Australian Government
Department of Health and Aged Care

Medical Devices and Human Tissue Advisory Committee - Terms of Reference

The Prescribed List (PL) of Benefits for Medical Devices and Human Tissue Products

Purpose

The Medical Devices and Human Tissues Advisory Committee (MDHTAC) is a ministerially appointed committee composed of an independent Chair and members with expertise in health technology assessment, specialist surgery/interventional work, health economics and/or consumer issues.

MDHTAC's primary role is to make recommendations to the Minister for Health and Aged Care (Minister) and advise the Department of Health and Aged Care (Department) about the suitability of medical devices and human tissues products (products) for listing on the Prescribed List of Benefits for Medical Devices and Human Tissue Products (Prescribed List or PL) and their associated benefits, or on amending the details of the existing billing codes (for the products already listed on the PL), or on any other post-listing activities as required. The Prescribed List identifies the minimum amount payable by private health insurers for medical devices and products.

The MDHTAC's recommendations and advice are based on an assessment of comparative clinical effectiveness and cost-effectiveness of products using the best available evidence compared with other similar products already listed on the PL or alternative treatments. It is one of the eligibility requirements that there is evidence available that the product is no less clinically effective than the comparator [either listed on the PL or, if there are no appropriate comparators listed on the PL, the alternative treatments]. This process ensures that privately insured Australians have access to a range of products that are clinically effective and represent value for money.

Roles and function

The role of the MDHTAC is to make recommendations and provide advice to enable the Minister to exercise his or her powers under the *Private Health Insurance Act 2007* and the Department to administer the PL. This includes:

- making recommendations on whether the applicants provided sufficient evidence demonstrating suitability of the products for listing on the PL and whether any conditions of listing may need to be placed on the billing code
- advising about the benefits for products to be listed on the Prescribed List if required
- advising on the applications seeking to amend the existing billing codes on the Prescribed List
- reviewing and advising on the listed products and/or benefits as appropriate
- advising on any other matters pertaining to the medical device and human tissue products listing arrangements.

The MDHTAC may refer the products to the Medical Services Advisory Committee (MSAC) either via the Evaluation Sub Committee of MSAC or directly to MSAC.

The MDHTAC will refer any concerns about safety of products that arise during assessment of applications to list products to the Therapeutic Goods Administration (TGA) for investigation and appropriate action.

The MDHTAC should liaise with the Pharmaceutical Benefits Advisory Committee (PBAC) and/or its subcommittees for advice on comparative clinical effectiveness and cost effectiveness of a new product incorporating a medicine.

The MDHTAC should liaise with the MSAC, the TGA and PBAC to develop assessment processes that maximise the use of the clinical and technical expertise of each body and reduce duplication of assessment.

The MDHTAC may establish subcommittees, comprising members or co-opted individuals with appropriate expertise, to assist the MDHTAC to perform its role under these Terms of Reference.

Each subcommittee will operate according to terms of reference approved by the MDHTAC and the Department.

The MDHTAC is not bound to accept the advice of its subcommittees in making recommendations to the Minister.

Composition

The MDHTAC's size and composition is determined in consultation with the Minister.

The MDHTAC will include an independent Chair and members appointed by the Minister.

Six members of the MDHTAC will also be appointed as Chairs of six Expert Clinical Advisory Groups (ECAGs) (one Chair per ECAG). Members who are appointed as a Chair of an ECAG will act as the expert discussant on the matters covered by their ECAG. The members of the MDHTAC who Chair an ECAG will be appointed as such by the Minister.

The MDHTAC will also be comprised of up to three additional members, one, a consumer representative and up to two clinical / health technology assessments experts (who do not reside on ECAG), all of whom will be appointed as members by the Minister.

Members must sign Deeds of Confidentiality and Conflict of Interest Declarations upon appointment, and are required to declare potential, perceived or actual conflicts for each meeting / issue being considered. The Chair, in collaboration with the Department, will determine if and how a perceived, actual or potential conflict of interest will be managed.

Membership and Chair appointments are for a two-year term, from 1 July 2023, unless specified otherwise by the Minister. The Minister, in consultation with the Department, can terminate any MDHTAC appointment at any time at its discretion.

The MDHTAC's composition may be changed from time-to-time to address the changes in the matters required to be discussed and advised on.

Quorum

It is expected that a quorum of half the members plus the Chair (or their proxy if allowed) be present at each meeting, however in the rare unforeseen circumstance that this is not possible, the Chair in consultation with members and the Department may agree on the minimum number of members required for a meeting to proceed. Such decisions should be made based on the numbers of applications and other items to be discussed and decided, and the variety of expertise and speciality required/present. The Chair (or their proxy) must always be present.

Only members who are the Chair of the MDHTAC, or a Chair of an ECAG, are allowed to have a proxy.

The Chair of the MDHTAC, if unavailable, may send a proxy to attend on their behalf.

Members who are a Chair of an ECAG, if unavailable, may send a proxy to attend on their behalf. The proxy must be a member from the same ECAG.

Where members cannot arrive at a consensus position, a vote will be taken, and the matter or issue decided by a simple majority. Members only will vote on matters relating to listing of products or amending the existing billing codes. In the event of a tied vote, the Chair will cast the deciding vote.

Meeting schedule

MDHTAC meets no less than three times per year either face-to-face or via videoconference. Sub-committees and working groups may also meet separately. Business that does not require the whole committee may also be conducted out of session, via email or videoconference.

Reporting

The MDHTAC reports to the Minister for Health and Aged Care or the Minister's delegate.