SHPA response to Therapeutic Goods Recall Processes - Seeking Feedback on Improvements to the Recalls Process, March 2023

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional organisation for the 6,100+ Hospital Pharmacists, and their Hospital Pharmacist Intern and Hospital Pharmacy Technician colleagues working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use. Embedded in multidisciplinary medical teams and equipped with exceptional medicines management expertise, SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care.

SHPA was kindly invited to attend the TGA's Recall Reforms stakeholder workshop held in April last year and welcomes the feedback from that session being incorporated into the proposed improvements. SHPA consulted its Medicines Information Leadership Committee as well as Directors of Pharmacy for feedback.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on jyik@shpa.org.au.

1. Increasing awareness and understanding

Q1. Did you know where to find guidance or information on recalls prior to reading this paper?

Yes. SHPA members utilise the System for Australian Recall Actions (SARA).

Q2. Do you have any feedback on our current recall guidance in the URPTG or on our website? What do you like about it? How could it improve?

No.

Q3. What are your preferred recommendations from the list? Please pick your top three preferences in order of 1st, 2nd and 3rd.

1st - having targeted information for different stakeholder groups for significant recalls

2nd - workshops or seminars for health professionals on how to effectively respond to a recall

3rd - upgrading our public information database – the System for Australian Recall Actions (SARA) to make it more searchable, user-friendly and modern

Q4. Do you have any other suggestions or strategies to improve our guidance and increase awareness of recalls?

No.

2. Improving communication

Q5. Do you see any benefits if we communicate more with different stakeholders, such as patient advocacy groups and professional bodies, before commencing a recall?

Yes.

Q6. If yes, why do you think this is important? If no, what are your concerns and are there situations when we should not consult before commencing a recall?

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Professional bodies can provide another channel to alert healthcare providers of urgent recalls and prepare members for actions required.

Q7. Are there other questions we should be asking in our urgent notification of a potential recall?

Ask if other products by the same manufacture are affected or if there are alternative agents that are not affected by recalls.

Q8. If you represent an organisation with an interest in recalls and don't receive notifications, would you like to be added to one of our lists? If yes, please give us the contact details we can use.

Jerry Yik, Head of Advocacy and Policy, jyik@shpa.org.au

Q9. If you have seen any recall communication material, what did you think? Could you rate it out of 5 on the following aspects? (5 being very good, 1 being very bad)

- 3/5 Was it easy to find?
- 4/5 Easy to read?
- 3/5 Was the key message clear?
- 4/5 Did it explain how to get more information?

Q10. What do you think are the best options from the list to improve our communications? Could you rank them from most beneficial to the least benefit?

Ranked from most beneficial to least beneficial:

1. Improving our website subscription service to allow automated emails/text message alerts for certain types of recalls
2. Increase our communication channels, including asking relevant partner organisations such as patient advocacy groups to send out information using their established networks
3. Better and more targeted use of social media
4. Use existing third-party communication networks, such as patient newsletters and private broadcast channels
5. Better outreach to groups representing vulnerable consumers, such as culturally and linguistically diverse (CALD) consumers, First Nations consumers, older consumers and consumers with a disability
6. Asking retailers to display the recall notice in their shopfront

Q11. Please give us any other suggestions you have. What other communication methods could we use to increase the distribution of recall information?

SHPA notes that the TGA website does not have the option of push notifications, so often in hospital settings, this process relies on a pharmacy staff member checking for updates each day. This can be time consuming and prone to information being overlooked.

Q12. Do you regularly receive either the TGA's recall notices or the recall letters from sponsors? Do you receive the same information from multiple sources?

Yes.

Q13. If you are part of a supply chain (wholesale, retail, hospital procurement, etc), to whom do you regularly need to pass recall information?

In hospital settings, recall information from procurement must be passed on to pharmacy staff who can them action and disseminate this information to all affected emergency departments, ward stock areas as well as outpatient clinics.

Q14. Are there any known or foreseeable weaknesses in this communication chain?

If communication is received late in the day the information may not be passed in a timely manner due to unavailability of pharmacy staff, particularly on weekends where there are reduced pharmacy services.

Q15. If you are a stakeholder who needs to track the recalled products, how do you do this effectively?

Information is disseminated to pharmacy staff with an agreed action plan. Pharmacy staff then locate affected products and either replace or provide advice on alternatives to medical and nursing colleagues.

Q16. Are there more efficient ways for recall information to reach the people who need to know?

The notification process is not always found to be consistent, with recall notices being sent to various people in hospital settings such as the purchasing staff, director of pharmacy, procurement team and CEO.

Information sent directly to inpatient wards or areas might mean that key information is misinterpreted without appropriate action taking place. Notifying pharmacy staff is most efficient but requires timely communication to allow time to take action, however, a consistent approach to sending recall notices to key people in the organisation who are able to facilitate the necessary actions following a recall would be more efficient.

Q17. How could we improve the visibility and transparency of therapeutic goods supply chains? For example, should government require sponsors to have a regulatory obligation to document their supply chain and goods distributed by any subsequent (downstream) supplier?

Greater visibility of the distributed goods would assist in making this process transparent.

Q18. Should we have more guidance for retailers, pharmacists or other healthcare providers on how to advise consumers or patients about recalls?

Yes. Guidance should be provided on alternative treatments available.

Q19. Do you think the current timeframe for TGA's release of recall information is appropriate?

Communication of recall notifications should be prompt, with the same day or next working day being an appropriate time frame. Where possible, higher risk recalls should be prioritised for shorter timeframes.

Q20. Do you think TGA should always wait until we have the sponsor's agreement on the recall before sending any information to other stakeholders?

A notice of potential recall may assist pharmacy departments in developing an action plan prior to the recall being agreed on by the sponsor. This would assist in mitigating risk for recalls of critical medicines.

Q21. Which of the options do you think is best, and why?

As described in answer to question 19, a same day recall notification would be appropriate for high risk recalls, with other recalls communicated by the next working day.

Q22. What risks do you see with any of the above options?

SHPA believes that communication regarding recalls is currently fragmented with emails and faxes coming from a range of sources such as sponsors, suppliers, wholesalers, federal, state and territory clinical safety and quality agencies, and/or other colleagues. These various channels of communication can mean that recalls are often received faster than formal notifications at times.

Urgent recalls can get overlooked during holiday periods as communication is sent to a generic email and not necessarily actioned promptly. SHPA recommends that urgent recalls need to be communicated via a phone call or emailed to an appointed person directly.

Q23. If you receive our recall email notifications, what is your feedback on the content of the email and Recall Notice?

SHPA believes it would be helpful to include with recalls which alternatives might be appropriate, and/or coordination of alternative supplies. For example, this could include signposting to avenues to procure SAS/S19 stock. This is currently determined by individual jurisdictions and/or individual hospitals. A streamlined approach would assist in providing alternative treatment promptly.

Q24. Would providing the sponsor's customer letter with our email notifications be beneficial? Should we continue to provide the recall summary notice, or just provide the sponsor's customer letter and a link to the SARA database summary?

Continue to provide the recall summary notice.

Q25. Do you have any other suggestions to improve our recall communications?

SHPA notes that recall notices are often received late afternoons which can be problematic especially on a Friday. Evenings and weekend services are staffed with less pharmacy staff that weekdays. This puts further strain on the health system as pharmacy staff are obligated to stay past their work hours to find affected products and to put actions in place such as alternatives. SHPA suggests that recalls are sent to stakeholders as early as possible to allow prompt response and protect patient safety.

3. Better recall descriptions

Q26. Do you agree with the new recall descriptions?

Yes.

Q27. If yes, what do you like about them? What are the benefits you see?

They are clear plain language descriptions of the recall categories and facilitates staff in identifying the appropriate actions.

Q28. If no, what are your concerns?

No comment.

Q29. Do you have any other suggestions for new terminology?

No comment.

4. Improving sponsor letters and other recall documents

Q30. What do you think of our current templates?

The templates are clear, identifying the issue and action required.

Q31. If you have received recall letters before, what information did you find most useful? Was there anything important missing, or you struggled to find?

Hospital pharmacy staff often must follow up with the manufacturer as they require more reasoning and details behind the recall and how it may impact other products by same manufacturer.

If all batches are recalled, pharmacy staff need to know what the defect is in detail so that they are aware of what they are looking for when recalling from wards and stock areas.

Critical medicines that have little or no alternatives at times must be utilised so if the issue is a label issue or packaging issue that does not affect clinical use, then pharmacy staff need to know if they can use that limited stock for patients that require it in emergency. SHPA recommends that the details outlining the exact defect would assist in pharmacy staff in making these critical decisions and not compromise patient safety.

Q32. Do you agree with the suggested options? If yes, what do you like about them?

Yes, SHPA agrees with the suggested options. The key details of the action would be beneficial to determine next steps in the recall process. Standardised TGA templates would improve consistency and clarity around recall notifications.

Q33. If no, what are your concerns?

No comment.

Q34. Do you have any other suggestions for improving our recall documents?

No comment.

Q35. Do you agree with the proposal to remove the initial report (2 weeks) as a requirement under most circumstances?

Yes, it creates unnecessary regulatory burden.

Q36. Do you agree that a risk-based approach to the reporting requirements would be beneficial? If not, what are your concerns?

Yes.

Q37. Do you think the questions asked of sponsors in the reports are appropriate?

Yes.

Q38. Would further guidance on recall reporting requirements and suitable CAPA information be helpful?

No comment.