



Australian Government
Department of Health
Therapeutic Goods Administration

Summary and outcomes: review of the regulation of certain self-testing in vitro diagnostic medical devices (IVDs) in Australia

Version 1.0, September 2020

TGA Health Safety
Regulation

Copyright

© Commonwealth of Australia 2020

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to tga.copyright@tga.gov.au.

Contents

Purpose _____	4
Summary of consultation _____	4
Direct-to-consumer genetic self-tests _____	4
Self-tests for infectious diseases _____	5
Self-tests for other serious diseases (non-infectious) _____	6
Consultation outcome and proposed future regulation of self-tests _____	6
Managing the risks _____	6
Re-making the Excluded Purposes Specification _____	7
Next steps _____	7

Purpose

The purpose of this document is to provide an overall summary of feedback received and outcomes of the consultation process to review the regulation of certain self-testing in vitro diagnostic (IVD) medical devices in Australia.

Home-use tests, also known as self-tests, for serious diseases (e.g. notifiable infectious diseases, sexually transmitted diseases, cancer, genetic markers of disease) have been prohibited from supply in Australia since 1 July 2010 under the Therapeutic Goods (Excluded Purposes) Specification 2010 (the Excluded Purposes Specification 2010). The exception was self-tests for Human Immunodeficiency Virus (HIV) which have been permitted since 2014 based on feedback from a consultation process. Most OECD countries do not have similar prohibitions on self-testing to those currently in Australia.

In accordance with the *Legislative Instruments Act 2003*, legislative instruments are automatically repealed after a fixed period of time (subject to some exceptions). This automatic repeal is called 'sunsetting'. The Excluded Purposes Specification 2010 will sunset on 1 October 2020. It was a legal requirement to perform a review prior to the remaking of the instrument to see if there was a continuing need for this regulation and if any prohibitions should be maintained. Feedback from the consultation informed the recommendation to re-make the Excluded Purposes Specification.

Summary of consultation

A [public consultation](#) process was conducted in late 2019, with 26 submissions received in response. A [summary of submissions](#) is available on the TGA website. Further targeted consultation on direct-to-consumer (DTC) genetic testing and infectious diseases specifically was conducted from April to July 2020.

An overwhelming majority of stakeholders supported the position that self-tests for cancer and DTC genetic testing for health-related purposes should continue to be prohibited from supply. However, overall, there was cautious support for allowing other self-tests where there are benefits that may offset the risks to public or individual health, such as for certain infectious diseases where supply may increase testing uptake in populations experiencing barriers to primary health. A summary of views is provided below.

Direct-to-consumer genetic self-tests

The overwhelming majority of stakeholders did not support genetic self-testing. It was considered the risks associated with DTC genetic testing could not be safely mitigated to reduce potential harms to an acceptable level.

Some of the key concerns raised by stakeholders included:

- ensuring the security and integrity of data and personal information obtained by DTC genetic testing companies, including its later use as well as the potential for data collected for a non-health related purpose later being used for a health purpose;
- potential for misinterpretation of the DTC genetic self-test data by consumers; and
- the increase in burden on health professionals to assist consumers seeking advice on interpretation of DTC genetic test self-tests results.

Self-tests for infectious diseases

The views on self-tests for serious infectious diseases were more diverse. Some respondents strongly supported the future availability of a number of infectious disease self-tests, while others were more cautiously supportive. Further targeted consultation with key stakeholders confirmed the view self-tests for serious infectious diseases should continue to be prohibited, except where there were greater benefits from the supply of certain self-tests, and the tests can be made safely available.

The benefits were identified as:

- increased uptake of testing in populations experiencing barriers to primary care such as people in rural and remote areas;
- increased uptake of testing in people who would not otherwise seek testing;
- reduced delays in testing and potential for earlier treatment; and
- supply of high quality self-tests (which have been evaluated and approved by the TGA) minimising the risk of purchase of unapproved devices by consumers over the internet from overseas.

It was emphasised by some stakeholders that many of the people most likely to use self-tests are not currently being tested by laboratory tests, and so wider testing could potentially bring significant public health benefits. The use of a self-test and the requirement for a laboratory test to confirm a positive result may result in additional notifications for public health surveillance purposes.

The majority of respondents identified self-testing for hepatitis C and influenza as examples where the benefits are likely to outweigh the risks. Other respondents identified particular self tests which may be safely supplied in the future, including:

- other respiratory infections such as respiratory syncytial virus (RSV);
- hepatitis C virus;
- blood borne viruses generally;
- sexually transmitted infections; and
- gastrointestinal and travel acquired infections.

At the same time, concerns were raised that public health surveillance of serious infectious diseases may be compromised if self-tests for certain diseases (e.g. measles, dengue and norovirus) were to be allowed.

Other concerns raised were the:

- potential for incorrect use and interpretation of the tests;
- need for confirmatory testing of positive results both to confirm any diagnosis and to enable public health surveillance of notifiable infectious diseases ; and
- need for patients to have access to appropriate support services to ensure follow-up testing and treatment if required.

Self-tests for other serious diseases (non-infectious)

The overwhelming majority of stakeholders supported the continuing exclusion of self-tests for cancer but did not comment on self-tests for other serious non-infectious diseases or disorders. One submission specifically proposed that self-tests for some serious conditions such as diabetes, kidney disease and heart diseases might have benefits for early detection and treatment.

Consultation outcome and proposed future regulation of self-tests

Taking into consideration the feedback received from stakeholders during the consultation process it was recommended the Australian Government re-make the Excluded Purposes Specification to allow a limited number of self-tests to be made available in Australia where there are particular benefits to public or individual health, and risks can be managed. The supply of Class 3 and Class 4 IVD self-tests for the following serious diseases and conditions will be allowed:

- chlamydia trachomatis;
- hepatitis B virus;
- hepatitis C virus;
- herpes simplex virus type 1 and 2;
- human immunodeficiency virus type 1 and type 2;
- neisseria gonorrhoea;
- seasonal influenza virus;
- treponema pallidum (syphilis);
- diabetes;
- kidney disease; and
- cardiovascular disease.

In relation to influenza virus, this is specific to seasonal strains of influenza virus only and does not include any strains that are novel or emerging (e.g. pandemic strains).

The supply of all other Class 3 and Class 4 IVD self-tests for serious diseases, including self-tests for cancer and genetic self-tests, and Class 2 IVDs for detecting faecal occult blood will continue to be prohibited unless they are being used for a government screening program. Self-tests solely intended for monitoring a previously diagnosed disease or condition were not previously prohibited and can continue to be supplied.

Managing the risks

During the consultation it was acknowledged that consumers can purchase self-tests over the internet and these tests have not undergone any evaluation to verify their quality or performance. It was considered preferable consumers have access to self-tests that have been subject to evaluation by the TGA. At the same time stakeholders emphasised such tests would need to be robust and of a high quality to mitigate risks associated with the performance and interpretation of the results.

During the consultation a range of risk mitigation strategies were discussed and how evaluation of self-tests by the TGA will support further mitigation of risks associated with use. It was determined that the evaluation of self-tests prior to approval will need to ensure:

- they have a high level of sensitivity and specificity to minimise false negative and false positive results;
- the sample collection, test performance and interpretation is straight forward and the instructions for use are easy to understand for lay persons;
- evidence is provided that the test performs satisfactorily in consumer usage studies;
- the limitations of the test are clearly identified, such as limitations of antibody testing;
- during the “window” period, and the importance of re-testing in situations where there may have been recent exposure or repeated exposures;
- there are clear instructions on when to seek clinical advice to confirm the presence of disease, obtain appropriate treatment and allow for notifiable infectious disease surveillance where necessary;
- information is provided on how to contact locally available support services; and
- consumers are aware of how to report poor performance of a self-test to the TGA.

Additional post-market requirements can also be imposed to help mitigate risk, such as the requirement to provide the TGA with periodic reports on the number of tests supplied and any adverse events (i.e., false negatives or false positives); and post-market laboratory evaluation of the tests to verify performance.

Re-making the Excluded Purposes Specification

The [Therapeutic Goods \(Excluded Purposes\) Specification 2020](#) has been re-made in accordance with the changes discussed above.

The new Excluded Purposes Specification comes into effect on 1 October 2020, allowing sponsors and manufacturers to apply to the TGA for inclusion of the specified self-test devices in the Australian Register of Therapeutic Goods (ARTG). Any tests allowed under the Excluded Purposes Specification can only be made available following evaluation of individual products by the TGA to ensure appropriate risk mitigations are in place.

Further detailed guidance on the TGA’s expectations and performance requirements, risk mitigations (including conditions to be imposed) for the specific self-tests is being developed to assist sponsors and manufacturers in applying for ARTG inclusion of their IVD self-tests. This guidance will be similar to the guidance document relating specifically to the [clinical performance requirements and risk mitigation strategies for HIV tests](#) available via the TGA website.

Next steps

As outlined above, the TGA is developing guidance to support the changes to the inclusion process for IVD self-tests in the ARTG.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	IVD Reforms, Medical Devices Surveillance Branch e	September 2020

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
<https://www.tga.gov.au>

Reference/Publication #