Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advertising COVID-19 rapid antigen point-of-care tests and self-tests (home use tests)

Information on the rules governing COVID-19 rapid antigen tests (RATs) advertising.

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As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates the advertising of therapeutic goods in Australia. The following guidance explains how parties can lawfully advertise COVID-19 rapid antigen tests.

Advertising under the *Therapeutic Goods Act 1989* (https://www.legislation.gov.au/Series/C2004A03952) (the Act) includes to promote the use or supply of a therapeutic good. Any publicly accessible content that meets this definition must comply with the advertising requirements for therapeutic goods in Australia.

This guidance only applies to COVID-19 rapid antigen tests included on the Australian Register of Therapeutic Goods (https://www.tga.gov.au/node/288148) (ARTG). The promotion of tests that have not been approved by the TGA (and thus not included on the ARTG) is not permitted.

The information set out in this guidance does not extinguish responsibilities under other relevant laws, including the Australian Consumer Law.

General considerations

The TGA has approved a number of COVID-19 rapid antigen tests for supply in Australia.

There are two types of rapid antigen tests. COVID-19 **rapid antigen point-of-care tests** can be supplied for use by specified health practitioners and trained staff under their supervision. Further information on the conditions of supply of these tests is available at COVID-19 Point-of-Care tests (https://www.tga.gov.au/node/288144).

An Excluded purposes specification for IVDs for self-testing (https://www.legislation.gov.au/Series/F2020L01150) which allows suppliers (sponsors) to apply for regulatory approval to supply self-tests for use at home in Australia is now in place. **COVID-19 rapid antigen self-tests (home use tests) can only be supplied to consumers for self-testing if they are approved by the TGA and included in the ARTG for that purpose.** Further information on the supply of self-tests is available at COVID-19 Rapid Antigen Self-tests (for home use) (https://www.tga.gov.au/node/288143).

Suppliers (sponsors) of COVID-19 rapid antigen tests and testing service providers must make sure that any publicly accessible advertising of rapid antigen tests is compliant with the Act, the *Therapeutic Goods Advertising Code* (https://www.legislation.gov.au/Series/F2021L01661) and the conditions of supply and use as they appear on the Australian Register of Therapeutic Goods.

The Advertising Code specifies the requirements for advertisements of health products. For example, it requires advertisements to be balanced, accurate, substantiated and not misleading. Under the Advertising Code, advertisements must:

- be consistent with the directions/instructions for use of the advertised product
- not exaggerate the efficacy or performance of the product or encourage inappropriate use
- not be likely to lead people to delay necessary medical attention, and
- not be inconsistent with public health campaigns.

The Advertising Code also includes requirements specific to the type of therapeutic good being advertised, whether it is a medicine, a medical device (such as a rapid antigen test) or an 'other therapeutic good'.

It is also important that any advertisement is consistent with government health messaging in relation to testing for infection with COVID-19.

Advertising COVID-19 rapid antigen tests lawfully

As well as ensuring advertisements for COVID-19 rapid antigen tests comply with the requirements for advertising therapeutic goods set out in the Act and the Advertising Code, advertisers must ensure advertisements are consistent with the terms of the legal advertising permission (https://www.tga.gov.au/resources/advertising-permissions/therapeutic-goods-restricted-representations-covid-19-and-influenza-test-kits-permission-2022) for COVID-19 rapid antigen tests (under section 42DK of the Act).

The TGA issued this legal permission to enable sponsors and other advertisers of COVID-19 rapid antigen tests to use the particular 'restricted representations' specified in the permission. Representations used in advertising that refer to a serious disease such as COVID-19 are

'restricted representations'. Under this legal permission, the permitted representations are:

- representations to the effect that COVID-19 rapid antigen tests may be used to detect possible infection with SARS-CoV-2 (COVID-19)
- representations referring to SARS-CoV-2 or COVID-19 contained within the name of a COVID-19 rapid antigen test
- any 'restricted representation' that is necessary to provide information about the proper use of the advertised COVID-19 rapid antigen test (this enables the advertisement to display the test's instructions for use document in addition to any other instructions in written, graphical, pictorial or video form).

To ensure that both the capabilities and limitations of these types of tests are conveyed accurately and completely, the permission requires that certain statements are included in the advertisement in a prominent way.

The following statements (or statements to the same effect) **must** be prominently displayed or communicated[1] (#fn1) in advertisements, **both** for point-of-care tests that are supplied for use by specified health practitioners and trained staff under their supervision, **and** for tests that are supplied for use by consumers for self-testing (home use):

- Negative test results do not exclude infection with COVID-19 (so face masks, social distancing and good hygiene practice must be maintained)
- Follow current government health messaging regarding confirmatory testing requirements.

The advertisement must specify if the advertised COVID-19 rapid antigen test is being supplied for self-testing (unsupervised testing in the home or other environment) or if the advertised test is being supplied for point-of-care testing only. If the advertised test is being supplied for point-of-care testing, only the advertisement must contain a statement, prominently displayed or communicated, that the advertised test:

- must be used by relevant practitioners, or persons under their supervision, who are trained in the correct use of the tests and interpretation of test results.

In addition to prescribing the inclusion of certain statements, the permission prohibits the use of other particular statements.

The advertisement **must not**:

- include a claim that the therapeutic goods are diagnostic (rather than to detect possible infection with COVID-19)
- state or infer that PCR (or other laboratory) testing for COVID-19 infection will never be required

- state that the goods are capable of early detection
- include claims relating to the accuracy, specificity, sensitivity or limit of detection of the therapeutic goods (except where such claims are included solely in instructions for use relating to the advertised test)
- include comparisons with other therapeutic goods, including other rapid antigen tests
- infer that the therapeutic goods are capable of determining whether or not a person is infectious, or the degree of their infectiousness
- include endorsements or testimonials.

What can I say about the advertised COVID-19 rapid antigen test?

Examples of what an advertiser can include in an advertisement, other than statements that **must** be included, are

- statements relating to the sample (or specimen type) that is needed for the test
- the testing time
- the cost of the test.

Testimonials and endorsements

To ensure COVID-19 rapid antigen tests are only advertised to impart the capabilities and limitations of the test, advertisements must not include testimonials or endorsements.

While COVID-19 rapid antigen tests are an important supplementary tool for use in efforts to curb the spread of COVID-19, they do not provide a diagnosis of COVID-19 infection. Only PCR testing is recognised as appropriate for providing definitive diagnosis of infection.

Additionally, it is unlawful to state or imply that the advertised goods are approved or endorsed by the TGA or any other government authority. Advertisements must not state or imply that the advertised good is "TGA approved". For further information, see our guidance on advertising therapeutic goods (https://www.tga.gov.au/how-we-regulate/advertising/how-advertise/advertising-guidance).

Advertising to health professionals

COVID-19 rapid antigen tests can be advertised to health professionals however if the information is publicly viewable, it must meet the requirements as outlined in this guidance and the restricted representation permission.

Advertising directed **exclusively** to health professionals and not available publicly, does not need to comply with the advertising rules. Advertising accessible by health professionals only may be limited through, for example, the use of firewalls, or a requirement to register your health professional credentials to gain access to the advertising. For further information, see our guidance on advertising to health professionals (https://www.tga.gov.au/node/289527).

Factual and balanced information that does not constitute advertising

Any party can publicly present factual and balanced information about the COVID-19 rapid antigen tests, and other therapeutic goods, that is not promotional and therefore not subject to the advertising rules. Some examples of factual and balanced information include:

- technical information relating to how the tests were developed and manufactured.
- scientific reports from reputable sources (like the World Health Organization) or from medical journals about COVID-19 rapid antigen testing, presented without promotional material or language included.
- comprehensive information presented in a way that doesn't, for example, emphasise the benefits of rapid antigen testing over its limitations.

For businesses facilitating rapid antigen testing in the workplace

Businesses wishing to advise that they have engaged health professionals to conduct COVID-19 rapid antigen testing in the workplace are able to provide this information to employees and visitors.

However, if a particular test is promoted as part of the advice, businesses must ensure they follow this guidance and the advertising requirements.

Further information

- Fact sheet: Obtaining approved COVID-19 rapid antigen tests (https://www.tga.gov.au/node/288225)
- The requirements described in this guidance are enabled by:
    - Therapeutic Goods (Restricted Representations - COVID-19 and Influenza Test Kits) Permission 2022 (https://www.tga.gov.au/resources/advertising-permissions/therapeutic-goods-restricted-representations-covid-19-and-influenza-test-kits-permission-2022)
    - The Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (https://www.legislation.gov.au/Series/F2021L01661)
    - The *Therapeutic Goods Act 1989* (https://www.legislation.gov.au/Series/C2004A03952)
- If you have questions about the legal requirements regarding advertising of therapeutic goods, including COVID-19 rapid antigen tests, please lodge an advertising enquiry online (https://compliance.health.gov.au/ac-enquiry) with the TGA.
- You can also contact the TGA on 1800 020 653 (free call within Australia) or 02 6289 4124.

Footnotes

[1] (#fn1s) Prominently displayed or communicated has the same meaning as in the Therapeutic Goods Advertising Code (https://www.legislation.gov.au/Details/F2021L01661) - that is:

a. either:

i. for a visual statement - easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; or

ii. for a spoken statement - able to be clearly heard and understood; and

b. repeated as often as is necessary to be noticed by a viewer or listener.

Topics:

COVID-19 (https://www.tga.gov.au/products/covid-19)

Medical devices (https://www.tga.gov.au/products/medical-devices)

In Vitro Diagnostic medical devices (IVDs) (https://www.tga.gov.au/vitro-diagnostic-medical-devices-ivds)

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COVID (https://www.tga.gov.au/covid)