Australian Government
Department of Health

Deputy Secretary

Mr Jason Lange
Executive Director
Office of Best Practice Regulation
Department of the Prime Minister and Cabinet
1 National Circuit
BARTON ACT 2600

Email: helpdesk-OBPR@pmc.gov.au

Dear Mr Lange

Certification Letter - Therapeutic Goods (Excluded Purposes) Specification 2010

I am writing to the Office of Best Practice Regulation (OBPR) regarding the Therapeutic Goods (Excluded Purposes) Specification 2010 (the Specification) which, as per the *Legislative Act 2003*, had been scheduled to sunset on 1 October 2020. Following consultation, it has been decided that the instrument is to be remade without significant amendment.

The TGA (Australian Government Department of Health) certifies that Therapeutic Goods (Excluded Purposes) Specification 2010 is operating effectively and efficiently, and that therefore a Regulation Impact Statement is not required for this regulation to be remade.

The assessment that the regulation is operating effectively and efficiently has been informed by a public consultation process over the period of October to December 2019 and further targeted consultation during April to July 2020. The stakeholders consulted include state and territory health departments, pathology and medical professional bodies, clinicians, consumer organisations and advocates, health research groups and industry.

Through the public and targeted consultation process, the majority of stakeholders supported the view that self-tests for cancer and genetic self-tests including direct-to-consumer genetic testing for health-related purposes, should continue to be prohibited from supply. However, overall, there was cautious support for allowing other self-tests for serious diseases where there are benefits that may offset the risks

to public or individual health. This includes self-tests for hepatitis, some sexually transmitted infections (STIs), seasonal influenza and some other serious non-infectious conditions. Stakeholders emphasised the need for confirmatory testing of positive results to confirm a diagnosis and to enable public health surveillance of notifiable infectious diseases, and that self-test devices are subject to appropriate post-market monitoring.

The benefits of allowing such self-tests include, increased access to testing, the potential to reduce delays in testing and treatment; and the supply of TGA approved self-tests may minimise the risk of purchase of unapproved tests from overseas. Evaluation of self-tests by the TGA will further mitigate risks arising from their use and will include safeguards to ensure that individuals who use self-tests are aware of the need to consult their doctor for confirmation of test results and appropriate treatment if required.

I acknowledge that OBPR will publish this letter for transparency purposes.

Yours sincerely

Adj. Professor John Skerritt
Health Products Regulation Group

/ September 2020