



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

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I, Jane Cook, as delegate of the Minister for Health, make the following specification.

Dated 10 December 2018

*(signed by)*

Jane Cook  
First Assistant Secretary  
Medicines Regulation Division  
Health Products Regulation Group  
Department of Health

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# Contents

1 Name.....	1
2 Commencement .....	1
3 Authority.....	1
4 Definitions .....	1
5 Repeals.....	3
6 Therapeutic goods information .....	3
<b>Schedule 1—Repeals</b>	<b>4</b>
<i>Therapeutic Goods Information (Medicine Shortages Information Initiative) Specification 2014</i>	4
<b>Schedule 2—Specified kinds of therapeutic goods information</b>	<b>5</b>
Part 1— Information relating to a shortage of a medicine that arises on or after 1 January 2019	5
Part 2— Information relating to a decision to permanently discontinue the supply of a medicine that is made on or after 1 January 2019	8
Part 3—Information relating to a shortage of a medicine that arose before 1 January 2019	11
Part 4—Information relating to a decision to permanently discontinue the supply of a medicine that was made before 1 January 2019	14



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## 1 Name

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

## 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	1 January 2019.	1 January 2019

Note: This table relates only to the provisions of this instrument as originally made.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 subsection 61(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) Register;
- (c) registered goods;
- (d) registration number;
- (e) reportable medicine;
- (f) shortage;
- (g) sponsor.

In this instrument:

*Act* means the *Therapeutic Goods Act 1989*.

**active ingredient** has the same meaning as in the Regulations.

**anticipated shortage**, in relation to a medicine, means a shortage other than a current shortage.

**ATC** means anatomical therapeutic chemical.

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**ATC classification system** means the Anatomical Therapeutic Chemical Classification System, an internationally accepted classification system for medicines that is maintained by the WHO and under which the WHO assigns ATC codes to all active ingredients contained in medicines based on the therapeutic indication for the medicine and classifies such ingredients into groups at 5 different levels according to the organ or system of the human body on which they act and the active ingredient's therapeutic, pharmacological and chemical properties, as in force or existing at 1 December 2018.

Note: The ATC classification system can be found (and viewed for free) on the internet at: [https://www.whooc.no/atc\\_ddd\\_index\\_and\\_guidelines/atc\\_ddd\\_index/](https://www.whooc.no/atc_ddd_index_and_guidelines/atc_ddd_index/) (while there is a cost to obtain an electronic (200€) or paper (60€) version of the whole system, this website contains a free index which can be used to search for a medicine and view its ATC code without charge).

**critical impact**, in relation to the discontinuation of the supply of a medicine, has the meaning given by subsections 30EG(2) and (3) of the Act.

**critical impact**, in relation to the shortage of a medicine, has the meaning given by subsections 30EF(2) and (3) of the Act.

**current shortage**, in relation to a medicine, means a shortage at a particular time if, at that time, the supply of that medicine in Australia will not, or will not be likely to, meet the demand for the medicine for all of the patients in Australia who take, or who may need to take, the medicine.

**discontinuation decision** has the meaning given by subsection 30EG(1) of the Act.

**MSII** means the voluntary Medicines Shortage Information Initiative that was administered by the Therapeutic Goods Administration for the period 2014 to 2018.

Note: The *Medicine Shortages Information Initiative: Protocol for all Australian Sponsors and the Therapeutic Goods Administration* can be found (and viewed for free) on the internet at: <http://www.tga.gov.au>.

**NIP** means the National Immunisation Program Schedule as in force or existing at 1 December 2018.

Note: The National Immunisation Program Schedule can be found (and viewed for free) on the internet at: <http://beta.health.gov.au>.

**Regulations** means the *Therapeutic Goods Regulations 1990*.

**substitute medicine**, in relation to a medicine which is in shortage or the subject of a discontinuation decision, means a medicine that has the same active ingredient as that medicine.

**therapeutic alternative**, in relation to a medicine which is in shortage or the subject of a discontinuation decision, means other therapeutic options that a health professional may consider as an alternative treatment for a patient who may be affected by a shortage or discontinuation of supply of that medicine.

**Therapeutic Goods Administration** or TGA, has the same meaning as in the Regulations.

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*trade name* has the same meaning as in the Regulations.

*WHO* means the World Health Organisation.

## 5 Repeals

Each instrument that is specified in Schedule 1 to this instrument is repealed as set out in that Schedule.

## 6 Therapeutic goods information

- (1) The kinds of therapeutic goods information set out in Part 1 of Schedule 2 are specified for the purpose of subsection 61(5C) of the Act, in relation to a shortage of a reportable medicine in Australia that arises on or after 1 January 2019.
- (2) The kinds of therapeutic goods information set out in Part 2 of Schedule 2 are specified for the purpose of subsection 61(5C) of the Act, in relation to a decision to permanently discontinue the supply of a reportable medicine in Australia that is made on or after 1 January 2019.
- (3) The kinds of therapeutic goods information set out in Part 3 of Schedule 2 are specified for the purpose of subsection 61(5C) of the Act, in relation to a shortage of a medicine in Australia that arises before 1 January 2019.
- (4) The kinds of therapeutic goods information set out in Part 4 of Schedule 2 are specified for the purpose of subsection 61(5C) of the Act, in relation to a decision to permanently discontinue the supply of a medicine in Australia that is made before 1 January 2019.

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).

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## **Schedule 1—Repeals**

Note: See section 5.

### ***Therapeutic Goods Information (Medicine Shortages Information Initiative) Specification 2014***

#### **1 The whole of the instrument**

Repeal the instrument



## Schedule 2—Specified kinds of therapeutic goods information

Note: See section 6.

### Part 1— Information relating to a shortage of a reportable medicine that arises on or after 1 January 2019

For each item in column 1 of the following table, the kind of therapeutic goods information specified in column 2 has the description given in column 3.

<b>Kinds of therapeutic goods information</b>		
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Item</b>	<b>Information</b>	<b>Description</b>
<b>Information about the medicine:</b>		
1	name of medicine	the trade name or brand name of the reportable medicine that is the subject of a notification to the Secretary under section 30EF of the Act (the <i>relevant medicine</i> )
2	active ingredient	the active ingredient, or active ingredients, of the relevant medicine
3	strength	the strength of the relevant medicine
4	dosage form	the dosage form of the relevant medicine
5	container	the type of container of the relevant medicine
6	registration number	the registration number of the relevant medicine
7	therapeutic class	the ATC code for the relevant medicine's active ingredient under the ATC classification system
<b>Information about the sponsor:</b>		
8	sponsor name	the name of the sponsor of the relevant medicine (the <i>relevant sponsor</i> )
9	sponsor's nominated public contact details	an Australian telephone number and/or email address nominated by the relevant sponsor for the purposes of responding to enquiries from the public seeking additional information about the relevant medicine
10	sponsor's nominated website details	the website address (URL) nominated by the relevant sponsor for the purposes of providing the public with additional information about the relevant medicine
<b>Information about the shortage:</b>		
11	status of the shortage	whether the relevant medicine is the subject of a shortage that: <ul style="list-style-type: none"> <li>(a) is an anticipated shortage;</li> <li>(b) is a current shortage; or</li> <li>(c) has been resolved</li> </ul>
12	reason for the shortage	the relevant sponsor's advice as to the general reason

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**Kinds of therapeutic goods information**

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<b>Column 1 Item</b>	<b>Column 2 Information</b>	<b>Column 3 Description</b>
		for the shortage of the relevant medicine, as follows: (a) commercial reasons; (b) manufacturing; (c) product recall; (d) unexpected increase in demand; or (e) other
13	commencement date of impact on supply	the relevant sponsor's advice as to: (a) for a current shortage—the date the shortage commenced; (b) for an anticipated shortage—the date that it is anticipated that the supply of the relevant medicine in Australia will not, or will not be likely to, meet the demand for the relevant medicine for all of the patients in Australia who take, or who may need to take, the relevant medicine
14	anticipated date the shortage will be resolved	the relevant sponsor's advice as to the date the supply of the relevant medicine in Australia will, or will be likely to, meet the demand for the relevant medicine for all of the patients in Australia who take, or who may need to take, the relevant medicine
15	availability level	the relevant sponsor's advice as to the current availability level of the supply of the relevant medicine, as follows: (a) available—there are no constraints or restrictions on supply; (b) limited availability—the relevant medicine is available in limited quantities throughout the supply chain; (c) only available under government programs — in relation to a medicine that is a vaccine, the relevant medicine is only available for Commonwealth (NIP) or State and Territory government immunisation programs and is not available in the private market; (d) emergency supply only—the relevant sponsor is imposing controls on the supply of the relevant medicine; or (e) unavailable—the relevant medicine is not available
16	patient impact	whether the impact of the shortage is: (a) critical; (b) medium; or (c) low

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**Kinds of therapeutic goods information**

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<b>Column 1 Item</b>	<b>Column 2 Information</b>	<b>Column 3 Description</b>
17	supply details and other information	any information, or links to any information, in relation to: (a) the supply arrangements in relation to the relevant medicine; (b) substitute medicines for the relevant medicine, including supply arrangements and use; (c) therapeutic alternatives to the relevant medicine, including supply arrangements and use
18	TGA management action	details of action that has been or is being taken by the TGA in relation to managing the shortage
19	updated	date that the entry was last updated

In this Part:

**low impact**, in relation to a shortage of a reportable medicine that is not of critical impact, means a shortage that is assessed as low patient impact in accordance with the assessment framework set out in the *Management and Communication of Medicine Shortages and Discontinuations in Australia – Guidance for Sponsors and Other Stakeholder Bodies* published in November 2018.

**medium impact**, in relation to a shortage of a reportable medicine that is not of critical impact, means a shortage that is assessed as medium patient impact in accordance with the assessment framework set out in the *Management and Communication of Medicine Shortages and Discontinuations in Australia – Guidance for Sponsors and Other Stakeholder Bodies* published in November 2018.

Note: The *Management and Communication of Medicine Shortages and Discontinuations in Australia – Guidance for Sponsors and Other Stakeholder Bodies* can be found (and viewed for free) on the internet at: <http://www.tga.gov.au>.

## Part 2— Information relating to a decision to permanently discontinue the supply of a reportable medicine that is made on or after 1 January 2019

For each item in column 1 of the following table, the kind of therapeutic goods information specified in column 2 has the description given in column 3.

<b>Kinds of therapeutic goods information</b>		
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Item</b>	<b>Information</b>	<b>Description</b>
<b>Information about the medicines:</b>		
1	name of medicine	the trade or brand name of the reportable medicine that is the subject of a notification to the Secretary under section 30EG of the Act (the <i>relevant medicine</i> )
2	active ingredient(s)	the active ingredient, or active ingredients, of the relevant medicine
3	strength	the strength of the relevant medicine
4	dosage form	the dosage form of the relevant medicine
5	container	the container type of the relevant medicine
6	registration number	the registration number of the relevant medicine
7	therapeutic class	the ATC code for the relevant medicine's active ingredient under the ATC classification system
<b>Information about the sponsor:</b>		
8	sponsor name	the name of the sponsor of the relevant medicine (the <i>relevant sponsor</i> )
9	sponsor's nominated public contact details	an Australian telephone number and/or email address nominated by the relevant sponsor for the purposes of responding to enquiries from the public seeking additional information about the relevant medicine
10	sponsor's nominated website details	the website address (URL) nominated by the relevant sponsor for the purposes of providing the public with additional information about the relevant medicine
<b>Information about the discontinuation:</b>		
11	status of the discontinuation	whether the relevant medicine will be or has been permanently discontinued by the relevant sponsor
12	reason for the discontinuation	the relevant sponsor's advice as to the general reason for the discontinuation decision, as follows: (a) commercial reasons; (b) manufacturing; (c) product recall; (d) unexpected increase in demand; or (e) other
13	market deletion date	the sponsor's advice as to the date from which the

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**Kinds of therapeutic goods information**

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<b>Column 1 Item</b>	<b>Column 2 Information</b>	<b>Column 3 Description</b>
		sponsor will cease, or has ceased, supply of the relevant medicine to the Australian market
14	availability level	<p>the relevant sponsor’s advice as to the current availability level of the supply of the relevant medicine, as follows:</p> <ul style="list-style-type: none"> <li>(a) available—there are no constraints or restrictions on supply;</li> <li>(b) limited availability—the relevant medicine is available in limited quantities throughout the supply chain;</li> <li>(c) only available under government programs — in relation to a medicine that is a vaccine, the medicine is only available for Commonwealth (NIP) or State and Territory government immunisation programs and is not available in the private market;</li> <li>(d) emergency supply only—the relevant sponsor is imposing controls on the supply of the relevant medicine; or</li> <li>(e) unavailable—the relevant medicine is not available</li> </ul>
15	patient impact	<p>whether the impact of the discontinuation is:</p> <ul style="list-style-type: none"> <li>(a) critical;</li> <li>(b) medium; or</li> <li>(c) low</li> </ul>
16	supply details and other information	<p>any information, or links to any information, in relation to:</p> <ul style="list-style-type: none"> <li>(a) the supply arrangements in relation to the relevant medicine;</li> <li>(b) substitute medicines for the relevant medicine, including supply arrangements and use;</li> <li>(c) therapeutic alternatives to the relevant medicine, including supply arrangements and use</li> </ul>
17	TGA management action	details of action that has been or is being taken by the TGA in relation to managing the discontinuation
18	updated	date that the entry was last updated

In this Part:

***low impact***, in relation to a discontinuation of the supply of a reportable medicine that is not of critical impact, means a discontinuation that is assessed as low patient impact in accordance with the assessment framework set out in the *Management and Communication of Medicine Shortages and*

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*Discontinuations in Australia – Guidance for Sponsors and Other Stakeholder Bodies* published in November 2018.

**medium impact**, in relation to a discontinuation of the supply of a reportable medicine that is not of critical impact, means a discontinuation that is assessed as medium patient impact in accordance with the assessment framework set out in the *Management and Communication of Medicine Shortages and Discontinuations in Australia – Guidance for Sponsors and Other Stakeholder Bodies* published in November 2018.

Note: The *Management and Communication of Medicine Shortages and Discontinuations in Australia – Guidance for Sponsors and Other Stakeholder Bodies* can be found (and viewed for free) on the internet at: <http://www.tga.gov.au>.

## Part 3—Information relating to a shortage of a medicine that arose before 1 January 2019

For each item in column 1 of the following table, the kind of therapeutic goods information specified in column 2 has the description given in column 3.

<b>Kinds of therapeutic goods information</b>		
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Item</b>	<b>Information</b>	<b>Description</b>
<b>Information about the medicine:</b>		
1	name of medicine	the trade name or brand name of the medicine that was the subject of a notification to the Secretary under the MSII (the <i>relevant medicine</i> )
2	active ingredient	the active ingredient, or active ingredients, of the relevant medicine
3	strength	the strength of the relevant medicine
4	dosage form	the dosage form of the relevant medicine
5	container	the type of container of the relevant medicine
6	registration number	the registration number of the relevant medicine
7	therapeutic class	the ATC code for the relevant medicine's active ingredient under the ATC classification system
<b>Information about the sponsor:</b>		
8	sponsor name	the name of the sponsor of the relevant medicine (the <i>relevant sponsor</i> )
9	sponsor's nominated public contact details	an Australian telephone number and/or email address nominated by the relevant sponsor for the purposes of responding to enquiries from the public seeking additional information about the relevant medicine
10	sponsor's nominated website details	the website address (URL) nominated by the relevant sponsor for the purposes of providing the public with additional information about the relevant medicine
<b>Information about the shortage:</b>		
11	status of the shortage	whether the relevant medicine is the subject of a shortage that: <ul style="list-style-type: none"> <li>(a) is an anticipated shortage;</li> <li>(b) is a current shortage; or</li> <li>(c) has been resolved</li> </ul>
12	reason for the shortage	the relevant sponsor's advice as to the general reason for the shortage of the relevant medicine, as follows: <ul style="list-style-type: none"> <li>(a) commercial reasons;</li> <li>(b) manufacturing;</li> <li>(c) product recall;</li> <li>(d) unexpected increase in demand; or</li> </ul>

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**Kinds of therapeutic goods information**

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<b>Column 1 Item</b>	<b>Column 2 Information</b>	<b>Column 3 Description</b>
		(e) other
13	commencement date of impact on supply	the relevant sponsor's advice as to: <ul style="list-style-type: none"> <li>(a) for a current shortage—the date the shortage commenced;</li> <li>(b) for an anticipated shortage—the date that it is anticipated that the supply of the relevant medicine in Australia will not, or will not be likely to, meet the demand for the relevant medicine for all of the patients in Australia who take, or who may need to take, the relevant medicine</li> </ul>
14	anticipated date the shortage will be resolved	the relevant sponsor's advice as to the date the supply of the relevant medicine in Australia will, or will be likely to, meet the demand for the relevant medicine for all of the patients in Australia who take, or who may need to take, the relevant medicine
15	availability level	the relevant sponsor's advice as to the current availability level of the supply of the relevant medicine, as follows: <ul style="list-style-type: none"> <li>(a) available—there are no constraints or restrictions on supply;</li> <li>(b) limited availability—the relevant medicine is available in limited quantities throughout the supply chain;</li> <li>(c) only available under government programs — in relation to a medicine that is a vaccine, the relevant medicine is only available for Commonwealth (NIP) or State and Territory government immunisation programs and is not available in the private market;</li> <li>(d) emergency supply only—the relevant sponsor is imposing controls on the supply of the relevant medicine; or</li> <li>(e) unavailable—the relevant medicine is not available</li> </ul>
16	patient impact	whether the impact of the shortage is: <ul style="list-style-type: none"> <li>(a) critical;</li> <li>(b) medium; or</li> <li>(c) low</li> </ul>
17	supply details and other information	any information, or links to any information, in relation to: <ul style="list-style-type: none"> <li>(a) the supply arrangements in relation to the relevant medicine;</li> <li>(b) substitute medicines for the relevant medicine, including supply arrangements and use;</li> </ul>



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<b>Kinds of therapeutic goods information</b>		
<b>Column 1 Item</b>	<b>Column 2 Information</b>	<b>Column 3 Description</b>
		(c) therapeutic alternatives to the relevant medicine, including supply arrangements and use
18	TGA management action	details of action that has been or is being taken by the TGA in relation to managing the shortage
19	updated	date that the entry was last updated

In this Part:

**low impact**, in relation to a shortage of a medicine that is not of critical impact, means a shortage that is assessed as low patient impact in accordance with the assessment framework set out in the *Medicine Shortages Information Initiative: Protocol for all Australian Sponsors and the Therapeutic Goods Administration* published in May 2014.

**medium impact**, in relation to a shortage of a medicine that is not of critical impact, means a shortage that is assessed as medium patient impact in accordance with the assessment framework set out in the *Medicine Shortages Information Initiative: Protocol for all Australian Sponsors and the Therapeutic Goods Administration* published in May 2014.

Note: The *Medicine Shortages Information Initiative: Protocol for all Australian Sponsors and the Therapeutic Goods Administration* can be found on the internet (and viewed for free) on the internet at <http://www.tga.gov.au>.

## Part 4—Information relating to a decision to permanently discontinue the supply of a medicine that was made before 1 January 2019

For each item in column 1 of the following table, the kind of therapeutic goods information specified in column 2 has the description given in column 3.

<b>Kinds of therapeutic goods information</b>		
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Item</b>	<b>Information</b>	<b>Description</b>
1	name of medicine	the trade name or brand name of the medicine, that was the subject of a notification to the Secretary under the MSII (the <i>relevant medicine</i> )
2	active ingredient(s)	the active ingredient, or active ingredients, of the relevant medicine
3	strength	the strength of the relevant medicine
4	dosage form	the dosage form of the relevant medicine
5	container	the type of container of the relevant medicine
6	registration number	the registration number of the relevant medicine
7	therapeutic class	the ATC code for the relevant medicine's active ingredient under the ATC classification system
<b>Information about the sponsor:</b>		
8	sponsor name	the name of the sponsor of the relevant medicine (the <i>relevant sponsor</i> )
9	sponsor's nominated public contact details	an Australian telephone number and/or email address nominated by the relevant sponsor for the purposes of responding to enquiries from the public seeking additional information about the relevant medicine
10	sponsor's nominated website details	the website address (URL) nominated by the relevant sponsor for the purposes of providing the public with additional information about the relevant medicine
<b>Information about the discontinuation:</b>		
11	status of the discontinuation	whether the relevant medicine will be or has been permanently discontinued by the relevant sponsor
12	reason for the discontinuation	the relevant sponsor's advice as to the general reason for the discontinuation decision, as follows: (a) commercial reasons; (b) manufacturing; (c) product recall; (d) unexpected increase in demand; or (e) other
13	market deletion date	the sponsor's advice as to the date from which the sponsor will cease, or has ceased, supply of the relevant

<b>Kinds of therapeutic goods information</b>		
<b>Column 1 Item</b>	<b>Column 2 Information</b>	<b>Column 3 Description</b>
		medicine to the Australian market
14	availability level	<p>the relevant sponsor's advice as to the current availability level of the supply of the relevant medicine, as follows:</p> <ul style="list-style-type: none"> <li>(a) available—there are no constraints or restrictions on supply;</li> <li>(b) limited availability—the relevant medicine is available in limited quantities throughout the supply chain;</li> <li>(c) only available under government programs — in relation to a medicine that is a vaccine, the medicine is only available for Commonwealth (NIP) or State and Territory government immunisation programs and is not available in the private market;</li> <li>(d) emergency supply only—the relevant sponsor is imposing controls on the supply of the relevant medicine; or</li> <li>(e) unavailable—the relevant medicine is not available</li> </ul>
15	patient impact	<p>whether the impact of the discontinuation is:</p> <ul style="list-style-type: none"> <li>(a) critical;</li> <li>(b) medium; or</li> <li>(c) low</li> </ul>
16	supply details and other information	<p>any information, or links to any information, in relation to:</p> <ul style="list-style-type: none"> <li>(a) the supply arrangements in relation to the relevant medicine;</li> <li>(b) substitute medicines for the relevant medicine, including supply arrangements and use;</li> <li>(c) therapeutic alternatives to the relevant medicine, including supply arrangements and use</li> </ul>
17	TGA management action	details of action that has been or is being taken by the TGA in relation to managing the discontinuation
18	updated	date that the entry was last updated

In this Part:

**low impact**, in relation to a discontinuation of a supply of a medicine that is not of critical impact, means a discontinuation that is assessed as low patient impact in accordance with the assessment framework set out in the *Medicine Shortages Information Initiative: Protocol for all Australian Sponsors and the Therapeutic Goods Administration* published in May 2014.

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***medium impact***, in relation to a discontinuation of a supply of a medicine that is not of critical impact, means a discontinuation that is assessed as low patient impact in accordance with the assessment framework set out in the *Medicine Shortages Information Initiative: Protocol for all Australian Sponsors and the Therapeutic Goods Administration* published in May 2014.

Note: The *Medicine Shortages Information Initiative: Protocol for all Australian Sponsors and the Therapeutic Goods Administration* can be found on the internet (and viewed for free) on the internet at: <http://www.tga.gov.au>.