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Dear Professor Skerritt,

I am writing to provide comments to the Therapeutic Goods Administration's *Review of the regulation of certain self-testing in vitro diagnostic medical devices (IVDs) in Australia*. As you are aware, AFAO was strongly supportive of the TGA's decision to remove HIV self-testing IVDs from the Excluded Purposes Specification in 2014 and welcomed the registration of the first HIV self-test in Australia in late 2018.

AFAO's strong view is that:

- Australia's regulatory arrangements for diagnostic medical devices must better recognise the expectations of consumers greater control, convenience, access and autonomy in their healthcare
- safety, usability and performance – both pre- and post-registration – must be rigorously assessed to protect confidence in Australia's regulatory regime
- these imperatives must be upheld alongside equally vital requirements for rapid and convenient access to new technologies
- greater weight must be given by the TGA to the public health value of new technologies in providing new pathways for people with undiagnosed infection to become aware of that infection and seek healthcare
- risk mitigation approaches should be carefully calibrated so as not to obviate this public health value
- greater input from consumers in regulatory decision-making on consumer-controlled technology is required to ensure a diversity of perspectives and countervail professional biases and interests.

AFAO strongly urges the TGA to allow the legal supply of self-tests for infectious diseases, including HIV, in Australia.

The fourth *National STI Strategy 2018-2022* highlights that STIs remain a public health challenge in Australia. Over the past five years, the prevalence of some STIs has continued to rise in several priority populations. Increased rates of infectious syphilis in gay men and Aboriginal and Torres Strait Islander people, increases in gonorrhoea in gay men and gonorrhoea and chlamydia in young people are of significant concern[1]. Removing barriers to convenient and frequent testing is critical in supporting the early diagnosis and treatment of STIs within priority populations. Early diagnosis and treatment offer individual benefit and additionally interrupts the cycle of onward transmission.

The most recent data, from 2017, shows there was a total of 100,775 chlamydia notifications, 28,364 gonorrhoea notifications and 4,398 syphilis notifications in Australia. These data represent increases of 80% in gonorrhoea and 135% in syphilis over the previous 5 years[2]. While chlamydia notifications have historically remained relatively stable, there has been an increase of 13% since 2015. To address this issue, STI testing must be easier and more convenient. Allowing STI self-tests to be considered for registration would open new avenues STI testing access.

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1 Department of Health (2018) Fourth National Sexually Transmissible Infection Strategy, available at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1//$File/STI-Fourth-Nat-Strategy-2018-22.pdf

2 Kirby Institute (2018) HIV, viral hepatitis and sexually transmissible infections in Australia: Annual surveillance report 2018, available at: https://kirby.unsw.edu.au/sites/default/files/kirby/report/KI_Annual-Surveillance-Report-2018.pdf

STIs are often asymptomatic, particularly in women. Chlamydia is only symptomatic in an estimated 25% of women and up to 50% of men[3]. Many men and most women with gonorrhoea are asymptomatic or have very mild symptoms. Untreated STIs can lead to direct and indirect complications including pain and discomfort, ectopic pregnancy, foetal and neonatal death, pelvic inflammatory disease, infertility, facilitation of HIV transmission, and neurological disease. Social stigma of STIs creates barriers to people accessing testing and treatment. As well as tackling the issue of untreated STIs, self-testing for STIs may also normalise testing for these infections, which in turn may decrease stigma and fears attached to STI screening.

Studies from Europe and the USA confirm that self-testing for STIs is a feasible approach for both men and women from a variety of settings, including high risk, low income, and resource-poor communities[4]. For most individuals, self-collection and testing of urine or vaginal specimens at home has been shown to be considered by users as an easy, acceptable, and often preferred method of testing over testing at a clinic[5,6]. Improvements in testing rates for STIs could, therefore, be achieved with self-testing technologies. Making self-tests available may encourage individuals with less access to clinical care, who may not otherwise be tested, to self-test for STIs. In almost all studies related to STI self-testing, higher testing rates were achieved in both men and women with self-tests when compared to STI testing in clinics[7].

In recent years many STI self-testing technologies have improved with greater sensitivity and specificity being achieved. Increased sensitivity of diagnostic techniques facilitates self-sampling and sampling in non-clinical settings[8]. Studies among men who have sex with men have reported the acceptability and validity of self-collected rectal and oropharyngeal specimens and the willingness to collect these specimens at home[9]. Self-testing kits for STIs have been shown enhance personal comfort and empowerment[10]. Other studies have also shown the feasibility and acceptability of home collection of oral fluids, dried blood spots (DBS) and telephone results[11].

In the call for submissions, the inclusion of HIV self-tests on the ARTG is provided as an example of an IVD technology where the potential benefits outweigh the residual risks. In this instance, the inclusion of an HIV self-test on the ARTG has allowed for an increase in the overall rate of testing for HIV and a reduction in the number of undiagnosed cases of HIV in Australia. While we note that overly conservative risk mitigation is precluding the optimal take-up of HIV self-testing, the same logic can be applied to IVDs that can detect STIs and other BBVs such as chlamydia, gonorrhoea, syphilis and viral hepatitis. As such, the TGA should remove any regulatory barriers preventing these technologies from entering the Australian market.

Yours sincerely

Chief Executive Officer

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3 Department of Health (2018) Fourth National Sexually Transmissible Infection Strategy

4 Shih, S. et al. (2011) Screening for STIs in the home or in the clinic?, *Current Opinion in Infectious Diseases*, 24(1): 78-84.

5 Andersen, B. et al. (2002) Population-based strategies for outreach screening of urogenital chlamydia trachomatis infections: a randomised controlled trial, *Journal of Infectious Diseases*, 185(2): 252-258.

6 Ostergaard, L. et al. (1998) Efficacy of home sampling for screening of chlamydia trachomatis: randomised study, *BMJ*, 317(7150): 26-27.

7 Shih, S. et al. (2011) Screening for STIs in the home or in the clinic?, *Current Opinion in Infectious Diseases*, 24(1): 78-84.

8 Wayal, S. (2011) Home sampling kits for sexually transmitted infections: preferences and concerns for men who have sex with men, *Culture, Health and Sexuality*, 13(3): 343-353.

9 Ibid.

10 Llewellyn, C. et al. (2009) Are home sampling kits for sexually transmitted infections acceptable among men who have sex with men?, Journal of Health Service Research and Policy, 14(1): 35-43.

11 Wayal, S. (2011) Home sampling kits for sexually transmitted infections: preferences and concerns for men who have sex with men, *Culture, Health and Sexuality*, 13(3): 343-353.