Australian Government
Department of Health
Therapeutic Goods Administration

MMDR Consultation

Strengthening monitoring of medicines in Australia

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ARCS Webinar – MMDR Series

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TGA Health Safety Regulation

Review of Medicines and Medical Devices Regulation (MMDR review)

- The review was conducted by an expert panel and made 58 recommendations relating to the regulation of medicines, medical devices, post-market monitoring, complementary medicines and advertising of therapeutic goods.
- On 15 September 2016, the Australian Government released its response to the MMDR review.
- The Government accepted the majority of the review's recommendations in full or in-principle and announced a program of reform to facilitate their implementation.
- The Government response identified the need for consultation with stakeholders in progressing the reforms.

Seven bundles of work agreed and costed

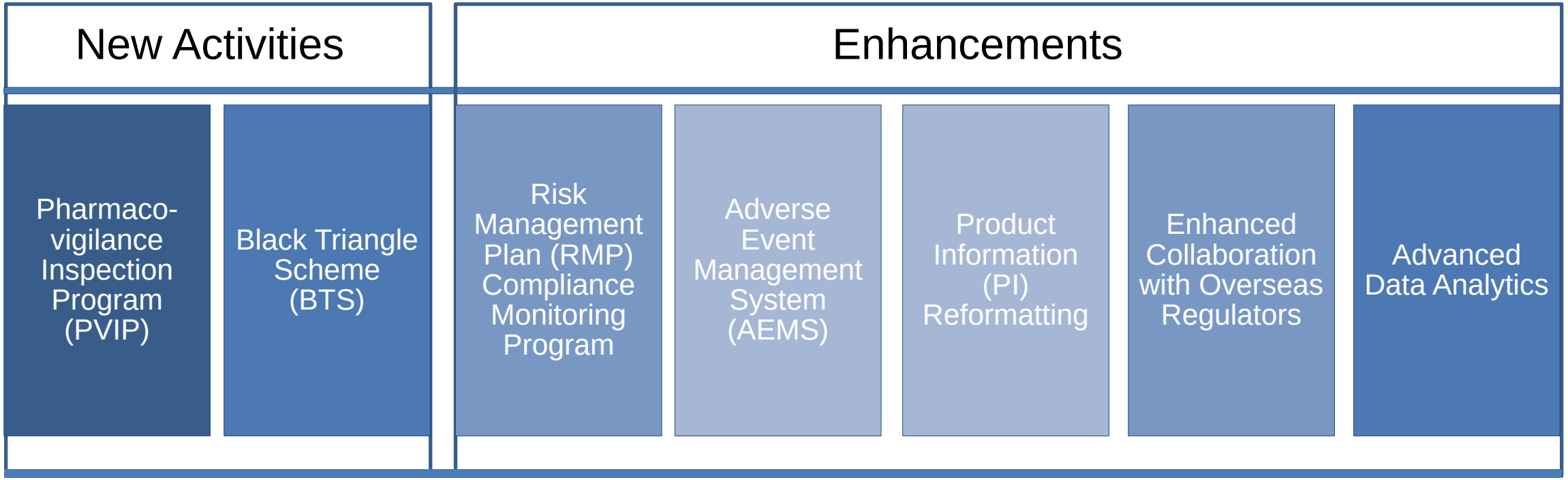
- Increasing Flexibility for Registration and Enhanced Post-Market Monitoring for **Prescription Medicines**
- Increasing Flexibility for Approval and Enhanced Post-Market Monitoring of **Medical Devices**
- Increasing Flexibility for Pre-Market Approval and Increased Evidence of Efficacy of **Complementary Medicines** for Consumers
- Simplified and More Effective Regulation of **Advertising**
- Streamlined Regulation of **Patient Access** to Therapeutic Products
- **Further Reviews**
- Rationalisation of **TGA Statutory Advisory Committees**

Legislative amendments

- The first amendment Bill was introduced into the lower house in December 2016.
- This Bill will facilitate:
  - Regulation-making power to set out details of the Priority Review pathway
  - Notifications for low-risk variations
  - Easier access to certain unapproved goods
  - Conformity assessment of medical devices by Australian companies
  - Timeframes for decision making for listed complementary medicines
  - Review and appeal rights for sponsors seeking approval to use new ingredients for listed medicines
  - Consolidation of TGA advisory committees
- The Bill was referred to a Senate Inquiry, which reported back on 27 March 2017

Implementing an Enhanced Medicines Vigilance Framework

The consultation *Strengthening monitoring of medicines in Australia* outlines the current pharmacovigilance activities undertaken by the TGA and details how current activities will be enhanced and new activities will be implemented to ensure the safety of Australian medicines.

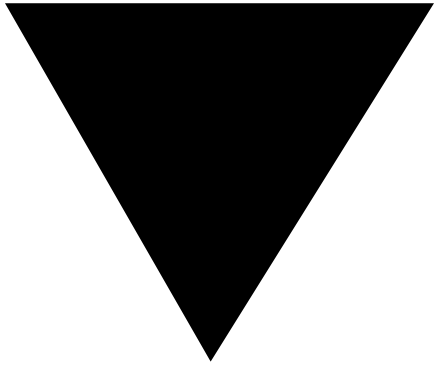


Pharmacovigilance Inspections Program

Implementation 1 September 2017

- Program will apply to Sponsors of:
  - prescription medicines
  - over-the-counter medicines
  - listed and registered complementary medicines.
- Risk-based prioritisation of sponsors for inspection, considering:
  - the risk that non-compliance is occurring, and
  - the potential consequences of this.
- In addition to prioritised inspections, sponsors may be selected for random inspections
- Again, TGA will take a cooperative compliance approach to work with sponsors in the first instance where there are non-compliance findings.

Black Triangle Scheme



- Will apply to newly registered prescription medicines for a period of five years where there is a safety concern or missing information
- Provisionally approved medicines will display the Black Triangle for the length of their provisional approval + five years
- Black Triangle will automatically end after five years, unless the TGA believes there are ongoing safety issues warranting retention of the symbol for a further period of time. Sponsors will notify TGA that they have removed the symbol
- Will be required to be displayed on the PI and CMI
- Implementation will be supported by intensive communication for health professionals and consumers between late 2017 – 2019

Risk Management Plan (RMP) Compliance Monitoring Program

Implementation 1 January 2018

- From the implementation date, TGA will undertake systematic compliance monitoring of RMP activities.
- Activities will be prioritised for monitoring using a risk-based matrix.
- Prioritisation will be based on criteria such as:
  - Provisionally registered products
  - First in pharmacological class
  - Identified safety concern of special interest that require additional monitoring/ mitigation
- Monitoring will operate within TGA's Regulatory Compliance Framework, we will seek to work with the sponsor in the first instance to achieve compliance.
- TGA will further undertake random inspection of sponsors' RMP compliance to ensure non-prioritised requirements are also met.

New and Improved Adverse Events Management System (AEMS)

Implementation 1 January 2018

- The new system will support both medicines and medical device adverse events.
- AEMS will support system to system exchange of adverse event reports using standardised international message formats. This will make it easier for sponsors to send adverse event information to the TGA.
- The new system will assist the TGA in enhancing its signal management capabilities through more advanced signal detection and data analysis processes.

Product Information (PI) Reformatting

Transition to begin January 2018

- TGA will be reformatting the Product Information (PI) leaflet to place the information most relevant to health professionals up front.
- This project will align the Australian PI with the requirements of comparable overseas regulators such as the European Medicines Agency and Medsafe NZ.
- Implementation of the change is proposed to begin January 2018 with full implementation by January 2020.
- A soft launch period may be considered

What else are we improving?

Ongoing activities

Enhanced Collaboration with Overseas Regulators

- Part of a broad focus on engagement between comparable overseas regulators to share information regarding medicines and medical devices across the product lifecycle.
- We have expanded our engagement with a number of comparable overseas regulators to regularly share information related to medicines safety.
- This enhanced collaboration will support the TGA to make decisions regarding medicines safety using the latest global information

Advanced Data Analytics

- The development of new systems, such as AEMS, and access to population-level data sets have provided an opportunity for TGA to establish a solid foundation for ongoing data analytics.
- TGA is now evaluating the use of 45 and Up data sets and working towards the implementation of analytics drawn from data sets held by the Department of Health and TGA.

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