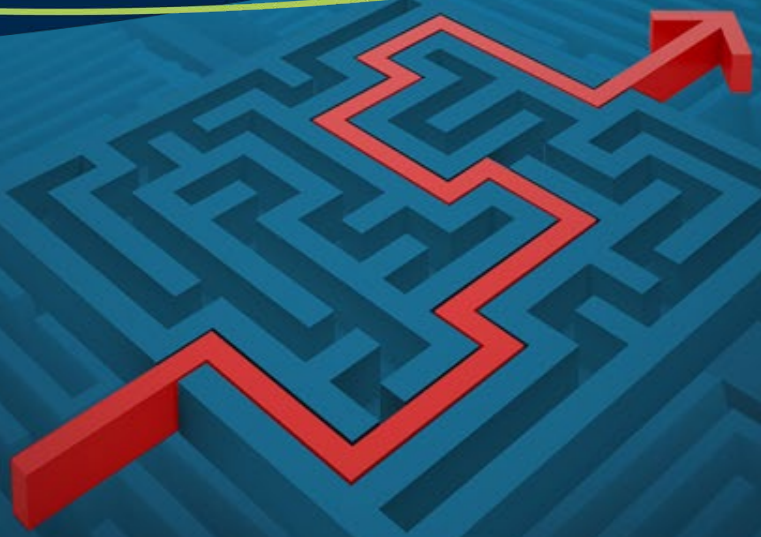
Australian Government
Department of Health
Therapeutic Goods Administration

SME Assist – ‘Meeting Your Obligations’

Post-market monitoring

Faye Lux
SME Assist

6 December 2019



TGA Health Safety Regulation

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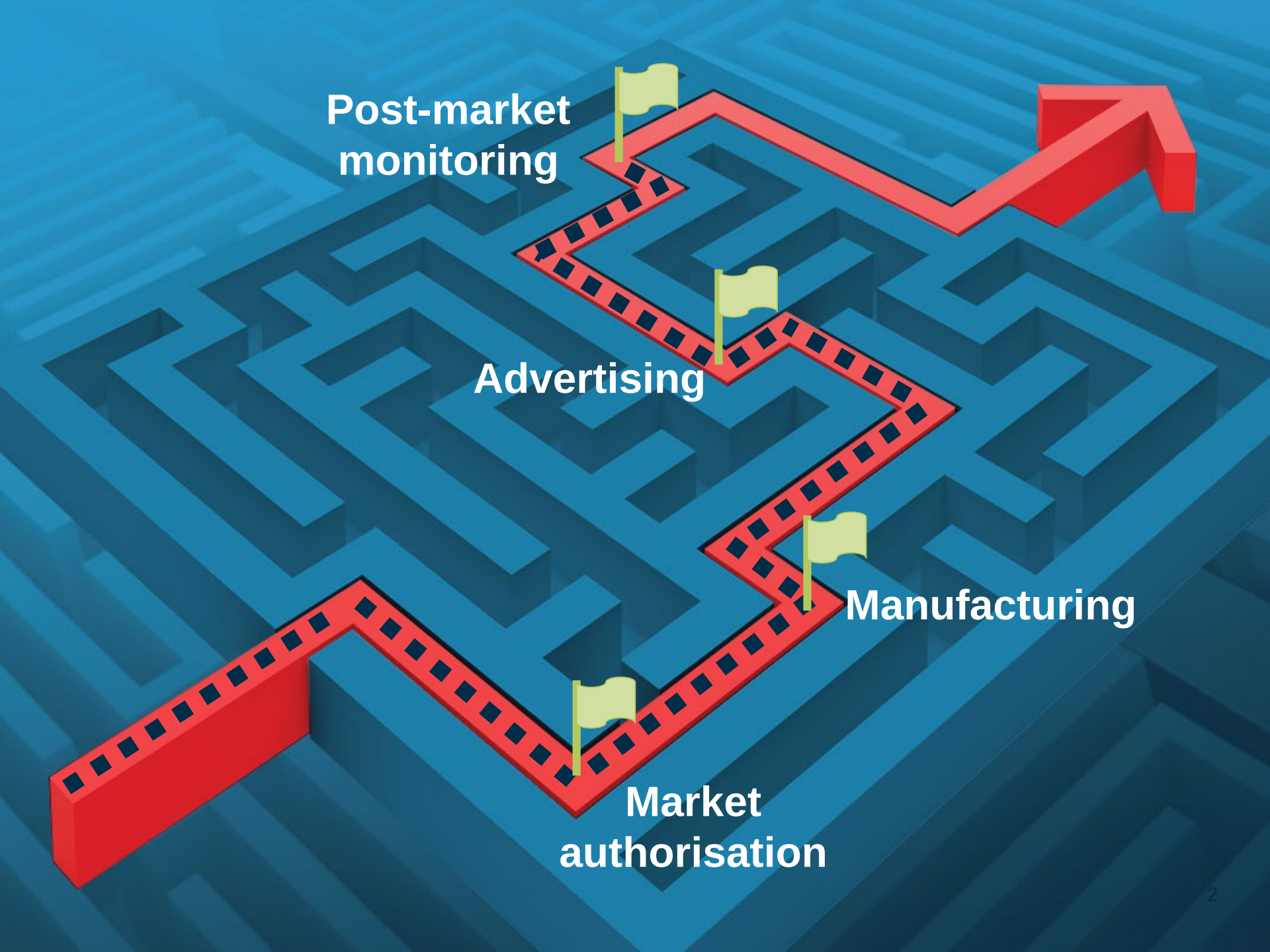

Post-market monitoring
Advertising
Manufacturing
Market authorisation

Post-market monitoring

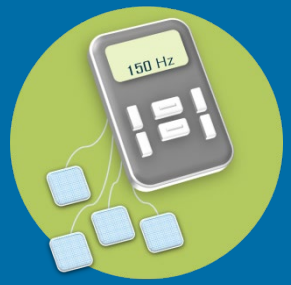
Medicines and biologicals

Medical devices

All therapeutic goods

Post-market monitoring

What to report



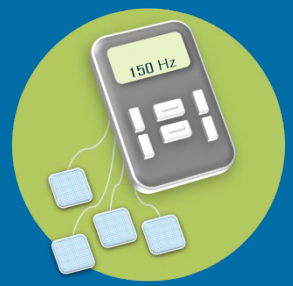
Adverse events

Deficiencies or defects

Medicine shortages

Adverse events

Reporting adverse events



Different pathways for different products

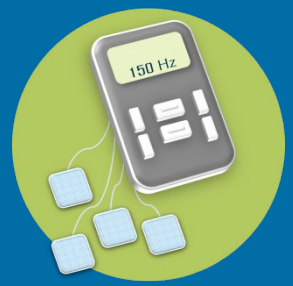
Adverse event and medicines defects section

- Within 15 days of listing your medicine, you must nominate a contact person for ⓘ**pharmacovigilance**
- You may be subject to pharmacovigilance inspections
- ⓘ **Biovigilance** for biologicals
- TGA may request information from you

Devices post-market monitoring section

- TGA perform desktop audits to ensure ⓘ**compliance** with Essential Principles
- Keep contact details in TGA Business Services (TBS) current and ‘generic’
- Possible inspections in the future

Reporting adverse events



Collect reports of adverse events

Adverse event and medicines defects section

Devices post-market monitoring section

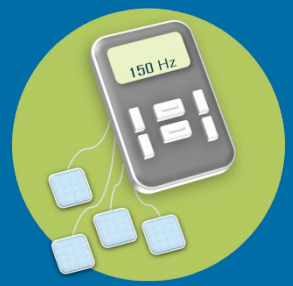
Collect all reported adverse events from any third party - consumers, health professionals, patients or other person.

Keep these records!

- Collect minimum 4 data points from all reported adverse events:
  - contact details of the reporter
  - contact details of the patient
  - one or more of the suspected medicine(s)
  - one or more of the suspected reaction(s)

- The adverse event reporting form will prompt you to obtain more details from the reporter
- Collecting as much information as possible is best practice

Reporting adverse events



Reporting terminology

Adverse event and medicines defects section

Mandatory

- adverse event
- adverse drug reaction
- serious adverse drug reaction
- significant safety issue

72 hrs

Devices post-market monitoring section

Mandatory

- adverse event
- near adverse event
- serious public health threat or concern

2 calendar days

Timeframes vary depending on the type of event

Reporting adverse events

How to report to TGA

Adverse event and medicines defects section

- **Serious adverse reactions** can be reported through:
  - TBS via Electronic Data Interchange (EDI), also known as E2B reports
  - TGA website online form
  - email: adr.reports@health.gov.au

- **Significant safety issues** are reported through email: si.coordinator@health.gov.au

Devices post-market monitoring section

- All events are reported via an online form through TBS

Other things to report

For (all) medicines

ⓘ **Medicine deficiencies or defects**
(any manufacture, handling or storage issues)

For prescription & some over the counter medicines

ⓘ **Medicine shortages**

CASE STUDY:
Daphne's adverse event report

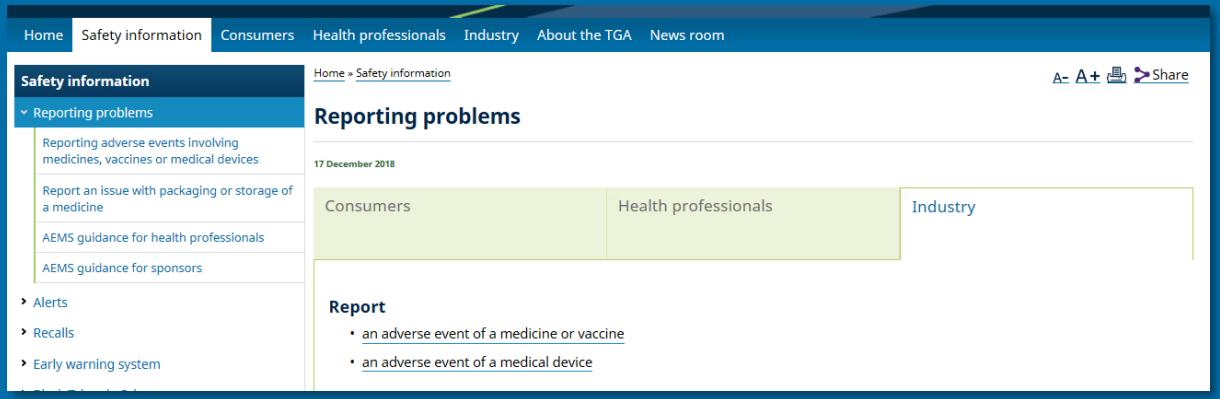
Someone said they got hurt by Daphne's device!

Daphne received an email from a stranger who said her TENs machine caused them wrist strain.

Daphne's a bit surprised anyone could get hurt from her TENs machine…

However, ignoring the email isn't best practice.

She logs onto the TGA website and looks up reporting an adverse event.



Daphne defines the type of adverse event

Daphne first has to consider the type of adverse event she has.

An incident that resulted in serious injury, illness or death to the patient, healthcare professional or other person.

An adverse event

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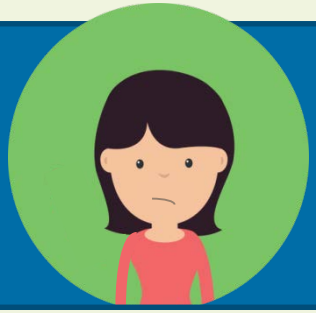

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A ‘near’ adverse event

A ‘near’ adverse event is the same, except that it ‘**could have**’ resulted in serious injury, illness or death to a patient, healthcare professional or other person.

Daphne defines the type of adverse event

Daphne first has to consider the type of adverse event she has.

An adverse event

If in doubt, report!

A ‘near’ adverse event

Collecting information

From the TGA website, Daphne determines that she needs to collect and provide (as a bare minimum):

- contact details of herself – the ‘reporter’ (name, address, phone number)
- patient identifier details (such as initials, date of birth or age, but their full name is not required for medical devices.)
- details of the product involved
- details of the suspected adverse event

Daphne contacts the patient again and gathers more details from him.

Report to TGA – the initial report

Daphne now wants to report this information to the TGA.

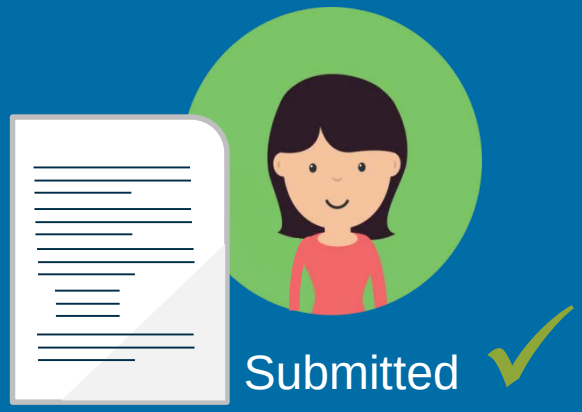
She's surprised to learn this is not through an e-mail or publicly available online form – but done through her TBS account.

Daphne is not familiar with this process, so she uses the Medical Device Incident Reporting System (MDIR) system user guide.

She successfully creates a new report of the incident through her TBS account. This is called her initial report.

This report goes to the MDIR.
Daphne receives a DIR (Device Incident Report) number for her reference.

Keep your DIR reference number



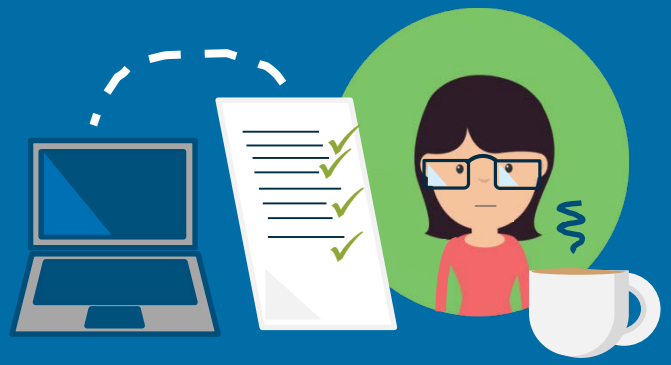
Report to TGA – the final report

The initial report prompts Daphne to provide more information on her own surveillance practices and quality control practices of her manufacturer.

Daphne needs to find and collate this information.

Then, Daphne will need to go back into her TBS account and update her initial report, using the DIR number.

After providing the additional information and hitting submit, the report then becomes a final report.



TGA gets back to Daphne

Once the final report arrives, TGA will contact Daphne in 3-4 business days via email - which contains more questions about the report.

- Daphne answers all questions and replies to the email.

TGA have had numerous reports of a similar incident from other TENs machine users.

- Because other sponsors have reported these cases, the TGA has built a clear picture that instructions on TENs machines need modification – as clearly there's an issue with people using them incorrectly!

Based on this information, TGA asks that Daphne (and those other sponsors) update her instructions for use leaflet to include extra clarity regarding its proper use.

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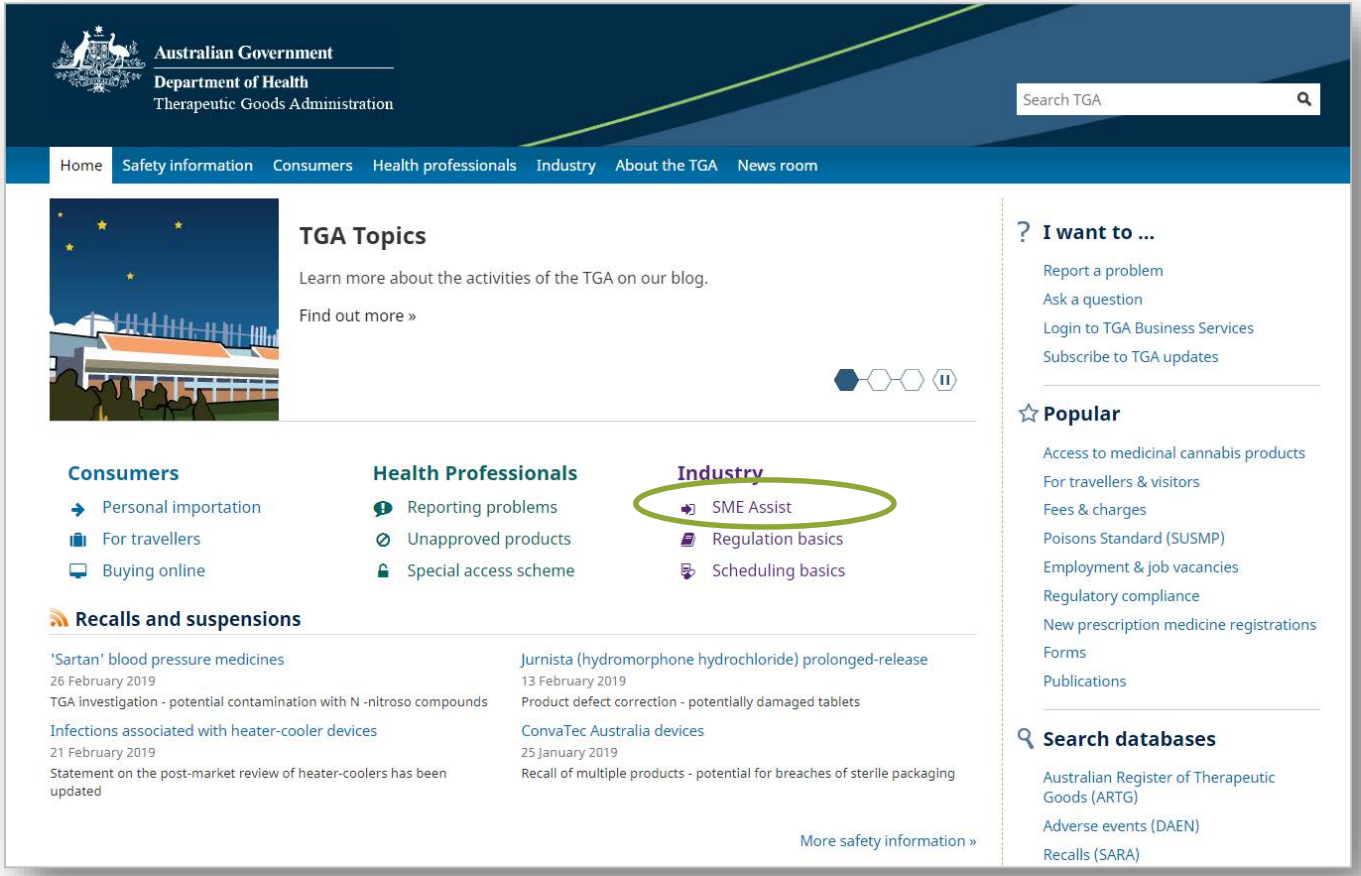
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Infections associated with heater-cooler devices
21 February 2019
Statement on the post-market review of heater-coolers has been updated
Jurnista (hydromorphone hydrochloride) prolonged-release
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