



IVD Reforms
Medical Devices Branch
Therapeutic Goods Association
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To the IVD Reforms

CONSULTATION: Review of the regulation of certain self-testing in vitro diagnostic medical devices (IVDs) in Australia

The Genetic and Rare Disease Network (GaRDN) represents over a hundred support organisations for genetic and rare diseases, who in turn represent thousands of Western Australians.

This submission is made by GaRDN. The Therapeutics Goods Association (TGA) should consider in their recommendation the following:

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?

- Either ensure a transparent evaluation of Direct to Consumer Direct Genetic Tests (DTC GTs) for use in Australia with broad consultation including consumers, clinicians and systems/paradigms (for example health, financial, legal, privacy/consent and insurance) alongside analysis of the appropriate education pathways and resources needed to support it. This includes pre-test discussion and post-testing counselling by appropriate health professionals, clear health referral pathways and easy to understand information to inform and empower the consumer. This should also include an analysis of supply and demand of genetics professionals to meet future needs.
- Or formally issue advice to the Australian public about the use of DTC GTs in a consumer-friendly format. This should encompass the potential for harm such as physical, psychological, social, economic and legal harms. As well as clear messaging relating to the paucity of scientific evidence supporting some of the statements about health issues from companies marketing DTC GTs.

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

- Genetic tests that provide advice about health issues without adequate scientific evidence should not be available. Person-centred care is best supported by meaningful engagement between consumers and health care professionals to enable the consumer to determine whether they should have genuine concerns about results, and therefore take appropriate action if required.

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?

- Provide plain language advice through a variety of channels about the potential risks of using DTC GTs and how these risks can be minimised. For example, the risk of psychological harm from the potential outcomes of a genetic self-test may be minimised through a pre-test discussion and post-testing counselling by an appropriate health professional.
- Medical advice to accompany any genetic self-tests, as well as the inclusion of follow up services such as genetic counselling and actionable recommendations by Health Professionals to address results.

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?

- GaRDN is of the view that no DTC GTs for serious health issues should be supplied. In principle, the potential for more harm than good could be achieved by supplying these types of tests.
- While it is acknowledged that it is important to enable consumers to make an informed choice about their health and wellbeing however we view this scenario as ethically unacceptable based on the National Health and Medical Research Council (NHMRC) National Statement and other ethical codes and guidelines for research in Australia.

We are available to represent the Western Australian Genetic and Rare disease community <https://gardn.org.au/> on 0499 516 946 or hello@gardn.org.au

Yours sincerely



Genetic and Rare Disease Network <https://gardn.org.au/>

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