Pages 1 to 11 deleted
s 38 - Documents to which secrecy provisions of enactments apply

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Therapeutic Goods Act 1989

Approval under subsection 19A(1)

Notice of approval for the importation and supply of specified therapeutic goods

This notice refers to the application made under section 19A of the *Therapeutic Goods Act 1989* (the Act) dated 20 December 2023 in relation to VYVANSE lisdexamfetamine dimesylate capsules 50mg (USA).

I am a delegate of the Secretary of the Commonwealth Department of Health and Aged Care under section 19A of the Act. This notice constitutes my decision under subsection 19A(1) to grant approval to the person identified in column 1 of Schedule 1 to this notice, to import and supply in Australia the therapeutic goods specified in column 2 of Schedule 1 to this notice.

I have granted this approval on the basis of being satisfied that:

(a) registered goods that could act as a substitute for the specified therapeutic goods are unavailable or are in short supply; and

(b) the goods that are the subject of your application are registered or approved for general marketing in one or more foreign countries specified by the Secretary in a determination under subsection 19A(3); and

(c) the goods are of a kind included in Schedule 10 of the *Therapeutic Goods Regulations 1990*; and

(d) the approval is necessary in the interests of public health.

This approval has effect for the period commencing on the date of this notice until **30 June 2024**.

This approval lapses if either:

(a) the period specified above expires or a decision is made under subsection 25(3) of the Act in relation to the goods, whichever should occur first; or

(b) the Secretary is satisfied that paragraph 19A(1)(a), (b), (c) or (d) of the Act, as the case requires, no longer applies in relation to the goods, or that a condition of this approval has been contravened; and the Secretary has given to the person to whom this approval is granted a notice to the effect that the Secretary is so satisfied.

This approval is subject to each of the following conditions pursuant to subsection 19A(6) of the Act as specified below:

1. The approval holder identified in column 1 of Schedule 1 must only import and supply the therapeutic goods specified in column 2 of Schedule 1, for the indication(s) specified in column 3 of Schedule 1, being those goods which are registered or approved for general marketing in the foreign country specified in column 4 of Schedule 1.

2. The approval holder must report any adverse events relating to the specified therapeutic goods to the TGA where the usual adverse events reporting processes apply; i.e. serious reports sent to TGA within 15 days.

3. The approval holder must supply the specified therapeutic goods with labelling written in English; in this case, the labels as attached to this notice.

4. The approval holder must distribute the Dear Health Care Professional Letter which has been reviewed and agreed to by the Therapeutic Goods Administration to health care professionals supplied with VYVANSE lisdexamfetamine dimesylate capsules 50mg (USA). A copy of this letter has been attached to this notice.

5. The approval holder must over-sticker the specified therapeutic goods with a label that specifies the name and address of the Australian sponsor, as detailed in the attachment.

6. The approval holder must inform the TGA once aware of any supply issues associated with VYVANSE lisdexamfetamine dimesylate capsules 50mg (USA).

7. The approval holder must provide the Secretary a report on the number of times VYVANSE lisdexamfetamine dimesylate capsules 50mg (USA) was supplied during the period of the approval and the quantities supplied. The report is to be provided within 28 days after the approval lapsed or expired (whichever is relevant).

The report is to be provided within 28 days after the end of the relevant reporting period.

Review rights

This decision is a reviewable initial decision for the purposes of the Act. If you are dissatisfied with my decision, you can find information about how to seek reconsideration of the decision in the Guidance for requesting reconsideration of an initial decision on the TGA website. More information is at Attachment 1 of this notice.

Copies of relevant legislation can be found on the Federal Register of Legislation at www.legislation.gov.au. The Act can be found at www.legislation.gov.au/Series/C2004A03952.

Signed electronically

Deborah Hay
Co-Director
Medicine shortages Section
Pharmacovigilance Branch
Health Products Regulation Group
Therapeutic Goods Administration
Department of Health and Aged Care

DELEGATE OF THE SECRETARY

17 January 2024

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Schedule 1

Specified therapeutic goods approved for importation and supply under subsection 19A(1) of the *Therapeutic Goods Act 1989*

Column 1	Column 2	Column 3	s38
Approval holder	Specified therapeutic goods	Indications	
Medsurge Healthcare Pty Ltd Unit 1 & 2, 6-7 Gilda Court Mulgrave VIC 3170 ABN: 92124728892	VYVANSE lisdexamfetamine dimesylate capsules 50mg (USA)	**Attention Deficit Hyperactivity Disorder (ADHD)** Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Treatment should be commenced by a specialist. A diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) implies the presence of hyperactive-impulsive or inattentive symptoms that caused impairment and were present before 12 years of age. **Binge Eating Disorder (BED)** Indicated for the treatment of moderate to severe BED in adults when non-pharmacological treatment is unsuccessful or unavailable. Treatment should be commenced and managed by a psychiatrist.	

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Attachment 1

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister in writing within 90 (calendar) days after the initial decision notice is given and be accompanied by any information that you wish to have considered by the Minister. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate this function to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the making of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

Prior to requesting reconsideration of an initial decision, persons affected by an initial decision are advised to refer to the TGA website < https://www.tga.gov.au/resources/resource/guidance/guidance-requesting-reconsideration-initial-decision#:~:text=The%20only%20decisions%20that%20are,the%20Therapeutic%20Goods%20Regulations%20or> for specific information and detailed guidance for making a request for reconsideration. A request for reconsideration should then be made in writing, signed and dated by the person requesting reconsideration and should include the following:

- a copy of the initial decision notification letter, i.e. this letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**decision.review@health.gov.au**'

Subject: "**<insert name of person/company making request>** - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989*"

Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. "… - Email 1 of 3", "… - Email 2 of 3" etc). All sequentially numbered emails must be given to the Minister on the same date.

Under section 60 of the Act, the decision upon reconsideration by the Minister (or the Minister's delegate) must be to either 'confirm', 'revoke' or 'revoke and substitute' the initial decision. The Minister (or the Minister's delegate) must give notice in writing of the outcome of the decision upon reconsideration to the person whose interests are affected, within 60 (calendar) days after making a request for reconsideration. If the Minister (or the Minister's delegate) fails to give such notice within 60 days, the Minister (or the Minister's delegate) is deemed to have confirmed the initial decision.

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

70041842

Each capsule contains:
Lisdexamfetamine dimesylate
50 mg (equivalent to 28.9 mg
lisdexamfetamine)

SEE PACKAGE INSERT FOR DOSAGE INFORMATION

NDC 59417-105-10

Vyvanse®
(lisdexamfetamine dimesylate) capsules

50 mg

Rx only

C II

100 CAPSULES

Takeda

Pharmacist: Medication Guide to be dispensed to patients

Store at room temperature, 20°C to 25°C (68°F to 77°F). Excursions permitted between 15°C and 30°C (59°F to 86°F): dispense in tight, light-resistant container as defined in the USP

Distributed by:
Takeda Pharmaceuticals America, Inc.
Lexington, MA 02421

US Pat. Nos. 7,105,486 and 7,223,735
1631V8

medsurge

Date

Dear Healthcare Professional,

Shortage of VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle (AUST R: 199226), VYVANSE lisdexamfetamine dimesilate 60 mg capsules bottle (AUST R: 284021) and alternate supply arrangement under Section 19A of the *Therapeutic Goods Act 1989*.

The above Australian registered medicines are in shortage due to manufacturing issues.

Medsurge has been able to arrange for the supply of VYVANSE lisdexamfetamine dimesylate capsules 50mg (USA) and VYVANSE lisdexamfetamine dimesylate capsules 60mg (USA) as alternative products on a temporary basis. These product are NOT registered in Australia, and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until **Date** for the following indications:

Attention Deficit Hyperactivity Disorder (ADHD)
It is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Treatment should be commenced by a specialist.
A diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) implies the presence of hyperactive-impulsive or inattentive symptoms that caused impairment and were present before 12 years of age.

Binge Eating Disorder (BED)
It is indicated for the treatment of moderate to severe BED in adults when nonpharmacological treatment is unsuccessful or unavailable. Treatment should be commenced and managed by a psychiatrist.

Healthcare professionals should refer to the Australian Product Information for VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle (AUST R: 199226) & VYVANSE lisdexamfetamine dimesilate 60 mg capsules bottle (AUST R: 284021) for indication and dosing information. This is available at: https://www.ebs.tga.gov.au/

VYVANSE lisdexamfetamine dimesylate capsules 50mg & 60mg (USA) are identical in active ingredient, strength and contain the same excipient ingredients as the Australian registered products. They are registered and marketed in USA by Takeda Pharmaceuticals America, Inc.& therefore all labelling is in English.

It is important to note that the Australian registered VYVANSE lisdexamfetamine dimesilate capsules come in bottles of 30 capsules, whereas the S19A products VYVANSE lisdexamfetamine dimesylate capsules 50mg & 60mg (USA) come in bottles of 100 capsules.

Pharmacists should take extra care to ensure that the prescribed number of capsules are dispensed.

Medsurge Healthcare Pty Ltd
ABN 92 124 728 892

Unit 1&2, 6-7 Gilda Court
Mulgrave, VIC 3170,
Australia
sales@medsurge.com.au

t 1300 788 261
f 1300 788 262
medsurge.com.au

Any adverse events which are experienced with VYVANSE lisdexamfetamine dimesylate capsules 50mg & 60mg (USA) should be reported by healthcare professionals to Medsurge on 1300 788 261 or email sales@medsurge.com.au. Alternatively, this information can be reported to the TGA at https://www.tga.gov.au/reporting-problems.

Any product complaints about VYVANSE lisdexamfetamine dimesylate capsules 50mg & 60mg (USA) should be reported to Medsurge on 1300 788 261 or email sales@medsurge.com.au.

Please forward this information to relevant staff members in your organisation.

For further information, please contact Medsurge Healthcare on 1300 788 261 or email sales@medsurge.com.au.

Kind regards,

Senior Regulatory Affairs Officer

Medsurge Healthcare

The over-sticker will have following information.

Medsurge Healthcare

Unit 2, 6-7 Gilda Court

Mulgrave VIC 3170

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Therapeutic Goods Act 1989

Approval under subsection 19A(1)

Notice of approval for the importation and supply of specified therapeutic goods

This notice refers to the application made under section 19A of the *Therapeutic Goods Act 1989* (the Act) dated 20 December 2023 in relation to VYVANSE lisdexamfetamine dimesylate capsules 60mg (USA).

I am a delegate of the Secretary of the Commonwealth Department of Health and Aged Care under section 19A of the Act. This notice constitutes my decision under subsection 19A(1) to grant approval to the person identified in column 1 of Schedule 1 to this notice, to import and supply in Australia the therapeutic goods specified in column 2 of Schedule 1 to this notice.

I have granted this approval on the basis of being satisfied that:

(a) registered goods that could act as a substitute for the specified therapeutic goods are unavailable or are in short supply; and

(b) the goods that are the subject of your application are registered or approved for general marketing in one or more foreign countries specified by the Secretary in a determination under subsection 19A(3); and

(c) the goods are of a kind included in Schedule 10 of the *Therapeutic Goods Regulations 1990*; and

(d) the approval is necessary in the interests of public health.

This approval has effect for the period commencing on the date of this notice until **30 June 2024**.

This approval lapses if either:

(a) the period specified above expires or a decision is made under subsection 25(3) of the Act in relation to the goods, whichever should occur first; or

(b) the Secretary is satisfied that paragraph 19A(1)(a), (b), (c) or (d) of the Act, as the case requires, no longer applies in relation to the goods, or that a condition of this approval has been contravened; and the Secretary has given to the person to whom this approval is granted a notice to the effect that the Secretary is so satisfied.

This approval is subject to each of the following conditions pursuant to subsection 19A(6) of the Act as specified below:

1. The approval holder identified in column 1 of Schedule 1 must only import and supply the therapeutic goods specified in column 2 of Schedule 1, for the indication(s) specified in column 3 of Schedule 1, being those goods which are registered or approved for general marketing in the foreign country specified in column 4 of Schedule 1.

2. The approval holder must report any adverse events relating to the specified therapeutic goods to the TGA where the usual adverse events reporting processes apply; i.e. serious reports sent to TGA within 15 days.

3. The approval holder must supply the specified therapeutic goods with labelling written in English; in this case, the labels as attached to this notice.

4. The approval holder must distribute the Dear Health Care Professional Letter which has been reviewed and agreed to by the Therapeutic Goods Administration to health care professionals supplied with VYVANSE lisdexamfetamine dimesylate capsules 60mg (USA). A copy of this letter has been attached to this notice.

5. The approval holder must over-sticker the specified therapeutic goods with a label that specifies the name and address of the Australian sponsor, as detailed in the attachment.

6. The approval holder must inform the TGA once aware of any supply issues associated with VYVANSE lisdexamfetamine dimesylate capsules 60mg (USA).

7. The approval holder must provide the Secretary a report on the number of times VYVANSE lisdexamfetamine dimesylate capsules 60mg (USA) was supplied during the period of the approval and the quantities supplied. The report is to be provided within 28 days after the approval lapsed or expired (whichever is relevant).

The report is to be provided within 28 days after the end of the relevant reporting period.

Review rights

This decision is a reviewable initial decision for the purposes of the Act. If you are dissatisfied with my decision, you can find information about how to seek reconsideration of the decision in the Guidance for requesting reconsideration of an initial decision on the TGA website. More information is at Attachment 1 of this notice.

Copies of relevant legislation can be found on the Federal Register of Legislation at www.legislation.gov.au. The Act can be found at www.legislation.gov.au/Series/C2004A03952.

Signed electronically

Deborah Hay
Co-Director
Medicine shortages Section
Pharmacovigilance Branch
Health Products Regulation Group
Therapeutic Goods Administration
Department of Health and Aged Care

DELEGATE OF THE SECRETARY

17 January 2024

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Schedule 1

Specified therapeutic goods approved for importation and supply under subsection 19A(1) of the *Therapeutic Goods Act 1989*

Column 1	Column 2	Column 3	s38
Approval holder	Specified therapeutic goods	Indications	
Medsurge Healthcare Pty Ltd Unit 1 & 2, 6-7 Gilda Court Mulgrave VIC 3170 ABN: 92124728892	VYVANSE lisdexamfetamine dimesylate capsules 60mg (USA)	**Attention Deficit Hyperactivity Disorder (ADHD)** Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Treatment should be commenced by a specialist. A diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) implies the presence of hyperactive-impulsive or inattentive symptoms that caused impairment and were present before 12 years of age. **Binge Eating Disorder (BED)** Indicated for the treatment of moderate to severe BED in adults when non-pharmacological treatment is unsuccessful or unavailable. Treatment should be commenced and managed by a psychiatrist.	

Australian Government

Department of Health and Aged Care

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Attachment 1

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As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister in writing within 90 (calendar) days after the initial decision notice is given and be accompanied by any information that you wish to have considered by the Minister. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate this function to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the making of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

Prior to requesting reconsideration of an initial decision, persons affected by an initial decision are advised to refer to the TGA website < https://www.tga.gov.au/resources/resource/guidance/guidance-requesting-reconsideration-initial-decision#:~:text=The%20only%20decisions%20that%20are,the%20Therapeutic%20Goods%20Regulations%20or> for specific information and detailed guidance for making a request for reconsideration. A request for reconsideration should then be made in writing, signed and dated by the person requesting reconsideration and should include the following:

- a copy of the initial decision notification letter, i.e. this letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**decision.review@health.gov.au**'

Subject: "**<insert name of person/company making request>** - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989*"

Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. "… - Email 1 of 3", "… - Email 2 of 3" etc). All sequentially numbered emails must be given to the Minister on the same date.

Under section 60 of the Act, the decision upon reconsideration by the Minister (or the Minister's delegate) must be to either 'confirm', 'revoke' or 'revoke and substitute' the initial decision. The Minister (or the Minister's delegate) must give notice in writing of the outcome of the decision upon reconsideration to the person whose interests are affected, within 60 (calendar) days after making a request for reconsideration. If the Minister (or the Minister's delegate) fails to give such notice within 60 days, the Minister (or the Minister's delegate) is deemed to have confirmed the initial decision.

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NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

70041843

59417-10610 3

NDC 59417-106-10

Vyvanse®
(lisdexamfetamine dimesylate) capsules

60 mg

Rx only

100 CAPSULES

SEE PACKAGE INSERT FOR DOSAGE INFORMATION

Each capsule contains:
Lisdexamfetamine dimesylate 60 mg (equivalent to 34.7 mg lisdexamfetamine)

Pharmacist: Medication Guide to be dispensed to patients

Store at room temperature, 20°C to 25°C (68°F to 77°F). Excursions permitted between 15°C and 30°C (59°F to 86°F): dispense in tight, light-resistant container as defined in the USP

Distributed by:
Takeda Pharmaceuticals America, Inc.
Lexington, MA 02421

US Pat. Nos. 7,105,486 and 7,223,735

1632V6

medsurge

Date

Dear Healthcare Professional,

Shortage of VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle (AUST R: 199226), VYVANSE lisdexamfetamine dimesilate 60 mg capsules bottle (AUST R: 284021) and alternate supply arrangement under Section 19A of the *Therapeutic Goods Act 1989*.

The above Australian registered medicines are in shortage due to manufacturing issues.

Medsurge has been able to arrange for the supply of VYVANSE lisdexamfetamine dimesylate capsules 50mg (USA) and VYVANSE lisdexamfetamine dimesylate capsules 60mg (USA) as alternative products on a temporary basis. These product are NOT registered in Australia, and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until **Date** for the following indications:

Attention Deficit Hyperactivity Disorder (ADHD)
It is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Treatment should be commenced by a specialist.
A diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) implies the presence of hyperactive-impulsive or inattentive symptoms that caused impairment and were present before 12 years of age.

Binge Eating Disorder (BED)
It is indicated for the treatment of moderate to severe BED in adults when nonpharmacological treatment is unsuccessful or unavailable. Treatment should be commenced and managed by a psychiatrist.

Healthcare professionals should refer to the Australian Product Information for VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle (AUST R: 199226) & VYVANSE lisdexamfetamine dimesilate 60 mg capsules bottle (AUST R: 284021) for indication and dosing information. This is available at: https://www.ebs.tga.gov.au/

VYVANSE lisdexamfetamine dimesylate capsules 50mg & 60mg (USA) are identical in active ingredient, strength and contain the same excipient ingredients as the Australian registered products. They are registered and marketed in USA by Takeda Pharmaceuticals America, Inc.& therefore all labelling is in English.

It is important to note that the Australian registered VYVANSE lisdexamfetamine dimesilate capsules come in bottles of 30 capsules, whereas the S19A products VYVANSE lisdexamfetamine dimesylate capsules 50mg & 60mg (USA) come in bottles of 100 capsules.

Pharmacists should take extra care to ensure that the prescribed number of capsules are dispensed.

Medsurge Healthcare Pty Ltd
ABN 92 124 728 892

Unit 1&2, 6-7 Gilda Court
Mulgrave, VIC 3170,
Australia
sales@medsurge.com.au

t 1300 788 261
f 1300 788 262
medsurge.com.au

Any adverse events which are experienced with VYVANSE lisdexamfetamine dimesylate capsules 50mg & 60mg (USA) should be reported by healthcare professionals to Medsurge on 1300 788 261 or email sales@medsurge.com.au. Alternatively, this information can be reported to the TGA at https://www.tga.gov.au/reporting-problems.

Any product complaints about VYVANSE lisdexamfetamine dimesylate capsules 50mg & 60mg (USA) should be reported to Medsurge on 1300 788 261 or email sales@medsurge.com.au.

Please forward this information to relevant staff members in your organisation.

For further information, please contact Medsurge Healthcare on 1300 788 261 or email sales@medsurge.com.au.

Kind regards,

Senior Regulatory Affairs Officer

Medsurge Healthcare

The over-sticker will have following information.

Medsurge Healthcare

Unit 2, 6-7 Gilda Court

Mulgrave VIC 3170

Pages 31 to 48 deleted
s 38 - Documents to which secrecy provisions of enactments apply