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

Response by Brian Wall, health care consumer advocate.

I am a member of the Consumer Advisory Panel, AGITG and of Cancer Voices SA, which is how I heard about his review, but I alone am responsible for the views and ideas expressed in this paper.

You ask for submissions to consider:

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?

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

Thank you for the opportunity to comment on this review. Unfortunately it has come to my notice late in the piece and so my comments are not as well-grounded in research as I would otherwise wish them to be, but I think there are some principles which I have applied when in a regulatory role and which I only see as being of greater important now I am a health care consumer (on a number of, indeed too many, fronts).

Apart for technical difficulty in carrying out the IVD test, which is clearly limiting when it is high, the principal (and perhaps only) criterion for assessment of whether something should or should not be made available to the public is public health benefit. We should not consider the medical model that it may disturb; or 'moral' questions, as happened with the morning-after pill at the behest of Senator Harradine. Nor should we consider whether or not it may reduce the burden on the public purse for e.g. visits to medical practitioners, or home visits by health practitioners to conduct testing, such as warfarin monitoring of elderly persons) that may be avoided by new technology; **except** that the money spent on these practices has an alternative benefit in health care or elsewhere, and should be applied where it will have most benefit.

My view is that the more freely available reliable tests for a medical condition are, the more likely it is that people will undertake testing, and that is a desirable outcome. The constraint on HIV was introduced at a time when an HIV diagnosis was a death sentence, and pre-test counselling was very desirable, and made post-test management much easier. Today no such situation exists with HIV or anything else I can think of.

Clearly a single test should never be taken as being absolutely true, and the need for a second test, usually using different technology and conducted in a structured setting is very important. I would suggest a statement to that effect should be included in all diagnostic tests for serious conditions.

I note that testing for genetic disease and genealogy are offered on the internet by all sorts of parties, many of which have some other vested interest which is not necessarily in the person's best interest, especially if the test if free or low cost. The public is often (perhaps usually) unaware of these ulterior motives. As the saying goes if you are not paying for the services you are the product. Ancestry's sale of DNA testing data to third parties like google are an example of what I consider to be mis-use of such tests, but to prohibit the practice may be akin to ordering back the tide. Public education is required, but is sadly lacking.

There may one day be an international framework regulating genealogical testing, and if there was one that would be a good thing, but in the meantime it is hard to see that we can do much more than educate the public that their genetic information is being on-sold. This is, in any case, a matter that would seem to lie outside the scope of the therapeutic goods legislation.

Similarly we would need public education concerning appropriate use of other genetic tests, e.g. for the BRCA 1 and 2 genes. With the ubiquity of the internet, it is going to be hard to prevent people who want to have this test accessing it outside the normal medical framework. What is important is that they understand the test is the beginning of a process, not the end of one. In that case of course, the next step is to seek medical advice, but it would be better if the anxiety to that point was avoided, but is perhaps impossible in the modern world. If we leave it to overseas suppliers, we have little control on the information that comes with the product. If we have it registered in Australia, we can ensure appropriate advice.

I believe the TGA should develop a decision framework for biological testing which assesses risk and benefit on a case by case basis, and restricts those where the risks *significantly* outweigh the benefits. My concern is that we have been too conservative in the past in making regulatory decisions on therapeutic goods. For example when NSAIDs were put in Schedule 3 for menstrual pain, they could not be advertised, which denied women the opportunity to know that effective treatment existed unless they happened to ask a pharmacist (hard to find in most pharmacies these days). The differences in medicines scheduling around the world today demonstrate how regulatory agencies act conservatively and inconsistently. For example, recently in the UK I saw sildenafil being sold over the counter, but in most of Europe I could not purchase famciclovir or similar treatments for cold sores without a prescription. It is hard to see a good public health reason for these differences. It comes down to value systems in the regulatory agencies and governments that have little basis in health science.

In the case of IVDs I believe they should be made available in every case I can think of (but I concede there may be compelling public health arguments to the contrary in a few cases) **and** be accompanied by readily accessible and reliable public information including advice that:

- a positive diagnostic test for a serious condition always needs confirmation, and
- it is only the beginning of a diagnostic work up not the end of one.

I believe the great weight of public benefit would lie with ready access to IVDs under Australian regulatory control rather than direct importation of overseas product or, very often, failure to access the test at all. In the case of infectious disease in particular, this may have serious negative consequences.

Thank you for considering my submission.

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20 November 2019.