GS1 Healthcare Conference

Thursday 22nd March, 10:10-10:35AM

Improving the Product Recall Process in Healthcare across Australia

GS1 Recallnet provides the healthcare sector with an improved and efficient recall process for healthcare products to improve patient safety

Presented by

- **Mark Brommeyer, Manager Supply Chain, NEHTA**
- **Mark Rendulic, Head of Quality ANZ, Sanofi**
- **Pete Losin, Director, Health Technology Management, Queensland Health**

Australia

GS1 Recallnet for Healthcare – Project Overview

Mark Brommeyer

Manager Supply Chain, NEHTA

21st Global GS1 Healthcare Conference

22 March 2012, Sydney

Agenda

1. Project Overview – Mark Brommeyer
2. A Supplier's Perspective – Mark Rendulic, Sanofi
3. A Healthcare Provider's Perspective – Pete Losin, Queensland Health

Project Overview

Project Need

- Product recalls have a large impact on all involved
- Product recalls are increasing
- Opportunities exist to improve the product recall process through new technologies, data standards and a more streamlined process

Project Mission

To deliver a single product recall notification system in the Australian healthcare sector, through a phased approach, to improve the speed and accuracy of the therapeutic goods recall process with the aim of improving patient safety.

Who is involved?

- All **Recall and Non-Recall Notification** processes in Australia
- **Direct Notifications from Sponsors** to where the recall notification needs to be action
- **Direct and structured feedback** from recipients to Sponsors
- **Support for Medicines** (including complementary) **and Medical Devices** only (other categories to be added in future phases)
- **B2B and B2G, not B2C** (notification to healthcare practitioners will be **investigated** but implementation would be part of future phases)
- Identify **process and other changes** that stakeholders need to establish in order to maximise the benefits of the recall system
- Develop **criteria/metrics for identifying improvements** to the recall process based on the new portal based process.

Project Timelines

Date	Activity
Mar – Jul 2012	• Complete development for Pilot System • Pilot preparation and process review
Jul 2012	• GS1 Australia User Acceptance Testing
Sep 2012	• End to End Industry Pilots – 24 Scenarios Identified • Post Pilot Report
Oct 2012	• Complete System changes based on Post Pilot Report
Nov 2012	• Complete GS1 Australia User Acceptance Testing
Feb/Mar 2013	• Launch Healthcare Service in Australia • Promote to industry

GS1 Recallnet – A Supplier's Perspective

Mark Rendulic – Head of Quality ANZ, Sanofi

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GS1 Recallnet
A Supplier's Perspective

- Why do we need to do it right?…. and right first time

  - **Ensuring patient safety at all times**
  - **Investments that companies may make in being ready (buying distribution lists, consultancy services, internal resources, insurance cover)**
  - **The potential damage of recalls to a company's reputation, share price and trading relationships**
  - **Adverse impacts from regulatory bodies**
  - **Ensuring patient safety at all times**

GS1 Recallnet
A Supplier's Perspective

- **Challenges in executing a recall today**

  - Gathering the data needed for a recall notification
  - Interaction with the regulator and providing concise, timely information
  - Notification with Customers, Distributors and other parties
  - Making sure the notifications are clear, crisp and understandable to minimise confusion to wholesale, pharmacy and patient level
  - Ensuring there is a commitment to acknowledging and taking action on notifications
  - Recovery and tracking progress and reporting.

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GS1 Recallnet
A Supplier's Perspective

- **Expected Benefits**

  - **A single, whole of industry portal that can reach all** targeted **Trading Partners**
  - **Tracking the receipt and action of the notification**
  - **More efficient communications with the TGA**
  - **Greater visibility of progress through enhanced reporting**
  - **Clearer more targeted communication reduces burden of over notification**
  - **Reduces risk and exposure to Sponsors and improved patient / consumer outcome**

SANOFI

Overall ~growth

- 2009: of the 314 notices received for biomedical devices / 90 **28%** affected QH

- 2010: 431 / 223 **51%**

- 2011: 614 / 339 **55%**

Many challenges

- Insufficient information
- Time to determine corrective action
- Internal communications challenges: how to file, retrieve and report on notification data
- Product tracking issues
- Difficulty in calling people to action
- No single system to track progress
- Repeat notifications and notification from multiple sources – burden of over notification

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Need to improve

- Increasing use of technology in healthcare
- Increasing number of devices
- New technologies becoming available
- Increasing complexity of technology
- Increasing complexity of treatments
- Increasing awareness and reporting of risks and incidents *(>70,000 patient issues reported annually, many involve medical devices)*
- Public expectations for safety

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Expected benefits of Recallnet

- A purpose built system rather than adaptations
- Ability to tailor who needs to receive the notification internally
- Improved tracking will enable greater recovery of affected product
- Systemised management including recall status and activity reporting
- More timely response for corrective action, reducing the potential for harm

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Key take away messages

- There is a growing need for industry and government to collaborate to improve the current recall process

- Aim is to reduce margin for error in managing product recalls – leading to lower risk and exposure

- The GS1 Recallnet project has enabled industry to collaborate in improving the timeliness and accuracy of the recall process in the Healthcare sector

- Time to get involved!

National E-Health Transition Authority
www.nehta.gov.au

Are you involved?

Thank You