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
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• Mark Rendulic, Head of Quality ANZ, Sanofi
• Pete Losin, Director, Health Technology Management, Queensland Health
GS1 Recallnet for Healthcare – Project Overview

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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?
Project Scope

• 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**

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

Mark Rendulic – Head of Quality ANZ, Sanofi
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
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.
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
GS1 Recallnet – A Healthcare Provider’s Perspective

Medical device recalls in Queensland Health

Presented by Pete Losin, Director, Health Technology Management, BTS
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
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
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
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!
Are you involved?
Thank You