

Therapeutic Goods Administration Consultative Committee (TCC)

Thursday 28 November 2024, Canberra

COMMUNIQUE

The Therapeutic Goods Administration Consultative Committee (TCC) met in Canberra on 28 November 2024. TCC includes representatives from peak industry bodies and consumer organisations, healthcare professionals and senior officials from the Therapeutic Goods Administration (TGA) in the Department of Health and Aged Care (DoHAC).

TCC Member Key Issues

Each member representative gave an overview of key issues affecting their sector. Priority areas include medicines shortages and medicines shortages reforms, the use of artificial intelligence, non-validated repair of medical devices, and the implementation and enforcement of vape reforms.

Other areas of focus included:

- extemporaneous compounding
- medicinal cannabis
- performance reporting and stakeholder engagement
- ongoing concern regarding non-compliant online advertising of goods that are therapeutic or claim to have therapeutic properties, and
- TGA capability uplift

Vape reform, implementation and enforcement

Members were briefed on vaping reform, implementation and enforcement. This included updated advice on reform timelines, TGA regulation and enforcement activities, and the introduction of new standards, new forfeiture powers, vape disposal activities and variations in regulation between states and territories. The TGA noted the importance of industry member engagement in educating consumers and providers on guidelines for the supply of vapes and that vape supply must occur through a pharmacy. Members recognised the significant amount of work that has been undertaken by the TGA, Australian Border Force, and State and Territory health and police services, to regulate the use of importation, manufacture and supply of vaping goods.

TGA Capability Uplift

Members were advised of the proposed TGA capability uplift action plan including findings, initiatives and alignment with broader departmental uplift themes. Members saw value in the proposed action plan and were supportive of the identified initiatives and uplift themes.

Use of Artificial Intelligence

Members were provided an update on the use of artificial intelligence (AI), including an overview of safe and responsible use of AI, Department of Industry, Science and Resources (DISR) consultations, and the summary and findings of TGA's consultation process and next steps. Members were given advice on proposed guardrails for identified 'high-risk' AI as well as an outline of the collaborative approach the TGA is taking with DISR in this space. Work is underway to clarify whether current legislation meets the intent of the proposed guardrails, and strengthening regulation of the use of AI. A report on findings will be provided to Government by the end of 2025. Members considered the findings from consultation processes, ongoing reviews with refinement where necessary, the need for international engagement and participation when developing standards, and updates to software related information and guidance on the TGA website to be completed.

Non-validated Repair of Medical Devices

Members considered advice provided on non-validated repair of medical devices, noting that the TGA regulates the import, export and initial supply of medical devices by sponsors (and through the sponsor - the manufacturer) but that the TGA does not regulate the use of medical devices by health professionals or consumers. It was noted that there has been an increase in the reporting of non-validated repair of medical devices globally and that a unified position between global regulators would be welcome. It was discussed that the TGA has limited visibility on the reporting of non-validated repair of medical devices and would appreciate any further advice on this matter from external stakeholders.

Medicines Shortages and Reforms

Members were given a presentation on the management of medicines shortages and shortages reforms with a focus on IV fluids and pre-exposure prophylaxis (PreP) shortages. The presentation provided advice on:

- the definition of shortages
- ongoing consultations to help inform focus areas
- medicines shortages life cycle and timeframes
- the addition of 23 medicines into the reportable medicines determinations to improve shortages reporting data
- dealing with anticipated shortages, and
- proposed remediation strategies when shortages are identified

Members were advised that the TGA continues to work with suppliers, state governments and health care professionals to gather further data on current and predicted medicines shortages.

Updates from the Chief Medical Advisor Unit

A representative from the Chief Medical Advisor Unit provided an update to members on:

- Women's Health Products Working Group
- Medicinal Cannabis Expert Working Group
- Extemporaneous Compounding

Members noted the update on the Medicinal Cannabis Working Group and work currently underway to review vertical integrated care models, delivery and safety issues in this space. Members were advised of a collaborative approach currently underway regarding wider regulatory reform of existing Commonwealth legislative provisions for compounding of medicines.

TGA Performance Report 2023-24 and TGA Stakeholder Survey 2024

Members were presented the 2023-24 TGA Performance report and 2024 Stakeholder survey results. The presentation outlined the key achievements against the TGA Business Plan for 2023-24. Members were also given a summary of results from the 2024 TGA stakeholder survey report around feedback, consultation, input and consultation metrics. It was noted that the results were generally positive and were trending upwards from previous years and areas for improvement were identified.

The next TCC meeting is currently scheduled for May 2025 in Sydney.

Meeting Attendance List – 28 November 2024

THERAPEUTIC GOODS ADMINISTRATION CONSULTATIVE COMMITTEE MEETING (TCC) - 28 November 2024		
Conference Room 1.03 Teams Videoconference		
Organisation	Attendee name	Attendance
External		
Medicines Australia	Ms Elizabeth de Somer	Apology
Medicines Australia	Ms Tham Vo (Alternate)	Yes - In person
GBMA	Ms Marnie Peterson	Yes - Teams (virtually)
Consumer Healthcare Products Australia	Dr Deon Schoombie	Yes - Teams (virtually)
CMA	Mr John O'Doherty	Yes - Teams (virtually)
MTAA	Mr Ian Burgess	Apology
MTAA	Dr Jasjit Baveja (Alternate)	Yes - Teams (virtually)
ADIA	Mr Kym De Britt	Apology
ADIA	Dr Sarah Raphael (Alternate)	Yes - In person
Ausbiotech	Ms Rebekah Cassidy	Apology
Pathology Technology Australia	Mr Dean Whiting	Yes - In person
Accord Australasia	Ms Bronwyn Capanna	Yes - In person (last meeting)
CHF	Dr Elizabeth Deveny	Yes - In person
RACGP	Dr Rebekah Hoffman	Yes - Teams (virtually)
RACP	Dr Deborah Campbell	Apology
AMA	Dr Michael Bonning	Yes - Teams (virtually)
AMA	Dr Nicholas Elmitt (Observer)	Yes - In person
PSA	Adj. Assoc. Professor Steve Morris	Apology
PSA	Ms Kay Sorimachi (Alternate)	Yes - In person