

Article Information

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Service: Corporate & Commercial, Intellectual Property & Technology

Sector: Health & Life Sciences

COVID-19 rapid antigen tests: complying with advertising and supply requirements

Amidst rising COVID-19 infections across the nation, the Therapeutic Goods Administration has issued new guidance on the public advertising and supply of COVID-19 rapid antigen tests.

Any sponsor of COVID-19 rapid antigen tests must comply with strict advertising requirements and conditions imposed on the supply of these tests.

Advertising of rapid antigen tests

Publicly accessible advertising of COVID-19 rapid antigen tests is regulated by the *Therapeutic Goods Advertising Code (No. 2) 2018* (Cth) (**Advertising Code**) and the *Therapeutic Goods Act 1989* (Cth) (**Therapeutic Goods Act**). In particular, any representation that refers to a serious disease, being COVID-19 in this instance, must be approved by the Therapeutic Goods Administration before being used in an advertisement.

The key measures of the Advertising Code include:

- Advertisements must be balanced, accurate, substantiated and not misleading to the public;
- Advertisements must be consistent with the instructions for use of the rapid antigen tests;
- Advertisements must not exaggerate the performance of the rapid antigen test or encourage inappropriate use;
- Advertisements must not encourage people to delay necessary medical attention; and
- Advertisements must not be inconsistent with COVID-19 public health campaigns.

The Therapeutic Goods Administration has recently issued legal permission to allow sponsors of rapid antigen tests to advertise to the public that such tests may be used as a screening tool to detect possible COVID-19 infections. The *Therapeutic Goods (Restricted Representations – COVID-19 Rapid Antigen Tests) Permission 2021 (Rapid Antigen Tests Permission)* came into effect on 19 August 2021.

For sponsors to rely on the Rapid Antigen Tests Permission, the following statements must be prominently displayed or communicated in their advertisement:

- COVID-19 rapid antigen tests must not be supplied for home testing;
- The test must only be used by trained practitioners, or persons under their supervision;
- Negative test results do not exclude COVID-19 infections such that persons must continue using face masks, social distancing and maintaining good hygiene; and
- Positive test results require immediate confirmatory PCR testing.

Further, sponsors must ensure that their advertising of rapid antigen tests is not inconsistent with COVID-19 health messaging. The advertisement must not:

- Claim that the rapid antigen test is diagnostic;
- Claim that confirmatory laboratory testing is not required;
- State that the test is capable of early detection of COVID-19;
- Include claims relating to the accuracy, specificity or sensitivity of the rapid antigen test;
- Include comparisons with other therapeutic goods;

- Infer that the rapid antigen test is capable of determining the degree of infectiousness; and
- Include endorsements or testimonials.

Upon satisfying these conditions, sponsors are permitted to advertise the rapid antigen test to the public as a screening tool for detecting COVID-19 infections.

It is important to note that if a sponsor is exclusively advertising the rapid antigen test to health professionals, with no potential for public accessibility, the specific advertising rules do not apply. However, if the advertisement is publically viewable in any way, it must comply with the advertising requirements.

Supply of rapid antigen tests

Although the advertising rules apply to advertising to the general public, it is strictly prohibited to supply a COVID-19 rapid antigen test for the purpose of home testing. The Therapeutic Goods Administration maintains that COVID-19 rapid antigen tests can only be supplied to accredited pathology laboratories, registered medical practitioners, registered paramedics, organisations that engage health professionals for administering/supervising the test, residential aged care facilities with a supervising health professional and Commonwealth, State or Territory departments.

If you are a sponsor

Rapid antigen tests provide a much-needed 'quick and easy' aid to screening possible infections of COVID-19; however, sponsors should be particularly cautious when advertising or supplying these tests. Failure to comply with the advertising requirements or conditions imposed on the supply of rapid antigen tests can carry serious consequences including imprisonment and severe civil penalties.