of a more transparent and action-oriented approach to the management of confirmed and serious medicine shortages.

The *Therapeutic Goods Amendment (2018 Measures No.1) Act 2018* (the Amendment Act) recently amended 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.

While the new mandatory reporting scheme principally applies to 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)), 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 Determination identifies such other medicines that are registered goods for this purpose, with the effect that the requirements of the new mandatory reporting scheme (principally set out in new sections 30EF and 30EG of the Act) will apply to them as well as to medicines containing a substance that is included in Schedule 4 or 8 to the current Poisons Standard.

The Determination identifies 11 medicines for this purpose:

- adrenaline autoinjector;
- glucagon injection;
- glyceryl trinitrate sublingual;
- levonorgestrel;
- monobasic sodium phosphate;
- naloxone injection;
- naloxone nasal spray;
- salbutamol autohaler;
- salbutamol inhaler;
- terbutaline inhaler;
- ulipristal.

These are all registered, over the counter medicines that are particularly important for the health of patients who need to take them, and as such are medicines for which it would be in the interests of public health for them to be covered by the requirements of the new scheme.

For example, salbutamol inhalers are a vital product for asthma sufferers, and adrenaline autoinjectors (i.e. EpiPens) have recently been the subject of shortages in Australia, due to manufacturing delays internationally. EpiPens are critical in the response to severe allergic reactions in many people, and the shortage of these products has attracted widespread attention including from media and healthcare professionals in recent months.

The inclusion of the above medicines will mean that sponsors of such 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 medicine will be 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 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 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, known as 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 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 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.

Including these 11 medicines in the new mandatory reporting scheme as reportable medicines will enable the TGA to better alert the Australian public to a shortage or permanent discontinuation and to provide timely advice about steps that may be taken to alleviate its effects and, significantly, to inform health practitioners so that they can work with patients to minimise the impact of these events on their health.

CONSULTATION

The TGA undertook public consultation between 28 March and 30 April 2018 on the management and communication of medicines shortages. The TGA received 50 responses from industry, healthcare professionals, industry peak bodies and consumer groups. The specific matters under consultation were: the definition of a medicine shortage; the medicines that should be within the scope of the new mandatory reporting scheme (including some of the medicines listed in the Determination – a number were added to the proposed scope of the new scheme after that consultation, such as naloxone nasal spray, which was only approved for marketing after that consultation took place); proposed reporting timeframes and the content of notifications; the proposed list of medicines for which a shortage or discontinuation would be of 'critical impact' for patients; and proposed penalties for non-compliance.

Virtually all 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. The Amendment Act only introduces civil penalties for non-compliance with requirements to report medicines shortages and permanent discontinuations, and does not include criminal sanctions.

The TGA also recently undertook targeted consultation between 17 October and 5 November 2018 with sponsors of all of the medicines to be included in the Determination, and with the peak industry body for such medicines, the Australian Self Medication Industry (ASMI). There was unanimous support from these stakeholders for the inclusion of the 11 medicines identified in the Determination in the new scheme.

Details of the Determination are set out in Attachment A.

The Determination 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 Determination is a disallowable legislative instrument, and commences on 1 January 2019.

ATTACHMENT A

Details of *Therapeutic Goods (Reportable Medicines) Determination 2018*

Section 1 Name

This section provides that the name of this Determination is the *Therapeutic Goods (Reportable Medicines) Determination 2018.*

Section 2 Commencement

This section provides that this Determination commences on 1 January 2019.

Section 3 Authority

This section provides that the legislative authority for making the Determination is subsection 30EH(2) of the *Therapeutic Goods Act 1989* (the Act).

Section 4 Definitions

This section principally highlights that a number of terms used in the Determination have the meaning given to them in subsection 3(1) of the Act – these are 'medicine', 'registered goods' and 'reportable medicine'.

Section 5 Reportable medicine

This section provides that the medicines set out in Schedule 1, being medicines that are registered goods, are determined to be reportable medicines for the purposes of subparagraph 30EH(1)(b)(ii) of the Act.

Schedule 1

Schedule 1 lists the reportable medicines for the purposes of section 5 of the Determination, being: adrenaline autoinjector, glucagon injection, glyceryl trinitrate sublingual, levonorgestrel, monobasic sodium phosphate, naloxone autoinjector, naloxone nasal spray, salbutamol autohaler, salbutamol inhaler, terbutaline inhaler and ulipristal.

ATTACHMENT B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Reportable Medicines) Determination 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

The *Therapeutic Goods (Reportable Medicines) Determination 2018* (the Determination) is a determination made by the delegate of the Minister under subsection 30EH(2) of the Act. The purpose of the Determination is to identify, for the purposes of subparagraph 30EH(1)(b)(ii) of the Act, those medicines (other than medicines which contain substances included in Schedule 4 or 8 to the current Poisons Standard) that must comply with the mandatory reporting requirements relating to medicine shortages and discontinuations under sections 30EF and 30EG of the *Therapeutic Goods Act 1989* (the Act).

The *Therapeutic Goods Amendment (2018 Measures No.1) Act 2018* (the Amendment Act) recently amended the Act to introduce mandatory reporting requirements for sponsors of mainly prescription medicines to report shortages, 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.

While the new mandatory reporting scheme principally applies to 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)), 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 Determination identifies 11 other medicines that are registered in the Register for this purpose, with the effect that the requirements of the new mandatory reporting scheme (these are principally set out in new sections 30EF and 30EG of the Act) will apply to them as well as to medicines containing a substance that is included in Schedule 4 or 8 to the current Poisons Standard. The medicines identified in the Determination are the following:

- adrenaline autoinjector;
- glucagon injection;
- glyceryl trinitrate sublingual;
- levonorgestrel;
- monobasic sodium phosphate;
- naloxone injection;

- naloxone nasal spray;
- salbutamol autohaler;
- salbutamol inhaler;
- terbutaline inhaler; and
- ulipristal.

These are all registered, over the counter medicines that are particularly important for the health of patients who need to take them, and as such are medicines for which it would be in the interests of public health for them to be covered by the requirements of the new scheme.

For example, salbutamol inhalers are a vital product for asthma sufferers, and adrenaline autoinjectors (i.e. EpiPens) have recently been the subject of shortages in Australia, due to manufacturing delays internationally. EpiPens are critical in the response to severe allergic reactions in many people, and the shortage of these products has attracted widespread attention including from media and healthcare professionals in recent months.

The inclusion of the above medicines will mean that sponsors of such 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 medicine will be 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 patients in Australia who take it or who may need to take it. 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.

A shortage or decision to permanently discontinue a reportable medicine will be of 'critical impact' where the reportable medicine is included in a legislative instrument made by the Minister, known as the Medicines Watch List, 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.

Civil penalties will apply where sponsors of reportable medicines do not notify the Secretary of a shortage or permanent discontinuation decision 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.

Including these 11 medicines in the new mandatory reporting scheme as reportable medicines will enable the Therapeutic Goods Administration (TGA) to better alert the Australian public to a shortage or permanent discontinuation and to provide timely advice about steps that may be taken to alleviate its effects and, significantly, to inform health practitioners so that they can work with patients to minimise the impact of these events on their health.

Human rights implications

The Determination 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.

Including these critical medicines in the new mandatory reporting scheme will enable patients and health practitioners to be better informed, and informed earlier, about shortages that affect them, and therefore to be in a better position to take steps to alleviate the impact of a shortage or discontinuation on patient health.

Before the introduction of the new scheme by the Amendment Act, a voluntary scheme was in place for the reporting of medicines shortages by sponsors. Under this scheme, however, a significant number of shortages of critical patient impact were not being reported, despite encouragement 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 of therapeutic goods which are not approved for marketing in Australia).

The new mandatory scheme, and the inclusion of the above medicines in it, addresses these concerns and represents an important improvement in both the awareness of medicines shortages and the public's capacity to access timely and appropriate alternative treatments.

This will also be bolstered through separate action to authorise, through the making of a legislative instrument under subsection 61(5D) of the Act, the publication of information about medicines shortages and permanent discontinuations by the TGA, so that this information is widely available for the public and health care practitioners.

Conclusion

The Determination 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