



6 December 2019

Consultation feedback on TGA

On behalf of the Monash University Public Health Genomics program, we welcome the opportunity to provide feedback regarding the renewal of the Excluded Purposes Specification, specifically as it pertains to the regulation of direct to consumer genetic tests.

1. Our research shows that recent increases in the popularity of direct-to-consumer (DTC) testing are resulting in an increased number of referrals to Australian publicly-funded clinical genetics services. Our recent survey of 11 Australian clinical genetic services (unpublished, Monash University researcher and University of Melbourne Masters student research) demonstrated that public genetics services in Australia have received more than 100 DTC testing related referrals in the past 10 years. This has resulted in a tangible burden on these already-pressured public health services. It is expected that the frequency will increase over time, with the decreasing cost and increasing consumer access to genetic testing. Public genetics services are already limited and have long wait lists (in Victoria, for example, average wait times have been up to nine months for an appointment^[1]).

If DTC regulations are relaxed to allow for entry of DTC health testing into the Australian market, this will result in a significant increase in the strain and burden on the already resource-limited publicly funded genetics services. Further, the results of DTC genetic tests are often technically inaccurate, and cannot be validated by clinical genetic testing services. This results in wasted time, resources and unnecessary patient concern. Any such relaxation should be coupled with a requirement that genetic counselling be made available with the delivery of the test results, and that results must adhere to a basic level of technical quality.

Companies deriving profit from delivering genetic test results directly to consumers in Australia must be required to ensure that they make appropriate health professionals available for support, interpretation or explanation of genetic test results to consumers who are confused or distressed following the receipt of results. Otherwise, those consumers are likely to seek referrals from their GPs (the most common source of referrals found in the unpublished research) to public genetics services. The added burden of referrals arising from DTC genetic tests has the potential to cause detriment to Australians already faced with long wait times to see genetics specialists for clinically indicated testing.

2. In the past, there has been significant difficulty in determining how and when the Specification applies to aspects of genetic testing. It is clear that although genetic tests have been included in the IVD framework, the framework, definitions and considerations were not purpose-built for the regulation of genetic testing. As genetic testing becomes cheaper, more accessible, and more widely of interest to the general public, the regulations as they pertain to DTC testing should be reviewed to demonstrate clearly (with examples that clearly address genetic testing scenarios) how these regulations apply to genetic testing. We also suggest the implementation of a mechanism whereby clarification can be formally

[1] Victorian State Government. (2016). *Genomic health Care for Victoria - A Discussion Paper* Melbourne, VIC: Department of Health and Human Services, State Government of Victoria, accessed at <https://www2.health.vic.gov.au/about/publications/policiesandguidelines/genomic-health-care-for-victoria-discussion-paper>

sought from the TGA (at no cost) regarding the operation of the regulations in specific circumstances. Determinations arising from these requests should be published on the TGA website to allow for transparent and efficient communication of regulation application.

We urge the TGA to consider more stringent and appropriate regulation of DTC genetic testing in Australia, to avoid further increasing the burden on public health services, and causing ongoing patient/consumer concern. Poor-quality DTC genetic testing also risks damaging the public perception of medical genetic testing, at a time when public enthusiasm and consumer participation is critical to realize the many health benefits possible. We continue to pursue research in this space and will update you with further details (and formal publications) as they become relevant. We will also provide an addendum to this submission with any relevant material in the near future. Please see our previously published articles below on the topic:

Regulation of Internet-based Genetic Testing: Challenges for Australia and Other Jurisdictions
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5818403/>

Five things to consider before ordering an online DNA test
<https://theconversation.com/five-things-to-consider-before-ordering-an-online-dna-test-92504>

Yours Sincerely

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