



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

# Medical Devices Consumer Working Group Terms of Reference

Version 2.1, May 2024

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## Purpose

The Medical Devices Consumer Working Group (MDCWG) provides a forum for the Therapeutic Goods Administration (TGA) to work with consumer and patient groups to implement the TGA's 2019 [Action Plan for Medical Devices](#) (Action Plan) and seek consumer perspectives on medical devices regulatory reforms.

The MDCWG ensures that medical device regulations and the reforms are patient-centred, and transparent, supporting the Action Plan in strengthening Australia's regulatory system, to improve health outcomes for patients who require medical devices. The MDCWG also advises on TGA's communication and engagement with consumers.

## Scope

The MDCWG is not a decision making or approval body. It plays an advisory role, lending expertise through members' lived experience or those whom the members represent.

## Terms of Reference

The Terms of Reference of the MDCWG are to:

- Consider and provide advice on proposed actions to improve medical devices regulatory transparency, including on:
  - adverse event reporting
  - emerging technologies and issues relating to medical devices
  - electronic instruction for use
  - patient information leaflets, and
  - other topics raised by the TGA or in discussions with the MDCWG.
- Discuss concerns affecting consumer groups, including First Nations, older Australians, culturally and linguistically diverse (CALD) communities, people living with a disability, and rural/remote Australians, to provide consumer viewpoints on medical devices and its regulation.
- Assist the TGA with engaging with relevant stakeholders through their networks including empowering consumers to:
  - find and use TGA developed resources and information
  - ask for credible and reliable health information, to support informed decision-making at the point of care, and
  - report medical devices related adverse events.
- Progress activities recommended in agreed workplans. These may include co-designing specific and targeted communication pieces based on particular topics.
- Invite or suggest speakers from relevant organisations to participate in conversations with the MDCWG, as required.
- A review of the Terms of Reference will be conducted at the end of the current membership term (to 31 January 2025). This will also include a review of the effectiveness of the MDCWG and its effectiveness in supporting the TGA's engagement with consumers.

For the purposes of this terms of reference, a 'consumer' is a medical device user; or a carer to a person who uses a medical device; and a potential user of medical devices.

## Role of Individual Working Group Members

- Understand the implications and outcomes of initiatives being pursued
- Have a broad understanding of TGA's role and responsibilities as the National Regulatory Authority
- Represent their consumers' and patients' perspectives on medical device use to the TGA
- Offer feedback and guidance about stakeholder expectations and specific projects, including those of First Nations, older Australians, CALD, disability, and rural/remote Australians
- Act as a conduit to share appropriate TGA information (resources, public promotion material, safety precautions and alerts) with consumers and broader networks
- Consider wider consultation strategies, resource implications and implementation steps, and suggest alternate mechanisms
- Be respectful of differences in opinion and approach including when providing feedback, and
- Honour confidentiality always.

## Membership

Each member organisation may nominate a member representative. Consumer organisations (members) will be appointed to the MDCWG subject to the endorsement of the Chair, the First Assistant Secretary, MDPQD. Membership will reflect a representation of consumers of medical devices.

In addition to consumer organisation members, the Chair may, at its discretion, invite other representatives to participate in MDCWG.

The Secretariat will maintain a list of appointed member organisations and their nominated representatives.

Membership will be until 31st January 2025, with an option for a 12-month extension.

## Membership Structure

**Chair:** First Assistant Secretary, MDPQD

### **Responsibilities:**

- Direct and facilitate the business and discussion of the working group
- Monitor the progress in the Working Group activities and its workplan(s)
- Preside over working group meetings, maintaining order and guiding the meeting through the agenda items
- Certify that the meeting occurred, attendance and the duration of the meeting
- Clarify the definitions of meeting, preparation time, travelling time, and the nature of 'other working group-related business'
- Make recommendations on working group related expenses, and
- Present reports and/or recommendations to the Minister for Health and Aged Care, or Department of Health and Aged Care.

Where the Chair is temporarily unavailable, the Chair may choose to appoint a temporary Chair to ensure progression of the Working Group's agenda.

## Consumer Members

- Arthritis Australia (NSW)
- Australian Patients Association (VIC)
- Cancer Council Australia (NSW)
- Consumers Health Forum of Australia (ACT)
- Contenance Foundation of Australia (VIC)
- Diabetes Australia (QLD)
- Federation of Ethnic Communities' Councils of Australia (ACT)
- Haemochromatosis Australia (WA)
- Haemophilia Foundation Australia (VIC)
- Health Consumers NSW
- Lung Foundation Australia (QLD)
- Limbs 4 Life (VIC)
- Multicultural Centre for Women's Health (VIC)
- National Aboriginal and Torres Strait Islander Ageing and Aged Care Council (NSW)
- National Older Persons Reference Group (part of the Older Persons Advocacy Network) (WA)
- National Seniors Australia (ACT)
- Older Persons Advocacy Network (NSW)
- Pain Australia (ACT)
- Physical Disability Australia (QLD)
- Royal Flying Doctors Service
- 2 Independent representatives (VIC)

## Proxy

Where a member representative is not available to attend a meeting, the member may nominate a proxy representative from within their organisation. The member should inform the Secretariat prior to the meeting to allow sufficient time to obtain the Chair's approval and ensure any paperwork and declarations of interest are actioned before the meeting.

## Resignation

Where a member resigns, a new member from the organisation may be appointed.

The appropriate stakeholder group may nominate a candidate for consideration by the Assistant Secretary, Medical Devices Surveillance Branch, through the Secretariat.

## Meeting frequency

The MDCWG is expected to meet at least twice per year online (video conferencing) or in-person. At least one whole of working group, in-person meeting is expected per year. Out of session meetings may be arranged to address specific time-critical issues if required.

The Chair can, and will, advise if there are changes to planned meetings.

## Sub-working groups

Sub-working groups may be formed as required. The role, membership and activities of any sub-committee will be determined by the First Assistant Secretary, MDPQD.

## Remuneration

Reimbursement will be based on the Department of Health and Aged Care's Remuneration Framework for Members of Non-Statutory Committees and align with section 11 Part 2 of the *Remuneration Tribunal (Remuneration and Allowances for Holder of Part-time Public Office) Determination*.

Members may request travel assistance on a case-by-case basis.

## Conflicts of Interest and Confidentiality

Members shall make an annual *Declaration of Interest* in support of nomination and a *Deed of Undertaking* in relation to confidential information prior to commencement of membership.

A *Meetings Declaration of Interest* form shall be sent to members prior to the issue of meeting papers.

## Secretariat

Secretariat support for the MDCWG is provided by the TGA, who can be contacted via email at [dwg.tga@health.gov.au](mailto:dwg.tga@health.gov.au).

The Secretariat is responsible for providing timely and effective organisational support to the Working Group meetings. They act as a central point for information and advice on the Working Group meeting processes and requirements, coordinating meeting agendas and supporting papers, minute-taking, ratification of minutes, and coordinating action items arising from meetings.

## Meeting Management

A meeting agenda and *Meetings Declaration of Interest* form shall be sent to members prior to the issue of meeting papers. Once the completed *Meetings Declaration of Interest* form is returned by all members the meeting papers will be issued by the Secretariat.

After each meeting, draft minutes will be provided to MDCWG members for comment.

A meeting statement is subsequently prepared by the Secretariat and provided to members.

The Secretariat will aim to adhere to the following timelines:

- call for agenda items approximately 4 weeks prior to meetings
- circulate a draft agenda and *Meetings Declaration of Interest* form to members approximately 2 weeks prior to the meeting
- once all meeting declaration forms are returned, circulate meeting papers prior to the meeting, and
- circulate draft minutes and Meeting Statement within 2 weeks for comments.

## Outcomes

The Meeting Statement is published on the TGA website following endorsement by members.

## Version history

Version	Description of change	Author	Effective date
V2.1	Publication with MDCWG edits, following review by members in February 2024	Devices Vigilance and Policy Section	May 2024
V2.0	Publication with MDCWG edits, following review by members in November 2023	Devices Vigilance and Policy Section	January 2024
V1.1	Publication with MDCWG edits	Devices Post Market Reforms and Reviews – Policy Team	February 2022
V1.0	Original publication	Devices Post Market Reforms and Reviews – Policy Team	November 2021



## **Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia  
Email: [info@tga.gov.au](mailto:info@tga.gov.au) Phone: 1800 020 653 Fax: 02 6203 1605  
Web: [tga.gov.au](http://tga.gov.au)

Reference/Publication #