



Australian Government

Department of Health

Therapeutic Goods Administration

Review of the regulation of certain self-testing in vitro diagnostic medical devices (IVDs) in Australia

Version 1.0, September 2019

TGA Health Safety
Regulation

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About this consultation

The Australian Government's deregulation agenda is guided by the principle that regulation should only be imposed where absolutely necessary and should not be the default position for dealing with public policy issues.

In accordance with the *Legislative Instruments Act 2003*, legislative instruments are automatically repealed after a fixed period of time (subject to some exceptions).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 is due to sunset on 1 October 2020.

This consultation will therefore seek to determine whether there are sound reasons for the Excluded Purposes Specification to be remade. It will assist the TGA to determine if the Excluded Purposes Specification:

- is fit for purpose and working effectively to prohibit supply of the specified self-testing IVDs;
- should be remade or remade with changes;
- is still required to exclude supply of certain IVDs for self-testing, or whether the benefits of the availability of IVDs for self-testing outweigh the risks associated with their use;
- is consistent with internationally harmonised standards where such exclusions exist.

The requirements of the [Therapeutic Goods \(Excluded Purposes\) Specification 2010](#) (the Excluded Purposes Specification) apply to certain home-use (self-testing) IVDs. The Excluded Purposes Specification came into force on 1 July 2010, at the same time as changes in the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) implemented the in vitro diagnostic medical device (IVD) regulatory framework.

After consultation, it was amended on 9 July 2014 to remove self-testing IVDs for Human Immunodeficiency Virus (HIV) from the scope of the legislative instrument, such that HIV self-tests can now be legally be supplied in Australia (subject to approval by the Therapeutic Goods Administration (TGA)).

Information on how to make a submission is provided at [How to submit](#).

History and current context

Prohibition on the supply of certain self-testing IVDs

Extensive consultation occurred prior to the introduction of the IVD regulatory framework in 2010. At the time a number of stakeholders raised concerns about the availability of home-use IVD medical devices to test for serious diseases (e.g., notifiable infectious diseases, cancer and genetic disorders). It was also recommended that all genetic tests be excluded from home-use. Stakeholders emphasised the importance of pre-test discussion and post-test counselling by health professionals for these diseases or conditions.

At the meeting of the Australian Health Ministers' Advisory Council (AHMAC) on 23 October 2003 it was agreed that all genetic tests and IVDs for the diagnosis of serious disorders such as cancer and myocardial infarction should be prohibited from home-use. The Excluded Purposes Specification was made in 2010 to give effect to the AHMAC recommendation.

Excluded Purposes Specification

The [Excluded Purposes Specification](#) specifies the following self-testing IVDs are excluded from supply:

- (a) Tests for the presence of, or exposure to, pathogenic organisms or transmissible agents (other than the Human Immunodeficiency Virus)¹, including agents that cause notifiable infectious diseases;
- (b) Genetic tests to determine the presence of, or susceptibility to, diseases in humans;
- (c) Tests to diagnose, aid in diagnosis or indicate the presence of a serious disease or condition, such as cancer or myocardial infarction;
- (d) Tests for the presence of markers that are precursors to a serious disease or condition, such as Pap smear tests (marker for cervical cancer) or prostate specific antigen tests (marker for prostate cancer).

These exclusions do not apply to a self-testing IVD if it was also to be used for any other purpose, including:

- (a) For testing for a disease or condition as part of a public health screening program sponsored by the government of the Commonwealth or a State or Territory;
- (b) for self-testing to monitor a diagnosed disease or condition;
- (c) for export only.

To illustrate the operation of the Excluded Purposes Specification, self-tests for blood glucose can be included on the Australian Register of Therapeutic Goods (ARTG) and legally supplied in Australia if they are intended for monitoring blood glucose in individuals who have previously been diagnosed with diabetes. However self-tests for blood glucose cannot be included on the ARTG if they are intended solely to diagnose diabetes.

Self-tests that are not restricted in Australia

Self-testing IVDs are not generally excluded from supply in Australia unless they meet the criteria set out in the Excluded Purposes Specification. This means that there are many self-tests on the market that are widely used including:

- pregnancy and ovulation tests;
- glucose monitors and test strips used for diabetes monitoring;
- coagulation monitoring devices and associated reagents;
- cholesterol testing devices.

There are genetic self-tests available in Australia that fall outside the MD Regulations and the Excluded Purposes Specification because they are not intended for determining the presence or susceptibility to a disease or condition, including tests to:

- provide personalised dietary recommendations and weight management solutions;

¹ The Excluded Purposes Specification was amended in 2014 to allow for the supply of HIV self-tests in Australia.

- predict athletic ability and risk of injury;
- determine paternity;
- determine ancestry.

Tests used by health professionals at the point of care

Rapid testing devices are widely used by doctors and other health professionals outside of medical testing laboratories. These devices are regulated in Australia as point of care (POC) testing devices. The Manufacturer's intended purpose for these devices will make it clear that they are intended for use by a health professional at the POC and are not intended for self-testing by a lay person².

A POC device may employ the same technology as a self-testing device however in the hands of a health professional trained in the use of the device the clinical performance may be superior. In the POC setting a health professional can also provide information to an individual on any limitations of the test including the risk of false positive or false negative results; and initiate any follow-up testing or treatment if required.

POC devices are not prohibited by the Excluded Purposes Specification and are not the subject of this consultation.

Is there a continuing need to prohibit the supply of certain self-tests in Australia?

Technological developments in recent years have made IVDs for self-testing less expensive and more readily available. There is also a growing desire by consumers to have more say in their healthcare decisions. Some consumers are making use of an exemption in the MD Regulations that allows them to order self-tests over the internet and import them into Australia for personal use, circumventing the Excluded Purposes Specification. The safety and performance of these tests has not been assessed by the TGA.

Self-testing devices may have a role to play in early screening for certain diseases and making testing available to consumers who would not otherwise be tested. However, there are concerns regarding the accuracy of these tests which may not be of the same standard as a laboratory test. Poor test accuracy may mean that the test gives a negative result when the person is truly positive for the disease or condition, or a positive result in people who do not have the disease or condition. Test accuracy is an important part of the evaluation undertaken by the TGA and tests which do not achieve acceptable standards would not be approved for inclusion on the ARTG.

It is also important to ensure that self-tests can be easily performed by inexperienced users (i.e. lay persons) and that the user can interpret the results correctly. Access to appropriate support services and follow-up testing may also be an important consideration.

² In the MD regulations lay person, for the use of an IVD medical device for self-testing, means an individual who does not have formal training in a medical field or discipline to which the self-testing relates

There may be benefits to wider availability of IVDs for self-testing which outweigh the risks associated with their use depending on the steps that can be taken to mitigate concerns. HIV self-tests illustrate this point.

HIV self-tests

In 2014, consultation on a proposal to allow inclusion on the ARTG and sale of self-testing IVDs for HIV identified the benefits of making HIV self-tests available including an increase in the overall rate of testing for HIV and reduction in the number of undiagnosed cases of HIV in Australia.

Measures are in place to mitigate the risks associated with the use of HIV self-test, such that the benefits outweigh the residual risks of their use; e.g.:

- risks of false negative or false positive results are addressed through evaluation by the TGA to ensure the tests meet minimum requirements for sensitivity and specificity;
- risks of incorrect use are addressed by ensuring that the instructions for use are clear and can reasonably be interpreted by inexperienced users;
- risk of misinterpretation of results are addressed by ensuring the instructions for use contain appropriate advice, particularly in relation to seeking health professional advice in the event of a positive result;
- as an additional risk mitigation, it may be a condition of approval that the sponsor provide support for users of the test through provision of on-line support services or 24/7 phone line.

In approving HIV self-testing IVDs the TGA has given consideration to issues that minimise risk in the hands of lay persons, e.g.:

- sample collection must be straightforward and able to be performed safely in the home testing environment;
- the test must be easy to perform with minimal operator intervention or procedural steps;
- stability of the product should be demonstrated across a range of operational and environmental conditions that may be encountered outside of the laboratory or health facility.

One (1) HIV Self-test IVD has been included on the ARTG and is now being supplied in Australia.

Should self-tests for other infectious diseases be allowed?

The Excluded Purposes Specification currently prohibits the supply of self-tests for infectious diseases (other than HIV), including [notifiable infectious diseases](#) (e.g. influenza, hepatitis C). While laboratory tests remain the 'gold standard' for diagnosing and confirming infectious diseases there are many advantages arising from rapid screening at the POC or in the home.

Self-testing devices for other infectious diseases may allow for early screening and intervention if required. It may also make testing accessible to consumers who would not otherwise be tested. This would include individuals who are not comfortable accessing current health services or do not have ready access to health services; e.g. people in remote communities.

Viral infections such as influenza which have seasonal peaks can lead to overwhelming demand on healthcare services particularly Emergency Departments (EDs) and general practitioners (GPs). The demands on EDs and GPs during these seasonal peaks could be reduced if reliable

self-testing devices that screen for influenza could be legally supplied in Australia, allowing consumers with flu-like symptoms to be tested at home before deciding whether to seek medical treatment. Earlier use of rapid screening for influenza could also reduce the severity of the disease by allowing for earlier treatment with antiviral drugs.

Self-testing for sexually transmitted and other infectious diseases (e.g. human papilloma virus, syphilis and chlamydia) would encourage earlier medical intervention and treatment when required. The availability of self-tests for viruses such as Hepatitis C may help increase testing rates and improve outcomes particularly in hard-to-reach populations³.

The concerns relating to self-tests for other infectious diseases are similar to those that were considered for HIV self-tests and include concerns regarding the accuracy of the test and risk of false negative or false positive results. Consumers with a false negative result may incorrectly assume they do not have a particular infection while a false positive result may cause undue distress to an individual. If self-tests for other infectious diseases were to be made available in Australia these concerns would need to be addressed and as is the case with self-testing IVDs for HIV, risk mitigations would need to be put in place to ensure that the benefits from use of the devices outweigh the risks. These mitigations could include ensuring:

- that sample collection and test procedures are straightforward and easy to perform;
- the test kit or device is robust and stable under a range of environmental conditions;
- that the sensitivity and specificity of the test is suitable to minimise the risk of false negative and false positive results;
- the interpretation of test results is clear and unambiguous and appropriate advice is available about follow up actions required and support services.



Considering the experience with HIV self-testing should self-tests for other infectious diseases be supplied and used in Australia subject to appropriate risk mitigations?

Are there any tests for particular infectious diseases that should not be available as a self-test? Please provide reasons why not.

Do you have any additional suggestions on how potential risks to consumers could be mitigated if self-tests for other infectious diseases were allowed to be supplied in Australia?

Please refer to [How to submit](#) your feedback to the TGA.

Should direct to consumer genetic tests be allowed?

Genetic tests to determine the presence of, or susceptibility to, diseases in humans are currently prohibited from supply in Australia under the Excluded Purposes Specification. This includes genomic tests such as Whole Genome Sequencing (WGS) and Whole Exome Sequencing (WES)⁴.

Genetic/genomic testing has a wide application in the diagnosis or prognosis of various diseases and disorders, or in determining predisposition to those diseases or disorders. During consultation on the IVD regulations in 2003, stakeholders emphasised the importance of pre-

³ [Fifth National Hepatitis C Strategy 2018-2022](#)

⁴ [Australian Genomics Health Alliance Genomics Glossary](#)

test discussion and post-test counselling by health professionals for these diseases or conditions and recommended that all genetic tests be excluded from self-testing.

Most genetic tests are generally not intended for use in the home (i.e. they are laboratory-based tests) and are requested by a doctor or other health practitioner who is responsible for counselling the patient on the interpretation of the results. In other cases, a consumer may decide to have a genetic test, collect a sample for referral to a laboratory for testing but nominate their doctor to whom the laboratory will also send the results. With the involvement of an appropriate health professional (e.g. doctor, genetic counsellor) these tests are not considered self-tests⁵ under the MD Regulations and are not prohibited under the Excluded Purposes Specification.

Direct to consumer genetic tests (DTC GT) are advertised directly to and purchased by the consumer, frequently over the internet. While the sample may be self-collected the actual testing may occur in a laboratory and the test results are returned directly to the consumer. DTC GT intended for determining the presence of, or susceptibility to, a disease or condition are currently prohibited under the Excluded Purposes Specification and cannot be legally supplied in Australia. However, DTC GT that are advertised and supplied from overseas are currently outside the reach of Australia's legislation. Some of these tests may have limited clinical evidence to support their use.

The most common DTC GT currently offered via the internet include tests to:

- predict susceptibility to common multifactorial conditions, such as diabetes, obesity and heart disease;
- determine carrier status for pregnancy planning or for pre-natal testing.

The number of services supplied via the internet cannot be determined but it would appear that consumers are increasingly accessing these services from overseas in response to their promotion.

While genetic testing can be a very powerful tool in diagnosing or predicting the risk of some serious diseases or conditions, the interpretation of many of those risk factors can be quite challenging and may have implications for family members. A lay person may be unnecessarily alarmed by results if the risks are misinterpreted or are not adequately explained in the report they receive. The involvement of a person's doctor or a genetic counsellor can help to minimise those concerns. Additionally, consumers may not be informed about potential secondary uses of their genetic/genomic data collected through DTC GT, including potential implications such as the data being sold or shared with other companies, reinterrogated and linked back to the consumer.

The potential advantages of DTC GT include increased access to testing, consumer autonomy, and individual empowerment allowing consumers to make independent medical decisions. DTC GT can allow consumers to take greater responsibility for their health, and adopt health-promoting behaviours, particularly if a higher risk of developing a particular disease is identified. However there is concern about consumer access to genetic information without medical consultation when the findings have the potential to significantly affect health outcomes.⁶

⁵ If a health professional with formal training in a field to which the testing relates is involved in the return of results to a patient, then it is not considered to be a self-test. See 'Background' for definitions of a 'Health Professional' and an 'IVD for self-testing'.

⁶ National Health and Medical Research Council (NHMRC), 'Direct-to-Consumer genetic testing statement' (2014) <https://www.nhmrc.gov.au/guidelines-publications/g9>.

Examples of mitigation strategies could include:

- IVDs that are not supported by appropriate clinical evidence and analytical performance data would not be approved for supply in Australia;
- supply in Australia could be conditional on the provision of appropriate consumer information and referrals to health professional services.

The risks associated with DTC GT can be minimised if the tests are regulated and evaluated by the TGA to ensure that any risks are appropriately mitigated. If DTC GT's that meet acceptable quality and performance standards could be supplied as self-testing IVDs in Australia they would offer consumers an alternative to overseas services of unknown quality and performance.



Should Direct to Consumer Genetic Tests be permitted in Australia (following evaluation by the TGA) to provide consumers with an alternative to overseas testing which has not been evaluated by the TGA for its quality and performance?

Are there any particular genetic tests that should not be available as a self-test? Please provide reasons why not.

Do you have any suggestions on how potential risks to consumers could be mitigated if genetic self-tests were allowed to be supplied in Australia?

Please refer to [How to submit](#) your feedback to the TGA.

Should self-tests for other serious diseases or conditions be allowed?

The Excluded Purposes Specification prohibits supply of self-tests to diagnose serious diseases⁷ or conditions (e.g. diabetes, cancer or myocardial infarction) as well as self-tests to identify the presence of markers that may be an indicator of a serious disease or condition (e.g. pap smear tests as a marker for cervical cancer, prostate specific antigen tests as a marker of prostate cancer).

However, as noted earlier in this paper, there are self-testing devices for some serious diseases that can be supplied in Australia because they are not specifically prohibited under the Excluded Purposes Specification. Examples include:

- glucose test strips and glucose monitors can be included on the ARTG for supply in Australia when they are intended for “monitoring” diabetes but would be excluded from supply if they were intended solely for diagnosing diabetes;
- sample collection kits which are supplied as part of bowel cancer screening tests can be included on the ARTG if they are part of a Government sponsored public health screening program.

Self-testing IVDs that are well-designed and are safe and effective when used by lay persons could extend screening to a wider range of serious diseases and empower consumers to take more control over their own health. However, the concerns regarding self-tests for serious diseases are similar to those already mentioned and include concerns regarding accuracy of the

⁷ Serious disease is defined in the MD Regulations as a disease that may result in death or long-term disability; may be incurable or required major therapeutic interventions; and must be diagnosed accurately, to mitigate the public health impact of the disease.

tests; the ability for them to be correctly used and interpreted; and the need for access to appropriate healthcare support services and follow-up testing.

If self-tests for serious diseases were allowed to be supplied in Australia they would be subject to mandatory assessment by the TGA prior to inclusion in the ARTG which would ensure that risks arising from their use are minimised and consumers are appropriately referred to healthcare services when required.



Should self-tests for serious diseases be able to be supplied in Australia following evaluation by the TGA to determine their safety and performance?

Are there any particular tests for serious diseases that should not be available as a self-test? Please provide reasons why not.

Do you have any suggestions on how potential risks to consumers could be mitigated if self-tests for serious diseases were allowed to be supplied in Australia?

Please refer to [How to submit](#) your feedback to the TGA.

Privacy and confidentiality considerations for self-tests

Health professionals and testing laboratories are subject to Commonwealth, State and Territory legislation which ensure that security and confidentiality of personal information and health records. The *Commonwealth Privacy Act 1988*, the *Competition and Consumer Act 2010* and Australian Consumer Law may also place obligations on vendors of self-testing devices or genetic testing services to ensure that information is held securely and confidentially. However, there may be concerns that these protections are not adequate; e.g. are the results of DTC GT protected from unauthorised disclosure to third parties such as life insurance companies.

Consideration of privacy, confidentiality and ethical concerns are important when determining what self-tests, particularly DTC GT, should be available in Australia.

Background information

Definition of an IVD medical device for self-testing

With the implementation of the IVD regulatory framework the term “IVD for home-use” was replaced by “IVD for self-testing”. The MD Regulations define an IVD medical device for self-testing as being an IVD medical device intended to be used:

- (a) in the home or similar environment by a lay person; or
- (b) in the collection of a sample by a lay person and, if that sample is tested by another person, the results are returned directly to the person from whom the sample was taken without the direct supervision of a [health professional](#) who has formal training in a medical field or discipline to which the self-testing relates.

Definition of a health professional

The definition of “health professional” in the MD Regulations is an inclusive one and includes a person who is:

- (a) a medical practitioner, a dentist or any other kind of health care worker registered under a law of a State or Territory; or
- (b) a biomedical engineer, chiropractor, optometrist, orthodontist, osteopath, pharmacist, physiotherapist, podiatrist, prosthetist or rehabilitation engineer.

For genetic testing a health professional would also include a genetic counsellor.

How are IVDs for self-testing regulated in Australia?

Classification

IVDs are classified into four (4) risk classes according to the health risk (either to the public or an individual) that may arise from an incorrect result with Class 4 being the highest risk classification. The risk classification of an IVD determines the specific regulatory requirements that will apply.

Therefore, it is important for manufacturers and sponsors of IVDs for self-testing to correctly apply the classification rules to their devices before making an application for inclusion in the ARTG (a requirement for legal supply in Australia).

Under Schedule 2A of the MD Regulations an IVD for self-testing is classified as a Class 3 IVD (moderate public health risk/high personal risk) or higher unless:

- (a) the result of the examination is not determining a serious condition, ailment or defect; or
- (b) the examination is preliminary and follow-up additional testing is required.

If (a) or (b) apply an IVD for self-testing may be a lower Class e.g., a self-test for pregnancy is a Class 2 IVD.

An IVD for self-testing may be Class 4 if testing for a transmissible agent that poses a high public health risk e.g., HIV.

Mandatory application audit

When an application is made to the TGA for inclusion of a Class 3 or lower classification IVD for self-testing on the ARTG the application is selected for compulsory assessment by the TGA (this is referred to as an application audit). This means that the TGA will assess whether the device will perform as intended as an IVD for self-testing. The instructions for use will be assessed to ensure they are appropriate for use and interpretation by a lay person with no formal training as a health professional. For example, blood glucose monitoring systems for self-testing are subject to mandatory application audit to ensure they are safe and easy to use and perform as intended by the manufacturer.

IVDs for self-testing that are Class 4 IVDs (such as self-testing IVDs for HIV) must undergo a more rigorous TGA conformity assessment which involves a comprehensive assessment of the quality and performance of the IVD as well as the manufacturer’s quality management system. An application audit is not required in such circumstance.

Restrictions on advertising of therapeutic goods

As self-testing IVDs are likely to be advertised to the general public in some manner there may be risks of inappropriate use if consumers are confused or misinformed as to the utility of the devices. However, advertisements to the public for self-testing IVDs (as therapeutic goods) are subject to the [Therapeutic Goods Advertising Code](#) (the Advertising Code). The promotion of self-testing IVDs must therefore comply with the requirements of the Advertising Code.

Restricted and prohibited representations

The Advertising Code specifies that a reference to a serious form of a disease, condition, ailment or defect is a restricted representation. A 'serious form' is one that:

- is medically accepted to require diagnosis or treatment or supervision by a suitably qualified health professional and is not suitable for self management, or
- where a self-test is available, it requires medical interpretation or follow-up.⁸

As such, the advertising of self-testing IVDs for a serious disease, condition, ailment or defect will contain restricted representations. An advertiser must apply to the TGA for approval to use a restricted representation in advertising.

Prohibited representations are also set out in the Advertising Code and apply to any representation regarding diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to:

- (i) neoplastic disease (including all types of cancer);
- (ii) sexually transmitted diseases;
- (iii) HIV and AIDS;
- (iv) hepatitis C virus;
- (v) mental illness

Any representations in relation to tests for these serious diseases are prohibited unless the TGA decides that it is necessary for the appropriate use of the test (e.g. on the label or packaging) or it is in the interests of public health for the test to be advertised. For example, the TGA recently permitted the use of prohibited representations to allow the advertising of a HIV self-test to the public⁹ through a number of specific channels.

Conditions may be applied to the use of the restricted or prohibited representations and may include limiting the ways in which an advertisement can be disseminated or requiring additional information to be provided whenever the representations are used.

⁸ Note: References to pregnancy, other than pregnancy with a medical, obstetric or surgical complication are not considered serious.

⁹ See <https://www.tga.gov.au/advert-exempt/therapeutic-goods-prohibited-and-restricted-representations-atomo-hiv-self-test-permission-no-2-2019>

How are IVDs for self-testing regulated by comparable overseas regulators?

The European Union (EU)

The [EU IVD Regulation \(IVDR\) 2017/746](#) definition of 'device for self-testing' aligns broadly with the Australian definition of 'IVD medical device for self-testing' but significantly the EU regulation is extended to include 'devices used for testing services offered to lay persons by means of information society services'.

Information society service is not defined in the IVDR *per se* but rather it references the definition in [Directive 99/34/EC](#) where information society service means 'any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services'.

This is an important feature in the EU regulations which will clarify the regulation of direct to consumer testing over the internet as IVDs for self-testing. By contrast, in Australia direct to consumer testing which is performed in a laboratory is not regulated as a self-testing IVD; only the collection device used by a lay person to collect the sample is considered a self-testing IVD.

The EU has no equivalent of Australia's Excluded Purposes Specification. Individual member states may, however, have national legislation that impact on the regulatory control of IVDs for self-testing such as DTC GT. For example, France, Germany and Portugal have specific legislation that defines that genetic tests can only be carried out by a medical doctor after the provision of sufficient information concerning the nature, meaning and consequences of the genetic test and after the consent of the person concerned. In Germany, the Human Genetic Examination Act restricts provision of DTC GT indirectly by providing that genetic tests can only be carried out by a medical doctor after the provision of sufficient information concerning the nature, meaning and consequences of the genetic test, and after the consent of the person concerned.

Other jurisdictions

The US FDA and Health Canada do not have any specific prohibitions on self-testing IVDs for serious diseases although the costs borne by the consumer may mean that market penetration is relatively low in comparison to point of care tests using similar IVDs. For example, the FDA has only approved one rapid self-test for HIV and few other self-tests for infectious diseases.

Consultation

The TGA is seeking feedback on whether the Excluded Purpose Specification is fit for purpose and the potential impact that remaking the Excluded Purposes Specification would have on affected stakeholders. Submissions should include information relevant to the questions raised in the paper which are also summarised below:

- Following evaluation by the TGA to determine their safety and performance, and considering the experience with HIV self-testing, should:
 - self-tests for other infectious diseases;
 - genetic self-tests (i.e., direct to consumer genetic testing);
 - self-tests for determining the presence of other serious diseases (e.g., cancer, diabetes);

be able to be legally supplied in Australia subject to evaluation and approval by the TGA with appropriate risk mitigation strategies?

- Are there any particular tests that should not be available in Australia as a self-test? Please provide reasons why not.
- Do you have any suggestions on how potential risks to consumers could be mitigated?

How to submit

Complete the [online consultation submission form](#) to upload your submission in either pdf or word format.

You can also submit your feedback directly to the TGA by email at: devicereforms@tga.gov.au. If you do so, **please ensure your submission is accompanied by a cover sheet**.

Alternatively, hardcopy submissions with a [printed coversheet](#) may be mailed to:

IVD Reforms
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

This consultation closes on 6 December 2019.

Submissions must be received by the closing date, please read this information in conjunction with the consultation page for [Review of the regulation of certain self-testing IVDs in Australia](#), for further details about enquiries and submission.

Next steps

Following closure of this consultation the TGA will review the feedback received and make recommendations to the Government on whether the Excluded Purposes Specification should be remade and, if so, whether it should be amended in any way. The TGA will then notify stakeholders of any changes in the operation of the Excluded Purposes Specification that are agreed by Government. This may take the form of any or all of the following:

- news bulletins published on the TGA website;
- specific guidelines on the Excluded Purposes Specification published on the TGA website.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch	27 September 2019

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