Australian Government
Department of Health
Therapeutic Goods Administration

Reporting medicine adverse events

Easier reporting for health professionals

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TGA Health Safety Regulation

- **1.2 million Australians have experienced an adverse drug event in the last six months.**
  (Pharmaceutical Society of Australia, 2019. Medicine Safety: Take Care)

- **More than 250,000 Australians are admitted to hospital each year because of problems related to their medicines at a cost in excess of $1.4 billion annually to the health system.**
  (Pharmaceutical Society of Australia 2020. Medicine Safety Forum: informing Australia's 10th National Health Priority Area.)

Supporting safe use of medicines and vaccines

Pharmacovigilance

Pharmacovigilance is the science and activity related to **detecting**, **assessing**, **understanding** and **preventing** adverse events and other medicine-related problems.

It comprises of:

- Collecting, assessing and monitoring data
- Looking at data to detect safety signals
- Exchange of this data with stakeholders, e.g. WHO, healthcare professionals, jurisdictions, sponsors
- Acting to protect patients and public health

Actions by the TGA to support safe use

- Inform health professionals and consumers through alerts and articles in publications (Medicines Safety Updates)
- Propose changes to product labelling, adding warnings, precautions, adverse events to the product information (PI) and Consumer Medicines Information (CMI)
- Request the sponsor to undertake post-marketing studies to investigate the safety concern
- Cancel the registration of the product, or limiting where it can be used

Reports from health professionals are essential

- Health professionals play an important role in the ongoing safety of medicines and vaccines in Australia
- When a report is submitted, it contributes to the collection of information that enables TGA to ensure the safety, effectiveness and quality of medicines and vaccines.
- Adverse events reports assist the post-market monitoring of the safety of medicines and vaccines.

Health care standards and codes that support adverse event reporting

- The **National Safety and Quality Health Service (NSQHS) Standards -** Standard 4 - ADR criteria 4.09
  All new suspected adverse drug reports experienced by patients during their episode of care are reported to the TGA.

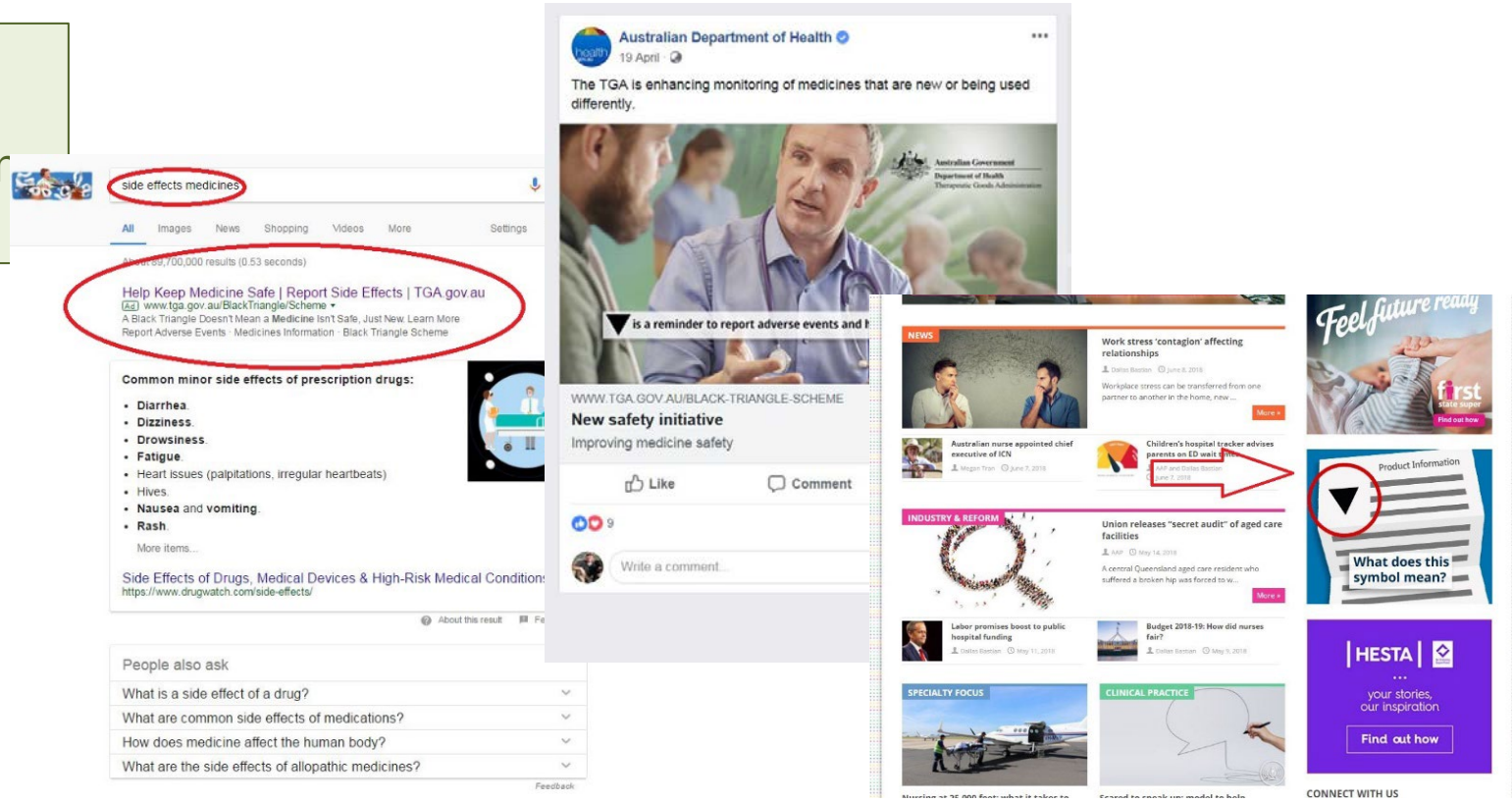
- **APHRA Medical Board Code - Code of conduct** for all registered healthcare providers
  Sec 4.11 and Sec 8.2 - Reporting adverse events to the relevant authority, as necessary and participating in systems for surveillance and monitoring of adverse events

- The **National Safety and Quality Primary and Community Healthcare Standards -** Item 3.16c
  Report suspected adverse drug reactions to the TGA

Education for health professionals about reporting

CPD Module

Available since December 2014 describing the why, what and how of reporting.

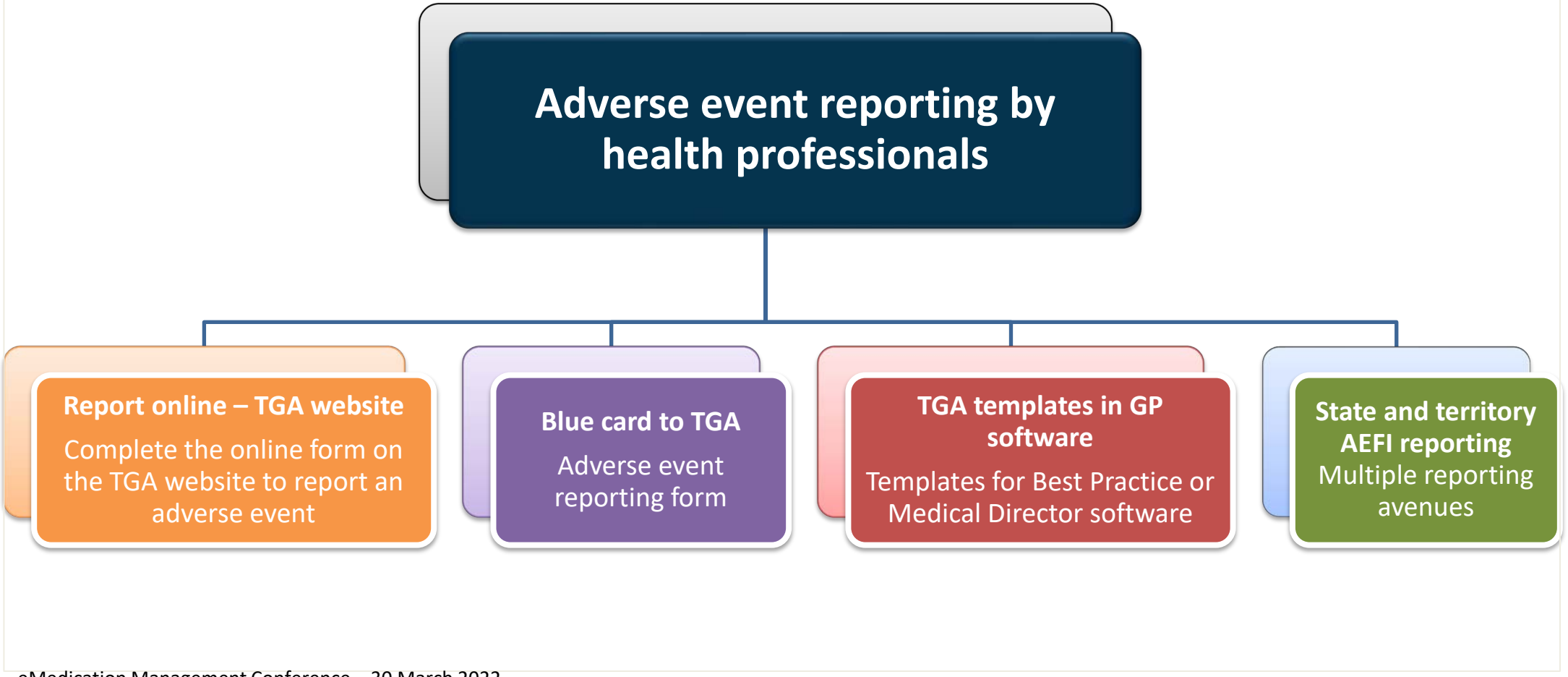


Advertising campaigns

Using Google AdWords on several hundred medically-focused websites and appearing directly in a number of journals.

Adverse event reporting - Current situation

Current ways of reporting by health professionals



What health professionals are telling us – GP pain points

Barriers to reporting adverse events

- Time, steps and manual activities needed to submit a report for time-poor GPs and nurses
- Confusion about reporting due to multiple avenues for reporting
- Need to upload record of adverse event report into patient's personal record resulting in additional administrative processing
- Lack of reliable internet connectivity for rural and remote doctors and those in aged care settings.

Improved management of medicine safety signals in Australia

- How?
  - making it easier for health professionals to report adverse events by integrating reporting within desktop software
  - streamlining data exchange between TGA and states and territories
  - better access to data on adverse events that have been reported to the TGA

Where are we now

- Further discovery - Engaging with software vendors
- Discussions with state and territory counterparts on improvements
- Improvements to the public TGA Database of Adverse Event Notifications (DAEN) for medicines

Questions?

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