RACGP
Royal Australian College *of* General Practitioners

Healthy Profession.
Healthy Australia.

4 December 2019

IVD Reforms
Medical Devices Branch
Therapeutic Goods Administration

Via Email: devicereforms@tga.gov.au
michelle.mcniven@health.gov.au

Dear Ms McNiven,

The Royal Australian College of General Practitioners (RACGP) thanks the Therapeutic Goods Administration (TGA), for the opportunity to comment on the 2019 *Review of the regulation of certain self-testing in vitro diagnostic medical devices (IVDs) in Australia*.

The RACGP supports the re-introduction of the Excluded Purposes Specification 2010 in order to exclude certain self-testing kits for home use.

The RACGP provides comment on the following points:

1. **The seriousness of the disease or condition**

   Pre- and post-test counselling by a health professional is an important factor for serious diseases eg. notifiable infectious diseases, cancer and genetic disorders. Serious diseases such as these should be excluded from home testing.

2. **Test sensitivity, specificity and costs**

   Test parameters should be well established prior to determining whether a test is suitable for at home use. Test sensitivity, or the ability to correctly identify those with the disease (true positive result), and specificity (true negative result) should be compared with the standard provided by laboratory testing. The costs of false negative results need to be carefully considered, including the risk associated with delayed diagnosis. Conversely, false positive results impact on patients in terms of anxiety and also insurance implications.

   Costs must be also weighed in terms of opportunity costs associated with the fragmentation of care that reduces the general practitioner's ability to provide opportunistic comprehensive monitoring, prevention, and self-management advice.

3. **Overdiagnosis**

   It is important to consider the implications of overdiagnosis (where there is disease but the patient does not benefit from detection of the disease) with use of these devices. This could lead to psychological distress, further testing, and additional financial costs.

4. **Benefits of self-testing**

   Where a test is time-critical and there are accessibility problems (eg. rural or remote settings, travel medicine requiring self-imposed quarantine) self-testing may be warranted.

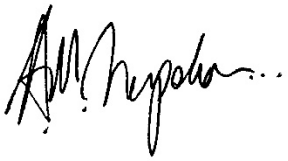
   Where a test is cheap and has proven high accuracy, it may provide an acceptable alternative. It should be recommended that the user of self-testing devices make follow-up arrangements with a health professional.

5. Governance

Clear governance arrangements should be in place, so that legal responsibility for the consequences of self-testing are established. In most cases this responsibility will rest with the manufacturer of the test.

Thank you for the opportunity to provide feedback. Please contact Mr Stephan Groombridge, Manager, eHealth and Quality Care on (03) 8669-0544 or at stephan.groombridge@racgp.org.au if you have any queries.

Yours sincerely,



Dr Harry Nespolon
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