# HIV Testing: How Australian Health Regulatory Bodies Facilitate Access to Medicines and Devices

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AUSTRALIAN FEDERATION OF AIDS ORGANISATIONS
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Australia's health system is regulated and funded by a number of separate bodies. An explanation of the function and purpose of the primary regulatory bodies is outlined below as well as some analysis of their relevance to HIV testing and treatment.

## *What is the Therapeutic Goods Administration (TGA)?*

The TGA is responsible for regulating therapeutic goods, including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products. Any product which has therapeutic claims must be entered in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia. The TGA is part of the Australian Government Department of Health.

The TGA regulates therapeutic goods through pre-market assessment, post-market monitoring and enforcement of standards, and licensing of Australian manufacturers and verifying overseas manufacturers' compliance with Australian standards. The TGA approves and regulates medicines and medical devices based on an assessment of risks against benefits measuring the products safety and quality.

## *What is the Pharmaceutical Benefits Advisory Committee (PBAC)?*

The PBAC's primary role is to recommend new medicines for listing on the Pharmaceutical Benefits Scheme (PBS). When considering an application to be listed on the PBS, the PBAC considers the clinical effectiveness, safety and cost-effectiveness of products registered on the TGA compared with other treatments.

## *What is the Medical Services Advisory Committee (MSAC)?*

The MSAC evaluates new medical services that have been proposed for public funding through the Medicare Benefits Schedule (MBS) and provides advice to Government on whether a new medical service should be publicly funded.

MSAC recommendations are made after an assessment of the medical service's comparative safety, clinical effectiveness, cost-effectiveness and total cost, using the best available evidence. The MSAC also considers amendments and reviews of existing services funded through the MBS.

## *What are the differences between the three separate bodies?*

In summary:

- The TGA approves medicines and medical devices for sale in Australia.
- The PBAC provides advice on what medicines should be funded through the PBS.
- The MSAC provides advice on what medical services should be funded through the MBS.

The TGA is a statutory body that is authorised by law to approve therapeutic goods in Australia. The PBAC and the MSAC are committees that advise governments. Their recommendations do not need to be accepted or implemented.



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## *How might the MSAC be relevant to HIV testing?*

HIV point of care (PoC) and self-tests in Australia must be approved for sale by the TGA before they are available to the public. However, the MSAC may also be relevant in funding or partially funding the provision of HIV PoC or HIV self-tests in Australia. Currently the MBS funds regular HIV testing, however the MSAC could be a potential avenue HIV PoC or self-tests to be subsidised as part of a General Practitioner consultation. If this was to occur, it could create a financial incentive for manufacturers to introduce these devices into the Australian market.

For this to occur, the MSAC would need to recognise that there is a need for these kinds of tests to be included in the suite of current HIV testing options included in the MBS. The MSAC assesses the service's comparative safety, clinical effectiveness, cost-effectiveness and total cost, so this would need to be demonstrated with these novel modes of HIV testing. The Minister for Health would then need to accept and implement this recommendation.

For a medical technology or service to obtain a recommendation from the MSAC for MBS funding a sponsor can submit an application to the MSAC for consideration or, in the alternative, the Department of Health can refer a technology to the MSAC. For a technology to be considered by the MSAC for MBS listing it must be registered on the ARTG.

An MSAC recommendation does not automatically mean that an item will be subsidised. For subsidisation to proceed the item needs to be connected to a program that is funded by the Department of Health. In effect, a MSAC recommendation is not confirmation that a service will materialise.

## *The TGA and HIV testing*

HIV testing devices are Class 4 devices, meaning that the TGA imposes additional requirements and conditions on their sale in Australia. This can include random factory inspections, periodic re-registration and market surveillance by the TGA (usually every six months). These conditions add to the costs of sponsor's costs of maintaining registration of therapeutic goods in Australia.

## *The PBAC and HIV testing*

The PBAC only makes recommendations on medicines and has no power to subsidise HIV test kits.

## *Conclusion*

Registration on the ARTG is a pre-requisite for seeking a recommendation from MSAC for funding. The costs of registration balanced against Australia's relatively small market size undermines potential sponsors' confidence in recovering the costs of registration and ongoing regulatory compliance. This environment means that potential sponsors of HIV test devices are reluctant to seek approval of their device in Australia.

To maximise the potential of PoC and self-testing to increase testing frequency among key populations not testing enough, and testing among non-testers, the MSAC could recommend PoC and self-testing as new MBS items. The items would fund the clinical consultation and cost of undertaking the PoC test or supplying the self-test to the patient. This arrangement could be population-wide or limited to an identifiable population group where the benefits of this kind of intervention are quantifiable.