Summary from the Medical Devices Consumer Working Group workshop

26 August 2022

Prepared for the Therapeutic Goods Administration

7 November 2022

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Agenda

The Medical Devices Consumer Working Group (MDCWG) met on 26 August 2022 to discuss its priorities and forward workplan for the next 12-18 months, building on the work of the group and in line with Strategy Three of the Action Plan for Medical Devices. To inform discussions, members discussed four topics of interest identified in a membership poll conducted prior to the workshop – adverse events reporting, changing the way the Therapeutic Goods Administration (TGA) communicates, Patient Information Leaflets (PILs) and Patient Implant Cards (PICs), and recalls.

Topic 1: Adverse event reporting

The TGA presented an overview of the adverse event reporting processes for medicines and recent improvements that have been made and noted:

- consumer and healthcare professional reports are important for adverse event signal detections. All reports contribute to datasets and are helpful for data and trend analysis, assisting the TGA to determine whether an event is associated with a particular medicine, and
- recent changes to the Adverse Event Management System (AEMS) and Database of Adverse Events (DAEN) – Medicines have focused on increased usability of the online forms and access to information, which has aided the boost of consumer reporting and awareness of adverse reactions.

Members discussed the recent changes, and considered whether similar changes could be applied to the medical devices adverse event reporting process. The following themes emerged from the group discussion:

1. The TGA has seen an **increase in consumer reporting of adverse events** (last year TGA received in excess of 35,000 for medicines and vaccines related consumer reports). Reports are **pooled to identify safety signals**. It is not possible to review each report for individualised feedback. This practice applies to medical device adverse event reporting as well. Members noted that when consumers take the time to report an adverse event, they expect the TGA to investigate their reported adverse event and know the outcomes of the investigation. Consumers may feel discouraged from reporting when there is limited response or an automated reply. Members appreciated the difficulty in customised responses and noted that improvements can be made to the standard TGA responses.

2. The **improvements to reporting timeframes to the DAEN - Medicines down from 90 days to 14 days** was commended. Members noted that medical devices reports take longer to publish (three months) than medicines because of the complexity in associating incidents with a device and the need to follow up with device manufacturers. While recognising this, members encouraged the TGA to look to improve the medical devices adverse event reporting timeframes where possible.

3. Members suggested ways to increase consumer accessibility and ease-of-use of the medical device **adverse event reporting form,** including working with members' networks to develop prompts and instructional text that assist form completion. Another suggestion included simplifying the reporting form, modelling it on the revised medicines reporting form.

4. Members suggested improving the **contextual information about adverse events reporting on the online landing page** and the **acknowledgment letters** to include information about what the TGA does with adverse events reports and an acknowledgement of the valuable contribution that reports have in post-market surveillance.

5. **Building networks of people (other consumers, support organisations or healthcare professionals) who can help consumers submit reports** was suggested as a strategy to improve medical device adverse reporting. Some members noted that some **health professionals may not be aware that they can assist** their patients to submit a report.

6. Members discussed the **language around adverse event reporting** and possibly using a term that is more meaningful to consumers than adverse event, similar to the term 'side effect' commonly used for medicines. Various suggestions included 'adverse impact', 'side effect' or 'undesirable event.'

7. Members suggested that **consumers may be interested in seeing reporting trends for their current or prospective medical device** and benefit from being able to search this information. The TGA explained that the beta DAEN – Medicines is able to perform these functions and that it may be possible to replicate in DAEN – Medical Devices. Risks were noted as consumers may misunderstand or misapply the information and not opt for or stop using the device even when it delivers therapeutic benefits.

8. Members recommended the **TGA work with other organisations** to whom consumers may make complaints about medical devices, like the Health Care Complaints Commission, for information to be shared. The TGA advised that it regularly meets with the Australian Competition and Consumer Commission and the Australian Health Practitioner Regulation Agency and discussed information sharing.

9. Members discussed **the possibility developing strategies** to improve equity of access, and reduce barriers, to consumer reporting of adverse events; **including undertaking analysis of current trends and multi-factorial analysis** of those who do and do not currently report adverse events.

Topic 2: Changing the way TGA communicates

The TGA opened session two with an overview of changes to the TGA website and its enhanced approach to consumer communication:

- key changes included: abolishing the split between industry, healthcare professional and consumer hubs and making all content consumer friendly; increasing compatibility with assisted technologies and different smart devices; and new mechanisms and channels to promote content, and
- using social platforms and different campaigns including 'micro-campaigns' to amplify messages and consumer outreach – an example; boosting a Facebook post on the *Five questions to ask your health professional before getting a medical implant* increased outreach to three million users, compared to less than 1,500 persons without the boost.

Members discussed TGA's efforts in changing the way it communicates, with a focus on identifying how consumer groups and networks can leverage newly implemented (or soon to be implemented) channels. The following themes highlighted:

1. **Improvements made to the TGA website will be well received** and beneficial to consumers.

2. There are opportunities to explore **alternative or additional TGA spokespeople, and use of influencers, community leaders, and grassroots connections** to reach particular sectors of the community. On some subject matters, breast implants for example, these other spokespeople may be more effective and may have greater credibility with the target audience and can strengthen the impact of messages. Drawing in **health services and health focused support groups (for example, Men's Shed) to expand the reach of TGA messages** was another example discussed.

3. Some segments of Cultural and Linguistically Diverse (CALD) communities may be less active with social media and other mediums such as ethnic radio could be used as a communication channel. Opportunities to **collaborate to reach ethnic groups** was suggested.

4. Using simple language is important and the **concepts being communicated** also needs to be simple to support understanding and absorption of TGA's messages. Leveraging **graphics** and ensuring information is not text-dense, then **testing content with focus groups and community networks** will ensure communication material are appropriate and effective.

5. All consumers want to be able to understand and use information more easily. Members discussed the **reading standards of TGA content** and the common use of technical and complex terms. The Australian Government recommended standard is at the Australian year 7 equivalent, but the Department of Health and Aged Care (including the TGA) is at the Australian year 8 equivalent. Members supported TGA's reading standards but are equally keen to see TGA work toward the Australian Government's recommendation where possible.

6. **Micro-campaigns** (Facebook post boosts, as an example) and **targeted campaigns** were supported as ways to increase consumer engagement. Consumers do not usually go to the TGA website unless deliberately seeking out information. Most are more familiar and comfortable with social media and its short, bite-sized content, or seeing campaign material in doctor's surgeries and pharmacies.

7. Members were willing to be **conduits for information sharing on behalf of the TGA** to ensure medical devices related content, including social media tiles generated by the TGA, is provided to consumer groups. Some members expressed concern about TGA content being amended or adjusted by consumer groups. Others noted that their organisations do not promote externally branded material and adjustments are need for their audience. The TGA will work with organisations on the content and approach.

Topic 3: Patient Information Leaflets and Patient Implant Cards

In advance of the workshop, members were provided with examples of Patient Implant Cards (PICs) and Patient Information Leaflets (PILs) to comment on. They were also invited to consult with their respective organisational networks, specifically with any consumers who have recently received a PIC or PIL, to understand their experience engaging with and using these documents. Members noted:

1. **Consumer accessibility of PICs and PILs** is affected by:
   - whether consumers know that PICs and PILs exist and proactively ask for them
   - health professionals' awareness and practice of providing a PIL prior to a procedure to inform patient choice and the PIC after the implant procedure.

2. There is anecdotal information that **PICs and PILs are not as well used as they could be.** Members suggested commissioning research (or an audit) about **the provision of PICs and PILs by clinicians**. The TGA advised that it was too early for this because hospitals are still in the process of embedding PICs and PILs in their processes and determining the best point in the patient journey to provide this material.

3. Targeted education and awareness would **encourage and empower consumers to ask for PICs and PILs themselves**. This will take time and will rely on information-sharing across networks.

4. Members suggested that the industry guidance document could encourage manufacturers and sponsors to include in PICs and PILs links for consumers to seek more information.

5. Members supported TGA's ongoing work to improve consumer access to PICs and PILs, and supported efforts to **add**:
   - the PIC or PIL to an electronic wallet
   - the PIC or PIL to a consumer's My Health Record, noting that the ability to do this already exists, though it is limited to entry in a free text field only
   - the unique device identifier to the consumer's discharge summary.

6. **Leveraging other medical groups to improve the provision of PICs and PILs** is important and the TGA agreed to:
   - remind medical craft groups of PICs and PILs and promote their use in patient care
   - write to the Australian Medical Association about using the PIC and PIL as a resource for the patients' informed consent process
   - recirculate the *Five questions to ask your health professional before you get a medical implant* resource to members for distribution among their networks.

7. Members noted the desire to have **Australian specific information on manufacturers' websites**, and accepted that there may be a limited ability to influence this especially where international manufacturers are concerned. The TGA would need to work with industry for such changes and any legislative backing required.

Topic 4: Recall

The TGA opened session four with a presentation describing the TGA's recall reform program, recent feedback about changes to the recalls program, and the *Recalls Reform discussion paper* which will be published in the future.

Members discussed TGA's work to improve its recalls procedure and opportunities for consumer groups to be involved. Discussion revolved around the following themes:

1. Members indicated an interest in engaging with the **upcoming Discussion Paper** and suggested including an outline of the current recall process, the relevant legislative powers and communication channels used when informing consumers about recalls in the paper.

2. There are limitations of the current approach to recalls, including a reliance on the voluntary cooperation of parties and the inability to **mandate recalls in certain circumstances**. Members asked about the enforceability of the recall process in light of anecdotal evidence of products remaining on pharmacy shelves despite being subject to a recall. The TGA advised that there are post recall reporting obligations and it follows up after a recall procedure.

3. Members **acknowledged the completed, ongoing and prospective work to reach consumers** affected by a recall and were keen for the TGA to **use their consumer networks to disseminate updates or recall information**. Such a strategy may not have a significant reach in the context of the general public but may inform parts that otherwise the TGA would not have accessed.

4. Members proposed using health professionals, particularly general practitioners, to reach or inform patients about a recall. The TGA advised that hazard alerts are generated and communicated to clinicians when problems arise with medical devices. It is then the clinician's responsibility to follow up patients for appropriate action depending on the nature and urgency of the alert.

Topic 5: Forward Workplan and Priorities

Action items

- TGA to recirculate the information required to be included in the Patient Information Leaflets (PILs) and Patient Implant Cards (PICs), and the '*Five questions to ask your health professional before you get a medical implant.*'
- TGA to write a letter to medical craft groups regarding PICs and PILs to promote awareness and use of materials with consumers.
- TGA to engage with the Australian Medical Association to encourage use of the PICs and PILs in informed consent and including it in guidance.
- TGA to send the *Recalls Reforms discussion paper*, when available, and organise a consumer briefing.
- TGA to organise other consumer briefings on relevant TGA consultation papers which may be of interest to consumers.
- MDCWG members to send the TGA a short description of each organisation for consolidation and circulation to members.

- Federation of Ethnic Communities' Councils of Australia to send information and engagement document (hard copy available at workshop) on the Australian Multicultural Health Collaborative to members.

Key priorities, way of working and forward workplan

The MDCWG agreed to **three key priorities** for the forward workplan:

- Regular **briefing sessions** on upcoming TGA medical device-related consultation papers that are of interest to consumers.
- Co-developing **revised content for adverse events reporting**, focusing on improving the consumer experience.
- Advising on **content changes for the TGA website**, focusing on subject matters of most interest and priority to consumers.

Members discussed the following to progress its priorities:

- A combination of virtual and face-to-face meetings, with members noting the value of coming together and meeting face-to-face at least once a year.
- Spotlighting specific topics and use of facilitation to draw out key messages and help sessions flow smoothly.
- TGA to develop content (social media tiles, messages, web content) for members to use within their respective networks, noting resource constraints in member organisations.
- The value of members co-developing website content with the TGA to ensure information will resonate with consumers.
- Feedback to the TGA on how provided TGA's content is systemically used and circulated to consumers through member organisational networks, to inform and improve effective communication channels.