Medical Devices Vigilance Program Information Session

Maria Ong

Devices Vigilance and Policy Section

Medical Devices Surveillance Branch

Department of Health and Aged Care, TGA

Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past, present and emerging.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

Welcome

Housekeeping

- This Webinar is being recorded
- The presentation will be made available in the upcoming weeks
- Any relevant links in this event will be broadcasted to you via the Slido app
- Q&A session will occur after todays presentation
- Live poll – how did we go, let us know

Difficulties hearing from computer?

Check your settings located under

"**Audio & Video**" tab located top of your screen:

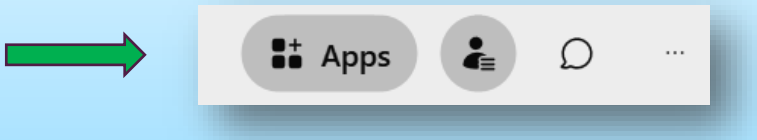
OR

Dial: 02 9338 2221 (+61-2-9338-2221)

Access code: 2652 566 1796

How to use Slido

Slido App

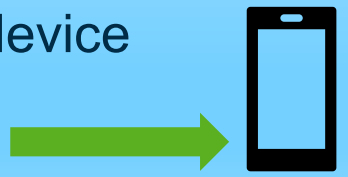


- Click on Apps+ icon
- Select “Slido”
- Open “Q&A” tab to ask questions
- Live Poll (use survey tab when prompted)

OR

Slido QR

Scan the QR code to access separately from your mobile device



Medical Devices Vigilance Program Information Session

Maria Ong

Devices Vigilance and Policy Section

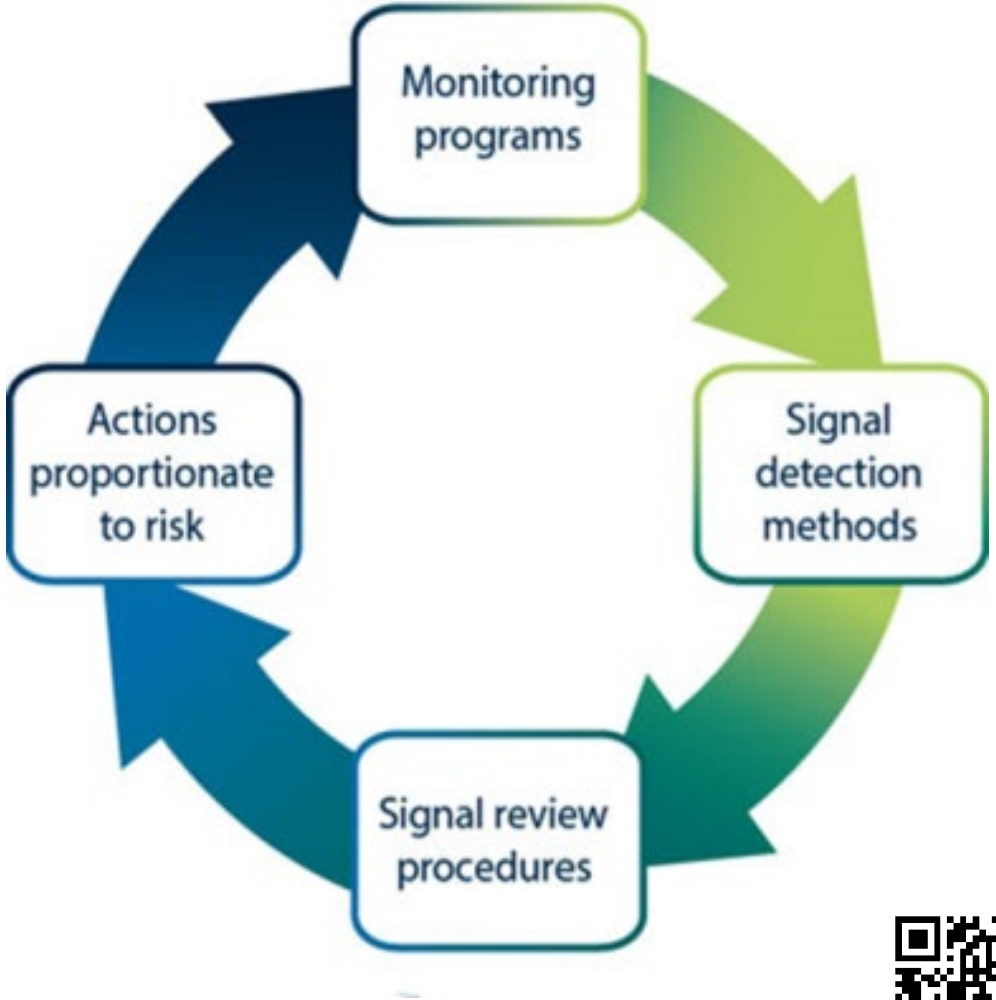
Medical Devices Surveillance Branch

Department of Health and Aged Care, TGA

Medical device sponsors post-market responsibilities

Medical devices sponsors play an important role in ensuring all products in Australia continue to meet the regulatory requirements over time.

The rationale behind post-market responsibilities is to ensure information about emerging safety or risk-related issues is being recorded systemically, investigated per the manufacturer's procedures, and reported to the TGA when necessary.



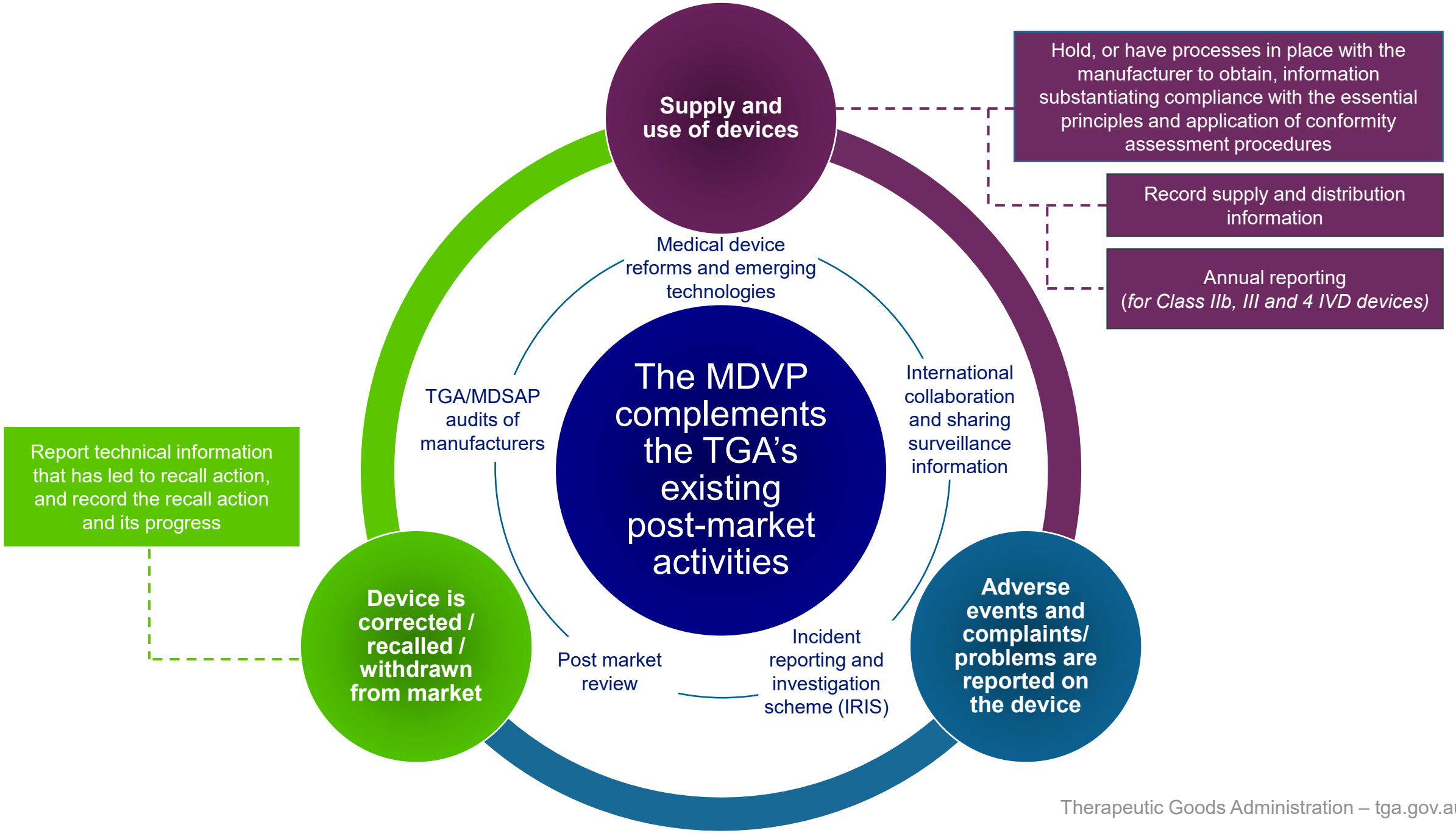
As a regulatory body, the TGA has authority to:

The Medical Devices Vigilance Program (MDVP)

The MDVP was developed after receiving public and Government support of the proposal – 2020 *Proposed enhancements to adverse event reporting for medical devices* consultation paper.

The MDVP will complement and enhance existing post-market surveillance activities:

- with an educational self-assessment tool - a resource for sponsors and a screening tool for the TGA
- through desktop audits and on-site inspections that will review and confirm compliance with post-market regulatory requirements.


Supply and use of devices
Hold, or have processes in place with the manufacturer to obtain, information substantiating compliance with the essential principles and application of conformity assessment procedures
Record supply and distribution information
Annual reporting (for Class IIb, III and 4 IVD devices)
Medical device reforms and emerging technologies
TGA/MDSAP audits of manufacturers
The MDVP complements the TGA's existing post-market activities
International collaboration and sharing surveillance information
Report technical information that has led to recall action, and record the recall action and its progress
Device is corrected / recalled / withdrawn from market
Post market review
Incident reporting and investigation scheme (IRIS)
Adverse events and complaints/ problems are reported on the device

Regulatory requirements reviewed by the MDVP

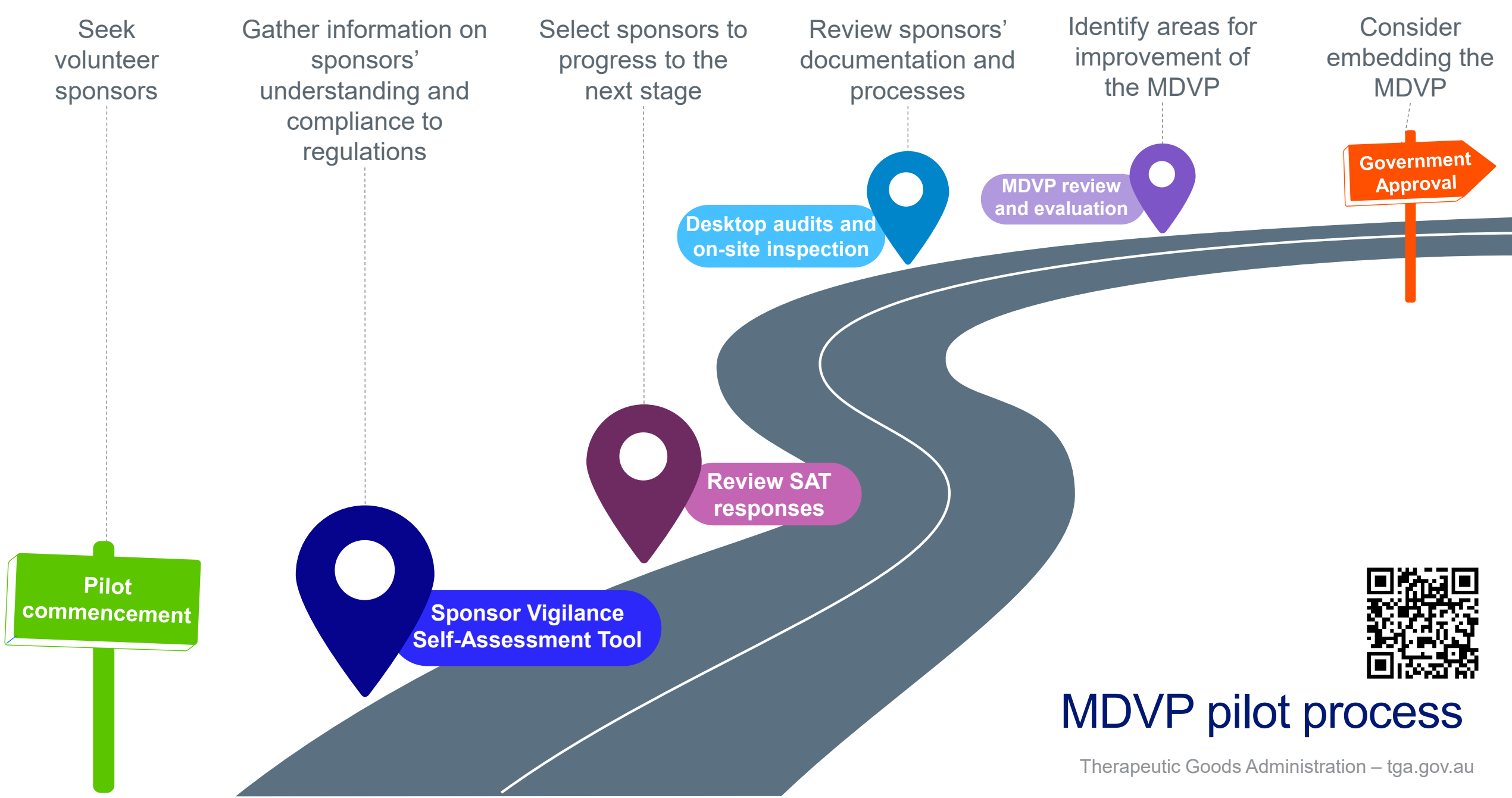
Therapeutic Goods Act 1989

Sections 41FN, KA, MP/MPA

Therapeutic Goods (Medical Devices) Regulation 2002

Clauses 5.7, 5.8, 5.8A, 5.10, 5.11, 8.1

- Information substantiating compliance with EPs and CAPs
- Receive, record, relay and retain adverse event reports and complaints/problems
- Record and report recall actions and its progress
- Record supply and distribution information
- Annual reporting (*for Class IIb, III and 4 IVD devices*)



MDVP pilot process

Sponsor Vigilance Self-Assessment Tool (SAT)

Review SAT responses

Desktop audits and on-site inspections

Pilot review and evaluation

Sponsors to complete the SAT in the TGA Consultation Hub

A user guide is available to help you prepare your responses

Sponsor Vigilance Self-Assessment Tool (SAT)

Review SAT responses

Desktop audits and on-site inspections

Pilot review and evaluation

SAT response from sponsor

Regulatory intelligence

Selection of sponsors

Selected sponsors progress to desktop audits and on-site inspections

Sponsor Vigilance Self-Assessment Tool (SAT)

Review SAT responses

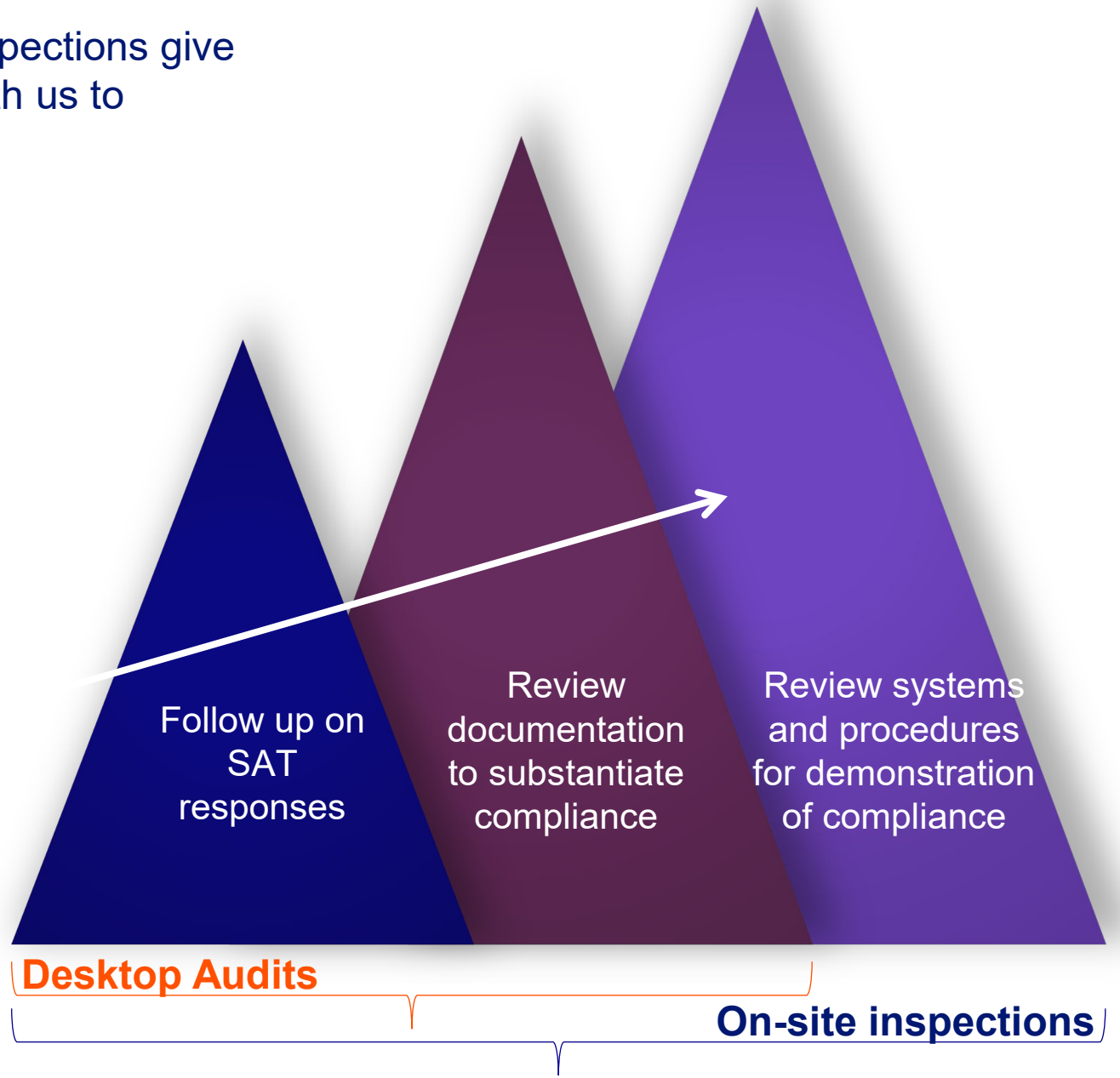
Desktop audits and on-site inspections

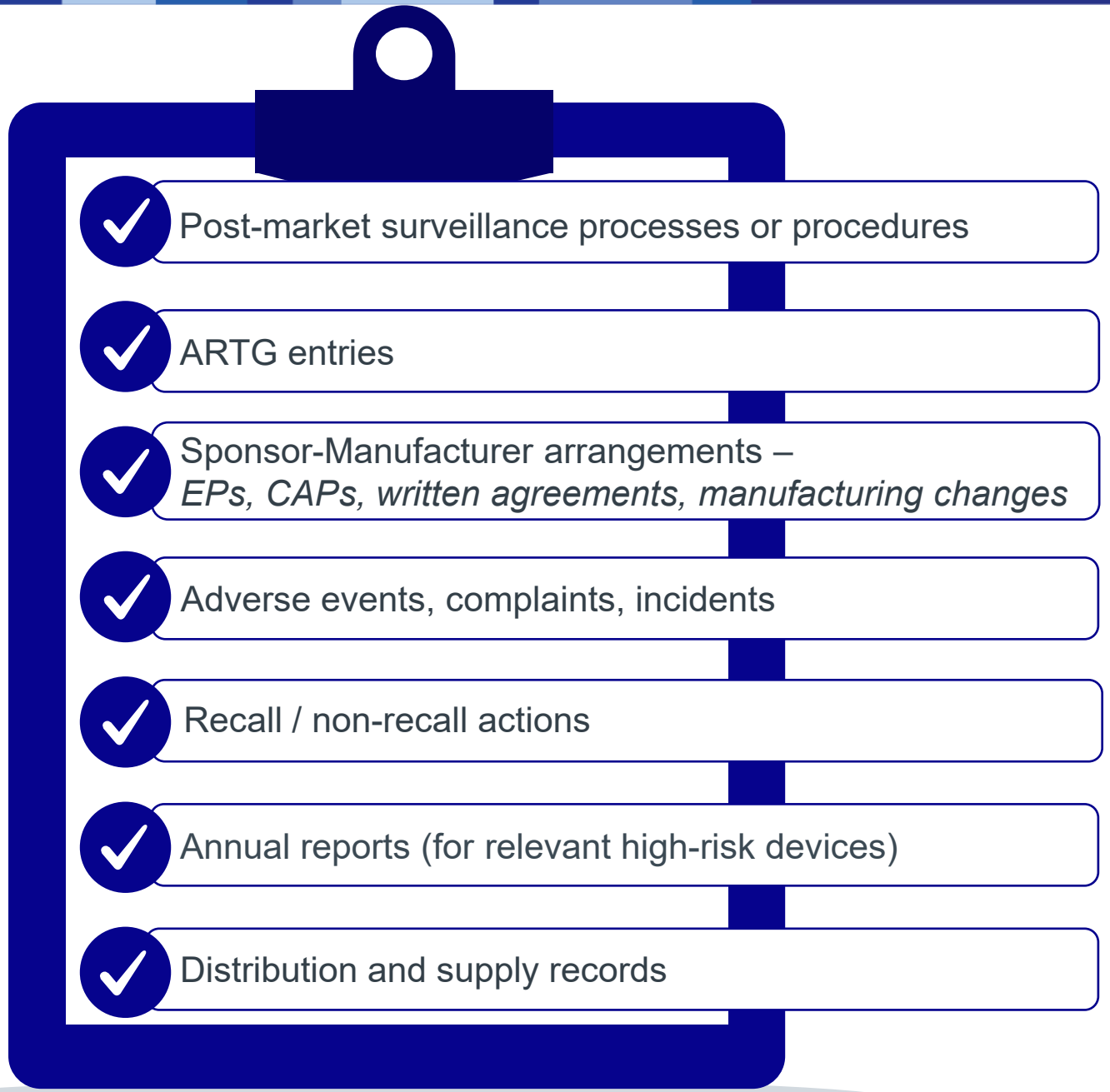
Pilot review and evaluation

Desktop audits and on-site inspections give you the opportunity to work with us to improve regulatory obligations

We will contact you if you are selected, to give you time to prepare and additional information

Not all desktop audits will result in an on-site inspection





Desktop Audit

Reviewing documents to substantiate regulatory compliance

On-site inspection

Reviewing systems and procedures to demonstrate compliance

Sponsor Vigilance Self-Assessment Tool (SAT)

Review SAT responses

Desktop audits and on-site inspections

Pilot review and evaluation

Evaluation and process improvements

Your feedback across pilot processes will inform any process improvements required

Report to Government

After review we will provide a report to the Minister for Health and Aged Care for consideration

Policy approval to embed MDVP

Evaluation and process improvements

MDVP Pilot Metrics Report

MDVP Pilot Metrics Report

On completion of the pilot we will publish a summary of our findings on the MDVP webpage

What's next?

A recording of this session may be published on the TGA website

Visit the MDVP webpage for updates

Information Session registrants will receive a link to the Sponsor Vigilance Self-Assessment Tool

Sponsor guidance is available on the MDVP webpage

Share the word with your networks

Medical Devices Vigilance Program Information Session

SAT Live Demonstration

Sharon Rogers

Devices Vigilance and Policy Section

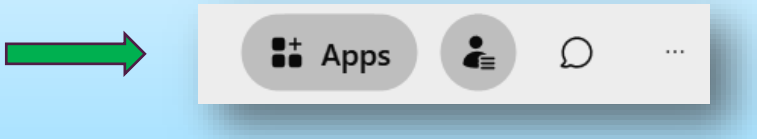
Medical Devices Surveillance Branch

Department of Health and Aged Care, TGA

How to ask questions

SLIDO

Slido App



- Click on Apps+ icon
- Select “Slido”
- Open “Q&A” tab to ask questions
- Live Poll (use survey tab when prompted)

OR

Slido QR

Scan the QR code to access separately from your mobile device

Survey - Poll

How did we go?

We'll be back with you in **1 minute.**

1. Please open SLIDO *(located from your APPS icon)*
2. Open the POLL tab
3. Complete short survey
4. We'll then commence Q&A

Anonymous or Open responses welcome

Questions

Maria Ong

Devices Vigilance and Policy Section

Medical Devices Surveillance Branch

Department of Health and Aged Care, TGA

Sharon Rogers

Devices Vigilance and Policy Section

Medical Devices Surveillance Branch

Department of Health and Aged Care, TGA

Contact us

Medical Devices Vigilance Program

MDVP@health.gov.au

Website and link references

Medical Devices Vigilance Program – Pilot: https://www.tga.gov.au/how-we-regulate/monitoring-safety-and-shortages/medical-devices-vigilance-program-pilot

Therapeutic Goods Act 1989: https://www.legislation.gov.au/Details/C2023C00102

Therapeutic Goods (Medical Devices) Regulation 2002: https://www.legislation.gov.au/Details/F2023C00565

Post market responsibilities for sponsors and manufacturers of medical devices: https://www.tga.gov.au/resources/resource/guidance/post-market-responsibilities-manufacturers-and-sponsors-medical-devices

Medical Device Incident Reporting and Investigation Scheme (IRIS): https://www.tga.gov.au/resources/resource/guidance/medical-device-incident-reporting-investigation-scheme-iris

Uniform Recall Procedure for Therapeutic Goods (URPTG): https://www.tga.gov.au/resources/resource/guidance/uniform-recall-procedure-therapeutic-goods-urptg

2020 Consultation – Proposed enhancements to adverse event reporting for medical devices: https://consultations.tga.gov.au/tga/copy-of-test-2-adverse-events-reporting-for-medica/

More information

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

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration