The Global Language of Business

The hazard of manual recall notices for healthcare

Case study

This case study provides a real-life example of the pitfalls of using manual methods to communicate these notices. It is drawn on a real-life experience with the names of the parties withheld to ensure there is no reputational damage to individuals and organisations.

Current recall practice

The communication of product recall and non-recall notices for Therapeutic Goods Administration (TGA) regulated products is commonly communicated manually via letter or fax to hospitals, pharmacy, aged care and other healthcare providers.

The challenge

A multi-national manufacturer and supplier of medical devices (the Sponsor) conducted a hazard alert and recall of one of their products in late 2016. This recall alert affected a number of healthcare providers and involved a significant amount of product. The outcomes for patients were listed as possibly adverse.

The notice was listed on the TGA website and alerts were sent both from the Sponsor Company and the TGA. The Sponsor Company alerts were originally sent via postal mail and then 10 days later to some recipients electronically.

More information

Contact the Recall Health team at:
GS1 Australia – Quality Services Support
T 1300 227 263 or
E gs1recallnetadmin@gs1au.org

Read more here:
www.gs1au.org/our-services/recall-health/

What took place

Recipient A

- Received notices from the Sponsor Company to its locations via postal mail, after 3 to 5 days
- The notice was actioned at the locations that received it but it was not clear to them that the notice had been sent to other critical recipients in the organisation

Recipient B

- Received notices from the Sponsor Company to its locations via postal mail, after 5 days
- They did not receive a notice at their central warehouse, which also had stock
- The central warehouse received the notice from a TGA alert which did not provide enough actionable information; causing an additional delay
- The Sponsor Company was unresponsive when more information was requested

Recipient C

- Did not receive the notice from the Sponsor Company or the TGA but from an informal channel to one location
- They were not aware of the notice for 6 days from the time the notice was listed on the TGA website

Recipient D

- Received the notice electronically from the Sponsor Company, 10 days after it was listed on the TGA website

The effect of that process

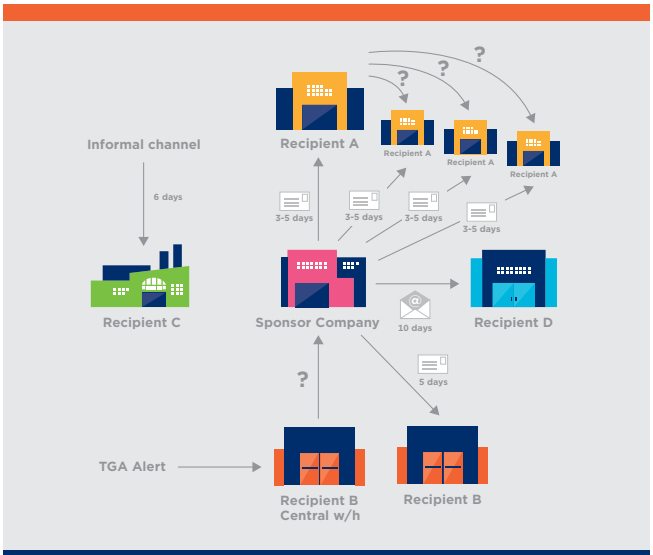
Receiving delayed critical incident product recalls, or non-recall notices, means affected products are used well after they should have been isolated or withdrawn from use. This is compounded when:

- Notices are not sent to the right locations
- Recipients do not have proper visibility across their own organisations - to ensure all affected stakeholders are informed

In this instance, there were no obvious reported adverse outcomes for patients. The potential for harm is there because efficient, effective and well-practised processes and technology were not used.

How to improve recall outcomes to benefit all

This case study shows that critical recall and non-recall notices can be difficult to action for Healthcare providers. Manual notices sent only via the post or fax provide no receipt confirmation. It is difficult for Sponsor Companies to confirm that the notices are reaching the correct contacts, in a timely manner.



Manual recall process from Case study

A delay of up to 10 days for Healthcare providers to receive a notice is unacceptable and may impact patient safety. This delay also creates more work for Sponsors and Recipients and harms the reputation of all parties involved. Electronic communication of the notice was available to the Sponsor organisation and many of their recipients at the start of the action. However, they chose not to use this option. The organisations that were sent their notice electronically received it almost immediately and were able to respond shortly after.

The solution

We know that using the GS1 Recall Health portal for communicating recall notices dramatically improves the certainty and timeliness of delivery:

- Recipients specify how notices flow to the right people, quickly and easily
- Recipients respond to the Sponsor, potentially removing the need to follow up manually and freeing up time to respond to other enquiries
- Configurable automatic follow-up processes take place if acknowledgement is not received or the recall is not actioned
- Audit trail of correspondence is maintained, making evaluation or investigation easier in the event of an adverse outcome due to slow or inadequate responses
- Users can Quickly and accurately identify a priority to follow up and close notices

The Recall Health portal was configured by Australian Health industry experts including representatives from the TGA, NEHTA (Digital Health Agency), sponsors and recipients to meet the TGA's URPTG requirements.

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