Australian Government
Department of Health
Therapeutic Goods Administration

Changes to sponsor requirements for supplying unapproved medicinal cannabis products in Australia

Information for industry

Petra Bismire
Director - Experimental Products Section
International Regulatory Branch
Medicines Regulation Division, Therapeutic Goods Administration

TGA Health Safety Regulation

22 November 2021

Welcome

- This webinar is being recorded
- If you need to contact the moderator – please use the **'Chat'** function
- Slides will be made available on the TGA website
- Questions to the **panel** – please use the **Q&A** tool
  - Questions will be answered at the end of the presentation
- Relevant links will be sent to you via the chat function box
- Live poll after presentation – how did we go?.

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Today's session

Today's session will assist industry to understand the changes in the sponsor requirements for supplying unapproved medicinal cannabis products in Australia.

- ✓ Changes to the requirement to submit Therapeutic Goods Order 93 (TGO93) declaration forms to the TGA for products
- ✓ Overview of the sponsor six monthly reporting obligations
- ✓ Reporting side effects
- ✓ Submission of TGA applications by active ingredient, rather than trade name
- ✓ Publishing a list of medicinal cannabis products on the TGA website.

Changes to the requirement to submit TGO93 declaration forms

- As of **22 November 2021**, sponsors of unapproved medicinal cannabis products are no longer required to submit a declaration of conformity with TGO 93.
- This change aims to reduce regulatory burden on the medicinal cannabis industry.
- Increased compliance measures will be imposed.

Your responsibilities haven't changed

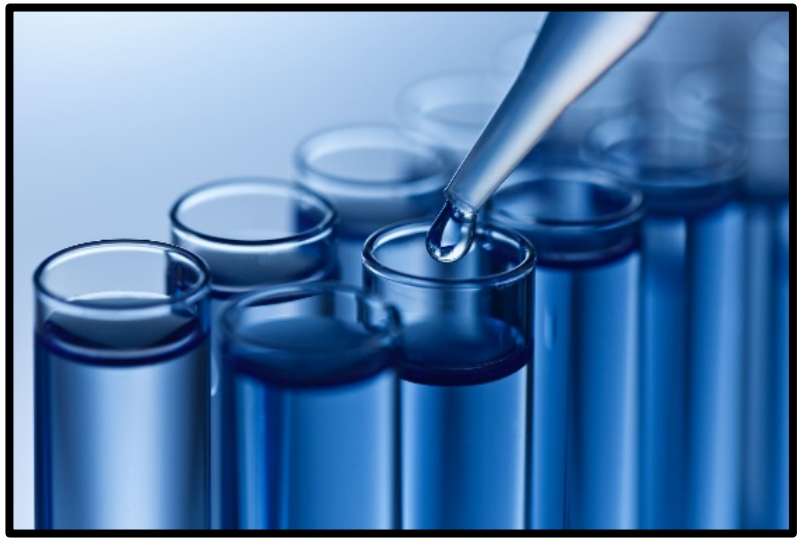
- Sponsors are legally responsible for ensuring that their products comply with-TGO 93, and all other relevant orders.
- Any breach is subject to a range of regulatory compliance actions, including civil and criminal penalties under sections 14 and 14A of the *Therapeutic Goods Act 1989* (the Act).

Guidance to comply with standards for medicinal cannabis is available on the TGA website.

- Conforming with Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017
- Complying with Therapeutic Goods (Microbiological Standards for Medicines) (TGO 100) Order 2018

Ongoing targeted testing

We will be continuing targeted audits and testing of medicinal cannabis products imported or supplied in Australia for compliance with TGO93.



Sponsor reporting obligations under the *Therapeutic Goods Regulations 1990* (reg 47B)

- We have developed a new six monthly report form to streamline this requirement
- You must provide the report to the TGA every six months listing the **product (brand name) details** and **quantities supplied** in Australia under the SAS, AP and clinical trials schemes
- Reporting periods are 1 January - 30 June (inclusive) and 1 July - 31 December (inclusive)
- Reports must be submitted within 1 month of the end of the relevant reporting period

Therapeutic goods supplied to health practitioners

Active ingredient/s* (name and strength) or device name	Trade name	Category of cannabinoid content (medicinal cannabis products only)**	Dosage form* (where applicable)	Quantity per dosage unit (where applicable)	Quantity of units supplied by pathway (Not applicable to nicotine vaping products)			
					Special access scheme	Authorised prescriber	Clinical trials	Total

Please attach additional pages as required

* Refer to TGA approved terminology where available

** Categories of medicinal cannabis products are available at Medicinal cannabis: Information for health professionals | Therapeutic Goods Administration (TGA):

- Category 1: CBD medicinal cannabis product (CBD ≥98%)
- Category 2: CBD dominant medicinal cannabis product (CBD ≥60% and <98%)
- Category 3: Balanced medicinal cannabis product (CBD <60% and ≥40%)
- Category 4: THC dominant Medicinal Cannabis Product (THC 60-98%)
- Category 5: THC medicinal cannabis product (THC

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au https://www.tga.gov.au
Reference/Publicatio

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Reporting side effects

- ✓ The TGA has an important role in monitoring the safety of 'unapproved' products.
- ✓ Authorised Prescribers and SAS approval holders must report adverse events or defects as a condition of approval.
- ✓ Adverse events or defects associated with the use of the medicine must be reported to the TGA within 15 calendar days after becoming aware of the adverse event.
- ✓ The preferred reporting route is via the online portal https://aems.tga.gov.au

SAS & Authorised Prescriber submissions by category of active ingredient

Effective from 22 November 2021

Why were the changes made?

- ✓ Reduction in administrative burden for prescribers who determine that an unapproved medicinal cannabis product is clinically suitable for their patient.
- ✓ Allow flexibility in brand substitution when needed, i.e. in the event of a product shortage or discontinuation.
- ✓ Facilitate improved patient access by enabling continuation of therapy in the event of a product discontinuation/shortage.

Active ingredient categories for medicinal cannabis products

Category	Category description	Category requirements	CBD content by category
Category 1	CBD medicinal cannabis product (CBD ≥98%)	• Schedule 4 Prescription Only medicines as per the Poisons Standard • cannabidiol comprises 98% or more of the total cannabinoid content of the medicine • any cannabinoids, other than cannabidiol, in the medicine are only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the medicine • the medicine contains no other active ingredients	98% Category 1
Category 2	CBD dominant medicinal cannabis product (CBD ≥60% and <98%)	• Schedule 8 Controlled Drugs as per the Poisons Standard • cannabidiol derived from cannabis comprises 60% or more and less than 98% of the total cannabinoid content of the medicine • other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine • the medicine contains no other active ingredients	60% Category 2
Category 3	Balanced medicinal cannabis product (CBD <60% and ≥40%)	• Schedule 8 Controlled Drugs as per the Poisons Standard • cannabidiol derived from cannabis comprises 40% or more and less than 60% of the total cannabinoid content of the medicine • other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine • the medicine contains no other active ingredients	40% Category 3
Category 4	THC dominant Medicinal Cannabis Product (THC 60-98%)	• Schedule 8 Controlled Drugs as per the Poisons Standard • other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise 60% or more and 98% or less of the total cannabinoid content of the medicine • cannabidiol derived from cannabis comprises 2% or more and less than 40% of the total cannabinoid content of the medicine • the medicine contains no other active ingredients	2% Category 4
Category 5	THC medicinal cannabis product (THC >98%)	• Schedule 8 Controlled Drugs as per the Poisons Standard • cannabinoids, other than cannabidiol, in the medicine are only those naturally found in cannabis and comprise more than 98% of the total cannabinoid content of the medicine • cannabidiol comprises less than 2% less of the total cannabinoid content of the medicine • the medicine contains no other active ingredients	0% Category 5

Changes to TGA approval letters

AP letter

Schedule 1:

Details of authority granted under subsection 19(5) of the Therapeutic Goods Act 1989

Reference (MAP21-0000589)

Column 1 Authorised Prescriber	Column 2 Specified therapeutic goods (or class of goods)	Column 3 Specified indication(s)	Column 4 Treatment directions (if any)
[redacted]	Authorised Prescriber Estab. Hx-Category 1-CBD medicinal cannabis product (CBD≥98%) - - Oral liquid CBD≥98% Percent Oral Liquid Oral	For the following indication(s): Refractory anxiety in adult patients	

SAS letter

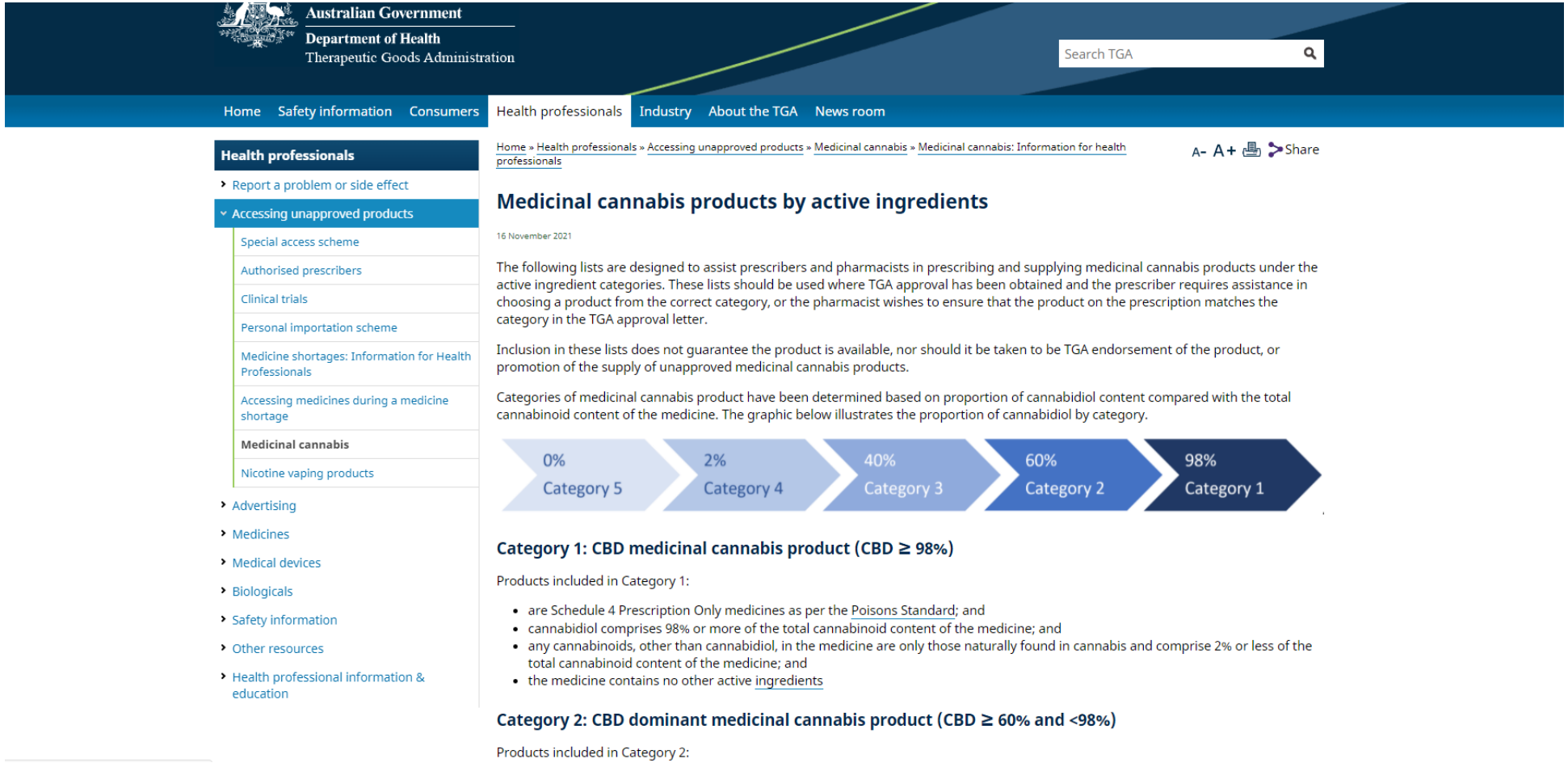
Schedule 1

Reference: MB21-000[redacted]

Column 1 Approval holder	Column 2 Specified medicine	Column 3 Patient	Column 4 Conditions
[redacted] (12345679) Test Business Practice for Ayyaz 4 jennifer street Woden ACT 2900	*Medicine:* Category 1-CBD medicinal cannabis product (CBD≥98%) *Product description:* Capsule	*Patient initials:* RD *Patient gender:* Female *Patient DOB:* 12 Jun 1985	*Purpose:* anxiety *Dosage:* .

Published list of products by category

[Medicinal cannabis products by active ingredients | Therapeutic Goods Administration (TGA)]



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Medicinal cannabis products by active ingredients

16 November 2021

The following lists are designed to assist prescribers and pharmacists in prescribing and supplying medicinal cannabis products under the active ingredient categories. These lists should be used where TGA approval has been obtained and the prescriber requires assistance in choosing a product from the correct category, or the pharmacist wishes to ensure that the product on the prescription matches the category in the TGA approval letter.

Inclusion in these lists does not guarantee the product is available, nor should it be taken to be TGA endorsement of the product, or promotion of the supply of unapproved medicinal cannabis products.

Categories of medicinal cannabis product have been determined based on proportion of cannabidiol content compared with the total cannabinoid content of the medicine. The graphic below illustrates the proportion of cannabidiol by category.

Category 1: CBD medicinal cannabis product (CBD ≥ 98%)

Products included in Category 1:

- are Schedule 4 Prescription Only medicines as per the Poisons Standard; and
- cannabidiol comprises 98% or more of the total cannabinoid content of the medicine; and
- any cannabinoids, other than cannabidiol, in the medicine are only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the medicine; and
- the medicine contains no other active ingredients

Category 2: CBD dominant medicinal cannabis product (CBD ≥ 60% and <98%)

Products included in Category 2:

Where to go for support

- **Webpages** have been updated:
  - Medicinal cannabis: Information for sponsors and manufacturers - Medicinal cannabis: Information for sponsors and manufacturers |
  - Medicinal cannabis: Information for health professionals - Medicinal cannabis: Information for health professionals |
- **Support tools** have been created:
  - Description of the active ingredient categories - Active ingredient categories for medicinal cannabis products |
  - List of medicinal cannabis products by category of active ingredient - Medicinal cannabis products by active ingredients |
  - Authorised Prescriber Scheme List of medicines with an established history of use
- **Guidance documents** have been updated:
  - Authorised Prescriber guidance document: Authorised Prescriber Scheme |
  - SAS Online System guidance - Special Access Scheme (SAS) online system guidance |
  - Authorised Prescribers Online System guidance- Authorised Prescriber Scheme online system guidance |

Petra is currently reading over your submitted questions.

We'll be back shortly for **Q&A**

We appreciate your participation in our live poll.

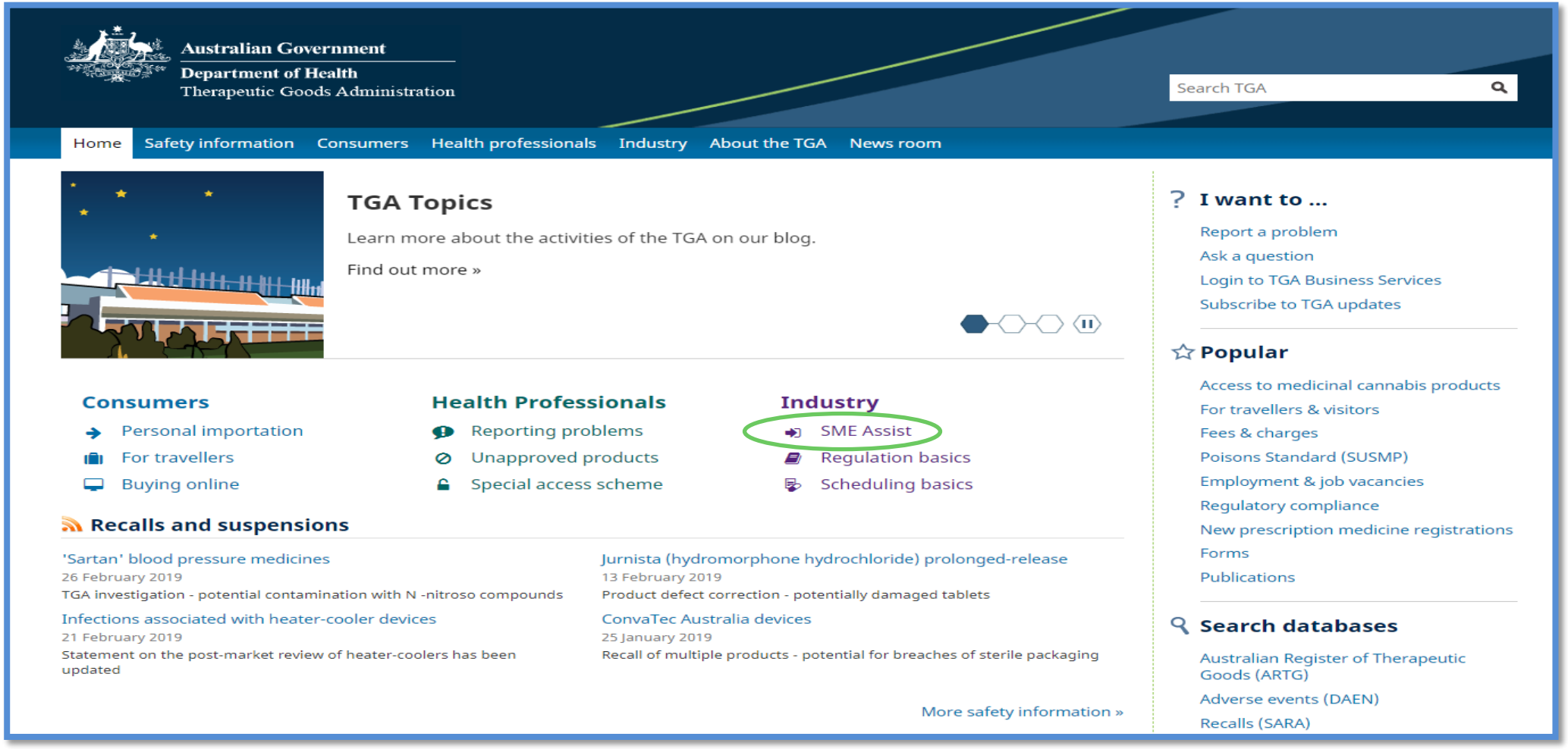
LIVE POLL

QUESTIONS

Websites and Contacts

Patient access and six monthly reporting	medicinal.cannabis@health.gov.au
Over-the-counter (OTC) medicines	otc.medicines@health.gov.au
Prescription medicines	application.entry.team@health.gov.au
The Office of Drug Control (ODC)	dcs@health.gov.au
Advertising	tga.advertising@health.gov.au
TGA Manufacturing	gmp@health.gov.au

SME Assist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Recalls and suspensions
'Sartan' blood pressure medicines
26 February 2019
TGA investigation - potential contamination with N -nitroso compounds
Infections associated with heater-cooler devices
21 February 2019
Statement on the post-market review of heater-coolers has been updated
Jurnista (hydromorphone hydrochloride) prolonged-release
13 February 2019
Product defect correction - potentially damaged tablets
ConvaTec Australia devices
25 January 2019
Recall of multiple products - potential for breaches of sterile packaging
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Contact us

Experimental Products Section

medicinal.cannabis@health.gov.au

More information – Social media

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	Twitter	https://twitter.com/TGAgovau
	YouTube	https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw
	Topic blogs	https://www.tga.gov.au/blogs/tga-topics
	Linkedin	https://www.linkedin.com/company/therapeutic-goods-administration/
	Instagram	https://www.instagram.com/tgagovau/?hl=en

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