



HM Government



Association of British Insurers

# Concordat and Moratorium on Genetics and Insurance

March 2005



# **Concordat and Moratorium on Genetics and Insurance**

If you would like more copies of this document, please contact:

Department of Health  
652C Skipton House  
80 London Road  
LONDON SE1 6LH

Tel: 020 7972 1518  
Fax: 020 7972 1717

# Concordat and Moratorium on Genetics and Insurance

## Introduction

1. The Government and the insurance industry recognise and wish to respond to understandable concerns about the potential use of personal genetic data by insurance companies. They consider that the relationship between medical data and insurance underwriting should be proportionate and based on sound evidence. They also accept the commercial principle that, unless otherwise agreed, insurance companies should have access to all relevant information to enable them to assess and price risk fairly in the interest of all their customers.

2. They agree to:

- (i) create a policy framework ('Concordat') for cooperation that provides that insurers' use of genetic information is transparent, fair and subject to independent oversight, building on existing voluntary codes of practice;
- (ii) extend the existing voluntary Moratorium on insurers' use of predictive genetic test results by five years to 1 November 2011, and to review this Concordat in 2008.

3. This document provides a single high-level policy agreement on the use of genetic test results in insurance underwriting practices. It is informed by discussions between the Association of British Insurers, its member companies and the Government, the Genetics and Insurance Committee (GAIC) the Human Genetics Commission (HGC), patient groups and other interested parties.

## Background

4. Genetic testing is in its infancy and its long term implications for insurance, preventative medicine or treatment is indeterminate. The majority of genetic tests confirm diagnoses of ill health and inform treatments. Such diagnostic testing falls into the same category as other clinical technologies. The Concordat is concerned only with the far smaller number of tests used to predict future illness. Only in recent years has it become possible to design tests that examine genetic material for changes that may predict future disease. Even with such advances, very few tests can predict with any certainty when an illness might begin, or how severe it might be. There remain concerns that a minority of patients might be deterred from taking predictive genetic tests, if they fear that insurance companies may discriminate against them unfairly on the basis of the test results. The Concordat addresses those fears.

5. The Concordat preserves the principle that, unless otherwise agreed, insurance companies should have access to all relevant information to enable them to assess and price risk fairly in the interest of all their customers. So, if a customer for life insurance knows (from medical information, family history or tests) of a specific risk to his or her health, it should in all normal circumstances be disclosed. If the risk is not disclosed, the insurance company may face more, and more costly, claims than it was able to assume in setting the price of its insurance policies. This could potentially affect the future pricing or availability of insurance cover to all.

6. The current approach works in practice because the number of policies affected by non-disclosure of predictive genetic test results is low. The moratorium allows customers who have had adverse predictive genetic test results to obtain significant levels of cover, whilst protecting the customers of individual insurers from the consequences of extremely high claims, which have not been priced for.

## Purpose

7. The Concordat establishes a robust and flexible framework for cooperation between the Government and the Association of British Insurers and its members, and builds on the voluntary Code of Practice already implemented by the Association. It is designed to balance societal concerns with the need for a commercially viable, long term and fair insurance market. The Concordat sets out the policy on how predictive genetic tests may be used and creates strict arrangements for their use by:

- requiring higher standards of evidence of increased risk than apply to other forms of medical information used by insurers;
- subjecting the evidence to scrutiny and approval by a Government appointed independent committee;
- creating a rigorous compliance process beyond the statutory and regulatory requirements; and
- creating an independent mechanism for handling any complaints that fall outside the jurisdiction of the Financial Ombudsman Service.

The Concordat and Moratorium protect the interests of both customers and insurers, by preserving customers' access to insurance, and insurers' right of equal access to information about risks.

## Parties

8. The parties to this Concordat are the Government of the United Kingdom and Devolved Administrations ('the Government'), and the Association of British Insurers ('the ABI'). The ABI is the trade association for Britain's insurance industry. Its more than 400 member companies provide over 97% of the insurance business in the UK. The Government is represented by the Secretaries of State for Health and Trade & Industry and the Chancellor of the Exchequer.

9. Adoption of the Concordat is voluntary and is intended to be binding in honour only. It is a statement of intent and does not create legal obligations between the parties. However, some aspects, including the Moratorium, are in practice considered to be binding on all member companies of the ABI, via its Code of Practice.

10. Nothing in this Concordat should be construed as conflicting with statutory requirements or with other professional duties and obligations.

## General principles

11. The parties to this Concordat agree the following principles:

- Insurers should not treat customers who have an adverse predictive genetic test result less favourably than others without justification;
- The technical, clinical and actuarial relevance of predictive genetic test results should be subject to independent oversight through GAIC;
- Customers should receive clear explanations of their rights. They should have access to a free, independent service for resolving complaints;

- Insurers and customers should have equal access to information that is material and relevant for insurance underwriting, except as provided for by the Concordat and the Moratorium on access to predictive genetic tests by insurers.

### Predictive genetic tests

**12.** This agreement applies to predictive genetic tests, which examine the structure of chromosomes (cytogenetic tests) or detect abnormal patterns in the DNA of specific genes (molecular tests). It does not apply to non-genetic medical tests, for example blood or urine tests for cholesterol, prostate cancer, liver function or diabetes.

**13.** GAIC has said that it will consider applications to approve the use of predictive genetic test results by insurers for conditions that are:

- Monogenic (single gene disorders that are inherited in a simple fashion);
- Late-onset (symptoms are delayed until adult ages); and of
- High penetrance (a high probability that those with the gene will develop the disorder).

### Policy on the use of predictive and diagnostic genetic test results

**14.** Insurers have agreed a set of measures intended to reassure patients so that they are not deterred from taking a predictive genetic test by fear of potential insurance consequences. The measures cover:

- the nature and detail of information sought from customers;
- how insurers will handle information provided voluntarily by customers; and
- the use made of that information.

**15.** The ABI will continue to work with GAIC, patient interest groups and industry stakeholders to examine methods of improving access to insurance for people with genetic diseases through, for example, development of standardised information about rare genetic conditions to give a common evidence base to underpin underwriting decisions.

### Information sought from customers

**16.** Insurers agree that:

- (i) Customers will not be asked to, nor be put under any pressure to, undergo a predictive genetic test in order to obtain insurance.
- (ii) Customers will not be asked to disclose another person's predictive test results, such as a blood relative's test.
- (iii) Customers will not be asked to disclose any predictive or diagnostic genetic test results acquired as part of clinical research.
- (iv) Customers will not be required to disclose any predictive genetic test results that are made available after their policy has started, for as long as that policy is in force.
- (v) Customers who have taken a predictive genetic test before the date of this Concordat will be treated in the same way as customers taking tests under the terms of the Concordat.
- (vi) Insurers are permitted to seek, with customers' consent, access to certain family medical history, diagnostic (but not predictive) genetic test results, and to reports from GPs in order to accurately price the additional risk from any health problems an applicant discloses.

- (vii) Customers can be asked by insurers to disclose the adverse results of predictive genetic tests approved by GAIC under specific conditions, when they apply for insurance policies over the financial limits of the moratorium.
- (viii) Insurers have stringent procedures for seeking access to relevant medical information held by a GP or other clinician, agreed between the ABI and the British Medical Association.
- (ix) Insurers will protect personal medical information in accordance with ABI Genetics Code.
- (x) Insurers will destroy medical evidence when it is no longer relevant to them.
- (ii) The broad classes of insurance for which genetic test results may be relevant are confined to the following products:
  - life;
  - critical illness; and
  - income protection.
- (iii) Where they make use of the results of GAIC approved tests to impose special terms or conditions, they will not impose unjustified exclusions from cover, or other special terms or conditions, which have the effect of preventing a policyholder from making a claim for a condition that is not related to the genetic condition identified by an approved test.
- (iv) If a predictive genetic test is disclosed by mistake, insurers will ignore it.

## Handling of information provided voluntarily

### 17. Insurers agree that:

- (i) Customers may choose to disclose predictive genetic test results that are in their favour in order to over-ride family history information. Individual insurance companies will publish information about the way they will use such test results to inform their underwriting decisions.
- (ii) Most insurance companies will take into account the result of such a voluntarily disclosed genetic test, even if it has not been approved by GAIC, provided that the result is from a reputable source.

### Use of information

### 18. Insurers agree that:

- (i) They will not use information from predictive genetic test results to underwrite travel insurance, private medical insurance, or any other one-off or annual policy, or for long term care policies.

## The Moratorium

**19.** The Moratorium on insurers' use of predictive tests is a key part of the overall Concordat. It makes an exception to the principle of disclosure. It allows patients who have taken a predictive genetic test to obtain significant levels of cover without disclosing the results of that test. Insurers have been prepared to bear the risks and costs of non-disclosure, which are spread across the broad pool of policyholders, because the number of policies affected by non-disclosure of predictive genetic tests is low. Accordingly the insurance industry and Government have agreed that the Moratorium should be extended.

**20.** The terms of the Moratorium are as follows:

- (i) Customers will not be required to disclose the results of predictive genetic tests for policies up to £500,000 of life insurance, or £300,000 for critical illness insurance, or paying annual benefits of £30,000 for income protection insurance (the 'financial limits'). More than 97% of policies issued in 2004 were below these limits in each category.

- (ii) When the cumulative value of insurance exceeds the financial limits, insurers may seek information about, and customers must disclose, tests approved by GAIC for use for a particular insurance product, subject to the restrictions in the Concordat.
- (iii) The Moratorium will expire on 1 November 2011, unless it is explicitly renewed through the Concordat.

## Compliance

21. The ABI will continue to run an annual exercise assessing the compliance of its member companies with the ABI Code of Practice and the Moratorium, the results of which are published. GAIC will continue to comment on this compliance report. Government and ABI will explore further and consult GAIC and the HGC on the detailed aspects of the compliance and complaints system, in conjunction with the revision of the ABI Code of Practice.

### Code of Practice

22. The ABI will consult on and publish an updated Code of Practice ("the Code") laying down the standards that insurers should meet. Compliance with the Code is a condition of membership of the ABI. The new Code will update the detailed arrangements for the internal handling of genetic test results by nominated genetics underwriters and Chief Medical Officers within companies. It will also set strict standards for security and confidentiality of medical information. The ABI will revise and reissue the Code from time to time.

### Resolution of disputes and complaints

23. Customers have the right to ask an insurer to provide information on whether, and if so, how, a predictive test result has contributed to an underwriting decision. They have the right of appeal against an underwriting decision and a right to have a complaint heard fairly.

24. An insurer must tell a customer that they have the right to complain about a decision where a predictive test result has been disclosed and a customer believes that they have been unfairly treated. An insurer must explain the complaints process and adjudication system. It must investigate a complaint and give the customer a written decision as soon as is practicable and within the time limits set for authorised insurers by the Financial Services Authority.

25. Where a dispute is unresolved after this process, a complaint may be made:

- (i) under the terms of the Financial Ombudsman Service, if a complainant believes that they have suffered or may suffer financial loss, material distress or material inconvenience as a result of an insurer's wrongful act or omission. The service, which is available to customers once a contract is signed, is free to customers and decisions are binding on insurers and complainants, subject to the right of insurers to seek judicial review or complainants to go to Court in the normal way; or
- (ii) to the ABI, who will look again at all the material facts and decide whether a breach of the Code, Concordat or Moratorium has occurred. The service is free to customers and is binding on insurers.

26. The ABI may refer cases to GAIC if it is unable to resolve them or if it believes that the case has wider implications concerning genetic testing. Customers may also appeal to GAIC if the ABI is unable to resolve a complaint to the customer's satisfaction about the way that an insurer has dealt with their case.

27. The Committee will adjudicate on the use and interpretation of predictive genetic tests by insurers. It may review the material evidence and may seek further information before reaching a decision. The service is free to customers and Insurers agree to be bound by decisions taken by GAIC. However, the Committee will not be able to give personal

advice about insurance, or to deal with complaints about the ABI process, about firms which are not insurance companies or members of the ABI, the operation of an insurance policy, or an insurer's proper use of its commercial judgement.

**28.** If a customer receives a final decision from GAIC or from the ABI, with which they are not satisfied, they may ask the ABI to convene an independent tribunal under the terms of its Code of Practice. The tribunal will be authorised to fine companies and compensate customers, normally within six months. The tribunal service is free to customers and is binding on insurers.

**29.** In every case a customer's legal rights are unimpaired. They remain free to take court proceedings against an insurer at any time.

#### **The Genetics and Insurance Committee (GAIC)**

**30.** GAIC has developed and published the technical, clinical, and actuarial criteria for evaluating predictive genetic tests, their application to particular conditions and their reliability and relevance to particular types of insurance. GAIC's core duty will remain that of evaluating predictive genetic tests against those criteria and publicising its findings.

**31.** GAIC will provide independent, wide-ranging oversight of how insurers are using predictive genetic tests. It will continue to report to Health, Treasury, and Department of Trade and Industry Ministers on proposals it receives from insurance providers and the subsequent level of compliance by the industry. GAIC will publish an annual report containing details of tests reviewed and of insurers' compliance with the Concordat, Moratorium and ABI Code of Practice.

**32.** GAIC will liaise with the clinical genetics community, patient groups and experts in insurance and actuarial sciences. GAIC will monitor and publish trends on the nature and volume of NHS predictive genetic testing for late-onset, high penetrance single gene conditions, such as Huntington's Disease. It will also work with HGC to provide a horizon-scanning capability for potential future developments relevant to genetics and insurance.

#### **The Human Genetics Commission**

**33.** HGC will continue to advise Ministers on the ethical, legal and social implications of wider developments in genetics and their implications for healthcare and the adequacy of the regulatory framework that applies to human genetics. It will work closely with GAIC where these considerations relate to genetics and insurance.

#### **Duration and review**

**34.** The Concordat comes into effect on 14 March 2005. It may be updated in the light of experience, research findings and developments in genetic technology, and clinical practice.

**35.** The Moratorium on insurers' use of predictive genetic tests dating from 1 November 2001 will be extended by an extra five years until 1 November 2011.

**36.** There will be a review of the operation of this Concordat and Moratorium in 2008.



