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COVID-19 testing at home: new regulation to allow rapid antigen self-tests

With Australia expected to reach vaccination targets in mere weeks, the Therapeutic Goods Administration is reassessing its position on the supply of COVID-19 rapid antigen self-tests.

Change in regulation to allow supply of self-tests for home use

Aligning with the transition of Australia's national COVID-19 response, the Therapeutic Goods Administration (**TGA**) announced that they would make a new regulation on 1 October 2021 to allow companies to seek approval to legally supply COVID-19 rapid antigen self-tests for use at home in Australia after 1 November 2021. Currently, the supply of self-tests is prohibited under the *Therapeutic Goods (Medical Devices – Excluded Purposes) Specification 2020* (**Excluded Purposes Specification**) for risk of under-reporting and reliability. However, with the national target of 70% double vaccination approaching quickly, the TGA is undertaking necessary work to allow the supply of self-tests in order to improve accessibility to testing and allow individuals to obtain quick results. Nevertheless, it will be important for sponsors to inform customers that the rapid antigen self-tests do not replace the requirement of confirmatory PCR testing or health advice from medical practitioners.

Before 1 October 2021

The TGA invited sponsors to register an expression of interest in supplying COVID-19 rapid antigen self-tests. Rather than a pre-approval process, this was a chance for sponsors to ask initial questions and check requirements so that they are prepared when the Australian government announces the commercial provision of self-tests.

Key information for sponsors of self-tests to prepare

When applying for inclusion of rapid antigen self-tests on the ARTG, sponsors will need to provide (among other things):

- Appropriate certification of manufacture of the self-tests;
- Instructions for use of the tests, including safe disposal;
- Studies that support the analytical and clinical performance of the test such as sample stability, sensitivity of at least 80%, specificity of at least 98%, ability to account for false negatives and false positives and controls that verify the correct performance of the test;
- Ease with which a lay person could use and interpret the test, including providing usability studies;
- Specifications on whether the test is intended to detect varying COVID-19 strains in both symptomatic and asymptomatic persons;
- Information on any associated hardware or software to support analysis, recording or transmitting of results; and
- Statistically appropriate information to allow the TGA to evaluate the rapid antigen self-test.

Top priority is to ensure that the instructions for rapid antigen self-tests are easy to read and interpret, available in multiple languages and usable by lay persons with different literacy levels. Sponsors must provide access to additional resources such as online videos or at least pictorial instructions on their website and must also run a telephone help line.

After 1 October 2021

Once the TGA has passed the regulation on 1 October 2021, sponsors will be able to apply for inclusion of COVID-19 rapid

antigen self-tests in the Australian Register of Therapeutic Goods, for supply commencing 1 November 2021. Each application will be evaluated by the TGA on a case-by-case basis, taking into consideration the clinical performance and risk mitigation of the test.

A note of caution

Sponsors and potential customers should keep an eye on State regulations. At the time of writing, Western Australia and South Australia have prohibited or restricted use of SARS-CoV-2 Rapid Antigen Tests as an acute illness diagnostic tool for COVID-19. For further information, the Western Australian and South Australian government websites can be consulted.

Conclusion

With the new wave of COVID-19 rapid antigen self-tests about to hit Australia, sponsors must ensure that they have appropriate systems in place to supply reliable, accurate and accessible testing for consumers.