Sponsor Information & Training Day

Tuesday 9 September 2014
Hyatt Hotel, Canberra
Session A4: Medical Devices

Hugh Cameron
Director, Regulatory Affairs, ANZ
BD
Recall and non-recall actions of medical devices

What are they?
What is the process – URPTG?
Different types and ways these are carried out
Responsibilities of the manufacturer, sponsor and TGA
Update of the URPTG
Presenters

• Hugh Cameron
  – Director, Regulatory Affairs, ANZ BD

• Mick O’Connor / Joshan Joy
  – Recalls & Advertising Section
    Office of Product Review
    Monitoring & Compliance Group
    Therapeutic Goods Administration
Recalls and non-recall actions
Session A4: Medical Devices

Mick O’Connor
Director
Recalls & Advertising Section
Office of Product Review

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Overview

- Recalls Unit functions
- URPTG – the recall procedure
- Recall and non-recall actions
- Legislation including mandatory provisions
- Recall process
- URPTG Update & GS1 RecallsNet
Recalls Unit Functions

- Recall actions
- Non-Recall actions
- Product tampering issues
- Notifications from overseas regulators
- Monitoring emerging product issues
The URPTG (current) 2004 edition

Available online at www.tga.gov.au/industry/recalls-urptg.htm

Session A4: Medical Devices – Recall and non-recall actions
URPTG – Recall actions

A recall is a market action taken to resolve a problem with a therapeutic good for which there are deficiencies in safety, quality, efficacy (performance for devices) and/or presentation.

There are three types of recall actions:

- **Recall** – the permanent removal of deficient goods from the market or from use
- **Recall for Product Correction** – repair, modification, adjustment, re-labelling, update to instructions or labelling
- **Hazard Alert** – providing information to health practitioners regarding the issues to implantable medical devices and advice on how to manage such patients
URPTG – Non-Recall actions

- **Safety Alerts** – advice regarding a specific situation where the therapeutic good meets all specifications but under a specific situation might present an unreasonable risk of substantial harm.

- **Product Notifications** – issue of precautionary information about a therapeutic good, in a situation that is unlikely to involve significant adverse health consequences.

- **Product Withdrawal** – sponsor removal from supply or use for reason not related to quality, safety, performance or presentation.

- **Quarantine** – suspension of further supply by the sponsor pending investigation of a problem/incident.
Legislative Context

- *Therapeutic Goods (Medical Devices) Regulations*, Schedule 3 (Conformity assessment procedures) Part 1.4(3)(c), Part 4 4.4(3)(c), Part 5 5.4(3)(c)

- Even though most of the recall actions are initiated by the manufacturer, such actions are required under the medical devices legislative framework and are not voluntary
Legislative Context (Cont’d)

- **The Therapeutic Goods Act 1989 (the Act):**
  - s30EA for medicines and OTGs, **s41KA for medical devices**, s32HA for biologicals and s42V for goods subject to actual or potential tampering
- **Competition and Consumer Act 2010:**
  - notification to ACCC for safety related recall actions (s128)

Section 41KA (medical devices) of the *Therapeutic Goods Act* covers the Secretary’s powers and processes for **mandating** device recalls not only for currently ‘included’ devices, but also for **exempt, cancelled or illegally** supplied devices.
Responsibilities – Sponsors

- Submitting proposed communication strategy and draft letters to the TGA
- Submitting a “risk assessment” (usually known as a health hazard assessment) undertaken by the manufacturer for the issues identified
- Maintaining product distribution details (and providing to the TGA) to assist in facilitating a recall action
- Having established recall procedures in place to undertake a product recovery/correction/hazard alert
- Taking primary responsibility for implementing the recall action (but can authorise third parties) and reporting the progress of the recall action
Classification & Level of Recall

• Recall Class* (based on risk):

  Class I - potential threat to life or serious injury
  Class II - could cause illness or mistreatment
  Class III - does not pose a significant hazard to health

  * Not to be confused with ‘Included’ medical devices classification

• Level of recall (wholesale, hospital, retail and consumer) based on significance of the hazard and the channels by which the products have been distributed.
Responsibilities – TGA

- Reviews risk assessment, amends (as necessary) and approves the proposed recall strategy
- Advises stakeholders (primarily the state and territory health departments) of recall actions including release of distribution details to monitor the effectiveness of the recall
- Closes-out the recall action after the TGA is satisfied about the conduct of the recall action and that appropriate corrective action has been identified to prevent recurrence of the issues

Additional processes

- Publication of all recalls since July 2012 in searchable Recalls database, [SARA](#)
- TGA web statements for all Hazard Alerts, consumer level and sensitive recalls
Follow-up reporting

The reporting requirements are:

- 2 and 6-week progress reports are required after the commencement of the recall
- Close-out report requirements (usually 3 months or another agreed timeframe):
  - the results of the recall - quantity of stock returned, outstanding etc;
  - the means of disposal, destruction or correction to the recalled goods and confirmation that this has been carried out; and
  - details of the root cause analysis and corrective action to prevent the problem from recurring.
Other issues

URPTG update

- The TGA is currently developing a document which will incorporate the feedback over the years from our stakeholders including the industry and also the work undertaken during the B2B project with NZ MedSafe as part of ANZTPA
- Planned external consultation expected end of 2014 or early 2015

GS1 RecallsNet

- provides sponsors with an alternative method for notifying the TGA of recall actions and communicating with customers who have been supplied defective products
- The TGA has contributed to the development of GS1 RecallsNet Healthcare through the provision of advice to GS1 Australia on the requirements and procedures outlined in the URPTG
- Has published a clarifying statement on the TGA website
Session A4: Medical Devices – Recall and non-recall actions
Quarterly Trend - Recall actions for medical devices (excluding IVDs)
Quarterly Trend - Classification of devices undergoing recalls actions

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What are they?

Recalls and associated actions are our “friends”
What are they?

Frequently painful
What are they?

• Ensure patients / users are protected / can effectively use

• Demonstrate our Manufacturers’ QMSs are working effectively

• Protect Company / Industry reputation

• Compliance is our responsibility
What are they?

Think what may happen if we didn’t conduct Recalls…
What is the process?

Actively discuss with Recalls Unit

Pay close attention to what the URPTG asks (and doesn’t ask) for
URPTG

• Is not legislation
  “…an agreement between the therapeutic goods industry and Commonwealth and State/Territory health authorities.”

• As a Sponsor, you have to determine how to comply
• Information to be provided
  – Details of the problem / product
  – Risk Assessment and proposed action
    • Type of hazard / assessment of risk
    • Action / Classification / Level proposed
URPTG

• Availability of alternative product

• Have a focused approach
  – provide the information necessary for a successful outcome

• Importantly
  – Collaborative process
  – TGA will liaise with Sponsors and provide advice and assistance
URPTG

• Confidentiality
  – “It is recognised that some of the information provided may be of a commercially sensitive or private nature and such information will be treated appropriately.”
  – Mark it as such if you think this is the case

• Some States / Territories may communicate widely on Recalls
  – Issues with multiple communications and Recall returns
Types / Ways

• Depends on Classification and Level
  – It’s a continuum:
    • Class III with single / minimal customers
    • Class I at the retail / consumer level
    • With everything between
Types / Ways

• Hard copy / fax / e-mail – confirm receipt
• Receipt of acknowledgement forms

• GS1 RecallNet
  Watch outs
  – Liability?
  – Coverage?
  – Improvements into the future

• Requirement should be to Recall effectively without specifying the medium
Manufacturer Responsibilities

An effective QMS that

• Maintains effective feedback
• Formalises evaluation methods
• Communicates and receives inputs
Sponsor Responsibilities

• Requirement to report to TGA in a timely fashion
• Established relationship with manufacturer & TGA
• Best practice = written procedure
• Distribution records
• Quality holds
• Receive and action complaints
• Action the Recall and report
  – 48 hours from approval
  – 2 and 6 week reports, with final closeout report
A future URPTG

• Not so “medicine-centric”

• Focus on the customer / end-user

• Use terms that don’t confuse customers / end users

• Recognise that the product SME is at the Design Centre

• Avoid redundant communications
QUESTIONS?
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