Consumers Health Forum of Australia

SUBMISSION

Therapeutic Goods Administration Consultation: Review of the regulation of certain self-testing IVDs in Australia

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Submission to the Therapeutic Goods Administration Consultation: Review of the regulation of certain self-testing IVDs in Australia.
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Introduction

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in health care consumer affairs. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

Robust regulatory systems are essential in ensuring the safety of consumers who use medicines, and in addressing any issues quickly when they arise. The Therapeutic Goods Administration (TGA) plays a pivotal role in ensuring the medicines available to consumers meet and uphold community expectations and Australian regulatory standards.

CHF appreciates the opportunity to provide feedback to the review of the regulation of certain self-testing IVDs in Australia. Our response to the consultation following discussion with our Members is below.

Consultation Questions

Infectious Disease Self-testing IVDs

Considering the experience with HIV self-testing should self-tests for other infectious diseases be supplied and used in Australia subject to appropriate risk mitigations? Are there any tests for particular infectious diseases that should not be available as a self-test? Please provide reasons why not. Do you have any additional suggestions on how potential risks to consumers could be mitigated if self-tests for other infectious diseases were allowed to be supplied in Australia?

After consultation with our Members we believe that self-testing IVDs for infectious diseases should be supplied and used in Australia. We do not believe there are any particular infectious diseases for which self-testing should be prohibited. We believe that on balance the benefits of self-testing will outweigh the risks. It will help reduce the predicted high numbers of people who have an infectious disease but are undiagnosed, for example there are an estimated 100,000+ people in Australia who have Hepatitis but are currently undiagnosed. The option of self-testing may help reduce the numbers of people who are currently infected but undiagnosed. In addition, it will provide an easy, convenient and affordable way for people to be tested if they are exposed to an infectious disease, for example if their sexual partner notifies them of an infectious disease diagnosis. This will be particularly valuable for those who are not comfortable being tested clinically based on their initial concerns about potentially being infected, whether for social, cultural or stigma reasons.

There are several risk mitigation strategies that we suggest would, at a minimum, need to be required for self-testing kits. Firstly all self-testing kits must instruct the user to speak to a doctor to get a confirmatory clinical diagnosis and discuss treatment options should they test positive on the self-test kit. Secondly all self-test kits must come with consumer co-designed instructions that clearly explain how to operate the self-test kit and interpret the results.

Thirdly campaigns aimed at both consumers and health professionals should be run to ensure both parties are appropriately equipped and supported to respond to the results of self-test kits.

Genetic Self-testing IVDs

Should Direct to Consumer Genetic Tests be permitted in Australia (following evaluation by the TGA) to provide consumers with an alternative to overseas testing which has not been evaluated by the TGA for its quality and performance? Are there any particular genetic tests that should not be available as a self-test? Please provide reasons why not. Do you have any suggestions on how potential risks to consumers could be mitigated if genetic self-tests were allowed to be supplied in Australia?

After consultation with our Members, the CHF is unable to give a definite 'yes' or 'no' answer as to whether direct to consumer self-genetic testing should be provided in Australia. This is because the consumer organisations that CHF represents currently have differing views on the issue. As such we believe that the TGA will need to do further, targeted consultation on this question to properly develop a regulatory framework that meets consumer needs in the current global market.

Some CHF Members believe that direct to consumer genetic tests should continue to be prohibited by the TGA. They note that while the other self-testing IVDs being considered in this consultation test for the presence of a disease, illness or condition in an individual; genetic testing tests for both the presence of those things and potential susceptibility to those things. Not only in the individual being tested but also those with whom they have a genetic relation. In addition, the results of test for genetic illnesses, such as Lynch Syndrome, are very complex and can be misinterpreted- potentially leading to incorrect diagnosis, management and regimes. Due to these factors, it is the position of these CHF's Members that pre-test and post-test counselling and support from a health professional such as a Genetic Counsellor is required for genetic illness diagnosis. And as such they believe self-testing IVDs should remain prohibited. In addition, given the availability of overseas tests of unknown quality, as noted in the TGA Consultation paper, these CHF Members believe that the TGA should partner with consumer organisations to co-design a campaign and materials that discuss the potential risks and pitfalls these un-reviewed overseas tests can present.

However, on the other hand, due to the existence of those overseas tests some CHF Members believe that "the genie is out of the bottle" and the current prohibition should end. They argue that consumers only having access to uncontrolled, un-reviewed overseas tests with questionable levels of accuracy and reliability poses a greater risk than allowing for direct to consumer genetic tests to be permitted for use in Australia. These CHF Members believe that by having tests to go through the TGA approval process to be permitted in Australia then at least consumers will not be relying on substandard overseas products that may give incorrect results. However further resources will need to be allocated to help educate and empower consumers to respond to the results of genetic self-testing given the complexity of genetic conditions. This would include a campaign to inform consumers about the risks of using un-

reviewed overseas kits in comparison to the kits reviewed and approved by the TGA. In addition manufacturers and sponsors should be required to co-design with consumers robust post-market systems that ensure consumers who use self-testing devices are given appropriate information, recommendations and instructions in language they understand that minimises the potential risks self-testing kits may pose due to levels of health literacy around genetics.

CHF Members raised an additional concern that direct-to-consumer genetic tests will not be "do it at home and get a result in 15 minutes" test kits, as with the other self-test IVDs in this consultation, but will require consumers to send their genetic data off to a laboratory for analysis. If this is the case, then there are additional concerns about issues such as the reliability of those labs, NATA accreditation, data storage and data security that already apply to broader consumer genetic testing that will also need to be resolved. If adequate provisions are not put in place to protect consumers and their genetic data, then the risks of these test could very likely outweigh potential benefits.

It was also noted how poorly resourced services like Genetic Counsellors currently are in Australia and CHF Members questioned whether the current system would be able to adequately cope with the increased numbers of testing, diagnosis and treatment that self-testing kits would result in. Although we acknowledge that those concerns are outside the direct scope of the TGA, we would urge the TGA to collaborate with relevant health agencies to ensure appropriate resourcing and services are available should direct to consumer testing become available.

Serious Disease Self-testing IVDs

Should self-tests for serious diseases be able to be supplied in Australia following evaluation by the TGA to determine their safety and performance? Are there any particular tests for serious diseases that should not be available as a self-test? Please provide reasons why not. Do you have any suggestions on how potential risks to consumers could be mitigated if self-tests for serious diseases were allowed to be supplied in Australia?

After consultation with our Members we believe that self-testing IVDs for serious diseases should be supplied and used in Australia. We do not believe there are any particular serious diseases for which self-testing should be prohibited. We believe that on balance the benefits of self-testing will outweigh the risks.

As with infectious disease self-test IVDs. there are several risk mitigation strategies that we suggest would, at a minimum, need to be required for serious disease self-testing kits. First all self-testing kits must instruct the user to speak to a doctor to get a confirmatory clinical diagnosis and discuss treatment options should they test positive on the self-test kit. Second all self-test kits must come with consumer co-designed instructions that clearly explain how to operate the self-test kit and interpret the results. Third would be running campaigns aimed at both consumers and health professionals to ensure both parties are appropriately equipped and supported to respond to results.

Additional Feedback

Based on the experience of HIV self-testing CHF Members shared, the restrictions on advertising self-tests need to be reviewed to ensure that they permit appropriate levels of awareness raising. The restrictions on the HIV self-testing kits are severely hampering the ability for organisations to raise awareness about the existence of the option to self-test. Particularly in vulnerable communities who are at risk of diseases or illnesses but may not be comfortable commencing with a clinical appointment. This has a two-fold negative effect- firstly consumers who would benefit from self-testing are unable to use the testing kits and secondly manufactures can struggle to produce the self-test kits in an economically sustainable manner. While the CHF strongly supports the current prohibition on direct to consumer advertising by manufacturers and sponsor of medical devices, we believe that there is a need for consumers to be made aware about the existence of self-testing IVDs as they become available. As such we believe that the TGA should partner with consumer organisations to develop public awareness campaigns and materials as self-testing devices become available in Australia that do not promote any specific devices, products or brands but raise awareness of the concept of self-testing kits both generally and for specific illnesses or conditions.

In addition to the above, it is essential that self-testing kits be made as widely available as possible. Based on feedback from CHF Members, we believe that the restrictions applied to HIV self-testing kits that limit the number of locations they can be purchased are counterproductive and not acceptable for those self-test kits or other self-testing kits. The aim should be to have these kits as widely available as pregnancy tests, or at least in every pharmacy as well as through online retailers. Not only will wide availability aid in the normalisation of self-testing, having them available in places such as pharmacies will give consumers the option to speak with a health professional if they wish to get assistance or advice at the point of purchase. Alternatively, by having them widely available online consumers who do not wish to speak to a health practitioner at the early stages of this process will have that option. For both scenarios, we would strongly encourage the TGA to require the involvement of consumers and consumer organisations, as well as health professionals and device sponsors, in the process of designing instruction material for self-testing IVDs to ensure that consumers are able to properly and effectively use them without problems.

Much of the feedback we received from our Members related to concerns about the accuracy, precision and reliability of self-testing kits potentially being substandard and leading to high incidences of false positive or false negative tests. While these are fair concerns to have, we don't believe that such concerns warrant continued prohibition of self-testing. More specifically, we have confidence that the regulatory framework TGA uses to assess whether medical devices are to be permitted for distribution in Australia will ensure that any self-testing IVD is appropriately accurate, precise and reliable to minimise the risk of false positive and false negative results. The CHF would suggest that many of these current concerns relate to uncertainties and questions about existing self-testing technology while the proposed regulation change considers self-testing technologies that may developed in the future. As

such we commend the TGA for thinking ahead and "future proofing" the regulations in this manner rather simply regulating in a reactionary manner based on the current state of play.

As mentioned in the genetic-self-testing section, an assumption of this response that approved self-testing IVDs will operate in the same manner as the HIV self-test kits or pregnancy tests. Namely that a consumer will be able to do the test at a time and place of their convenience and then receive a result directly from the kit within a short period of time. With there being no requirement of the consumer to collect a sample and then send it away to another location to be tested and have the result sent back to them. Should this not be the case and such "sample collect and send" self-test kits are considered for provision in Australia, then there will need to be explicit regulations developed around items such as the ownership of such samples and the results data, how samples and data are securely stored by the location that does the testing etc.

A strong theme that emerged from CHF Members was a response to a perception that self-testing kits were currently prohibited, and may continue to be prohibited, because the TGA or health professionals believed that consumers could not be trusted to use to them properly. That consumers would react in an "unsafe" manner if a self-test result was positive and they did not have a health professional present for immediate discussion. While the CHF does not believe the TGA or health providers necessarily hold this view, we note that that consumers should be empowered in their healthcare and not given paternalistic "protection". In this context this includes not only being given access to self-testing kits but being given the ability to confidently and appropriately use them. While we acknowledge that Australia does have low levels of health literacy, the solution to this is not to prohibit products "for the consumers own good" but to educate and empower consumers to improve their health literacy and be actively involved in their own healthcare.

Finally, despite the importance of this proposed regulatory amendment to the consumers many of CHF Members represent none of the CHF Members we contacted to get input for our submission were aware of this consultation. We found that lack of awareness to be quite concerning and suggestive that more work is needed by the TGA to raise the profile of its public consultations amongst the wider public.