A Common Framework of Principles for direct-to-consumer genetic testing services
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## Principles for the provision of genetic testing services directly to the consumer

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Introduction

The development of the Principles

These Principles have been developed by a collaborative working group comprising representatives from the genetic testing industry, experts in regulation, clinical and molecular genetics and genetic counselling, representatives from groups that support individuals with genetic conditions and the UK Department of Health.

The group was convened and supported by the UK Human Genetics Commission (HGC), the UK Government’s advisory body on developments in human genetics and their ethical, legal, social and economic implications.

The need to develop high level Principles for direct-to-consumer genetic tests was first identified during a workshop, convened by the HGC, to discuss the desire for a UK code of practice. Whilst this workshop identified an appetite for specific guidance on good practice, a key outcome was the recognition that the provision of direct-to-consumer genetic testing services took place in an international market that crossed national borders and regulatory jurisdictions. In order to promote consistency the decision was made to initiate a common framework of principles as a high-level document having general applicability across all jurisdictions.

The HGC is not a regulatory body. It hopes that these Principles will lead to the development of codes of practice that take account of existing regulatory structures and may identify where there is a need for additional regulation or legislation. Suitable systems for monitoring these codes of practice will be required.

Purpose

The purpose of these Principles is to promote high standards and consistency in the provision of genetic tests amongst commercial providers at an international level in order to safeguard the interests of people seeking genetic testing and their families. The Principles identify areas where individual providers, professional organisations, regulatory bodies, and/or national jurisdictions should have defined measures in place, and the nature of those measures. The Principles are not intended to supersede any national laws and they should be used in accordance with applicable international instruments and domestic law.

Genetic test results have the ability to give rise to a broad spectrum of responses. How an individual responds to the results of a genetic test will depend, sometimes to a great extent, on the personality of that individual and their understanding of the test result and its implications. Therefore, the consequences for an individual of taking a genetic test will vary significantly depending on the individual taking a test, the information provided and the context in which the test is taken. When a genetic test is provided outside a framework of healthcare, special attention must be given as to how that individual may respond to the results of the genetic test and the subsequent impact the test results may have on that individual and their family. With this in mind, these Principles have been developed with the best interests of consumers at the forefront.
Scope

These Principles are intended to cover all situations in which it is possible for a private consumer to purchase a genetic test without prescription by a qualified medical professional, subject to statutory regulation. The Principles cover:

- tests that are provided directly to the public without an intermediary between the consumer and the test provider
- tests that are provided via a non-medical intermediary, such as a pharmacist or alternative health practitioner
- tests that are commissioned by the consumer but where a medical practitioner or a health professional is involved in the provision of the service

The Principles address the situation where genetic tests are marketed directly to consumers rather than to qualified medical professionals.

The Principles are intended to cover all aspects of direct-to-consumer genetic testing services, including the marketing and advertising of tests, the collection, analysis and storage of biological samples, the interpretation of results and the provision of results to the consumer.

Although these Principles are intended to be applied as broadly as possible, it is also recognised that, depending on the nature of the genetic test, not all principles will be applicable in all circumstances (see ‘how to use the principles’ section of this document).

Whilst these Principles have been developed specifically for direct-to-consumer genetic testing services, it is possible that many of these Principles would also be applicable to other direct-to-consumer susceptibility/pre-dispositional health tests other than those defined in table 1.

These Principles do not cover genetic testing carried out purely for medical research purposes, approved by a Research Ethics Committee (REC) where the results of the genetic test are not disclosed to the consumer nor do they apply to genetic tests for forensic purposes. The Principles also exclude whole genome sequencing, which is not widely commercially available at the time of writing, although this will be considered in the context of planned future revision. Whilst the provision of whole genome sequencing tests will need consideration in the near future, these were omitted from these Principles to prevent significant delay in publication.

Table 1: Types of tests covered by these principles

Genetic tests covered by these Principles may be categorised in the following way:

1. Diagnostic tests
   Tests intended to diagnose a medical condition in a person with symptoms and/or signs.

2. Pre-symptomatic tests
   Tests intended to predict that an asymptomatic person has a high probability of developing a condition, for example, BRCA tests for breast cancer and mutation testing in some autosomal dominant single-gene disorders, such as Huntington Disease. This is sometimes referred to as predictive testing.
3 Carrier testing  Tests intended to show that a person is a carrier of a condition, so that although they are not themselves affected, there is a risk they may have affected children.

4 Prenatal diagnostic tests  Tests intended to identify medical information about a fetus or to establish fetal sex.

5 Susceptibility/Pre-dispositional health tests  Tests intended to provide an indication of the absolute lifetime risk and/or relative risk of an individual developing a condition compared with the general population for example, APOE tests for Alzheimer’s disease and tests for Age Related Macular Degeneration.

6 Pharmacogenetic tests  Tests intended to predict the response profile of an individual to a drug or course of therapy

7 Nutrigenetic tests  Tests intended to provide information about an individual’s responsiveness to a particular nutrient or diet and how this affects metabolism, health status and risk of disease.

8 Lifestyle/behavioural tests  Tests intended to provide information about an individual’s:
  - behavioural propensities
  - performance capacities (physical or cognitive) or
  - response to certain environmental conditions and that are designed to assist the individual to modify the outcomes of any of these by elective changes in behaviour (not including the administration of prescribed medicines).

9 Phenotype tests  Tests intended to provide information about how an individual’s phenotype is conditioned by their genotype, for example, tests that indicate the genetic basis of a person’s eye colour.

10 Genetic relatedness tests  Tests intended to determine/or provide information about a genetic relationship, including paternity and maternity tests.

11 Ancestry tests  Tests intended to provide information about an individual’s relatedness to a certain ancestor or ancestral group and/or how much of an individual’s genome is likely to have been inherited from ancestors from particular geographical areas or ethnic groups.

Definitions

Terms in these Principles are used with the following meanings unless otherwise indicated or determined by context:

‘Genetic test’ – a test to detect the presence or absence of, or a change in, a particular sequence of DNA, gene or chromosome or a gene product or other specific metabolite that is primarily indicative of a specific genetic change.

‘Genetic test in the context of inherited or heritable disorders’ – a test falling into any of the first four categories of table 1 (above) that is capable of providing information that may have important implications for the health of the person concerned or members of their family, or have important implications concerning reproductive choices.

‘Condition’ – a medical condition caused, solely or in part, by changes in genes or chromosomes.
‘Trait’ – any physical or behavioural feature determined, at least in part but almost always in combination with other factors, by an individual’s genotype.

‘Test provider’ – an individual, company organisation or other entity providing genetic test services to the public or a section of the public, including those services marketed or provided by an intermediary who is not a nationally recognised medical practitioner.

‘Health professional’ – a clinical geneticist, genetic counsellor, medical practitioner or any other health professional who has undergone appropriate training in the interpretation of genetic information and has achieved the required competencies.

‘Absolute risk’ – observed or calculated risk of an event in a defined population over a specific period of time.

‘Relative risk’ – ratio of the risk of an outcome in the affected group to the risk of the outcome in the control group over a specified period of time.

**How to use the Principles**

The Principles are set out in the anticipated order of relevance in the testing pathway.

There are certain Principles that are applicable to only certain categories of tests. Where this is the case, the text indicates which categories of test the principle should be applied to. Insofar as they are relevant to the test in question, all other Principles should be applied to any genetic test supplied directly to the consumer.

Some tests – generally genetic tests in the context of inherited or heritable disorders – should be provided only to consumers who are given suitable opportunity to receive individualised pre- and post-test counselling (see principle 5.1).

The consequences for an individual of taking a genetic test depend not only on the nature of the test and the information it can reveal but also on the personal and familial circumstances of the individual taking the test. Therefore, when designing a direct-to-consumer genetic testing service, the test provider should consider both the type of test being provided and the impact of that test. Where the results of a test are likely to have a significant or potentially detrimental impact on consumers the test provider should ensure that consumers have reasonable access to appropriate support and professional advice. In particular, the test provider should consider whether the test results should be provided only in the context of a consultation with a suitably qualified health professional, and make provisions accordingly.

**Impact criteria.** In considering what additional support is appropriate, test providers should take the following impact criteria into account:

- if used for diagnostic purposes, the severity of the condition to be diagnosed and the likely impact of the diagnosis on the person diagnosed
- if used for predictive purposes, the degree of reliability of the prediction
- if the test is intended to predict the development of a progressive disorder, the likely speed of degeneration
• the potential for the test to have a significant impact on the clinical management of the individual taking the test
• the potential of the results of the genetic test to have a significant or life-altering impact on the behaviour of the individual taking the test
• the potential for the results of the genetic test to provide health-related information about a third party, such as a biological relative
• the potential for the test to provide genetic information about a fetus
• whether the test is a stand-alone test or if there are other confirmatory tests
• the potential of the test to have a significant impact on personal relationships and the stability of families

The APOE test for Alzheimer’s disease is an example of a test that would evoke the impact criteria; the results of this test are likely to have significant impact on the individual taking the test and have the potential to create significant anxiety, both for the individual tested and their close biological relatives, even though the test itself can only weakly predict the likelihood of developing Alzheimer’s disease.

Review of the Principles

The Human Genetics Commission intends to review the uptake and impact of these Principles 18–24 months after publication with a full review of the content of the Principles 5 years after publication. If you wish to submit comments to feed into either of these reviews please email the HGC at DTCPrinciples@dh.gsi.gov.uk, stating the nature of your interest and providing your comments.
Principles for the provision of genetic testing services directly to the consumer

1. Purpose and scope

1.1 These Principles are intended to ensure good practice in the provision of genetic testing services directly to the consumer. The test provider should strive to provide a high-quality service that meets the expectations of the consumer whilst safeguarding their interests.

1.2 The Principles apply to tests marketed to or ordered directly by a consumer or by a non-medical intermediary acting on the consumer’s behalf; they are not intended to apply to tests ordered by a medical professional on biological material taken from an individual as part of a professional investigative or diagnostic procedure in respect of that individual by that professional.

2. Marketing and advertising

2.1 Where relevant, the test provider should comply with any legislation or voluntary codes for advertising of medical tests, including genetic tests or other clinical services and they should also comply with more general guidance (including legal guidance) covering consumer advertising.

2.2 Promotional and technical claims for genetic tests should accurately describe both the characteristics and the limitations of the tests offered, and the test provider should not overstate the utility of a genetic test.

2.3 Where a claim is made about the clinical validity of a genetic test, the claim should be supported by relevant evidence published in peer reviewed scientific literature and the test provider should give standard references to this literature.

2.4 The test provider should be aware of the risk of bias when quoting evidence and ensure that evidence is presented transparently with reference to the criteria used to include and/or exclude published literature when this is cited as evidence of the applicability or effectiveness of the test.

2.5 Information about tests which are available only in the context of a consultation with a health professional or are only provided to consumers with both individualised pre- and post-test counselling should make it clear that tests are available only in that context.

3. Regulatory Information

3.1 The test provider should make available the evidence of the association between a genetic marker and a disease, condition or trait for the genetic tests that they supply. Ideally, the associations should be validated at genome wide significance level in more than one large case control study and in a cohort of the ethnic/geographic background relevant to the client. The associations should be published in peer-reviewed scientific journals, they should be undertaken in line with the recommendations made in the STREGA statement*, and the provider should supply standard references for these publications.

3.2 Standard statistical methodologies accepted by the scientific community should be used to calculate the risk of the disease, condition or trait, and the evaluation of the algorithms used should be made available by the test provider for standard review and scrutiny.

4. Information for prospective consumers

4.1 The test provider should supply easily understood, accurate, appropriate and adequate information, which is also available in accessible formats, to consumers before obtaining consent for a genetic test. The following should be provided:

- general information about genetics to enable a consumer to understand the scientific basis of genetic testing, the role of genes in health and disease, and conditioning phenotypes, and the technologies applied to generate the knowledge
- a clear explanation of the relative roles of genetics, environmental factors, lifestyle choices and other factors in determining health, disease and phenotype
- specific information about genetic tests offered
- information about counselling offered in connection with the test including whether counselling is included in the cost of the test and for what costs the consumer will be liable if they withdraw following pre-test counselling
- information about the presentation of results in statistical form, such as relative and absolute risk assessments or likelihood of inclusion/exclusion as a genetic relative, so that an individual can understand test results that are provided
- information about measures taken by the test provider and laboratories to ensure the confidentiality of personal records and security of biological samples
- information about the maximum period of storage of the biological sample and personal records, and procedures for storage, transfer and disposal of biological samples and personal records
- information about whether biological samples may be used for any secondary purposes, such as additional research purposes, and about or whether personal genetic information may be passed on to third parties and, if so under what conditions and to whom
- information about procedures for handling and resolving consumer complaints
- information about the manner in which the test results will be provided and, if applicable to the genetic test, information about the requirement for pre- and post-test counselling
- a statement that the results of the test might be able to reveal information about genetic relationships
- a statement that the results of the genetic test might have implications when purchasing life insurance
- a statement that third parties, such as law enforcement agencies, may have access to consumers’ biological samples without their consent if laws exist that would permit this
- information about specific procedures that might need to be followed if the test is to be used for official purposes, such as certain chains of evidence that might need to be maintained in some jurisdictions, if the test is to be used in the courts of law
• a statement that taking DNA from someone else without their consent is generally ethically inappropriate and is a criminal offence in some jurisdictions
• information about what will happen to consumers' biological samples, and personal and genetic data, if the company ceases trading

4.2 The test provider should provide information to consumers about the association between a genetic variant and a disease, condition or trait for each genetic test that they offer in a format that is easy to understand.

4.3 The test provider should make available to consumers, information about the scope of the test, its accuracy and limitations. Information about the analytical and clinical validity* of each of the genetic markers used in the test should be made available. Other factors, such as behaviour or environmental conditions, that will play a role in determining the development of the condition or trait under investigation should be listed.

4.4 The test provider should provide information about the likely outcomes of the genetic test and the decisions that a consumer may face after taking the test. They should also identify prospectively any likely further investigations that a consumer or member of their family may wish to pursue after receiving the test results.

4.5 If a test provider intends to use a consumer's biological samples and/or associated personal or genetic data for research purposes, the consumer should be informed whether the research has been approved by a research ethics committee or other competent authority, whether the biological sample and data will be transferred to or kept in a biobank or database, and about measures to ensure the security of the sample. The consumer should be informed of any risks or potential benefits associated with participating in the research and whether they will receive feedback on research findings that relate to them (see Principle 6.6).

4.6 If a test provider intends to use the results of a genetic test to make a recommendation to a consumer to purchase a therapeutic product, such as a nutritional agent or supplement, the test provider should make available information about the link between the genetic test result and the efficacy of the indicated product. The test provider should also provide information about other lifestyle choices and behavioural modifications that are known to have a preventative or therapeutic value in relation to the trait linked to the genetic markers tested and whether the consumer can purchase the recommended therapeutic product elsewhere.

4.7 Where the test result indicates that the consumer may benefit from an alteration in the dosage of a medicine, or from an alternative medicine to one currently being taken, the test provider should make available information about the link between the genetic test result and the metabolism of the indicated medicines (see Principles 3.1 and 11.3).

4.8 The test provider should make it clear how and whether a consumer can receive updated test results as part of the service they supply.

4.9 Where appropriate, outside the context of a consultation with a suitably qualified health professional, the test provider should inform consumers about recommendations or known

* Clinical validity includes information about (1) the relationship between the genetic marker and the condition or trait and (2) test performance, which may include the following characteristics of the genetic marker: sensitivity, specificity, positive and negative predictive values, likelihood ratios and areas under the ROC curve.
actions that may help the consumer to take informed decisions about their health or welfare in
the light of the test results, including informed interaction with the health care system.

4.10 Where appropriate, the test provider should supply consumers with information about health
professionals who are able to offer further advice or support.

4.11 For tests in categories 1–6, an appropriately qualified professional, with recognised training and
qualifications, employed by or representing the test provider, who is regulated by an appropriate
professional body, should be responsible for ensuring that consumers are provided with all of
the information specified in this section of the Principles. This requirement should apply to tests
in other categories where similar professional structures exist.

5. Counselling and support

5.1 Where the test is a genetic test in the context of inherited or heritable disorders, that test should
only be provided to consumers who are given a suitable opportunity to receive pre- and post-test
counselling.

5.2 The counsellor should have the appropriate skills and competencies and should be accountable
to a relevant professional body.

5.3 After receiving the information provided in part 4 and receiving any offer of pre-test counselling,
consumers should have the opportunity to cancel purchase of the test without incurring further
costs relating to the test.

6. Consent

6.1 In designing a direct-to-consumer genetic testing service, the test provider should give
consideration, not only to the nature of the test and the information that it generates, but also to
the personal and familial circumstances that may be relevant to consumers.

6.2 A genetic test should be carried out only after the person concerned has given free and informed
consent. Informed consent can only be provided when a consumer has received sufficient
relevant information about the genetic test to enable them to understand the risks, benefits,
limitations and implications (including the implications for purchasing insurance) of the genetic
test.

6.3 The test provider should take reasonable steps to assure themselves that a biological specimen
provided for testing was obtained from the person identified as the sample provider.

6.4 The test provider should require consumers to sign a statement confirming that they give their
informed consent to the specific genetic tests to be undertaken on their biological material. The
document should record the sample provider’s age and that they have read and understood the
information with which they have been provided. The statement should include an explanation
of what will happen to the consumer’s biological samples and personal data if the controlling
share of the company is taken over by a third party.

6.5 The test provider should retain documentary evidence of the provision of informed consent
by the consumer for the duration of storage of the consumers’ biological samples and personal
records.
6.6 Separate, specific, informed consent should be requested by the test provider if the test provider wishes to perform further tests that are not covered by the original consent or if biological samples are to be stored by the test provider after the consumer has been provided with the genetic test results. Likewise, separate informed consent should be requested by the test provider before biological samples are used for any secondary purposes, e.g. research, or before any third party is permitted access to biological samples. Consumers’ biological samples and personal genetic data should only be used for research that has been approved by a research ethics committee (REC) or other relevant competent authority.

6.7 Except in exceptional circumstances provided for by law and appropriate guidance, companies offering direct-to-consumer genetic tests should not provide tests to adults unable to provide informed consent.

6.8 Companies offering direct-to-consumer genetic tests should be aware of the laws that exist in some countries prohibiting DNA theft, which make it illegal to obtain or test DNA without the consent of the person from whom it originated. In line with these laws a test provider should make consumers aware of the law and should not perform a test if they have reason to believe that a biological sample they have been provided with for genetic testing purposes has been taken from a third party who has not given their consent for the tests to be performed. Requests to recover DNA for genetic testing purposes from secondary objects or materials, when there is reason to believe that the person from whom the DNA originates is still alive, should raise suspicion and should be declined.

6.9 The following principle applies to tests in categories 1-3, 5 and 6 (and categories 7 and 8 where these have been evaluated as ‘high impact’ – see ‘How to use the Principles’). Genetic tests in respect of children when, according to applicable law, that child does not have capacity to consent should normally be deferred until the attainment of such capacity, unless other factors indicate that testing during childhood is clinically indicated. If postponement would be detrimental to the child’s health, or the management of the child’s health may be altered significantly depending on the test result, then testing should be organised by a health professional who has responsibility for ensuring that any medical intervention or screening indicated will be arranged and proper arrangements made for any subsequent care.

7. Data protection

7.1 Genetic information is sensitive personal data and requires the highest level of security and confidentiality. Records containing personal data and genetic information that can be linked to an identifiable person should be subject to privacy protection and security in accordance with professional guidance and applicable laws on data protection and confidentiality.

7.2 The test provider and laboratories should not release biological samples or records containing personal data and genetic information that can be linked to an identifiable person to any third party without the prior consent of the person to whom they relate, unless required to do so in accordance with national legislation for example, pursuant to a Court order.

7.3 Companies who wish to record consumers’ details on to a database that will be held by the test provider, a laboratory or a professional associated with the testing procedure, should obtain prior consent from the consumers. Consent should also be obtained prospectively for consumers to be contacted in the future by these organisations or individuals.
7.4 If a test provider ceases trading, they should dispose of personal and genetic data securely or provide for transfer of responsibilities in accordance with the terms of consent given by the consumer.

8. Sample handling

8.1 The use, storage, transfer and disposal of biological samples provided for genetic testing should be carried out in accordance with applicable legal, ethical and professional standards. The nature, purpose and maximum duration of the storage should be specified.

8.2 Biological samples should be used, stored, transferred and disposed of in conditions that ensure their security.

8.3 If a test provider ceases trading, they should dispose of consumers’ biological samples securely or provide for transfer of responsibilities in accordance with the terms of consent given by the consumer.

9. Laboratory processes

9.1 The analysis of biological samples for the purpose of providing genetic testing services should be provided by competent laboratories. Competence can be established by accreditation to the International Organisation for Standardisation (ISO) standards 15189 or 17025 or other equivalent recognition consistent with the OECD* guidelines for quality assurance in molecular genetic testing. Achievement of laboratory accreditation requires monitoring the quality of laboratory performance through proficiency testing.

9.2 Genetic tests used as part of a direct-to-consumer genetic testing service should be able to identify the genotype of interest both accurately and reliably.

9.3 Laboratories should have policies in place to apply corrective measures if their performance falls outside of parameters determined by the laboratory’s quality assurance programme.

9.4 Laboratory personnel should have appropriate professional qualifications that meet recognised standards, underpinned by education and training, to assure competence in laboratory procedures in the provision of genetic tests.

10. Interpretation of test results

10.1 For tests in categories 1–6, interpretation of genetic test results should be carried out under the responsibility of an appropriately qualified professional, with recognised training and qualifications, working within the standards determined by an appropriate professional body and regulated by this professional body, employed by or working on behalf of the test provider. Similar standards should apply to tests in other categories where similar professional structures exist. There should be no remuneration structure in place that would allow this individual to benefit directly from any particular interpretation of the test results or the sale of any services or products related to those results.

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10.2 The qualified professional responsible for the interpretation of genetic test results should ensure that the interpretation of genetic test results is accurate and take steps to ensure that these results are comprehensible to the consumer.

10.3 Where genetic test results are provided in the form of a risk assessment, the risk assessment should be based on robustly evaluated algorithms. Standard statistical methodologies should be used to convert risks reported in scientific literature to the risk of a disease, condition or trait for an individual compared with the general population risk, as well as lifetime risks or lifetime incidences. Results should make clear the distinction between relative risks and absolute risk.

10.4 Test providers should regularly review the available evidence on which their interpretation is based.

11. Provision of results

11.1 The results of genetic tests and the significance that should be attributed to a particular genetic test result should be described to the consumer in a format that is easy to understand.

11.2 When testing for a condition or trait, where such conditions or traits are determined, at least in part, by other, non-genetic factors in addition to genetic markers, the test provider should make consumers aware of these other factors when providing results of genetic tests. In addition, the test provider should supply an indication of the level of significance that an individual should attribute to the genetic test results in comparison with the significance of these other factors, and this should be provided to the consumer in a format that is easy to understand.

11.3 When providing consumers with the test results for tests in category 6 (pharmacogenetic tests), the test provider should strongly recommend that the consumer does not alter the dosage of any existing medication on the basis of the test results and to take the results of the pharmacogenetic test to a medical practitioner for personalised interpretation of the test result. The test provider should give the consumer appropriate information to take with them to their medical practitioner to aid the interpretation of the test results.

11.4 The test provider should take care not to overstate the value or significance of the results of the genetic test when providing the test results.

11.5 The test provider should state clearly when a genetic test result can only give an indication of relative risk in relation to the general population as opposed to an absolute risk, bearing in mind that either might only be calculable in the context of a family history analysis.

11.6 The test provider should have in place a process to evaluate how well consumers are able to understand the background information and test results they have received, and take steps to improve their information and results provision in accordance with the findings.

11.7 The test provider should ensure that the provision of genetic test results is undertaken in such a way as to retain the confidentiality of personal and genetic data. When genetic test results are provided electronically, the test provider should ensure that appropriate security measures are in place to maintain the confidentiality of data transmitted. If the option of sending test results via email is offered by the test provider, consumers should be made aware that this method is generally not secure.
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11.8 The test provider should not release genetic test results to any third parties, including insurance companies, health professionals, solicitors or other medical practitioners without the specific prior consent of the sample provider.

11.9 Test providers who interpret un-interpreted data obtained from genetic tests that have been provided by a third party laboratory should comply with all the aspects of these Principles that are relevant to the services they provide. Likewise, test providers who only undertake the genetic analysis and do not interpret the test results should comply with all the aspects of these Principles that are relevant to the services they provide.

12. Continuing support

12.1 For tests in categories 1–6 (and categories 7 and 8 where these have been evaluated as ‘high impact’ – see ‘How to use the Principles’) the test provider should be able to provide consumers, at the time of testing or at any subsequent stage, with information about opportunities that are available for any further consultation with health professionals.

13. Complaints

13.1 The test provider should have written procedures in place for acknowledging and investigating complaints. Staff who manage and respond to complaints should have received appropriate training.

13.2 The test provider should nominate a member of staff to oversee the handling of complaints. This person should be responsible for the management of the investigation of the complaint and the effective operation of the complaints procedure.

13.3 The complaints procedure and the name and contact information of the person to contact regarding complaints should be easily accessible to consumers. This information should be available in formats that are accessible for people who are unable to access standard print.

13.4 The test provider should ensure that complaints are dealt with in a reasonable time-period and consumers should be informed promptly of the outcome of the complaint.

13.5 If a consumer remains dissatisfied with the investigation or outcome of their complaint, they should be made aware of what further recourse might be available to them.
Appendix – Membership of the working group

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