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

I, Nicholas Henderson, as delegate of the Minister for Health and Aged Care, make the following instrument.

Dated 13 June 2024

Nicholas Henderson
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

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

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsections 61(5AB) and (5D) of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

(a) medicine;
(b) Secretary;
(c) shortage;
(d) sponsor.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

aggregated data set means data that is an aggregate of the individual data sets for a medicine from all data sources that provided data to the TGA for the medicine.

aggregated visual means the medicine availability modelling forecast (either in report form, live modelling form or any other form) for a 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 modelling process to obtain estimates of expected medicine availability.

alternative treatment means a medicine that may be used as an alternative for another medicine that is in shortage, is at risk of being in shortage, or has been permanently discontinued, for a patient who may be affected by the shortage or discontinuation of supply.

Australian Border Force has the same meaning as in the *Australian Border Force Act 2015*.

data source means any of the following:

(a) a pharmacy;
(b) a department or authority of a State or of a Territory;
(c) a sponsor, or a peak body representing sponsors;
(d) a wholesaler, or a peak body representing wholesalers;
(e) a private hospital, or a peak body for the private hospital sector.

Foreign Affairs Department means the Department responsible for external affairs, including relations and communications with overseas governments and United Nations agencies, trade, and international development and aid.

Home Affairs Department means the Department responsible for border control (other than quarantine and inspection), border security and customs, and includes the Australian Border Force.

Industry Department means the Department responsible for manufacturing and commerce, biotechnology and the co-ordination of supply chain resilience policy.

individual data set means any data provided to the TGA by a data source for a medicine that is in shortage, is at risk of being in shortage, or has been permanently discontinued, and includes data about the following:

(a) the supply of, or demand for, the medicine;
(b) the current and expected availability of the medicine (including the quantity of the medicine);
(c) when the medicine is expected to become available.

MAWG means the Medicine Availability Working Group, which:

(a) is coordinated by the TGA; and
(b) is comprised of representatives of State and Territory health departments; and
(c) may include an expert adviser.

MSAG means a Medicine Shortage Action Group, which:

(a) is convened and coordinated by the TGA for a medicine or a group of related medicines that are, or are anticipated to be in shortage or discontinued; and
(b) is comprised of healthcare professional peak bodies, consumer representative groups, and other key stakeholders relevant to the medicine.

national demand means the expected demand for a medicine for all the patients in Australia who take, or who may need to take the medicine.

NEMA means the National Emergency Management Agency, under the Home Affairs Department.

supply deficit means the shortfall in supply of a medicine, as a percentage of the expected demand for the medicine for all the patients in Australia who take, or who may need to take the medicine, over a specific period of time.

Therapeutic Goods Administration, or ***TGA***, means the part of the Department known as the Therapeutic Goods Administration.

therapeutic goods information has the meaning given by subsection 61(1) of the Act.

5 Release of therapeutic goods information

(1) 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.

Note: Under subsection 61(5AA) of the Act, the Secretary may release to a person, body or authority that is specified, or is of a kind specified, under subsection 61(5AB), specified kinds of therapeutic goods information for a specified purpose.

(2) 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.

Note: Kinds of therapeutic goods information specified under subsection 61(5D) of the Act may be released by the Secretary to the public under subsection 61(5C).

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

Note: See subsection 5(1).

Therapeutic goods information that may be released to a person, body or authority			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kinds of therapeutic goods information**	**Persons, bodies or authorities**	**Purposes**
1	individual data sets and aggregated data sets	the following persons, bodies or authorities: (a) an expert adviser in the MAWG (if any); (b) the part of the Department responsible for administering the Pharmaceutical Benefits Scheme	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
2	the aggregated visual for a medicine	the following persons, bodies or authorities: (a) the MAWG; (b) an expert adviser in the MAWG (if any); (c) a MSAG; (d) the part of the Department responsible for administering the Pharmaceutical Benefits Scheme; (e) the Foreign Affairs Department; (f) the Home Affairs Department; (g) the Industry Department; (h) the NEMA	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

Note: See subsection 5(2).

Therapeutic goods information that may be released to the public	
Column 1	**Column 2**
Item	**Kinds of therapeutic goods information**
1	information about a medicine, and the availability of the medicine, including (but not limited to) the following: (a) the sponsor of the medicine; (b) 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; (c) the estimated proportion of national demand for the medicine that is available (including if none is available); (d) the estimated proportion of the usual or expected supply of the medicine that is available (including if none is available); (e) the predicted future supply and availability of the medicine over time; (f) the estimated supply deficit of the medicine
2	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
3	information about an alternative treatment, and the availability of the alternative treatment, including (but not limited to) the following: (a) the sponsor of the alternative treatment; (b) the predicted future supply and availability of the alternative treatment over time
4	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: (a) the predicted impact (if any) on supply of the medicine that is in shortage or discontinued; (b) the predicted impact (if any) of usage of the alternative treatment on the availability of the alternative treatment