Submission to the FSC Consultation on FSC Life Insurance Draft Code of Practice 2.0 including Moratorium on Genetics Tests in Life Insurance

Dr Andrea Belcher, Tiffany Boughtwood, A/Prof Ainsley Newson & Prof Kathryn North, *on behalf of the Australian Genomics Health Alliance*

Introduction

The Australian Genomics Health Alliance (Australian Genomics) is a national research collaboration of clinicians, researchers, geneticists, counsellors and patient advocates working together to provide evidence for the equitable, effective and sustainable delivery of genomic medicine in healthcare. Currently funded by the National Health and Medical Research Council (NHMRC) (2016-2020; GNT1113531), Australian Genomics' research encompasses four main Programs of work: Establishing a national diagnostic and research network in genomics;

1. Developing a national approach to genomic data federation and analysis;
2. Informing health policy, conducting health economic analyses, applying implementation science methods and addressing ethical implications; and
3. Evaluating the needs of the genomic workforce.

This research program is embedded in clinical practice, with patients with rare diseases and cancers being prospectively recruited for genomic testing in clinical Flagship projects. Information from the clinical Flagships in turn drives the four Programs of work. Australian Genomics engages a network of more than 400 clinicians, researchers, diagnosticians and genetic counsellors to coordinate the recruitment of more than 5,000 patients for genomic testing across Australia.

This submission, which can be made public, considers the terms of a Moratorium on the use of genetics tests in life insurance proposed by the FSC as part of the current review of the FSC Life Insurance Code of practice.

Australian Genomics' activities relevant to the use of genomic information in life insurance and related policies

Australian Genomics:

- is tasked by the NHMRC with 'preparing Australia for the genomics revolution in healthcare', which includes identification, exploration and mitigation of potential barriers to the acceptance and adoption of genomics;
- is recruiting patients for genetic and genomic testing and is ethically bound to advise patients during the consent process that the testing may impact upon insurance applications;
- is regularly asked by patients and family members about the potential for discrimination in insurance and what access insurance companies have to test results;
- has a position statement on the use of genomic information in life insurance and related policies which has been provided to FSC previously.

The view of Australian Genomics on the use of genomic information in life insurance and related policies

Australian Genomics:

- supports a nationally consistent approach to the use of genomic information by the insurance industry: one that ensures those undertaking clinical testing and/or participating in research are not subject to inappropriate discrimination in life insurance and related policies;
- believes the Australian Government should take a leadership role in regulating the use of genomic information by the insurance industry and implement a Moratorium on the use of genetic test results;
- recognises the need for the development and promotion of clear patient and consumer advice on this matter and recommends the development of educational material for health professionals on the potential insurance implications of genomic testing.

Summary of this submission

Australian Genomics:

1. supports an objective of Australians being able to access insurance products equitably and fairly;
2. asks that only genetic and genomic tests with demonstrated scientific and clinical validity and utility are used in life insurance underwriting;
3. asks that the disclosure of results from research projects is excluded from the Moratorium;
4. asks that careful consideration is given to the financial limits to ensure that large numbers of applicants (or high proportions of applicants in particular sub-sections of the market) are not required to disclose the results of genetic tests;
5. asks that all life insurers be encouraged and enabled to participate in the Moratorium;
6. asks that there is open and transparent compliance monitoring and reporting on the Moratorium's operation to encourage consumer confidence;
7. welcomes the willingness to have favourable genetic test results taken into account as part of underwriting assessments, if an applicant chooses to disclose such a result;
8. encourages a prominent consumer and industry (both financial and medical) education and awareness campaign as the Moratorium moves forward.

Addressing the draft Moratorium terms proposed by the FSC

1) Objective of the Moratorium

Australian Genomics supports the development of an outcome that will enable Australians to access insurance products equitably and fairly and acknowledge the requirements of the insurance industry around information symmetry. The announcement of a proposed Moratorium is an important first step.

2) Scope of the Moratorium

The definition of a genetic test in the proposed Moratorium is silent on whether the test is diagnostic or predictive (i.e. was the test done to confirm or rule out a diagnosis based on existing symptoms, signs or abnormal non-genetic test results or was the test to predict a future risk of disease in individuals currently without symptoms of a genetic disorder). Australian Genomics notes that the Parliamentary Joint Committee Inquiry recommendation focussed specifically on predictive tests, which is consistent with the UK Code.

Point 6 of the draft Moratorium (Appendix 4) defines a genetic test for the purpose of the Moratorium 'as a test which examines a person's chromosomes or DNA'. Point 9 of the draft Moratorium seems to suggest that life insurers could request and use results of any genetic test (previously taken, planned or considered) if the financial limits are exceeded, without any regard to:

- the current scientific and medical understanding of the genetic contribution to the condition(s)
- the specificity and sensitivity of the test
- the clinical validity and utility of the test
- the accreditation of the lab(s) that did the test
- whether the test was done in a research context
- whether it was a direct-to-consumer test and if so, what quality standards and validity the test had

<u>Scientific and clinical validity and utility</u>

A comprehensive process is needed to ensure that only results with clinical and analytical validity and utility are used in life insurance underwriting. The Australian Law Reform Commission Review 2003 (Essentially Yours), recommended a process in which regulators, the insurance industry and genomics and health professionals regularly assess and determine which genetic tests are suitable, having regard to their scientific reliability, actuarial relevance and reasonableness (recommendation 27-1). Such a process should form part of any Moratorium.

<u>Research testing</u>

Clinical genomic testing and research testing are different with the main differences being the clinical actionability of the results and the purpose of testing.

The National Statement on Ethical Conduct in Human Research (2007, Updated 2018) specifies that once there is sufficient evidence and agreement that a genomic research findings or result is clinically significant, there needs to be confirmation testing according to applicable guidelines, e.g. at a National Association of Testing Authorities (NATA)-accredited laboratory (section 3.3.29). In practice this means, where there is appropriate clinical significance, research results become clinical results. Therefore, the Moratorium should exclude the disclosure of results from research projects, that is projects undertaken with human research ethics committee approval, and only request disclosure of results from clinical testing.

The exclusion of research testing results is also consistent with the UK Code (2018) which states "results obtained exclusively in the context of scientific research will not need to be disclosed."

The exclusion of research testing from insurance underwriting is also important in the context of participant engagement in research. In order to continue to improve the value of genomic medicine, participant involvement in research is critical. Removing the obligation to disclose research results will provide much greater certainty for people interested in participating in genomic research.

Opt-in to the Moratorium by non-FSC members

From the consumer perspective it would be best if all life insurers were bound by the Moratorium. Section 1.1b of the Code of Practice appears to outline a mechanism for non-FSC members to be bound by the Moratorium through entering into a formal agreement with the FSC and the Life CCC to adopt Chapter 1. However, point 4 of the Moratorium seems to be more restrictive indicating that the "Moratorium applies to people taking out or increasing individually underwritten life insurance (including group insurance) *with a Financial Services Council (FSC) member*." If it is the FSCs intention that non-members could opt-in to the Moratorium, the wording of point 4 in Appendix 4 should be amended to make this clear.

Ongoing application of the Moratorium for policies initiated during the term

Point 5 of the draft Moratorium sets out the start and end date of the Moratorium. However, to remove any concerns consumers might have about future changes to the Moratorium, particularly after the proposed end date, this section should also explicitly state that the Moratorium will continue to apply to policies that were taken out under its terms.

3) Financial limits

The objective of the Moratorium is stated as being to promote genetic inclusion by ensuring people can access a level of life insurance without being asked about the result of a previously taken genetic test. The question then becomes, what financial limits are appropriate to achieve this objective for the majority, if not all applicants. It could be argued that having any limits will result in ongoing consumer fears about the impact of a genetic test result on their ability to obtain life insurance products.

It seems that setting the limits too low could lead to a large numbers of policy applicants having to either disclose results or have multiple policies (and the associated costs) to achieve their desired level of cover. In the UK, the ABI has reported that over the period of the Concordat & Moratorium (now a Code), the limits applied in that market covered 95% of policies, meaning only 5% of applicants had to disclose a genetic test result. Notwithstanding the differences in the UK and Australian life insurance markets, this benchmark would seem to be a reasonable one to strive for to ensure people are not dissuaded from taking genetic tests or taking part in genetic research.

However, it is not clear how the proposed financial limits in the draft Moratorium would perform against this benchmark. While it is acknowledged that the limits have been chosen to align, in a financial sense, with limits in a number of European countries, it is not clear what the limits will mean in the Australian market in terms of the numbers of applicants for the different policy types (lump sum death cover, total permanent disability cover (TPD), trauma or critical illness cover and income protection) and from different market sectors (retail, direct or group) that will be asked

about the results of genetic tests. Therefore, it is suggested that there should be continuous monitoring of the performance of the Moratorium during the period from 2019 – 2024, including assessment of how many applicants are being asked about the results of tests as a result of the financial limits and whether this is consistent with the objective of the Moratorium.

4) Compliance Monitoring

In addition to the proposed Moratorium section on 'Review' (points 13 and 14 of Appendix 4) there should also be regular compliance monitoring and annual reporting on the operation of the Moratorium. It is acknowledged that sections 24 and 25 of the Code provide details on governance and monitoring, enforcement and sanctions of the Code of Practice, however these sections and Appendix 4 do not specify how the operation of the Moratorium will be monitored. In order to build consumer confidence and enable Government to assess whether further regulation is required to ensure discrimination is not occurring (as per recommendations of PJC Review), measures relevant to the operation of the moratorium should be reported on regularly through the FSC to the LCCC and the Australian Government. Such measures could include, but not be limited to, the number of companies bound by the code, the level of use of genetic test results for underwriting different policies and sectors of the market, the numbers and types of breaches of the Moratorium, numbers of complaints and outcomes of dispute resolution processes.

5) Government involvement

The proposed Moratorium represents a form of industry self-regulation. However, the Parliamentary Joint Committee Inquiry Report Recommendation 9.4 indicated that the Australian Government should have a role in monitoring developments to determine whether legislation or another form of regulation is required. To address this recommendation and maximise consumer confidence, it would be beneficial if the Australian Government had a role in the operation of the Moratorium or were a party to it, that is, the Moratorium took the form of an agreement between the Government and the Industry.

In addition, the Australian Government should have a role in the review of the Moratorium in 2022, which should be undertaken independently of the FSC and LCCC.

6) Complaints handling

For clarity, the Moratorium (Appendix 4) could make it explicit that complaints in relation to the operation of the Moratorium will be handled through the same mechanism as complaints about other parts of the code (this process being outlined in section 22).

7) Any other matters

Separate to the Moratorium, there needs to be an effective communication and education campaign that ensures consumers, health and financial services professionals understand when genetic and genomic information can be used in relation to life insurance products.