Notice under section 41FP of the *Therapeutic Goods Act 1989:*

Conditions on a device included in the ARTG (2nd August 2021)

The following conditions are imposed in relation to the inclusion of the Device in the ARTG:

1. The person in whose name the Device is included in the ARTG (the ***sponsor***) may only supply the Device to one or more of the following:

    a. a laboratory that is an accredited pathology laboratory within the meaning of the *Health Insurance Act 1973*;
    b. a medical practitioner who is registered under a law of a state or territory to practice medicine, a person registered under a law of a state or territory to practice paramedicine (a ***paramedic***), or an organisation, business or institution that employs or engages a medical practitioner or a paramedic, where the medical practitioner or the paramedic is responsible for performing or supervising the performance of the test, and both the medical practitioner and the paramedic (and any person acting under their supervision to perform the test) have received training in the correct use of the device and the interpretation of the test result;
    c. a residential care or aged care facility that employs or engages a paramedic (as defined above) or a health practitioner within the meaning of the *Therapeutic Goods Act 1989*, where the paramedic or the health practitioner is responsible for performing or supervising the performance of the test, and both the paramedic and the health practitioner (and any person acting under their supervision to perform the test) have received training in the correct use of the device and the interpretation of the test result;
    d. an organisation, business or institution that does not have the primary function of providing healthcare services but employs or engages a paramedic (as defined above) or a health practitioner within the meaning of the *Therapeutic Goods Act 1989*, where the paramedic or the heath practitioner is responsible for performing or supervising the performance of the test, and both the paramedic and the health practitioner (and any person acting under their supervision to perform the test) have received training in the correct use of the device and the interpretation of the test result
    e. a department of the Commonwealth, state or territory, with responsibility for health, or a department or other agency of the Commonwealth, state or territory acting on its behalf.

2. The Device must not be supplied for the purpose of self-testing.

The imposition of the above conditions is necessary to prevent imminent risk of death, serious illness or serious injury. Accordingly, the changes to the conditions specified above take effect on the date on which this notice is given to you by operation of paragraph 41FP(2)(a) of the Act.

In practice, the changes will provide greater clarity as to the supply of the Device. The changes require health practitioners are appropriately trained in the correct use of the Device and the interpretation of test results. The changes also require sponsors to maintain records of such training and supply; and make clear that the Device cannot be supplied for the purpose of self-testing.

Legislation:

Therapeutic Goods Act 1989 (www.legislation.gov.au/Details/C2021C00207)

Therapeutic Goods (Medical Devices) Regulations 2002 (www.legislation.gov.au/Details/F2021C00390)

To further guide interpretation of these Conditions, and to provide additional information on supply and use of rapid antigen tests, the TGA has released a series of Q&A, available here:

https://www.tga.gov.au/qas-conditions-supply-rapid-antigen-tests