EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medicines Watch List) 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 (Medicines Watch List) Determination 2018* (the Determination) is a determination made by the delegate of the Minister under subsection 30EJ(1) of the Act.

The purpose of the Determination is to identify key reportable medicines for which a shortage or a decision by the medicine's sponsor to permanently discontinue its supply will be of critical impact for the purposes of the reporting requirements for medicines shortages and discontinuations in 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 'reportable medicines' (these are mainly prescription medicines, along with a small number of other medicines that are registered in the Australian Register of Therapeutic Goods (the Register) and determined by the Minister by legislative instrument to be subject to the new scheme) 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.

Under new sections 30EF and 30EG of the Act, a sponsor of a reportable medicine must notify the Secretary, using the relevant 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.

Under subsections 30EF(2) and 30EG(2) of the Act, a shortage or permanent discontinuation of a reportable medicine will be of 'critical impact' if the medicine is included in a legislative instrument made by the Minister under section 30EJ of the Act, signalling that the Minister is satisfied that a shortage or permanent discontinuation of the medicine could cause significant morbidity or death for patients in Australia.

The Determination is such an instrument – made by the Minister under subsection 30EJ(1) of the Act, for the purposes of identifying a range of vital reportable medicines for which the delegate of the Minister is satisfied that a shortage or discontinuation of would have the potential to result in significant morbidity in patients in Australia or in the death of one or more patients in Australia.

The Determination includes, for example, sodium nitrate IV (which is used to combat cyanide poisoning), medicines for emergency or critical care use such as adrenaline IV and morphine IV, medicines containing certain anticoagulants such as warfarin, vaccines that are included in the National Immunisation Program Schedule as at 1 July 2018 (the schedule is accessible, for free, on the Department of Health's new website beta.health.gov.au/) and antivenoms such as brown snake antivenom and box jellyfish antivenom.

The making of the Medicines Watch List will provide certainty to sponsors and the public in relation to the reporting obligations for medicines included in the list. The effect of inclusion in the Determination for sponsors of such medicines is that any shortage of, or any decision by the sponsor to permanently discontinue, their product, will be required to be notified to the Secretary within the shorter of the timeframes applying under sections 30EF and 30EG of the Act - outlined above.

A shortage or permanent discontinuation of a reportable medicine that is not included in the Determination may still be of critical impact under subsections 30EF(3) or 30EG(3) if 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.

In relation to the reporting of shortages within the above timeframes, it is also 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.

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.

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 medicines in the Determination is designed to safeguard consumers by ensuring that it is clear that medicines sponsors must report any shortage or permanent discontinuation of these important medicines as soon as possible and within the shorter timeframes specified in sections 30EF and 30EG of the Act, so that patients and health practitioners are aware of the shortage as early as possible and are able to take timely steps to alleviate the impact on patient 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; 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.

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 (Medicines Watch List) Determination 2018*

Section 1 Name

This section provides that the name of this Determination is the *Therapeutic Goods (Medicines Watch List) 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 30EJ(1) 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' and 'reportable medicine'.

Section 5 Medicines Watch List

Section 5 provides that the medicines set out in Schedule 1, being reportable medicines, are determined to be medicines for the purposes of subsections 30EF(2) and 30EG(2) of the Act.

Schedule 1

Schedule 1 lists these medicines for the purposes of section 5 of the Determination including, for example, medicines that contain activated charcoal, medicines containing misoprostol for use in obstetrics, and funnel web spider antivenom.

ATTACHMENT B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Medicines Watch List) 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 (Medicines Watch List) Determination 2018* (the Determination) is a determination made by the delegate of the Minister under subsection 30EJ(1) of the *Therapeutic Goods Act 1989* (the Act). The purpose of the Determination is to identify key reportable medicines for which a shortage or a decision by the medicine's sponsor to permanently discontinue their supply will be of critical impact for the purposes of the reporting requirements for medicines shortages and discontinuations in sections 30EF and 30EG of 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.

Under new sections 30EF and 30EG of the Act, a sponsor of a reportable medicine must notify the Secretary, using the relevant 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.

Under subsections 30EF(2) and 30EG(2) of the Act, a shortage or permanent discontinuation of a reportable medicine will be of 'critical impact' if the medicine is included in a legislative

instrument made by the Minister under new section 30EJ of the Act, signalling that the Minister is satisfied that a shortage or permanent discontinuation of the medicine could cause significant morbidity or death for patients in Australia.

The Determination is such an instrument – made by the Minister under subsection 30EJ(1) of the Act, for the purposes of identifying a range of vital reportable medicines for which the delegate of the Minister is satisfied that a shortage or discontinuation of would have the potential to result in significant morbidity in patients in Australia or in the death of one or more patients in Australia.

The Determination includes, for example, sodium nitrate IV (which is used to combat cyanide poisoning), medicines for emergency or critical care use such as adrenaline IV and morphine IV, medicines containing certain anticoagulants such as warfarin, vaccines that are included in the National Immunisation Program Schedule as at 1 July 2018 (the schedule is accessible, for free, on the Department of Health's new website beta.health.gov.au/) and antivenoms such as brown snake antivenom and box jellyfish antivenom.

The effect of inclusion in the Determination for sponsors of such medicines is that any shortage of, or any decision by the sponsor to permanently discontinue, their product will be required to be notified to the Secretary within the shorter of the timeframes applying under sections 30EF and 30EG of the Act - outlined above.

A shortage or permanent discontinuation of a reportable medicine that is not included in the Determination may still be of critical impact under subsections 30EF(3) or 30EG(3) if 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.

In relation to the reporting of shortages within the above timeframes, it is also 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.

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.

Including these medicines in the Determination is designed to safeguard consumers by ensuring that it is clear that medicines sponsors must report any shortage or permanent discontinuation of these important medicines as soon as possible and within the shorter timeframes specified in sections 30EF and 30EG of the Act, so that patients and health practitioners are aware of the shortage as early as possible and are able to take timely steps to alleviate the impact on patient 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.

Determining these medicines as being ones for which a shortage or discontinuation will be of critical impact will ensure that the 2 working day reporting requirements under the new scheme will be attuned to those medicines that are particularly important for patients (e.g. medicines for emergency or critical care use such as adrenaline IV, and antivenoms including brown snake antivenom), and in so doing will enable patients and health practitioners to be better informed as early as possible about shortages of such products and better able 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 Therapeutic Goods Administration (the TGA) was not always able to alert the Australian public to shortages, 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 requirement for any shortage or discontinuation that is of critical impact to be reported quickly, 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 discontinuations by the TGA, so that this information is widely available to 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