

## **AMA submission on the NH&MRC Draft Statement and Resource for Consumers: Direct-to-Consumer Genetic Testing submission (June 2014)**

### **Q1. Is the draft Statement presented and written in a manner that is easy to understand?:**

Yes. The AMA particularly supports the three elements identified by the NHMRC as integral to the appropriate delivery and use of health-related genetic testing:

- professional involvement and education;
- a robust evidence base;
- consumer information and support.

We commend the NHMRC's emphasis that potential DTC genetic test consumers should consult their General Practitioner before initiating DTC testing, to consider the implications for themselves and their family.

### **Q2. Is the draft Statement comprehensive and does it cover all of the key issues?:**

The Statement is comprehensive and strikes a responsible balance between recognising the rights of consumers to use DTC genetic tests and emphasising the inherent challenges and adverse implications posed by such testing. The AMA strongly agrees with the NHMRC's statement that 'genetic tests should be underpinned by robust evidence about their role in clinical care. This means that the use of a genetic test should lead to clinical decisions that improve patient outcomes.' We commend the NHMRC in stating that 'Most DTC tests are still research activities and, at this current time, are of questionable and unestablished clinical value.'

### **Q4. Is more advice needed in the draft Statement on legal risks, risk rated insurance or privacy issues?:**

It's important to highlight the risk of using DTC genetic testing on family members who cannot consent on their own behalf (eg., children, adults with impaired decision-making capacity). Should DTC genetic tests allow 'substitute consent' for testing, the tested individual will have to contend with the relevant privacy issues, including issues related to insurance, in the future.

### **Q5. Is more advice needed in the draft Statement on the usefulness of DTC genetic testing?:**

It's important to include the following information from the consumer information resource into the Statement as well - 'Due to the possible problems with accuracy and quality of DTC tests, your doctor will not be able to use it as the basis for health advice.' This is important to clarify in the Statement as consumers may not understand why a doctor cannot use DTC test results (eg., inaccuracy, not reliable, wrong test, etc.) Further, DTC genetic tests may also cause additional financial burden to the consumer if they have to pay for repeat tests through the Australian healthcare system.

**Q1. Is the draft Resource for Consumers presented and written in a manner that is easy to understand?:**

Yes. The draft resource will be a useful tool for assisting patients to discuss DTC genetic testing with their doctors.

**Q2. Is the draft Resource for Consumers comprehensive and cover all of the key issues?:**

As above, it is important to briefly address the issue of 'substitute consent' for DTC genetic tests (eg., a parent using DTC genetic testing for their child). Even if many DTC genetic tests do not currently allow 'substitute consent', it may happen in the future and the surrogate needs to understand the ethical and legal implications for the person on whose behalf they have consented.

**Q3. Is there any further advice that should be included in the draft Resource for Consumers on the accuracy of DTC genetic testing?:**

Yes, there are several issues raised in the draft Statement that would be very useful to also include in the information resource to ensure consumers are better informed when deciding on DTC genetic testing; for example,

- briefly address the role and importance of various health professionals, including medical practitioners, clinical geneticists, and genetic counsellors, involved in the genetic testing process. This may help consumers understand the complexity of genetic testing and that appropriate support is important to understand test results and their implications;
- emphasise that professional involvement is important in providing individuals and their families with balanced information and an appropriate clinical context;
- reiterate the statements that 'most DTC tests are still research activities and, at this current time, are of questionable or unestablished clinical value. International reports on DTC testing have found that consumers can sometimes be provided with misleading information and interpretations that are of little or no practical use; DTC genetic testing companies have been found to return different interpretations of the same DNA sample, due to different analytical or post-analytical approaches; Some companies' disease predictions conflict with established risk for medical conditions';
- emphasise that it is preferable for consumers to see their doctor to discuss DTC genetic testing before they initiate such a test.

**Q4. Is more advice needed in the draft Resource for Consumers on legal risks, risk rated insurance or privacy issues?:**

As above, briefly address 'substitute consent'.

**Q5. Is more advice needed in the draft Resource for Consumers on the usefulness of DTC genetic testing?:**

We commend the statement that says 'Due to the possible problems with accuracy and quality of DTC tests, your doctor will not be able to use it as the basis for health advice.' It is worth acknowledging that some people may seek DTC genetic tests because they think it will be less expensive than

medical genetic testing; however, this may not be the case and such tests may need to be repeated using proper medical genetic testing.