Australian Government
Department of Health
Therapeutic Goods Administration

Advertising COVID-19 Rapid Antigen Tests

21 August 2021

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* (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 registered on the Australian Register of Therapeutic Goods. The promotion of unregistered tests is not permitted.

It is prohibited under TGA regulations to supply COVID-19 rapid antigen tests to consumers for self-testing (home use). All advertisements for COVID-19 rapid antigen tests that are in the public domain (such as on company websites) must prominently state that the tests cannot be supplied for self-testing (home-use).

The information set out in this guidance does not extinguish responsibilities that any party has under other relevant laws, including but not limited to, the Australian Consumer Law.

General considerations

The TGA has approved a number of COVID-19 rapid antigen tests for supply in Australia. Currently, they can only 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 Applying for TGA assessment of a COVID-19 test for inclusion in the ARTG (//www.tga.gov.au/applying-tga-assessment-covid-19-test-inclusion-artg).

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 *Therapeutic Goods Advertising Code* (https://www.legislation.gov.au/Series/F2018L01524) 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

- must not exaggerate the efficacy or performance of the product or encourage inappropriate use
- must not be likely to lead people to delay necessary medical attention and
- must not be inconsistent with public health campaigns.

The Advertising Code also includes specific requirements for an advertisement.

It is important that any advertisement for a test of this kind is consistent with government health messaging in relation to testing for infection with COVID-19.

Advertising COVID-19 rapid antigen tests lawfully

Representations used in advertising that refer to a serious disease, such as COVID-19, are 'restricted representations' and must be approved by the TGA before being used in an advertisement. More information about restricted representations (//www.tga.gov.au/restricted-representations) is available on the TGA website.

The TGA has issued a legal permission (//www.tga.gov.au/advert-exempt/therapeutic-goods-restricted-representations-covid-19-rapid-antigen-tests-permission-2021) (under section 42DK of the Act) which enables sponsors and other advertisers of COVID-19 rapid antigen tests to use the 'restricted representations' specified in the permission. This includes representations to the effect that COVID-19 rapid antigen tests may be used as a screening tool to detect possible infection with COVID-19.

To ensure that the capabilities and limitations of these types of tests are conveyed accurately and completely, the permission requires that certain statements are prominently displayed or communicated in the advertisements.

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

The following statements (or statements to the effect of) MUST be included in the advertisement:

- the COVID-19 rapid antigen test must not be supplied for the purpose of self-testing
- the COVID-19 rapid antigen test must only be used by relevant practitioners, or persons under their supervision, who are trained in the correct use of the goods and the interpretation of the test results
- negative test results do not exclude infection with COVID-19 (so face masks, social distancing and good hygiene practice must be maintained)
- positive test results or symptomatic persons require immediate confirmatory testing with a polymerase chain reaction (PCR) test.

Wherever the permitted representation is used the advertisement MUST NOT:

- include a claim that the therapeutic goods are diagnostic
- state or infer that PCR (or other laboratory) testing is not needed
- 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

- include comparisons with other therapeutic goods
- 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?**
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> Examples of what an advertiser can include in an ad, apart from the statements that must be included, include statements relating to the sample (or specimen type) that is needed for the test, the testing time and the cost of the test.

Testimonials and endorsements

Ordinarily, testimonials and endorsements are permitted in certain advertisements for therapeutic goods. However, to ensure COVID-19 rapid antigen tests are only advertised as necessary to impart the key capabilities and limitations of the test, advertisements for these tests must not include testimonials or endorsements. While COVID-19 rapid antigen tests are an important supplementary screening tool for use in efforts to curb the spread of COVID-19, they are not equivalent to PCR testing which is the gold standard test used in managing outbreakIt is unlawful to state or imply that the advertised goods are approved or endorsed by the TGA or any other government authority. For example, advertisements must not state or imply that the advertised good is "TGA approved". Further information about these requirements can be found on the TGA website (//www.tga.gov.au/hubs/advertising-therapeutic-goods).

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. Further information about directing advertisements exclusively to health professionals is published on the TGA website (//www.tga.gov.au/advertising-health-professionals).

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

- sharing scientific reports from reputable sources (like the World Health Organization) about COVID-19 rapid antigen testing, without including promotional material or language
- presenting comprehensive information that doesn't emphasise the benefits over, for example, the risks and 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

- The arrangements described in this guidance are enabled by:
  - The Therapeutic Goods (Restricted Representations- COVID-19 Rapid Antigen Tests) Permission 2021 (//www.tga.gov.au/advert-exempt/therapeutic-goods-restricted-representations-covid-19-rapid-antigen-tests-permission-2021)
  - The Therapeutic Goods Advertising Code (No.2) 2018 (https://www.legislation.gov.au/Details/F2021C00763)
  - The *Therapeutic Goods Act 1989* (https://www.legislation.gov.au/Details/C2021C00207)
- 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.tga.gov.au/advertising-enquiry/) with the TGA.
- You can also contact the TGA by phone on 1800 020 653 (free call within Australia) or 02 6289 4124 (for mobiles that do not allow 1800 calls).

Category: Medical devices/IVDs
Tags: regulatory guidance, medical devices, COVID-19 tests, rapid antigen tests, businesses
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