

2 December 2019

IVD Reforms
Medical Devices Branch
Therapeutic Goods Administration
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RE: Review of the regulation of certain self-testing IVDs in Australia

Thank you for asking the Royal College of Pathologists of Australasia (the College) to comment on the above.

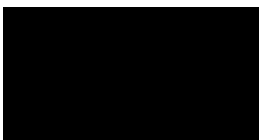
The College is firmly of the opinion that Genetic tests should not be allowed to be marketed directly to consumers. Please see attached a copy of the RCPA Position Statement on this issue.

Most genetic diseases are multifactorial, have complex genetics and biology, low prevalence or low penetrance requiring medical interpretation. Even if there is analytically accurate genetic test available the interpretation must be done in context which requires a medical consultation. Accordingly, the College considers the potential risk of mis-diagnosis and mis-management of genetic self - testing greatly outweighs the potential benefits of greater personal autonomy. The focus should on increasing access to professional genetic services in Australia to counter the increasing use of unregulated overseas testing.

For serious life threatening diseases such as cancer and Myocardial Infarction the patient should be seeking medical care not entertaining self testing. The personal risks are too high and outweigh any perceived benefits. MI testing by paramedics in ambulances is more appropriate. Promoting self - testing that has the potential for serious harm should be prohibited.

With regards to self-testing of infectious diseases, it would be useful to see if there is any evidence that HIV self-test availability has been useful. Has it actually increased the overall rate of HIV testing, and has it reduced the number of undiagnosed cases of HIV in Australia? If there is good evidence, then perhaps self-testing for influenza could be considered. Often during influenza season, it can be hard to get into a doctor's surgery to have a test for influenza, which adds a delay to obtaining antiviral drugs. Self-testing could also help less severe cases from needing to see a doctor. One possible disadvantage of self-testing for influenza would be less notifications to State Health departments (which currently occurs with pathological diagnoses of influenza).

Yours faithfully



Chief Executive Officer