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TGA Review of the regulation of certain self-testing in vitro diagnostics medical devices (IVDs) in Australia – Consultation.

Pathology Technology Australia Ltd - Response

3 December 2019

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Pathology Technology Australia Ltd is the peak body representing the developers, manufacturers and suppliers of technology used for testing human health in medical laboratories, hospitals, community settings and at home.

Introduction

Pathology Technology Australia and its members sincerely appreciate the opportunity to respond to this consultation process and look forward to further discussion on the topic as opportunities arise.

As a general principal Pathology Technology Australia supports the Australian Government's deregulation agenda – ***that regulations only be imposed where absolutely necessary and should not be the default position for dealing with public policy issues*.**

We also agree that a review of the prohibition on the supply of certain self-testing IVD devices is necessary; with the objective of relaxing some of the conditions, while at the same time, minimizing the risk of harm to the Australian public through various measures.

We agree that availability of suitable technology, increased affordability of devices and the global nature of communications and the supply chain; mean that Australians can obtain devices and testing services from outside the regulator's jurisdiction. We view this as problematic and having several potential negative consequences; not the least of which are harm to the public and loss of confidence in the legitimate IVD industry.

It is with these comments in mind that the members of Pathology Technology Australia generally support the removal of the current prohibitions and favour bringing self-testing in under reasonable regulation. At the same time, we support a system where members of the public are encouraged to and can easily report adverse outcomes related to the use of these devices (physical or software) be they regulated or not. In this way the industry (suppliers and regulators together) can better assess the actual risks and deal with those as a priority. Pathology Technology Australia would also appreciate being part of a system for validating the performance of self-testing technology – to ensure a reasonable balance between the risks and the benefits. In our opinion, overly onerous regulatory requirements will drive the unregulated self-testing device supply chain.

If TGA decides to relax the prohibition, we believe this gives an opportunity for a clear educational campaign directed to the public and made available on-line, in medical clinics, through professional medical associations and through health consumer groups.

The educational campaign should address the importance, when conducting self-testing, of;

- Discussing this with a healthcare professional
- Only use devices registered with the TGA; indicating how this can be confirmed
- Be aware that their personal information and health results should be safeguarded (including the potential dangers of sending samples for genetic testing)
- Know how to access the adverse event reporting service of self-testing devices (be they registered or not).

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A further initiative which may be implementable through My Health Record could be that individuals can register the results of self-testing in their own records.

PTA has consulted with other stakeholders such as RACGP, CHF and the Pharmacy Guild. Of note here is that PTA and CHF are broadly in agreement with the approach outlined in this submission.

In addition to self-testing, it may also be worth mentioning that our members strongly support the use of self-collection devices; especially for reasons of cultural diversity, personal values and in remote settings. Self-collection devices for tests ordered by a healthcare professional should remain included on the ARTG and should come with clear instructions and evidence of usability testing in a real-world setting. This may offer an alternative to consumers considering the use of a self-testing device.

Specific Response to the Consultation

- ***Following evaluation by the TGA to determine their safety and performance, and considering the experience with HIV self-testing, should:***

  - ***self-tests for other infectious diseases;***
  - ***genetic self-tests (i.e., direct to consumer genetic testing);***
  - ***self-tests for determining the presence of other serious diseases (e.g., cancer, diabetes);***

  be able to be legally supplied in Australia subject to evaluation and approval by the TGA with appropriate risk mitigation strategies?

  YES – Pathology Technology Australia believes there is a role for more self-testing devices. There should be no general prohibition as such; but there does need to be appropriate review of device performance, a reasonable medical need and enough guidance and support for consumers to safely use the device. Self-test devices should be subject to TGA assessment and registration. Where a device is already registered for professional use; suitable demonstration of safety and robustness needs to be demonstrated for a self-testing application. All self-testing devices should come with a strong suggestion for the user to seek professional advice; be that from a community clinic, a GP or appropriate HCP.

- ***Are there any particular tests that should not be available in Australia as a self-test? Please provide reasons why not.***

  Pathology Technology Australia agrees with the stance taken by certain EU countries regarding genetic sequencing self-testing for disease susceptibility, heritability or serious disease diagnosis. Consumers should be strongly encouraged to contact their healthcare professional if contemplating such tests. There should also be strong messaging around the dangers of using devices or services (not accredited in Australia) for such self-testing.

- ***Do you have any suggestions on how potential risks to consumers could be mitigated?***

  Pathology Technology Australia has several suggestions to reduce risk and set consumer expectations correctly:

  1) There should be a requirement to demonstrate the public or personal health benefits of a new self-testing device. There should be reasonable evidence of the benefits to the consumer or the public, over and above the benefits of having the same test performed in the community setting (PoC test), hospital or private pathology lab. Benefits might include the importance of timely testing, accessibility to testing when there are cultural or confidentiality barriers, the remote location of a consumer and broader public health interests.
  2) The test's performance in the hands of a typical self-test user, needs to be demonstrated via performance studies. For tests where an erroneous result has significant risk, approval must be conditional on the performance data showing that the risk of an erroneous result is low (as per Essential Principle 15).
  3) Approved self-testing devices need a straightforward IFU included with the test device. We also suggest use of current communication tools such as in-home smart devices, monitored email, websites and social media platforms (including links to professional advice services) to provide instructions and follow up information to the consumer.
  4) Technology can be leveraged – wherever possible - to provide feedback to disease surveillance programs / notifiable disease registers.
  5) When possible, consumers should be encouraged to record results of any self-test into their own My Health Record.
  6) There needs to be simple to use adverse event reporting services established where consumers can report facts on their adverse outcome. This needs to accommodate reporting on registered and unregistered devices and should facilitate upload of pictures and relevant documents. GPs and other healthcare professionals also need to have access to this service.
  7) There should be a broad-based educational campaign through multiple channels to address the important issues around self-testing and to set the correct expectations.
  8) We suggest a review of the current restrictions on advertising devices to ensure education and awareness campaigns can be effective.

<u>Further Commentary on Each of the Consultation Topics</u>

Self-testing for other infectious diseases

With the registration and successful use of a self-test device for HIV, it seems reasonable to open this up to suitable technology for self-testing all infectious diseases except those of very low prevalence in Australia (less than 1 in 100,000 cases detected per year). We agree that there is both a personal and a public health interest in making such self-testing available. As a minimum we would want to see self-tests available for the commonly occurring hepatitis viruses, STI's, respiratory, gastrointestinal and travel-acquired blood borne infections; for example, malaria. Where such self-test devices may exist in the future; and in addition to self-collect; we would also support self-testing for entities such as papilloma virus - even though this has a high correlation to cervical cancer. This is analogous to Hep C self-testing, even though there is a relatively high causal link to liver cancer.

Further detail would need to be provided on how this would impact ARTG inclusions which are currently subject to restricted representations for the purposes of advertising to consumers.

With emerging technologies for discriminating viral versus bacterial infections of the respiratory tract, important opportunities arise to access early intervention for influenza and reduce unnecessary antibiotic use for self-limiting respiratory viruses. Also providing an opportunity to reduce unnecessary antibiotic use.

All devices for self-testing infectious diseases need to reach a level of benefit that outweighs those arising from the in-field user error rates. The risk verses benefit approach should be addressed in the previously mentioned educational programs (setting correct expectations about the use of such devices). This would assist to mitigate an event where incorrect results are sensationalised due to the risk factors not being understood by the consumer.

Direct to consumer genetic tests (DTC GT)

There are already unregulated tests that consumers in Australia are accessing at very high rates. Ancestry testing is probably the highest single application of genomic testing globally. MIT Technology Review (Feb 2019) estimated that 26 million people world-wide have added their DNA to the 4 largest ancestry DNA databases; and that this number will reach 100 million within 24 months. Anecdotally, the third most common Christmas gift in Australia for 2018 was a DNA test kit for one of the ancestry services. Likewise, there is a large (but unknown) number of prenatal genetic tests performed when Australian mothers-to-be send their sample to local and overseas testing services.

Nucleic acid testing technology is moving extremely fast so we need to take care not to lock out potentially useful – direct to consumer IVDs – by a new prohibition regulation that could sunset in 2030. At the same time, we are very mindful of the complexities of genetic testing for disease susceptibility, heritability or to diagnose a serious disease. Whilst ancestry is not a therapeutic outcome there are already the beginnings of genetic tests looking at diseases as an extension of this, and the public will be quite accustomed to sending their sample away for a result (as exemplified on recent free to air TV morning shows).

Our recommendation is to follow along the lines of certain European countries when it comes to genetic sequencing for disease susceptibility, heritability or serious disease diagnosis. Even with this constraint, self-collection devices need to be readily available, especially for reasons of cultural diversity, personal values and in remote settings.

However, we recommend leaving open the opportunity to use nucleic acid testing technology that might facilitate self-testing for infectious diseases, especially in areas of viral versus bacterial infections.

Self-test for other serious diseases or conditions

In the opinion of our members, serious disease such as most cancers, are often complex in nature and we do not generally support self-testing.

We do support self-collection devices for these conditions for the reasons discussed previously.

Some of the other serious conditions, such as diabetes, kidney disease and heart diseases – especially chronic conditions - might well benefit from some self-testing devices when available. Use of self-testing devices in these conditions might lead to early detection and treatment, reducing the overall cost of disease management.

Consumer empowerment in their own healthcare can also lead to a better understanding and awareness of their condition and taking greater responsibility for their own healthcare outcomes. There is evidence of such in the PrEP cohort of men at high risk of HIV.

For diabetes, in addition to glucose self-testing, there is already good acceptance of HbA1c as a diagnostic and monitoring test and may be a future candidate for a self-testing application.

Likewise, for the Acute Coronary Syndromes, self-testing devices might not be too far away. The rule-out applications of this are obvious in remote settings and where professional medical intervention may require costly air evacuation.

Finally, for Kidney disease, urine dipsticks to measure urine protein and albumin have been available for almost 50 years. It is likely that fingerstick creatine and calculated eGFR, or other markers of kidney health, will be suitable for self-testing.

Summary

Pathology Technology Australia supports the removal of prohibition on certain self-testing devices. We do so for several key reasons, and by making key recommendation:

1. The logic for removal of prohibition on HIV self-testing applies to all common infectious diseases.
2. Consumers have access to completely unregulated testing devices and services already.
3. We run the risk of these unregulated devices and services causing harm and or loss of confidence in regulated devices and services.
4. Registration requirements for self-testing devices need to follow a risk-based evaluation system like that already established under the current regulations.
5. Technology and communications are advancing at pace and if we don't harness the best these have to offer now, we are likely to lose the opportunity.
6. Where we see the need for caution is in the use of human genome sequencing for genetic testing and diagnosis of serious conditions.
7. There is a need for widespread education and public awareness, which can be facilitated through current communications and social media platforms.
8. Users of self-testing devices should be strongly encouraged to do so in partnership with a healthcare professional.
9. There needs to be a simple to use Adverse Events reporting mechanism established to accept reports of both registered and unregistered device performance.

This concludes our response.