Improvements to the Therapeutic Goods Recall Processes Discussion Paper

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This submission has been prepared jointly between Cancer Council Australia (Cancer Council), the Clinical Oncology Society of Australia (COSA), and Medical Oncology Group of Australia (MOGA).

Cancer Council is Australia's peak national non-government cancer control organisation and advises the Australian Government and other bodies on evidence-based practices and policies to help prevent, detect and treat cancer.

The Clinical Oncology Society of Australia is the peak national body representing health professionals from all disciplines whose work involves the care of cancer patients.

Medical Oncology Group of Australia is the national, professional organisation for medical oncologists and the profession in Australia.

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Cancer Council, COSA and MOGA thank the Therapeutic Goods Administration (TGA) for the opportunity to provide feedback to its Discussion Paper. We support the TGA further revising the Uniform Recall Procedure for Therapeutic Goods (URPTG) to ensure the best outcomes for all Australians. This submission outlines our feedback to the Discussion Paper detailing Improvements to the Therapeutic Goods Recall Processes.

Cancer Council, COSA and MOGA look forward to providing further input to the next phase of the TGA's work in reviewing the recalls process, namely, the review of existing mandatory powers to determine how it can support effective recall processes.

Find below our feedback on the Discussion Paper, around its identified five themes and the Survey Questions:

1. Increasing awareness and understanding about recalls

1. Did you know where to find guidance or information on recalls prior to this survey?

Yes.

2. 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?

Cancer Council, COSA and MOGA ask that the current recall guidance in the URPTG and on its website be strengthened by taking a more health consumer / patient centric focus and considering how the information would likely be received by consumers who are not expert or overly familiar with the work of the TGA or Australia's medicine and device regulatory system. Inclusions such as a definitions section, particularly of sponsor and terminology such as safety, quality, efficacy and hazard, would be helpful to health consumers / patients. Including these definitions would enhance the website as many health consumers / patients, particularly people affected by cancer, may not automatically understand such terms and their role within the context of a recall, or understand them differently to the intent of the TGA as they are used slightly differently in the general lexicon. It will also be helpful to include text that encourages health consumers / patients to discuss any applicable recalls with their health practitioner, because the latter is better placed to explain the specific implications of any recall action for treatment going forward. One example of the difference in use of terminology, is that Cancer Council refers to people with cancer or people affected by cancer (i.e., those beyond the direct patient), as our (health) consumers.

3. What do you think are the best recommendations from the dropdown list? Please pick your top three preferences in order of 1st, 2nd, and 3rd.

1st preference (i.e. the best recommendation)

Workshops or seminars for health professionals on how to effectively respond to a recall.

2nd preference

Having targeted information for different stakeholder groups for significant recalls.

3rd preference

Creating more general awareness and educational material for consumers.

Cancer Council, COSA and MOGA identified the above as priorities representing the needs and preferences of people affected by cancer and our health profession members. There is a crucial communication point between health professionals and health consumers / patients when discussing treatment options. Health professionals need to be well prepared to discuss recall situations with their patients and make recommendations about ongoing treatment in the context of the recall. However, health consumers / patients will also seek out information independently, and so must be supported with accessible high quality information to support their decision making and subsequent action.

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

Accessing health professionals through professional opportunities such as conferences, journal articles and via health practitioner Colleges and peak bodies is appropriate to reach that target audience.

Social media intended to reach the health consumer / patient population will miss many people who do not frequently use these mediums, including older people who are more likely to have cancer.

We also recommend the TGA consider utilising a range of spokespeople and communication channels when promoting recalls, as the audiences for recall information are very diverse and are likely to respond differently to different spokespeople and channels.

2. Improving communication

Stakeholder engagement before a recall

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?

Cancer Council, COSA and MOGA agree that there are benefits to the TGA communicating more with stakeholders such as health consumer / patient advocacy groups and professional bodies, before commencing a recall.

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?

By preparing health consumer and patient advocacy groups and professional bodies with information relevant to their constituents, they will be able to support the dissemination of TGA recall notifications in a timelier manner and enhance the reach of the TGA's messages to specific groups of health consumers / patients and health professionals. These organisations have a reach and connection with their constituents that the TGA does not have, and are trusted and established sources of information relevant to the particular condition or profession. They are uniquely placed to disseminate information on such recalls through their existing channels and integrating it into their routine materials and communications.

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

Not at this stage.

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.

N/A.

How information is distributed

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) –

- **Was it easy to find?**

4

- **Easy to read?**

4

- **Was the key message clear?**

4

- **Did it explain how to get more information?**

1

Q10. What do you think are the best options from the above list to improve our communications? Could you rank them from most beneficial (1st) to the least benefit (2nd)?

1. 1st (most benefit): 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.
2. Increase our communication channels, including asking relevant partner organisations such as patient advocacy groups to send out information using their established networks.
3. Use existing third-party communication networks, such as patient newsletters and private broadcast channels.
4. Better and more targeted use of social media.
5. Asking retailers to display the recall notice in their shopfront.
6. 2nd (least benefit): Improving our website subscription service to allow automated emails/text message alerts for certain types of recalls.

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

Cancer Council, COSA and MOGA make the following important points to explain the above rankings:

- Although people who are older (55+ years) or less information technology literate are less likely to use the internet to research health information, the internet is increasingly the first place people use to seek health related information.[1]
- People who use the internet often seek out consumer perspectives from those who have similar conditions, interests and experiences as themselves.[2]
- Similarly, those from culturally and linguistically diverse backgrounds, draw upon a range of information and formal sources to obtain information about and access services to address health needs.[3, 4] Cultural beliefs and practices commonly influence health-seeking behaviour.[5]

Accordingly, targeted outreach to groups representing vulnerable consumers as outlined above, through community leaders, representatives, and organisations, is one such method that should be considered. Improving communications to these groups, will in turn lead to more informed decisions and access to appropriate health products to address health needs.

Another important component of working with organisations, like Cancer Council, is developing strategies to mitigate the potential risk of misinformation surrounding product recalls. For example, 13 11 20, Cancer Council's free confidential telephone support service in each state and territory, is facilitate the provision of trusted information and support for people affected by cancer. The risk of misinformation spreading in an online environment is high, and this risk should be considered in future messaging/communication channels.

<u>Communicating in complex supply networks</u>

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?

N/A.

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

N/A.

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

Cancer Council, COSA and MOGA note that the Discussion Paper states that:

> *"When a sponsor notifies us of a new proposed recall, they give us their customer list. This includes wholesale and retail companies, pharmacies and hospitals who have been supplied with the affected product. We share these customer details with the S&T recall coordinators. The coordinators then assist with identifying, tracing and quarantining the product within* ***the public hospital systems****, and notifying other relevant organisations within their jurisdictions who may be affected." (our bolding)*

Cancer Council, COSA and MOGA ask the TGA to clarify what, if any, processes are followed by the State & Territory recall coordinators, to assist with identifying, tracing, and quarantining the recalled product within *private hospitals*. To have no process to notify private hospitals about recalls, is a large gap that could place health consumers /patients at significant risk.

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

Cancer Council offers a range of sun protection products. All profits from the sale of Cancer Council sun protection products sold help to fund our research, prevention and work supporting people affected by cancer.

Cancer Council licenses our brand to a Sponsor to monitor the recall status of products, to ensure that appropriate action is taken, should a recall be put in place.

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

No further suggestions at this stage.

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?

Sponsors are likely to be aware of their supply chain, including where goods are distributed by subsequent (downstream) suppliers. Therefore, a regulatory obligation to have documentation will likely involve little cost, but overall provide a benefit of supporting recall processes in terms of more direct and timely access to such information.

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

Cancer Council, COSA and MOGA support providing more guidance for all stakeholders to better advise health consumers / patients about recalls.

The timing of recall notifications

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

Two working days is reasonable for less critical recalls however we support the adoption of a risk-based approach.

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?

Risks to public health should always be avoided and minimised where possible. A blanket obligation to always wait for sponsor's agreement, without appropriate flexibility for the TGA, may create undue risk to public health. The TGA could develop a process and criteria it will apply to determine whether they will send such recall information in the absence of such agreement.

Q21. Which of the above options do you think is best, and why? And Q22. What risks do you see with any of the above options?

The Discussion Paper refers to the two working day time delay for the TGA to notify key stakeholders and include the recall summary in the public SARA database, after agreement is made between the TGA and sponsor to commence the recall. This timeframe was based on the rationale of allowing the sponsor time to contact their customers directly and the past practice of sending recall notifications by letter.

Rather than completely altering the 2-day timeframe, we suggest that the formal adoption of a risked-based approach is considered by the TGA. While for many recalls a 2-day window is very unlikely to lead to adverse consequences, there are some products and situations where a shorter timeframe is favourable. Our primary consideration is potential risk to health consumers / patients, and we recommend that ensuring safety and effective communication to health consumers / patients be the primary driver of a risk-based approach.

The content of our recall notices

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

N/A.

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?

Noting that there may be duplication, we support the suggestion that the TGA provide a copy of the sponsor's customer letter with its recall summary notice. In a case of a recall, full and complete information is the preference and customers can use the SARA database to minimise confusion and affirm the TGA's position on the recall.

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

No further suggestions at this stage.

3. Better recall descriptions

Review of Overseas Terminology and Simplified Australian Terminology

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?

The proposed new recall descriptions are simpler for consumers to understand and allow for elaboration in the detail in a way that does not cause as much ambiguity in the classification level.

Q28. If no, what are your concerns?

N/A.

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

No. Cancer Council, COSA and MOGA note that the TGA reviewed recall categories used internationally and assessed that alignment is not possible and no existing approach is appropriate to completely adopt for use in Australia.

4. Improving sponsor letters and other recall documents

Options to improve recall documents

Q30. What do you think of our current templates? • Do you have any feedback on the current content or draft wording? • Do you have any feedback on the presentation/style of the templates? • Are the templates easy to read? Will the key message be clear?

Given the noted challenges in draft documents provided to the TGA by sponsors, it is reasonable and recommended that the TGA continue to provide training, education and awareness raising to enable sponsors to provide improved responses using the templates.

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?

N/A.

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

Cancer Council, COSA and MOGA are supportive of the Discussion Paper's outlined options to improve recall documents, along with further training on how sponsors can better meet the TGA's requirements in their initial drafts, the first time.

Q33. If no, what are your concerns?

N/A.

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

Not at this stage.

5. Reporting progress with a recall

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

Yes.

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?

Yes, the Discussion Paper overview of sponsors' feedback suggests this would help.

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3. Markova V, Sandal GM, Pallesen S. Immigration, acculturation, and preferred help-seeking sources for depression: Comparison of five ethnic groups. BMC Health Services Research. 2020;20(1).
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