Australian Government
Department of Health
Therapeutic Goods Administration

GPs' role in quality use of medicines in Australia

Enhancements to Australia's medicines vigilance scheme

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GP17 RACGP Conference

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TGA Health Safety Regulation

Overview

- How are medicines made available for use in Australia?
- Why do we want to monitor the safety of medicines once registered?
- How can GPs help ensure Quality Use of Medicines and why would they want to?
- You need information to be informed
- What do patients expect from GPs when they prescribe a medicine – what information do they want?
- What's new?

How are medicines made available for use in Australia?

TGA assesses safety, efficacy and safety…

… PBAC assesses cost effectiveness

Why do we want to monitor medicines' safety once registered?

Post-market monitoring identifies …

- New adverse events or a change in the rates of known adverse events.
- Production and other quality issues.

Response to the thalidomide tragedy

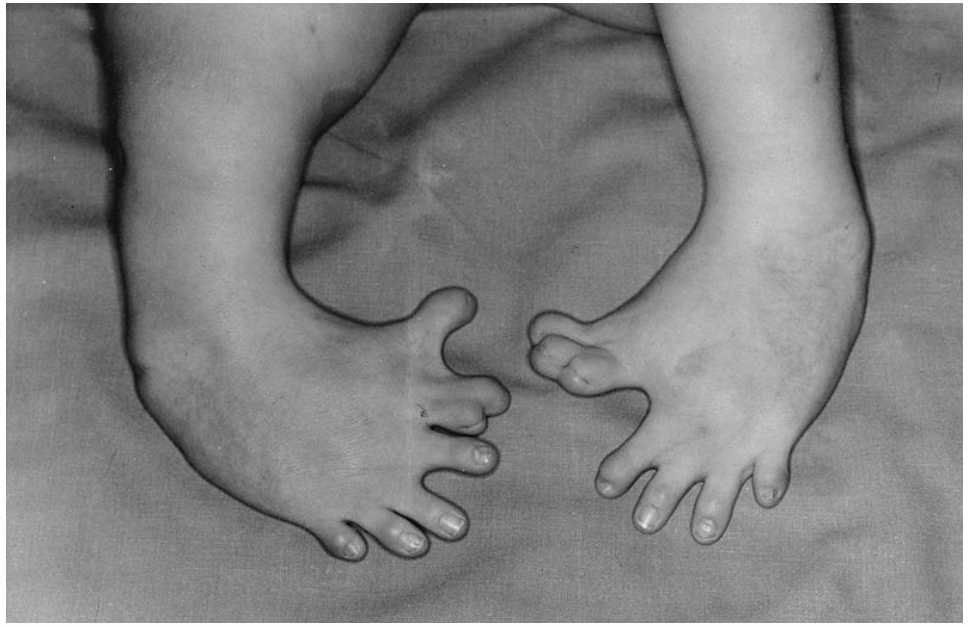


Photo: Otis Historical Archives National Museum of Health and Medicine

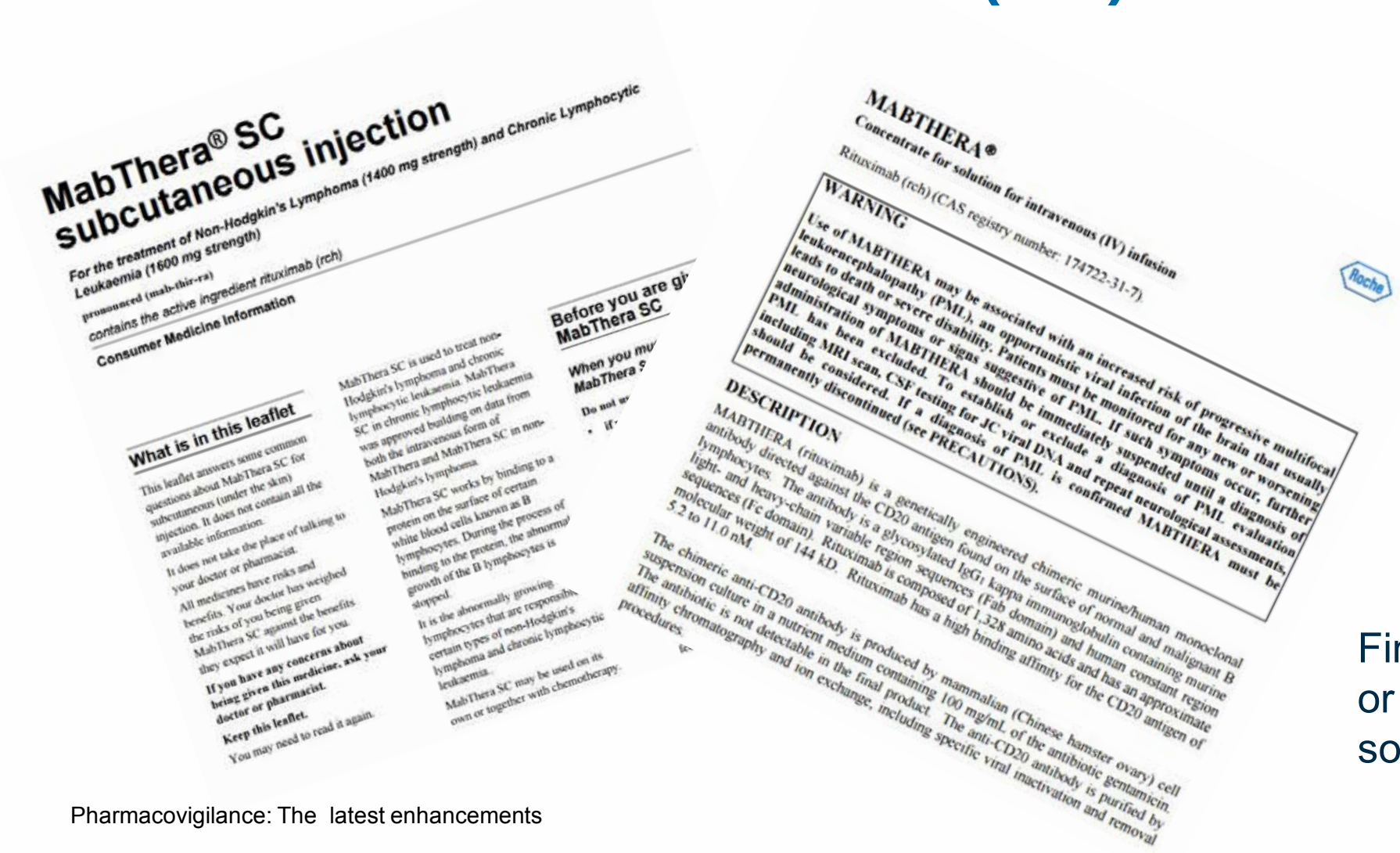
The birth defects caused by thalidomide caused governments around the world to strengthen their monitoring and regulation of medicines safety.

You need information to be informed

Providing the best healthcare requires information to flow various ways, including:

- from **patient** to **doctor**
- from **doctor** to **patient**
- from **TGA** to **doctor**
- from **doctor** to **TGA**.

Consumer Medicine Information (CMI) and Product Information (PI)



MabThera® SC subcutaneous injection

For the treatment of Non-Hodgkin's Lymphoma (1400 mg strength) and Chronic Lymphocytic Leukaemia (1600 mg strength)

pronounced (mab-thir-ra)

contains the active ingredient rituximab (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MabThera SC for subcutaneous (under the skin) injection. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given MabThera SC against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

MabThera SC is used to treat non-Hodgkin's lymphoma and chronic lymphocytic leukaemia. MabThera SC in chronic lymphocytic leukaemia was approved building on data from both the intravenous form of MabThera and MabThera SC in non-Hodgkin's lymphoma.

MabThera SC works by binding to a protein on the surface of certain white blood cells known as B lymphocytes. During the process of binding to the protein, the abnormal growth of the B lymphocytes is stopped.

It is the abnormally growing lymphocytes that are responsible for certain types of non-Hodgkin's lymphoma and chronic lymphocytic leukaemia.

MabThera SC may be used on its own or together with chemotherapy.

Before you are given MabThera SC

When you must be given MabThera SC

Do not

MABTHERA®

Concentrate for solution for intravenous (IV) infusion

Rituximab (rch) (CAS registry number: 174722-31-7)

WARNING

Use of MABTHERA may be associated with an increased risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. Patients must be monitored for any new or worsening neurological symptoms or signs suggestive of PML. If such symptoms occur, further administration of MABTHERA should be immediately suspended until a diagnosis of PML has been excluded. To establish or exclude a diagnosis of PML evaluation including MRI scan, CSF testing for JC viral DNA and repeat neurological assessments should be considered. If a diagnosis of PML is confirmed MABTHERA must be permanently discontinued (see PRECAUTIONS).

DESCRIPTION

MABTHERA (rituximab) is a genetically engineered chimeric murine/human monoclonal antibody directed against the CD20 antigen found on the surface of normal and malignant B lymphocytes. The antibody is a glycosylated IgG1 kappa immunoglobulin containing murine light- and heavy-chain variable region sequences (Fab domain) and human constant region sequences (Fc domain). Rituximab is composed of 1,328 amino acids and has an approximate molecular weight of 144 kD. Rituximab has a high binding affinity for the CD20 antigen of 5.2 to 11.0 nM.

The chimeric anti-CD20 antibody is produced by mammalian (Chinese hamster ovary) cell suspension culture in a nutrient medium containing 100 mg/mL of the antibiotic gentamicin. The antibiotic is not detectable in the final product. The anti-CD20 antibody is purified by affinity chromatography and ion exchange, including specific viral inactivation and removal procedures.

Roche

Search databases

- Australian Register of Therapeutic Goods (ARTG)
- Adverse events (DAEN)
- Recalls (SARA)
- Prescribing medicines in pregnancy
- Consumer Medicines Information (CMI)
- Product Information (PI)
- Medicine shortages
- Australian Public Assessment Reports for prescription medicines (AusPARs)

Find them via www.tga.gov.au or in widely available clinical software

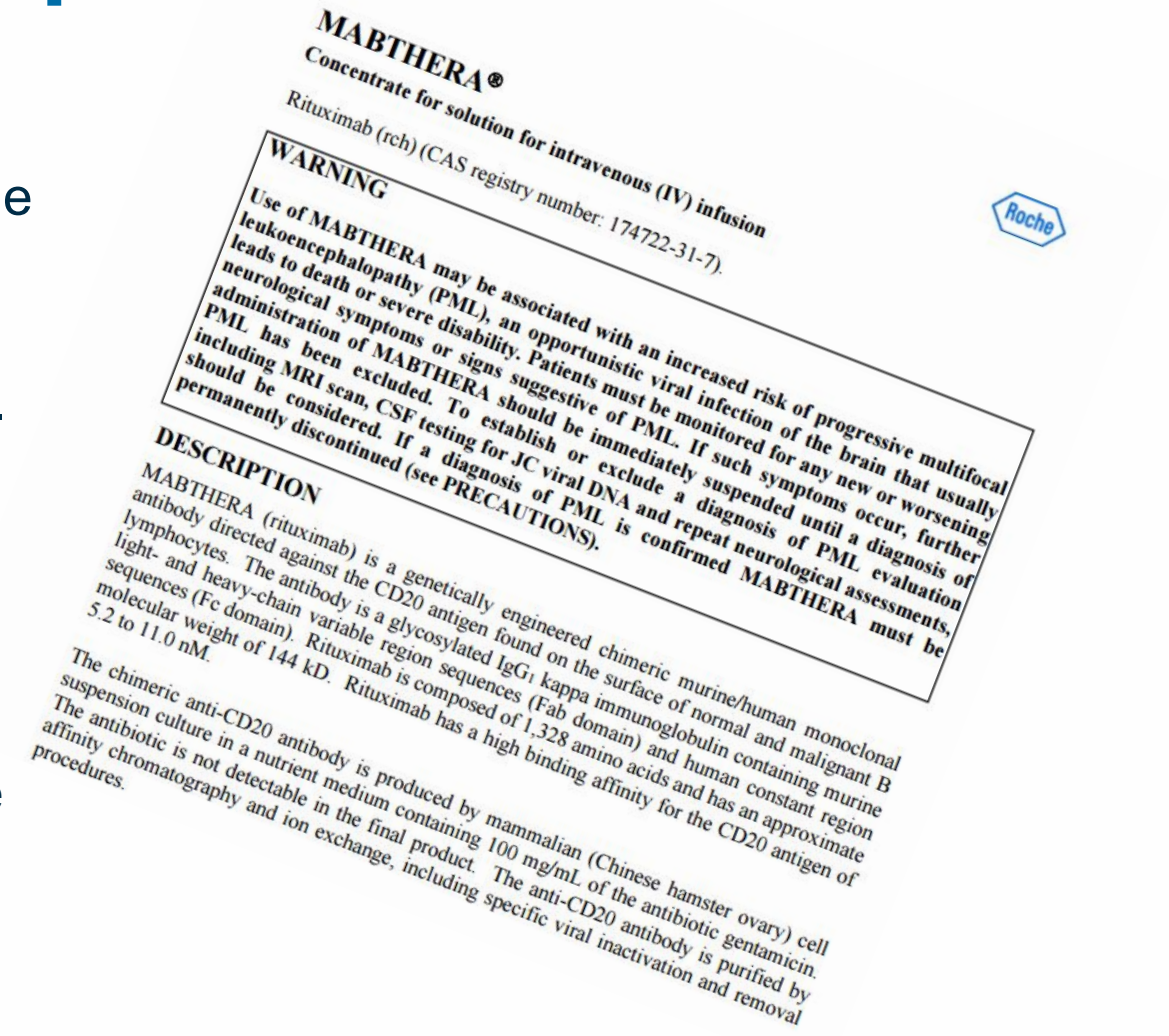
Information from doctor to patient: CMIs

- Provide the CMI to the patient or advise them how they can obtain the CMI from their pharmacist.
- The CMI provides important information about the symptoms that patients may have when they use the medicine you have prescribed.
- Providing a CMI improves compliance.

Information from TGA & spon doctor: PI

- A product information (PI) document has been written by the pharmaceutical company responsible for the medicine and approved by the TGA.
- A PI provides objective information about the quality, safety and effectiveness of the medicine.
- This information is intended to assist health professionals in prescribing and dispensing medicines.

Find PIs via:
www.tga.gov.au, the Medsearch app or widely available clinical software



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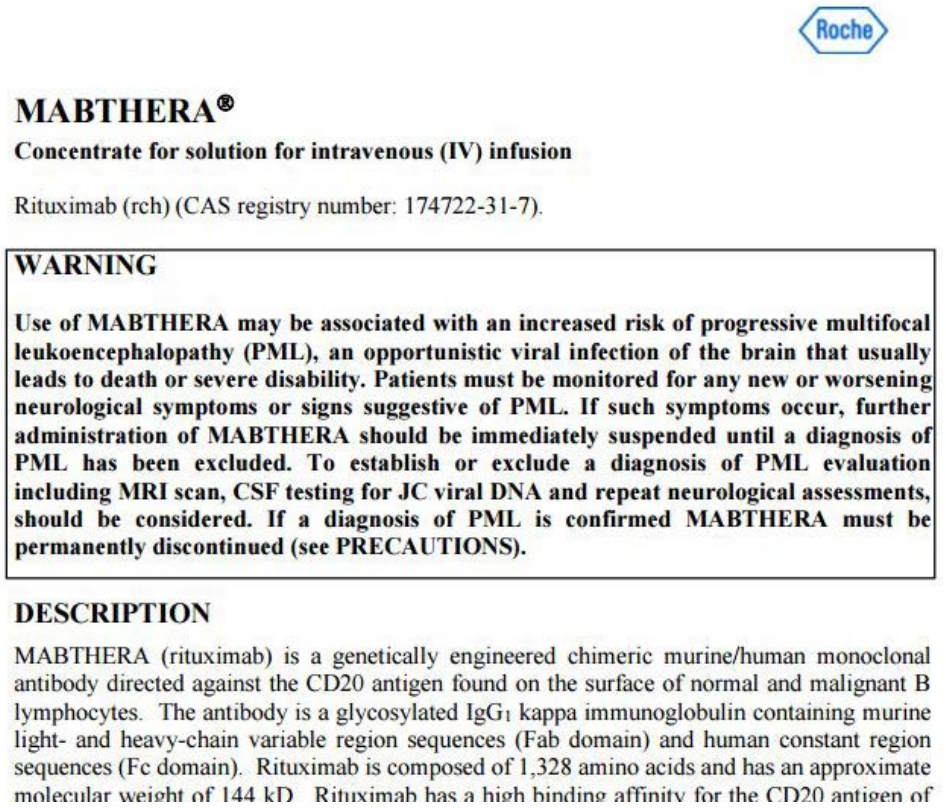
Product Information reformatting

The Product Information (PI) is being reformatted to:

- improve its usability for health professionals, by bringing critical clinical information to the front of the
  - indications, dosage and administration, contraindications, precautions, adverse events
  - align format with other countries
- Transition to the new format will be over three years
- All PIs in the market will be in the new format by the end of 2020



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Other sources of information from TGA

The TGA publishes a range of other information relevant to GPs including:

- Medicines Safety Update (MSU) and Medical Devices Safety Update (MDSU)
- Safety alerts
- Recalls
- Monitoring communications
- Medicines shortages notifications

Subscribe at www.tga.gov.au/subscribe-updates

Information flowing from doctors to TGA please report your adverse events

- GPs are among those best-placed to provide the most useful adverse event reports.
- Analysis of adverse event reports is a major tool used in monitoring medicine safety in Australia.
- The easiest way to report is online via our website.

www.tga.gov.au/reporting-problems

Image: www.gratisography.com

▼ Black Triangle Scheme

- Identifies new medicines and those being used in new ways
- Encourages the reporting of adverse events associated with their use
- The symbol and text will appear on the PI and CMI, and TGA-related materials

PI: ▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events.

CMI: ▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

Black Triangle Scheme – inclusion criteria

- All new medicines, except:
  - biosimilars
  - seasonal influenza vaccines
- Medicines with a provisional extension of indications
- Extensions of indication into significantly different conditions or patient groups may be included
  - e.g. for an oncology to rheumatology indication

▼ Black Triangle Scheme – implementation

- Scheme starts in **January 2018**
- 5 year duration for standard registration and then lapses
- Provisional registration period
- Inclusion automatically lapses at the end of the agreed period

Black Triangle Scheme – more information

- We will conduct information campaigns for both health professionals and consumers in coming months using a range of channels.
- Keep an eye on your professional bodies' journals and newsletters.
- More information is also available on the TGA website.

Visit: www.tga.gov.au/black-triangle

New Provisional Approval path

A new **Provisional Pathway** will allow certain medicines to be provisionally registered on the ARTG:

- Some medicines will be able to reach Australian patients up to two years earlier.

- An option where the **potential benefit** of earlier availability **outweighs the risk** that additional data are still required.

The TGA particularly encourages adverse event reports for these medicines.

Other monitoring

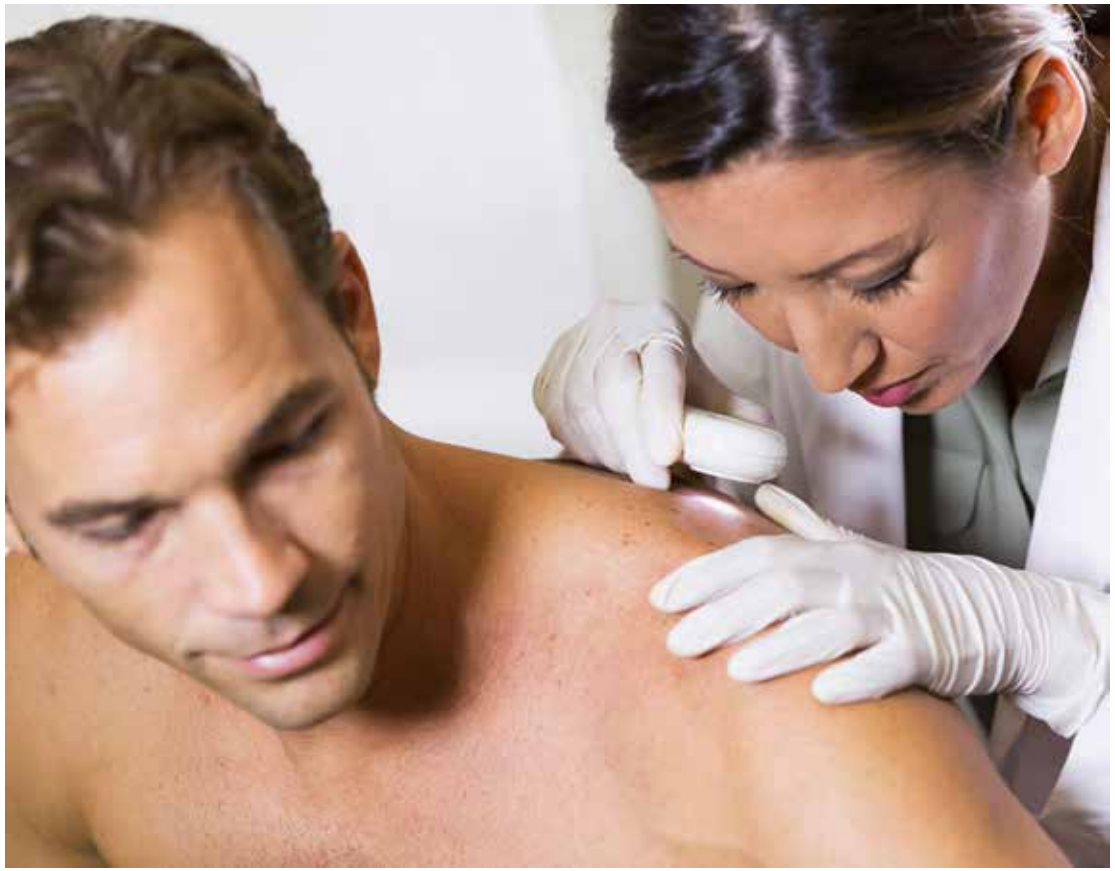
- **AusVaxSafety** – A national collaborative active vaccine safety surveillance initiative
  - **SmartVax** and **Vaxtracker** – Software programs run by GPs and immunisation clinics that send an SMS or email to patients or carers following vaccination
  - **STARSS** – Study evaluating the use of SMS and telephone follow-up after vaccination
- We are trialing combining and monitoring de-identified information from various sources to detect safety signals.
- We will be able to use data from ‘My Health Record’ when the program is up-and-running.

Your role as a health professional

GPs can play an important role by reporting any suspected adverse events to the TGA.
We are particularly interested in:

- suspected reactions involving new medicines (this is where Black Triangle comes in!)
- serious or unexpected reactions to medicines
- serious medicine interactions

- You don't need to be certain, just suspicious!
- Reports can be made online, or by phone, fax or email
- Visit the TGA website for more information: **www.tga.gov.au/reporting-problems**



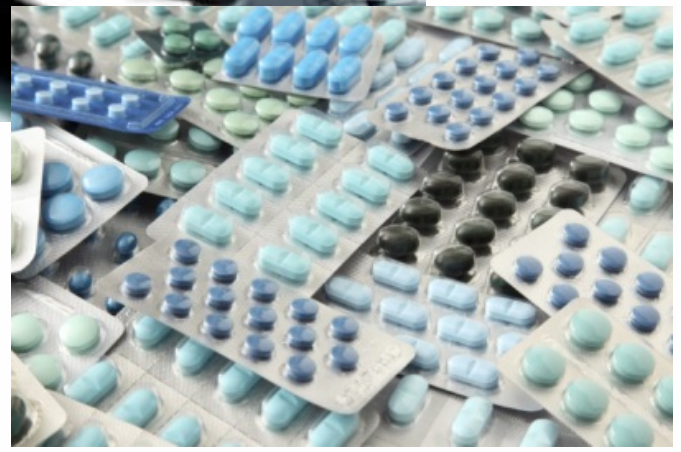
Codeine Rescheduling

Up-scheduling of codeine to Schedule 4 (Prescription Only)

- From 1 February 2018, medicines containing codeine will no longer be available without a prescription
- The rescheduling decision was made on the grounds of public safety and potential for abuse
- Research shows that over-the-counter low-dose codeine can cause:
  - opioid tolerance
  - dependence
  - addiction
  - poisoning
  - death
- Addiction as a result of regular use can occur without the patient realising
- Visit the TGA website (www.tga.gov.au/codeine-info-hub) for resources on codeine access or visit the TGA exhibition space for more information

Therapeutic Goods Evaluation Panel

Would you like to evaluate for the TGA as an External Evaluator?



- The TGA is currently looking to appoint suitably qualified and experienced individuals and organisations with expertise in various scientific and medical fields to the Therapeutic Goods Evaluation Panel.
- Evaluation services in the areas of clinical medicines and technologies, nonclinical sciences and quality of pharmaceutical therapeutic goods.
- Request for Tender open on AusTender
- Industry briefings/information sessions in November 2017

TGA tenders (https://www.tga.gov.au/tga-tenders)

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