

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Information Specification—Medicine Shortages and Availability Data) Instrument 2024

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act is administered by the Therapeutic Goods Administration (the TGA) within the Australian Government Department of Health and Aged Care (the Department).

Section 61 of the Act provides that the Secretary may release specified kinds of therapeutic goods information to the public, and to certain organisations, bodies, or authorities. Subsection 61(1) of the Act defines ‘therapeutic goods information’, for the purpose of section 61, as information relating to therapeutic goods which is held by the Department and relates to the performance of the Department’s functions.

Subsection 61(5AA) provides that the Secretary may release to a specified person, body or authority (or one that is of a specified kind), specified kinds of therapeutic goods information, for a specified purpose. Subsection 61(5AB) relevantly provides that, for the purposes of subsection 61(5AA), the Minister may, by legislative instrument, specify a person, body or authority, the kinds of information and the purposes for which the information may be released under such arrangements.

Separately, subsection 61(5C) provides that the Secretary may release to the public specified kinds of therapeutic goods information. Subsection 61(5D) relevantly provides that the Minister may, by legislative instrument, specify kinds of therapeutic goods information for the purpose of subsection 61(5C).

The *Therapeutic Goods (Information Specification—Medicine Shortages and Availability Data) Instrument 2024* (the Instrument) is a legislative instrument made under subsections 61(5AB) and (5D) of the Act. It specifies, for the purposes of subsections 61(5AA) and (5C) of the Act:

- the kinds of therapeutic goods information that the Secretary may release to specified persons, bodies or authorities, and the purposes for which the Secretary may do so; and
- the kinds of therapeutic goods information that the Secretary may release to the public.

The Instrument principally supports the implementation of a framework for the sharing of medicine availability data at a national level, which facilitates a coordinated approach to the management of medicine shortages and discontinuations. It does so by authorising the Secretary to release specified kinds of medicine availability data to a number of relevant stakeholders, including the Medicine Availability Working Group (the MAWG), to assist in the development and implementation of strategies to manage medicine shortages and discontinuations.

The Instrument also authorises the Secretary to release to the public information about the availability of medicines across Australia. This includes, but is not limited to, recommended measures to potentially limit the impacts of a shortage or discontinuation of the medicine, and the estimated availability of alternative treatments. In this respect, the Instrument complements the *Therapeutic Goods (Information relating to Shortages and Discontinuations of Supply of Medicines) Specification 2018*.

Background

A medicine shortage occurs when there is unlikely to be enough of a medicine in Australia for all the people who need, or may need, to take it. Under the Act, a medicine is in shortage if supply of the

medicine will not, or will not be likely to, meet the normal or projected demand in Australia at any point during the next 6 months (section 30EI of the Act refers). A discontinuation is effectively a permanent shortage of a medicine.

Medicine shortages continue to occur for various reasons, ranging from shortages of raw materials to natural disasters, logistical difficulties, or unexpected increases in demand. In the absence of early intervention, a medicine shortage can impede the timely availability of medicines and risk interruption to treatment, affecting the health and wellbeing of patients. Timely access to medicine availability data is therefore critical to the effective management of medicine shortages.

In consultation with State and Territory health departments, wholesalers and peak bodies for sponsors, the TGA has designed a framework to enhance the sharing of medicine availability data, and medicine availability modelling forecasts that are based on this data, among key stakeholders (the data-sharing framework). Broadly, the purpose of this framework is to facilitate a coordinated approach to the management of medicine shortages and discontinuations across Australia.

Under the data-sharing framework, the TGA may invite various data sources to provide information about the supply of, or demand for, a medicine that is in shortage or has been discontinued, and the current and expected availability of that medicine. Relevant data sources include sponsors, wholesalers, private hospitals, pharmacies and State and Territory health departments. Participation in the data-sharing framework is voluntary, meaning that a data source may decline an invitation from the TGA to provide relevant data.

Individual data sets for a particular medicine from each data source are then aggregated and run through a dynamic modelling process to simulate the movement of the medicine through supply chains, quantify shortages and predict the future availability of the medicine. This is performed using a ‘stock-and-flow’ model, which considers the available quantity of the medicine at a particular point in time against a range of parameters (or assumptions) that may add to or detract from the available quantity. This modelling is performed by either the TGA or an expert adviser in the MAWG, and is critical to the selection of the most effective strategy for managing a particular medicine shortage or discontinuation.

To effectively test medicine shortage management scenarios, the TGA needs to be able to communicate the availability modelling forecast for a particular medicine, and the individual and aggregated data sets that form the basis of that forecast, with key stakeholders. Such stakeholders include:

- the MAWG, which is coordinated by the TGA and is comprised of representatives of State and Territory health departments, and may include an expert adviser;
- Medicine Shortage Action Groups (MSAGs), which are convened by the TGA in relation to a medicine or group of medicines that are or are anticipated to be in shortage or discontinued, and is comprised of healthcare professional peak bodies, consumer representative groups, and other key stakeholders;
- the part of the Department that is responsible for administering the Pharmaceutical Benefits Scheme (the PBS); and
- various other Commonwealth authorities such as the departments responsible for external affairs (Foreign Affairs Department), home affairs (Home Affairs Department), and industry (Industry Department).

Importantly, the data-sharing framework is separate to the reporting obligations that are imposed on sponsors by Part 3-2 of the Act. Sponsors of medicines that are ‘*reportable medicines*’ (as defined in the Act) must continue to notify the Secretary of any shortage or decision to discontinue the supply of that medicine in Australia.

Purpose

Framework for sharing medicine availability data

The purpose of the Instrument is to support the data-sharing framework by enabling the sharing of certain medicine availability data. The Instrument authorises the Secretary to release the following kinds of therapeutic goods information:

- to an expert adviser in the MAWG (if there is one), or the part of the Department responsible for administering the PBS—‘*individual data sets*’ and ‘*aggregated data sets*’; and
- to the MAWG, MSAG and specified Commonwealth authorities—the ‘*aggregated visual*’ for a medicine.

An ‘*individual data set*’ is any medicine availability data that is provided to the TGA by a data source for a particular medicine that is (or is at risk of being) in shortage or has been permanently discontinued. Relevantly, a ‘*data source*’ means a department or authority of a State or Territory, a sponsor or wholesaler (or peak body representing sponsors or wholesalers), a private hospital (or peak body for the private hospital sector), or a pharmacy. An ‘*aggregated data set*’ is an aggregate of the individual data sets provided to the TGA by all data sources for a particular medicine (from which, in almost all cases, it is not possible to determine which data source provided the individual data sets).

Individual and aggregated data sets are provided to an expert adviser in the MAWG (if there is one) to enable the adviser to model and predict the future availability of a medicine that is in shortage or has been permanently discontinued. If required, such data is also provided to the part of the Department responsible for administering the PBS, to enable it to determine whether PBS subsidised access should be arranged in relation to appropriate substitute medicines (i.e., medicines that have been approved by the Secretary under section 19A or specified by the Minister as substitutable medicines under section 30EK of the Act).

An ‘*aggregated visual*’ means the medicine availability modelling forecast (in report, live modelling, or any other form) for a particular medicine, which is created by the TGA or an expert adviser in the MAWG. The modelling forecast is created through the process of running the aggregated data set through a dynamic modelling process to obtain estimates of expected medicine availability. The aggregated visual is simply a visual display of the availability of stock of the medicine as a percentage of demand over time. By changing parameters (for example, to assume that a medicine will only be used for a specific indication, rather than multiple indications), the effectiveness of conservation measures (i.e. measures to potentially prolong medicine availability) can be tested.

In accordance with the Instrument, the Secretary may release an aggregated visual to a broader range of recipients than is the case for individual and aggregated data sets. This reflects that an aggregated visual provides future availability information that may be used by a range of bodies or authorities to inform strategies for managing medicine shortages.

In accordance with the Instrument, the Secretary may release an aggregated visual to an expert adviser in the MAWG (if there is one), the part of the Department responsible for administering the PBS, and the following recipients:

- the MAWG, noting its role in (among other things) developing and implementing medicine shortage or discontinuation management strategies;
- the MSAG for a particular medicine shortage or discontinuation, which will use the aggregated visual to provide recommendations on clinical shortage management strategies;
- the Department of Foreign Affairs (DFAT), noting its role in supporting both domestic and global health initiatives (including, for example, by cooperating with overseas governments and international organisations to address shared health challenges such as medicine shortages);

- the Department of Home Affairs (DHA) (including its operational arm, Australian Border Force), which may (among other things) be required to monitor the import, export and domestic transfer of scarce medicines and alternative treatments during medicine shortages;
- the Department of Industry, Science and Resources (DISR) noting its capacity to support key stakeholders in managing supply chain vulnerability, and provide timely advice in relation to early warning signs of disruptions to critical medicine supplies; and
- the National Emergency Management Agency, noting its role in providing national leadership and strategic co-ordination, across all levels of government and sectors, in preparation for or in response to disasters and emergencies.

The Instrument specifies the purposes for which the Secretary may release the specified kinds of therapeutic goods information. That is, to facilitate the consideration, analysis and communication of medicine availability data to support the management of medicine shortages and discontinuations, including the securing of an alternative or substitute medicine.

Release of medicine availability information to the public

The Instrument also authorises the Secretary to release to the public information about:

- a medicine, and the availability of the medicine, including (for example) the sponsor of the medicine, the expected commencement of a shortage or discontinuation of the medicine, and the predicted future supply and availability of the medicine over time;
- recommended measures to potentially limit the impact of a shortage or discontinuation of a medicine;
- a medicine that may be used as an alternative treatment to a medicine that is in shortage or discontinued, and the availability of that alternative treatment, including (but not limited to) the sponsor of the alternative treatment, and the predicted future supply and availability of the alternative treatment over time; and
- the predicted impact of usage of alternative treatments, or implementation of recommended measures, to potentially limit the impact of a shortage or discontinuation of a medicine, including (but not limited to) the following:
 - the predicted impact (if any) on supply of the medicine that is in shortage or discontinued;
 - the predicted impact (if any) of usage of the alternative treatment on the availability of the alternative treatment.

The release of this range of important information to the public is critical for the management of medicine shortages and discontinuations. It enables health practitioners to contribute to conservation measures (i.e. measures to potentially minimise the impact of the shortage or discontinuation), and to be better informed to manage their patient's treatment and revise treatment plans if required. It also ensures that the TGA can provide timely advice about the steps that can be taken to alleviate the effect of a shortage or discontinuation, if required, and minimise the impact of a shortage or discontinuation. This release of information to the public supports prompt action to be taken to address the needs of patients affected by a shortage or discontinuation. This is particularly important for higher risk medicines for which a shortage or discontinuation will be of critical impact.

Consultation

In August 2022, the TGA hosted a virtual workshop with representatives from State and Territory health departments, peak bodies for health professionals, sponsors, wholesalers and the private hospital sector, to discuss areas for improvement in relation to the sharing of medicine availability data at a national level. The purpose of this workshop was principally to identify the kinds of data that are most important to the forecasting of medicine availability, and to discuss ways in which such information could be more readily accessed and shared.

The TGA has since worked closely with State and Territory health departments, sponsors and wholesalers to design the data-sharing framework. Between August and September 2023, and between February and March 2024, the TGA engaged in targeted consultation. Stakeholders that were consulted include State and Territory health departments; wholesalers; sponsors; the private hospital sector; Consumer Healthcare Products (CHP) Australia; Clifford Hallam Healthcare; the NEMA; and DFAT, DHA and DISR. A total of 10 responses were received from sponsor peak bodies, wholesalers and wholesaler peak bodies, CHP Australia, and some State and Territory health departments. All respondents supported the data sharing framework.

Between August 2023 and May 2024, the TGA also held nine stakeholder meetings with representatives from State and Territory health departments, wholesalers, sponsors and the private hospital sector in relation to the data sharing framework. The feedback provided by stakeholders during these meetings was also broadly supportive of the framework. However, there were concerns raised about the potential for release of confidential information. To address these concerns, the Instrument limits the release of potentially commercially sensitive information (i.e., in individual and aggregated data sets) to only the expert adviser in the MAWG and the part of Department that administers the PBS.

Stakeholders raised no concerns about the release of information to the public.

Other details

An Impact Analysis (IA) was not required in relation to the development of the Instrument, as the matter of specifying kinds of therapeutic goods information under section 61 of the Act is the subject of a standing exemption from the requirement to prepare an IA (OBPR ID15070).

Details of the Instrument are set out in **Attachment A**.

The Instrument is compatible with 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**.

The Instrument is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on the day after registration on the Federal Register of Legislation.

Details of the *Therapeutic Goods (Information Specification—Medicine Shortages and Availability Data) Instrument 2024*

Section 1 Name

This section provides that the name of the instrument is the *Therapeutic Goods (Information Specification—Medicine Shortages and Availability Data) Instrument 2024* (the Instrument).

Section 2 Commencement

This section provides that the Instrument commences on the day after the Instrument is registered on the Federal Register of Legislation.

Section 3 Authority

This section provides that the legislative authority for making the Instrument is subsections 61(5AB) and (5D) of the *Therapeutic Goods Act 1989* (the Act).

Section 4 Definitions

This section provides definitions for a number of terms used in the Instrument. These include ‘aggregated data set’, ‘aggregated visual’, ‘alternative treatment’, ‘data source’, ‘individual data set’, ‘MAWG’, ‘MSAG’ and ‘supply deficit’.

The note to this section also makes it clear that a number of expressions used in the Instrument have the same meaning as in the Act, including ‘medicine’, ‘Secretary’, ‘shortage’ and ‘sponsor’.

Section 5 Release of therapeutic goods information

This section provides that, for the purpose of subsection 61(5AA) of the Act, in relation to each item in the table in Schedule 1, the kinds of therapeutic goods information specified in column 2 may be released to a person, body or authority (or kinds of persons, bodies or authorities) specified in column 3, for the purposes specified in column 4.

This section also provides that, for the purpose of subsection 61(5C) of the Act, the kinds of therapeutic goods information specified in the table in Schedule 2 may be released to the public.

Schedule 1 – Therapeutic goods information: release to a person, body or authority

This Schedule specifies the kinds of therapeutic goods information, the persons, bodies, or authorities, and the purposes for which the information may be released, for subsection 5(1) of the Instrument.

Item 1 of the table in Schedule 1 specifies:

- in column 2, as the information that may be released by the Secretary—
 - individual data sets, being any data provided to the Therapeutic Goods Administration (the TGA) by a data source for a particular medicine that is in shortage, is at risk of being in shortage or has been permanently discontinued, and includes data about the supply of, or demand for, the medicine, current and expected availability of the medicine (including the quantity of the medicine), and when the medicine is expected to become available; and

- aggregated data sets, being data that is an aggregate of the individual data sets for a particular medicine from all data sources that provided data to the TGA for the particular medicine;
- in column 3, as the persons, bodies or authorities to which the specified information may be released—an expert adviser in the MAWG (if any) and the part of the Department responsible for administering the Pharmaceutical Benefits Scheme (the PBS); and
- in column 4, as the purpose for which the specified information may be released—to facilitate the consideration and analysis of medicine availability data to support the management of medicine shortages and discontinuations, including the securing of an alternative treatment.

Item 2 of the table in Schedule 1 specifies:

- in column 2, as the therapeutic goods information that may be released by the Secretary—the aggregated visual for a medicine, being the medicine availability modelling forecast (either in report form, live modelling form, or any other form) for a particular medicine, that is created by the TGA or an expert adviser in the MAWG through the process of running the aggregated data set through a dynamic live modelling process to obtain estimates of expected medicine availability;
- in column 3, as the persons, bodies or authorities to whom the specified information may be released—
 - the MAWG;
 - an expert adviser in the MAWG (if any);
 - a Medicine Shortage Action Group;
 - the part of the Department responsible for administering the PBS;
 - the Department responsible for external affairs, including relations and communications with overseas governments and United Nations agencies, trade, and international development and aid, i.e. the Department of Foreign Affairs;
 - the Department responsible for border control (other than quarantine and inspection), border security and customs, including the Australian Border Force i.e. the Department for Home Affairs;
 - the Department responsible for manufacturing and commerce, biotechnology and the co-ordination of supply chain resilience policy, i.e. the Department of Industry, Science and Resources; and
 - the National Emergency Management Agency; and
- in column 4, as the purpose for which the specified information may be released — to facilitate the consideration, analysis and communication of medicine availability data to support the management of medicine shortages and discontinuations, including the securing of an alternative treatment.

Schedule 2 – Therapeutic goods information: release to the public

This Schedule specifies, for the purpose of subsection 5(2) of the Instrument, the kinds of therapeutic goods information which the Secretary may release to the public under subsection 61(5C) of the Act.

Item 1 of the table in Schedule 2 specifies information about a medicine, and the availability of the medicine, including (but not limited to) the following:

- the sponsor of the medicine;
- the date when, or period within which, a shortage or discontinuation of the medicine is expected to commence, and the anticipated period of the shortage;
- the estimated proportion of national demand for the medicine that is available (including if none is available);

- the estimated proportion of the usual or expected supply of the medicine that is available (including if none is available);
- the predicted future supply and availability of the medicine over time;
- the estimated supply deficit of the medicine.

Item 2 of the table in Schedule 2 specifies information about the predicted impact of a shortage or discontinuation of a medicine, and recommended measures to potentially limit the impact of the shortage or discontinuation.

Item 3 of the table in Schedule 2 specifies information about an alternative treatment, and the availability of the alternative treatment, including (but not limited to) the following:

- the sponsor of the alternative treatment;
- the predicted future supply and availability of the alternative treatment over time.

Item 4 of the table in Schedule 2 specifies information about the predicted impact of usage of alternative treatments, or implementation of recommended measures to potentially limit the impact of a shortage or discontinuation of a medicine, including (but not limited to) the following:

- the predicted impact (if any) on supply of the medicine that is in shortage or discontinued;
- the predicted impact (if any) of usage of the alternative treatment on the availability of the alternative treatment.

In very rare cases, it is possible that the release of information under the Instrument may enable the identification of certain individuals. This is because the specified information may contain the name of the sponsor of a particular medicine, which is the person who imports the goods into Australia, exports the goods from Australia, or manufactures the goods in Australia. The sponsor of a medicine is most often a company, but in very few cases may be an individual.

In most cases, the name of the sponsor for a medicine is already publicly available. In particular:

- the name of a sponsor for a medicine that is in the Australian Register of Therapeutic Goods (the Register) is displayed in the Register; and
- the name of a sponsor who has been granted an approval under section 19A of the Act to import or supply an ‘unapproved’ medicine is available on the database for such approvals on the TGA’s website.

However, the release of information under the Instrument about the sponsor of a medicine that is not in the Register, and is not the subject of an approval under section 19A of the Act, may result in the release of personal information about an individual that is not otherwise publicly available in the rare cases that the sponsor is an individual.

The Therapeutic Goods Administration (the TGA), as part of the Australian Government Department of Health and Aged Care (the Department), is an APP entity for the purposes of the *Privacy Act 1988* (the Privacy Act). Any use or disclosure of personal information would be consistent with the Privacy Act. The collection and use of the information specified in the Instrument by the TGA, and its disclosure, is critical to the effective management of medicine shortages and discontinuations, and to supporting continuity of care for patients. It is therefore important that the TGA be able to share the name of a sponsor with the public, and with the specified persons, bodies or authorities, even where the sponsor is (in very few cases) an individual.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Information Specification—Medicine Shortages and Availability Data) Instrument 2024

This disallowable 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 (Information Specification—Medicine Shortages and Availability Data) Instrument 2024* (the Instrument) is a legislative instrument made under subsections 61(5AB) and (5D) of the Act. It specifies, for the purposes of subsections 61(5AA) and (5C) of the Act:

- the kinds of therapeutic goods information that the Secretary may release to specified persons, bodies or authorities, and the purposes for which the Secretary may do so; and
- the kinds of therapeutic goods information that the Secretary may release to the public.

The Instrument principally supports the implementation of a framework for the sharing of medicine availability data at a national level, which facilitates a coordinated approach to the management of medicine shortages and discontinuations. It does so by authorising the Secretary to release specified kinds of medicine availability data to a number of relevant stakeholders, including the Medicine Availability Working Group (the MAWG), to assist in the development and implementation of strategies to manage medicine shortages and discontinuations.

The Instrument also authorises the Secretary to release to the public information about the availability of medicines across Australia. This includes, but is not limited to, recommended measures to potentially limit the impacts of a shortage or discontinuation of the medicine, and the estimated availability of alternative treatments. In this respect, the Instrument complements the *Therapeutic Goods (Information relating to Shortages and Discontinuations of Supply of Medicines) Specification 2018*.

Background

A medicine shortage occurs when there is unlikely to be enough of a medicine in Australia for all the people who need, or may need, to take it. Under the Act, a medicine is in shortage if supply of the medicine will not, or will not be likely to, meet the normal or projected demand in Australia at any point during the next 6 months (section 30EI of the Act refers). A discontinuation is effectively a permanent shortage of a medicine.

Medicine shortages continue to occur for various reasons, ranging from shortages of raw materials to natural disasters, logistical difficulties, or unexpected increases in demand. In the absence of early intervention, a medicine shortage can impede the timely availability of medicines and risk interruption to treatment, affecting the health and wellbeing of patients. Timely access to medicine availability data is therefore critical to the effective management of medicine shortages.

In consultation with State and Territory health departments, wholesalers and peak bodies for sponsors, the Therapeutic Goods Administration (the TGA) has designed a framework to enhance the sharing of medicine availability data, and medicine availability modelling forecasts that are based on this data, among key stakeholders (the data-sharing framework). Broadly, the purpose of this framework is to

facilitate a coordinated approach to the management of medicine shortages and discontinuations across Australia.

Under the data-sharing framework, the TGA may invite various data sources to provide information about the supply of, or demand for, a medicine that is in shortage or has been discontinued, and the current and expected availability of that medicine. Relevant data sources include sponsors, wholesalers, private hospitals, pharmacies and State and Territory health departments. Participation in the data-sharing framework is voluntary, meaning that a data source may decline an invitation from the TGA to provide relevant data.

Individual data sets for a particular medicine from each data source are then aggregated and run through a dynamic modelling process to simulate the movement of the medicine through supply chains, quantify shortages and predict the future availability of the medicine. This is performed using a ‘stock-and-flow’ model, which considers the available quantity of the medicine at a particular point in time against a range of parameters (or assumptions) that may add to or detract from the available quantity. This modelling is performed by either the TGA or an expert adviser in the MAWG, and is critical to the selection of the most effective strategy for managing a particular medicine shortage or discontinuation.

To effectively test medicine shortage management scenarios, the TGA needs to be able to communicate the availability modelling forecast for a particular medicine, and the individual and aggregated data sets that form the basis of that forecast, with key stakeholders. Such stakeholders include:

- the MAWG, which is coordinated by the TGA and is comprised of representatives of State and Territory health departments, and may include an expert adviser;
- Medicine Shortage Action Groups (MSAGs), which are convened by the TGA in relation to a medicine or group of medicines that are or are anticipated to be in shortage or discontinued, and is comprised of healthcare professional peak bodies, consumer representative groups, and other key stakeholders;
- the part of the Department that is responsible for administering the Pharmaceutical Benefits Scheme (the PBS); and
- various other Commonwealth authorities such as the departments responsible for external affairs (Foreign Affairs Department), home affairs (Home Affairs Department), and industry (Industry Department).

Importantly, the data-sharing framework is separate to the reporting obligations that are imposed on sponsors by Part 3-2 of the Act. Sponsors of medicines that are ‘*reportable medicines*’ (as defined in the Act) must continue to notify the Secretary of any shortage or decision to discontinue the supply of that medicine in Australia.

Purpose

Framework for sharing medicine availability data

The purpose of the Instrument is to support the data-sharing framework by enabling the sharing of certain medicine availability data. The Instrument authorises the Secretary to release the following kinds of therapeutic goods information:

- to an expert adviser in the MAWG (if there is one), or the part of the Department responsible for administering the PBS—‘*individual data sets*’ and ‘*aggregated data sets*’; and
- to the MAWG, MSAG and specified Commonwealth authorities—the ‘*aggregated visual*’ for a medicine.

An ‘*individual data set*’ is any medicine availability data that is provided to the TGA by a data source for a particular medicine that is (or is at risk of being) in shortage or has been permanently discontinued. Relevantly, a ‘*data source*’ means a department or authority of a State or Territory, a

sponsor or wholesaler (or peak body representing sponsors or wholesalers), a private hospital (or peak body for the private hospital sector), or a pharmacy. An ‘*aggregated data set*’ is an aggregate of the individual data sets provided to the TGA by all data sources for a particular medicine (from which, in almost all cases, it is not possible to determine which data source provided the individual data sets).

Individual and aggregated data sets are provided to an expert advisor in the MAWG (if there is one) to enable the adviser to model and predict the future availability of a medicine that is in shortage or has been permanently discontinued. If required, such data is also provided to the part of the Department responsible for administering the PBS, to enable it to determine whether PBS subsidised access should be arranged in relation to appropriate substitute medicines (i.e., medicines that have been approved by the Secretary under section 19A or specified by the Minister as substitutable medicines under section 30EK of the Act).

An ‘*aggregated visual*’ means the medicine availability modelling forecast (in report, live modelling, or any other form) for a particular medicine, which is created by the TGA or an expert adviser in the MAWG. The modelling forecast is created through the process of running the aggregated data set through a dynamic modelling process to obtain estimates of expected medicine availability. The aggregated visual is simply a visual display of the availability of stock of the medicine as a percentage of demand over time. By changing parameters (for example, to assume that a medicine will only be used for a specific indication, rather than multiple indications), the effectiveness of conservation measures (i.e. measures to potentially prolong medicine availability) can be tested.

In accordance with the Instrument, the Secretary may release an aggregated visual to a broader range of recipients than is the case for individual and aggregated data sets. This reflects that an aggregated visual provides future availability information that may be used by a range of bodies or authorities to inform strategies for managing medicine shortages.

In accordance with the Instrument, the Secretary may release an aggregated visual to an expert adviser in the MAWG (if there is one), the part of the Department responsible for administering the PBS, and the following recipients:

- the MAWG, noting its role in (among other things) developing and implementing medicine shortage or discontinuation management strategies;
- the MSAG for a particular medicine shortage or discontinuation, which will use the aggregated visual to provide recommendations on clinical shortage management strategies;
- the Department of Foreign Affairs (DFAT), noting its role in supporting both domestic and global health initiatives (including, for example, by cooperating with overseas governments and international organisations to address shared health challenges such as medicine shortages);
- the Department of Home Affairs (DHA) (including its operational arm, Australian Border Force), which may (among other things) be required to monitor the import, export and domestic transfer of scarce medicines and alternative treatments during medicine shortages;
- the Department of Industry, Science and Resources (DISR) noting its capacity to support key stakeholders in managing supply chain vulnerability, and provide timely advice in relation to early warning signs of disruptions to critical medicine supplies; and
- the National Emergency Management Agency, noting its role in providing national leadership and strategic co-ordination, across all levels of government and sectors, in preparation for or in response to disasters and emergencies.

The Instrument specifies the purposes for which the Secretary may release the specified kinds of therapeutic goods information. That is, to facilitate the consideration, analysis and communication of medicine availability data to support the management of medicine shortages and discontinuations, including the securing of alternative or substitute medicine.

Release of medicine availability information to the public

The Instrument also authorises the Secretary to release to the public information about:

- a medicine, and the availability of the medicine, including (for example) the sponsor of the medicine, the expected commencement of a shortage or discontinuation of the medicine, and the predicted future supply and availability of the medicine over time;
- recommended measures to potentially limit the impact of a shortage or discontinuation of a medicine;
- a medicine that may be used as an alternative treatment to a medicine that is in shortage or discontinued, and the availability of that alternative treatment, including (but not limited to) the sponsor of the alternative treatment, and the predicted future supply and availability of the alternative treatment over time; and
- the predicted impact of usage of alternative treatments, or implementation of recommended measures, to potentially limit the impact of a shortage or discontinuation of a medicine, including (but not limited to) the following:
 - the predicted impact (if any) on supply of the medicine that is in shortage or discontinued;
 - the predicted impact (if any) of usage of the alternative treatment on the availability of the alternative treatment.

This release of information to the public supports prompt action to be taken to address the needs of patients affected by a shortage or discontinuation. This is particularly important for higher risk medicines for which a shortage or discontinuation will be of critical impact.

Human rights implications

The Instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR) and the right to protection against arbitrary and unlawful interferences with privacy in Article 17 of the International Covenant on Civil and Political Rights (the ICCPR).

Right to Health

Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health.

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.

The Instrument promotes the right to health by facilitating the release of therapeutic goods information relating to medicine availability, to support the management of medicine shortages and discontinuations and support continuity of care for affected patients. The release of this information supports information sharing about medicine availability which can be used by other Commonwealth Departments to develop and implement medicine shortage management strategies.

Further, the release of this important availability information to the public is critical for the management of medicine shortages and discontinuations. It enables health practitioners to contribute to conservation measures (i.e. measures to potentially minimise the impact of the shortage or discontinuation), and to be better informed to manage their patient’s treatment and revise treatment plans if required. It also ensures that the TGA can provide timely advice about the steps that can be taken to alleviate the effect of a shortage or discontinuation, if required, and minimise the impact of a shortage or discontinuation.

Right to protection against arbitrary and unlawful interferences with privacy

Article 17 of the ICCPR provides for the right of every person not to be subjected to arbitrary or unlawful interference with privacy. The prohibition on interference with privacy prohibits unlawful or arbitrary interferences with a person's privacy, family, home and correspondence. It also prohibits unlawful attacks on a person's reputation. Limitations on the right to privacy must be according to law and not arbitrary, i.e. limitations must be reasonable and necessary in the particular circumstances, as well as proportionate to the objectives the limitations seek to achieve.

In very rare cases, it is possible that the release of information under the Instrument may enable the identification of certain individuals. This is because the specified information may contain the name of the sponsor of a particular medicine, which is the person who imports the goods into Australia, exports the goods from Australia, or manufactures the goods in Australia. The sponsor of a medicine is most often a company, but in very few cases may be an individual.

In most cases, the name of the sponsor for a medicine is already publicly available. In particular:

- the name of a sponsor for a medicine that is in the Australian Register of Therapeutic Goods (the Register) is displayed in the Register; and
- the name of a sponsor who has been granted an approval under section 19A of the Act to import or supply an 'unapproved' medicine is available on the database for such approvals on the TGA's website.

However, the release of information under the Instrument about the sponsor of a medicine that is not in the Register, and is not the subject of an approval under section 19A of the Act, may result in the release of personal information about an individual that is not otherwise publicly available in the rare cases that the sponsor is an individual.

The TGA, as part of the Australian Government Department of Health and Aged Care (the Department), is an APP entity for the purposes of the *Privacy Act 1988* (the Privacy Act). Any use or disclosure of personal information would be consistent with the Privacy Act. The collection and use of the information specified in the Instrument by the TGA, and its disclosure, is critical to the effective management of medicine shortages and discontinuations, and to supporting continuity of care for patients. It is therefore important that the TGA be able to share the name of a sponsor with the public, and with the specified persons, bodies or authorities, even where the sponsor is (in very few cases) an individual.

As such, the disclosure of the information would not be an arbitrary or unlawful interference with a person's privacy under Article 17 of the ICCPR, as the disclosure would be reasonable given it is appropriate and justified for the public to know who the sponsor is (even if it is an individual), and the disclosure would be necessary and proportionate to the objective of supporting continuity of care for patients in Australia who may otherwise be adversely affected by a medicine shortage or discontinuation.

Conclusion

The Instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and any engagement with the right to privacy in Article 17 of ICCPR is reasonable, necessary and proportionate.