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AMA Submission to the Therapeutic Goods Administration – review of regulation for certain self-testing in-vitro diagnostic medical devices (IVDs) in Australia

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Introduction

Thank you for the opportunity to provide feedback on the TGA's proposal to determine whether current prohibitions on certain self-testing in-vitro diagnostic medical devices (IVDs) should remain. The AMA in 2015 supported the TGA's performance requirements and risk mitigation strategies for HIV point-of-care tests and self-tests. The AMA assumes from the discussion paper that regulation would be similar to that in place for HIV self-testing, however the AMA requires more detailed information on the proposed performance requirements and risk mitigation strategies for the IVDs specified in the *Therapeutic Goods (Excluded purposes) specification 2010* under the *Therapeutic Goods Act 1989* to more comprehensively assess the consequences of these regulatory changes. The severity of risks and potential implications vary depending on the nature of the disease being tested for. The AMA believes that clinically supervised testing should remain the primary mode of testing.

The AMA recognises that consumers are currently able to bypass the prohibition outlined in the Act by purchasing self-testing IVDs of variable quality online from overseas suppliers. The AMA has concerns about the use of unregulated devices which have not had their quality, safety and performance evaluated. Poor quality and inaccurate self-testing IVDs can have significant consequences, posing risks to individual and population health. The fact that there are these risks, and that people are already accessing self-testing IVDs, suggest that such devices should be subject to TGA approval.

However, even with TGA quality-control, the AMA believes that the potential of self-testing devices can only be safely and confidently realised if there are further regulations and safeguards in place which extend beyond the scope of TGA authority. The AMA believes that there must be clinical confirmation of test results, monitoring of outcomes of usage, as well as information available to self-testers about counselling, care, treatment and prevention services. Strategies should also be undertaken to educate at-risk populations regarding the availability of TGA approved self-testing devices, and the risks of using products obtained illegally or from online

suppliers. The TGA needs to be appropriately funded to ensure pre- and post-market compliance monitoring occurs in a safe and efficient timeframe.

While the TGA may be in a position to require packaging and/or inserts that provide information on local care and support, matters related to public education, the clinical confirmation of test results and population level monitoring of outcomes would lie outside the scope of TGA activity.

General points

Self-testing IVDs may convey complex information to consumers. Self-testing relies on a consumer that has:

- a certain level of health literacy,
- the ability to read and understand test instructions,
- the ability to perform the test properly, and
- the ability to accurately interpret the results.

While the above may be within the capabilities of some of Australia's population, it will not be for all. This will undermine the reported potential benefits of self-testing that the TGA has outlined in its discussion paper. It is essential that self-testers understand the limitations of these tests, the importance of seeking medical practitioner advice to confirm positive (and sometimes negative) results, and how to contact counselling and support services. It is also important that consumers are able to safely and easily carry out the test.

Manufacturers need to clearly include on labels and product information the likely risk of false positive and false negative results for self-tests. While there have been significant improvements in the sensitivity and specificity of self-tests, results are not as accurate as laboratory or point of care (POC) testing.

Self-testing does not guarantee that a consumer will report or act on a positive reading. Accompanied with the IVD kit should include linkages to care.

It is imperative self-testing does not replace clinically supervised testing, but rather augments its capacity to reach more individuals outside its spectrum of care. The uptake in self-testing and the populations who embrace it therefore requires careful evaluation and monitoring. Along with the approval of such devices, it is essential there are ongoing efforts to promote clinically supervised testing and to raise awareness about the availability of POC testing at general practices, sexual health clinics and other facilities.

The AMA agrees that if the prohibition is lifted, there needs to be cross-collaboration with Federal, State and Territory governments to ensure patient data from self-testing IVDs are kept confidential and secure. There are also concerns that consumers are not adequately informed of the terms and conditions relating to company ownership and use of their personal data (particularly genetic data). There needs to be clear informed consent processes outlined by the

manufacturer and written in legislation. This is a significant ethical issue to resolve before prohibition is lifted.

Direct to consumer genetic tests

Direct to consumer (DTC) tests for health matters are problematic as individuals might undertake a genetic test without fully understanding and appreciating the purpose and implications of the test. Further, the individual might receive test results that are inaccurate, contradictory, misleading, taken out of context and open to misinterpretation. Due to the hereditary nature of genes, the results of the genetic test have implications that may extend beyond the individual who is carrying out the test.

In the context of providing health care, genetic testing should only be undertaken with a referral from a medical practitioner. The AMA strongly encourages any patients considering using a DTC genetic test to discuss the risks and benefits of DTC genetic testing with their general practitioner (GP) first. If a patient has already undertaken a DTC genetic test, the AMA encourages them to discuss the test results with their GP.

In order to alleviate the potential negative impacts of DTC genetic testing, the AMA advocates that consumer awareness campaigns are used to highlight the risks of DTC genetic tests. Education initiatives should also be targeted at health care professionals, providing information on the risks of DTC testing and support for advising patients on the use and interpretation of DTC genetic tests.

Serious diseases or conditions

Finding out you have a serious disease or condition can be extremely distressing. The AMA believes that in these cases, testing by a medical practitioner is more appropriate than self-testing IVDs. Pre- and post-counselling for serious diseases or conditions is an important part of the treatment process that will be undermined with the use of self-testing IVDs. A false positive creates unnecessary stress.

Self-tests for infectious diseases

Self-testing can give a consumer a false sense of security. Some self-tests do not pick up on an infection if the time between contracting the disease and specimen collection is too short to produce the number of antibodies/antigens required for a positive result. For example, a person's age, the time of infection and specimen collection, and the specific influenza strain can influence the result of a POC test for influenza[1]. There should be guidelines that communicate this risk to consumers.

[1] NPS MedicineWise (2009) *Rapid tests for the diagnosis of influenza.*, Centers for Disease Control and Prevention (2016) *Rapid Influenza Diagnostic Tests.*

There is a safety concern that if a consumer feels sick enough to test themselves and have a false negative result, there is a risk that they will not follow-up with their medical practitioner and potentially pass the disease on. Conversely, a consumer with minimal/no symptoms who may not otherwise seek attention may do so due to a positive result. While the TGA states that early screening for influenza may reduce demand on general practices, there are diseases of equal or greater concern that exhibit similar symptoms to that of influenza and require medical attention. As a result, it should be encouraged that the consumer visits their usual GP for flu-like illnesses.

GPs typically test for multiple sexually transmitted infections (STIs) in the same consultation and provide sexual health counselling to their patients. However, this will be lost if individuals who self-test for a single STI do not seek advice from their medical practitioner. This is particularly concerning as there is currently an increase in syphilis incidence[2] and an increase in multi-resistant gonorrhoea[3]. A net negative public health outcome could occur if GP advice and treatment is not sought.

Conclusion

The AMA believes that clinically supervised testing should remain the primary mode of testing. However, the AMA recognises the risks of consumers purchasing self-testing IVDs online from overseas and therefore supports in principle the regulation of certain self-testing IVDs for infectious diseases. The AMA has outlined several risks that need to be mitigated before lifting the prohibition can be considered. The AMA requires further detail into the performance requirements and risk mitigation strategies of specific self-testing IVDs. The AMA opposes allowing self-testing IVDs for DTC genetic tests, and tests for serious diseases or conditions and maintains that testing should only be undertaken with a referral from a medical practitioner. Further campaigning on the risks of using self-testing IVDs not approved by the TGA should occur.

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[2] Department of Health (2019) *Pregnancy care guidelines: Syphilis*.
[3] Lahra, M et al (2017) *Australian Gonococcal Surveillance Programme Annual Report.*