BELGIAN ADVISORY COMMITTEE ON
Bioethics

Opinion no. 32 of 5 July 2004 on the free availability of genetic tests

Request for an opinion of 8 December 2003

by the Belgian delegation on the "Steering Committee for Bioethics" (SCBI) of the Council of Europe, responsible for drawing up the draft additional protocol to the Treaty on Human Rights and Biomedicine, concerning human genetics.

At its sitting of 15 December 2003, the Advisory Committee on Bioethics decided at its own initiative to deal with the question concerning the problem of the free sale of genetic tests, referred to in Article 18.

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A. Context and introduction

The *Steering Committee on Bioethics/Comité Directeur pour la Bioéthique* (hereinafter referred to as CDBI) of the Council of Europe is currently drafting an additional protocol to the Treaty on Human Rights and Biomedicine, signed in Oviedo on 4 April 1997. This protocol relates to human genetics and will consist of two parts:

- the applications of genetics for medical purposes;
- the applications of genetics for non-medical purposes, in particular in the field of employment and insurance.

At the plenary meeting of the CDBI in March 2004 the delegations were given the following documents:

- CDBI/INF (2003)3 – working group on human genetics (CDBI-CO-GT4): working paper on the applications of genetics for medical purposes;
- CDBI/INF (2003)4 – working group on human genetics (CDBI-CO-GT4): explanatory memorandum to the working paper on the applications of genetics for medical purposes;
- CDBI (2004)3 – Steering Committee on Bioethics (CDBI): introductory note from the secretariat explaining the three points dealt with below.

The working group charged by the CDBI with drawing up the draft Protocol, indeed had three major questions which will be presented to the delegations of the member states of the Council of Europe at the Council's next plenary meetings (November 2004 and June 2005).
The three questions are as follows:

1. the Members States' position regarding the free sale of genetic tests;
2. the Members States' position regarding genetic tests in people who are not in a condition to give their consent and whereby there is no direct benefit for them;
3. the Members States' position regarding scientific genetic research.

In the light of the CDBI's future debates, the Belgian delegation informally asked the Committee for its opinion on the questions raised, specifying that what is involved here is only the application of genetic tests with the aim of obtaining information on the current and/or future state of health, with a preventive or therapeutic objective.
This opinion therefore does not take into account paternity tests.
At its plenary meeting of 15 December 2003 the Advisory Committee decided at its own initiative to take up the questions raised. The current opinion deals with the first question

concerning the free sale of genetic tests. The second and third questions will be covered in subsequent opinions.

In this opinion on the free sale of genetic tests, the reader is given a concise overview of the different kinds of genetic tests, and subsequently a summary of current practice and the legal framework within which this takes place. Then ethical considerations are formulated on various ethical values that play a role in the ethical debate surrounding the free sale of genetic tests. Finally a description is given of the two ethical standpoints that emerged among the members of the Committee, whereupon a number of general and specific recommendations are made.

B. Definitions and brief overview of the state of affairs regarding genetic tests

In genetic tests a distinction can be made between diagnostic genetic tests, predictive tests and susceptibility tests

Diagnostic genetic tests support clinical diagnosis. They are used to support a suspected clinical diagnosis in a patient. Diagnostic genetic tests are carried out in the search for a causal link between a possible anomaly in the genetic material and a particular symptomatology. The presence of a genetic anomaly confirms the suspected diagnosis, which was made on the basis of a clinical symptomatology.

These tests can enable us to anticipate the approach, to direct the choice of treatment and to avoid more pervasive tests having to be carried out.

Predictive genetic tests provide information on the increased risk that a person not showing any symptoms of a specific disease will be affected by this particular disorder later in life.

Among these tests with a predictive value, we make a distinction between tests for pre-symptomatic diagnosis and predisposition tests on the one hand, and susceptibility tests on the other.

Tests for pre-symptomatic diagnosis determine the genotype of a person belonging to a risk family, before the appearance of symptoms of the hereditary disorder running in the family. Thanks to these tests we can ascertain with certainty that a person with the mutation will be affected by the disorder later in life. Sometimes preventive treatment for that person can be dispensed in good time. For some hereditary diseases these tests make it possible, in the context of scientific research, to study the relations between the various mutations and their phenotypic expression. These tests can be carried out in adults and are also technically possible in minors (even neonatal), before birth (prenatal diagnosis (PND)) and even before

implantation (pre-implantation genetic diagnosis (PGD)). Of course there are specific ethical implications involved in the application of the tests in these latter three situations.

Predisposition tests concern the tracing of mutations which play a major part in causing family disorders which persons belonging to the family have a much higher risk of contracting. The tracing of the mutations can help their carriers to take effective controlling measures, as is the case in the hereditary form of breast and ovarian cancer, and to take preventive measures against hereditary non-polyposis colorectal cancer.

"Susceptibility tests" attempt to assess the risk (the probability) of the appearance of a future multifactoral disorder coming about through the effect of several genes, environmental factors and the interaction between the two – and whereby the mutation of a specific gene gives a slightly higher chance of the person contracting the ailment. This name is used to categorise, for example, some cancers, some cardiovascular complaints and some neuro-degenerative disorders.

The pre-symptomatic diagnosis test and the predisposition test have in common the fact that the test is requested by a person on the basis of the incidence of the hereditary disorder in the family. Susceptibility tests, on the other hand, are not offered to individual people on the basis of their family history, but are in principle offered to broader groups, without any connection to a family context.

From the foregoing, it is clear that there is a whole spectrum as regards the degree of certainty in the risk prediction, ranging from certainty (in the case of tests for pre-symptomatic diagnosis), through very high risk (in predisposition tests), to a slightly higher absolute risk (in the case of susceptibility tests). Susceptibility tests are characterised by the fact that they can show a degree of predestination. Many diseases are the consequence of the additive effect or direct interaction of products of different genes as well as environmental factors. Then there is the third factor, which is quite simply chance: two people with the same genome and with similar environmental influences can nonetheless be different. In other words, it is impossible to draw up a deterministic model, which we could use to predict an individual's health on the basis of full knowledge of his or her genome and environment, even if it were to become possible in the distant future to measure all these parameters. Since susceptibility tests only reveal that there is a (slightly) increased risk of contracting a multifactoral disorder in the future, one might ask how useful it is to know this weak prediction of the future state of health. One of the major problems of the susceptibility tests is that relative risks are easily misinterpreted, and that small absolute risks are blown up because the role of other genes and environmental factors are overlooked - in other words because an overly deterministic interpretation is given of these tests.

With the technology of DNA chips, it will be possible within five to ten years to obtain a genotyping of several thousand polymorphisms within a reasonable period (polymorphisms are variants that appear in more than 1% of the population and which are not necessarily pathogenic). This technique might be able to offer the possibility, in the framework of susceptibility tests, of drawing up risk profiles of a whole series of diseases (heart diseases, for example), which could in the distant future contribute towards more targeted and therefore more effective prevention.

B.1. Genetic self-tests

As regards the concept "test freely for sale", it is proposed here that reference be made to the definition given by the United Kingdom's *Advisory Committee on Genetic Testing* (ACGT), a definition which the *Human Genetics Commission* (HGC) adopted in its report "*Genes direct"* (on web site: http//:www.hgc.gov.uk). This definition relates to any genetic test to which the public has access outside the usual medical control system. It has the merit of choosing the concept "free access" in preference to the concept "sale" - the pertinent element, after all, being the lack of a doctor as intermediary. In the context of this opinion, we will therefore speak of "self-tests".

Two types of genetic self-tests can be distinguished:

1. tests offered in kits and offering the user the possibility of taking the test home with him;
2. tests carried out in a laboratory but whereby the test material is taken at home by the user himself *(home-sampling test)* and is sent by him to the laboratory for analysis. The results are sent by post or e-mail or given over the telephone.

Technically only the second type of genetic self-tests is possible in practice at the moment.
The choice of this definition naturally does not mean that no importance is attached in the rest of the opinion to its possible commercial exploitation.
On the other hand we will not be dealing in this opinion with the questions thrown up by the appearance on the market of self-tests for research purposes.

B.2. Practice of genetic tests in the eight genetic centres in Belgium

In principle genetic tests in Belgium are only carried out at one of the eight officially recognised genetic centres within a well-defined counselling context (a specific test protocol). In theory genetic centres only carry out tests with considerable clinical relevance. Moreover, these tests are carried out either at the request of the person concerned or, with his explicit consent, at the request of his GP or specialist practitioner. The result is only communicated to the person concerned himself and never to third parties, other than to professionals in the healthcare sector, and in this latter case this occurs only at the request of or in close

consultation with, and after the consent of, the person concerned. Confidentiality of the genetic information is essential here, in particular to avoid harmful consequences or discrimination for the persons concerned or their family.

The practice of both diagnostic and predictive genetic testing in the genetic centres is characterised by the importance attached to the counselling of the persons concerned (genetic consultation). To this end the genetic centres have multidisciplinary teams at their disposal. The composition of the multidisciplinary team can vary from centre to centre. The partner and sometimes other family members may be involved in the process of genetic testing, with the patient's consent. During these discussions, information is given on the disease, the way it is passed down, and the process involved in carrying out the test. In-depth consideration is given to the meaning of the test in the life of the person requesting it, and the background of the application or the test: how do the person requesting the test and his/her family experience the disease and the risk, what are the reasons for asking to have the test carried out, do they have an idea of what the impact of the test result will be for themselves and other members of the family, what support do they expect to receive from the people around them? The entire approach prior to the test being carried out aims at aiding a free, informed decision and preparing the support after the test result. After the result is made known, follow-up sessions are always planned. The number of sessions depends on the test result and the specific requirements ensuing from it.

The eight genetic centres are represented in the High Council for Anthropogenetics, a body set up by the federal government.

C. Legal framework and current practice

C. 1. General legal framework

At the moment there is no specific legislation in Belgium forbidding or regulating the direct sale of predictive genetic tests to private individuals.

A royal decree of 14 December 1987 (*Belgian Official Journal* of 25.12.1987) lays down the rules that the Centres for Human Genetics must observe. On the basis of this Royal Decree eight genetic centres are recognised (see Appendix 2).

The High Council for Anthropogenetics was created by the federal Ministry of Public Health in 1973. The High Council oversees the clinical and diagnostic activities of the eight Centres for Human Genetics and the seven Centres for the Tracing of Metabolic Disorders. Genetic research is only reimbursed by statutory health insurance if it is carried out at one of the

eight officially recognised Centres for Anthropogenetics. The supervisory activities are subsidised by the health ministries of the regional governments.
The directors of the Centres for Human Heredity are responsible for:
~the organisation of the clinical genetic services and the psychosocial genetic services;
~the quality of the genetic diagnosis:
-constitutional (pre- and postnatal) and acquired cytogenetics;
-molecular genetic tests: "Standard" molecular diagnosis is offered by every centre "Specific" tests for uncommon disorders are only carried out in a small number of centres, as part of a national collaborative campaign run by the High Council for Anthropogenetics. Molecular genetic tests include constitutional and onco-haematological tests. In the future it will be possible for additional laboratories (Centres for Molecular Diagnosis) to be certified to carry out a small number of onco-haematological tests;
~the development of clinical genetic research activities;
~the provision of general and specific information to the public, professionals and lay organisations.

At international level mention should be made of Article 12 of the Treaty on Human Rights and Biomedicine of 4 April 1997 (not signed by Belgium), which stipulates that predictive genetic tests can only be carried out provided there is adequate genetic counselling.

Along the same lines the International Declaration on Human Genetic Data, which was approved by UNESCO on 16 October 2003, states that "it is ethically imperative that when genetic testing that may have significant implications for a person's health is being considered, genetic counselling should be made available in an appropriate manner" (Article 11).

As regards the bringing of genetic tests onto the market in Belgium via the Internet, reference should be made to the law of 11 March 2003 on certain legal aspects of the services of the information society (*Belgian Official Journal* of 17.03.2003) and relevant royal decree of enforcement of 7 May 2003 (*Belgian Official Journal* of 07.07.2003), as well as the law of 8 December 1992 for the protection of personal privacy, in respect of the processing of personal data (*Belgian Official Journal* of 18.03.1993).

The law of 11 March 2003 is applicable to all "information services". This therefore means: all services provided by electronic means, i.e. which are originally sent and received by the recipient with the aid of computer equipment, even if for example a part of the service is provided physically. The sale of predictive genetic tests via web sites thus falls under this law, even if the blood samples or results are sent by post. Pursuant to Article 5 of this law, the provision of services of the information society by a service provider established on Belgian territory must comply with the requirements in force in Belgium. Every site which

offers this kind of service and is established in Belgium, is thus subject to Belgian law and in particular the law on the protection of privacy (*confer infra*).
The royal decree of 7 May 2003 implementing the law of 11 March 2003 moreover determines that the services of the General Board of Control and Arbitration of the federal Department for Economic Affairs can take specific measures for the limitation of the free traffic of a service of the information society provided by a service provider established in another European Union Member State. In addition to the fairly cumbersome procedure which this rule provides for, the limitation solely to web sites established on the territory of EU countries clearly appreciably curtails its scope.
As regards sites which sell genetic tests and are not established in Belgium but are accessible on Belgian territory, the law of 11 March 2003 makes it possible in some cases for service providers who "host" these sites to be held liable. A "hoster" established in Belgium of sites on which genetic tests are offered for sale, could be held liable if it/he did not take prompt action to remove the information or render access to it impossible as soon as it/he became aware of the illegal nature of the activity or information on its/his server.

Data such as the biological samples needed to carry out a genetic analysis, constitute personal data within the meaning of the law of 8 December 1992 on the protection of privacy in respect of the processing of personal data.
This law is applicable to the processing of personal data in the framework of activities by a body established on Belgian territory (site selling genetic tests which is established in Belgium), but also when the party responsible for processing the personal data is not established within the European Union, but calls upon automated or non-automated resources which are located on Belgian territory for the processing of personal data. All cases of genetic data being collected on Belgian territory by such sites selling genetic tests consequently fall under the scope of the law, irrespective of the nationality of the person concerned.

The law and its implementing decree of 13 February 2001 (Belgian Official Journal of 13.03.2001) lay down a number of principles that apply to every case of processing of personal data. For example, these texts regulate the way in which the collected data should be stored, as well as the subsequent use of this data. But for written consent on the part of the person concerned, personal data on health may only be processed under the responsibility of a professional practitioner in the healthcare sector and certain information should be given to the person concerned at the time the data is collected. The law provides for penalties for failure to observe the legal provisions.
The same principles for the protection of personal data are applied in other countries of the European Union. These principles are based on European directive 95/46/EC on the protection of natural persons in respect of the processing of personal data and on the free circulation of these data.

C.2. Legal framework and practice concerning medicines and medical tools/in-vitro diagnostic tests

Medicines in Belgium are subject to the law of 25 March 1964 on medicines (Belgian Official Journal of 17 April 1964) which regulates both their registration and their distribution and advertising. Every medicine in Belgium must have an explicit authorisation from the federal government's pharmaceutical inspectorate before the medicine can be brought onto the market (called registration). This authorisation is granted on the basis of a dossier on the effectiveness, toxicity and qualitative aspects of the product in question. In the framework of the European Union, harmonisation has been achieved in respect of the registrations for certain medicines. In these cases the European registration replaces the national registration procedure.

In Belgium there has always been a ban on the distribution of medicines by post. Nonetheless it is impossible to control the distribution by post of medicines that are bought by consumers in other countries. Despite the efforts of the Belgian government in the framework of the World Health Organisation (WHO) to adopt a regulation on the sale of medicines over the Internet, this has not been successful due largely to opposition from the USA. Delivery by post is not banned at European level either, although in a ruling of the European Court of Justice of11 December 2003, the free sale by post of medicines the purchase of which is subject to a medical prescription, is banned (web site: europa.eu.int/cj). To sum up, it can be stated that a European pharmacy can distribute medicines in other Member States, provided the medicine is allowed there, and its provision is not subject to a prescription in the country for which the medicine is intended.

Medical tools are regulated by European directive 93/42/EC. The national authorities recognise the competent bodies whose task it is to inspect medical tools and provide them with a CE label. This CE label then permits free circulation within the European Union of the appliance in question. However the distribution of medical tools is a competence of the national governments and for some medical tools, such as pacemakers for example, distribution is limited to pharmacies.

Medical tools for in-vitro diagnosis are regulated by European directive 98/79/EC. The Royal Decree of 14/11/2001 (Belgian Official Journal of 12/12/01) transposes this directive into Belgian law. This royal decree successively stipulates: the general conditions for the marketing and bringing into use of these tools (including well-defined requirements for self-tests, point 7 of Appendix 1); the administrative registration of the manufacturer, the conformity assessment procedures, the measures to be taken in the event of incidents on Belgian territory, advertising, use of languages, confidentiality, contributions and royalties. The other appendices of this decree explain the CE conformity declaration and procedures, the entire quality assurance system and the monitoring powers. The legislation does not

provide for any rules governing the distribution of in-vitro diagnostic tests. If provision should be made to limit their distribution, this will have to occur at European level, given that currently no restrictions can be imposed at national level as long as these tools bear a CE label.

C.3. Practice of genetic self-tests

Genetic tests only form a small proportion of all diagnostic tests, but a rapid expansion of this market can be expected. In 1996 200 laboratories in the USA carried out around 175,000 tests for 300 diseases or disorders with the exception of tests for some blood abnormalities and cytogenetic tests used to trace disorders such as *Down* syndrome.
In the bio-industry, various companies are evidently active in the development of genetic tests which they want to market (e.g. *Myriad Genetics, Great Smokies Diagnostic Laboratories and Sciona*).

Some companies and laboratories promote their tests over the Internet but ask for a doctor's medical certificate (e.g. *Myriad Genetics* tests for the hereditary form of breast cancer, cancer of the colon or melanoma or *Great Smokies Diagnostic Laboratories* for complex disorders). These may be specialist doctors or general practitioners. Some of these companies even provide for a specific additional training for the doctors. The only condition that the company lays down is that the doctor must be a recognised professional practitioner.

Other companies and laboratories offer tests immediately to the user via, for example, the '*you and your genes' genetic testing service* through the *Body shop* or on the Internet. It is these tests in particular that should be viewed as genetic self-tests given that they meet the following conditions:

- the user can purchase the test without a doctor's certificate or medical referral
- the test or the service offered permits the user to remove his own material or the biological material is removed by personnel who have not undergone any medical training
- the user is immediately notified of the results of the test, without any reference to a doctor and without counselling.

Following on from the test result, some of these firms offer the user advice on diet and lifestyle. These companies are of the view that an increase in user demand can be expected in the near future. A review of the supporting information supplied to the user by these laboratories was found to be inadequate by a group of experts (*Human Genetics Commission, Genetic services subgroup* 2001- see: www.hgc.gov.uk/genesdirect/).

After hearings on 17 and 18 May 2004 a patent held by the American firm *Myriad Genetics* was withdrawn by the "Opposition Chamber" of the European Patent Office (EPO). This patent protected a diagnosis method for ascertaining a predisposition for hereditary breast and/or ovarian cancer. After rejecting all petitions from the American firm, the EPO judged that the patent did not meet the requirements of the European Patent Convention"1. The patent holder can still appeal against this ruling to the EPO's Appeal Chamber.
It is perfectly conceivable that in the future laboratories established in countries outside the European Union will carry out marketing via the Internet for genetic self-tests and thus fall outside any regulation.

In the United Kingdom a study was carried out into the public demand for genetic self-tests (*direct genetic testing services*). The '*YouGov survey'* shows that 60% of the population regards it as improbable that they would use genetic self-tests. However, 81% of the respondents replied that they would consider genetic tests if these were offered by their doctor in the framework of a diagnosis or preventive examination. However, the researchers are of the view that at the time pregnancy self-tests were introduced, a comparable response was recorded, whilst today all women probably carry out a pregnancy test themselves before consulting their GP.

D. Ethical considerations concerning genetic self-tests

Free access to genetic tests, whereby no external persons have to be involved in the process, undeniably constitutes an application of the principle of personal autonomy. The possibility of purchasing discreet and anonymous tests can also seem important when the persons involved do not dare or wish to request any external help which would involve them having to have eye-to-eye contact with a GP or a team. In this respect direct access to genetic tests can be seen as a form of respect for the privacy of the individual.

Respect for the principle of the autonomy of the person and respect for personal privacy are irrefutably fundamental ethical principles of our society.

The principle of autonomy and the principle of respect for privacy, which are cited in favour of genetic tests being made available for everyone, should however be weighed up against arguments concerning the protection of the person and the members of his family and protection of third parties.

[1] Extract from the newspaper *Le Monde* of 28.05.04.

A number of these points were already discussed in Opinion no. 17 of 10 June 2002 on the ethical aspects of self-tests for the detection of HIV, in which similar considerations are found.
We will reproduce below some of the points that were listed in Opinion no. 17, in relation to their applicability to genetic tests.

D.1. Protection of the person and the members of his family

Free access to predictive genetic tests of course causes a number of questions to be raised regarding the protection of the person who carries out the test, and the members of his or her family.

In this respect, the following points should chiefly be stressed.

D.1.1. Interpretation of the results

Predictive genetic tests are so complex that a perfect interpretation and a perfect understanding of the results they give call for a high degree of expertise. Someone who knows little or nothing about genetics runs the risk of interpreting these results only in a very partial manner or even completely misinterpreting them.

The isolation of the person who is confronted with the results of his test is of such a nature as to be able to cause a feeling of panic to arise, or even to lead to a risk of suicide.

Given that the person concerned does not receive any genetic counselling at all, it is to be feared that he or she will feel totally desperate as regards the choices facing him or her after finding out the results (what medical follow-up should be provided, what information should or should not be given to the members of the family).

Moreover genetic tests do not just have an impact on the person who undergoes the test, but also the members of the family. The latter's right to be informed or not to be informed must be respected – something which in this case is not guaranteed. Furthermore, it is not impossible for the information given to them, with or without their informed consent, to be misleading.

Further to a negative result (in other words the absence of the pathogenic mutation or the polymorphism that involves a higher relative risk), someone could feel unjustifiably protected against this or any disease, and no longer take any preventive measures.

D.1.2. Discretion

The absolute reliability and watertightness of certain channels, and especially the Internet, can in no way be guaranteed. Examples of "hacking" of certain web sites (including sites that were considered to have been very secure) are legion in the history of the Internet.

The possibility of rapidly gaining access to tests outside the medical sector offers no guarantee whatsoever against misuse of the results by third parties (insurance companies and employers, for example). Paradoxically, direct access could therefore end up jeopardising the confidential nature of medical personal data. The laboratories that carry out the analyses tend to be located abroad and therefore fall outside the scope of Belgian legislation on data protection – so how can it be guaranteed that personal data are not sold to third parties?

D.1.3. Reliability of the tests

Tests offered over the Internet may be carried out in laboratories that escape the applicable Belgian legislation on the recognition of centres for human genetics. There is the fear that some of these laboratories do not observe quality standards meeting the requirements in Belgium or in other countries that have developed legislation on this subject.
The biological samples used can also easily be swapped (deliberately or accidentally). Considerable circumspection is therefore recommended as regards the accuracy of the results.

D.1.4. Storage and later use

The stability of DNA and the fact that it can easily be stored means there is the fear of private companies with commercial objectives establishing databases containing the genetic data collected during self-tests. Samples stored in this way could lead to misuse or the subsequent use by third parties with completely different intentions than those for which the original samples were taken (e.g. in the case of determining parentage, in the insurance sector). With the exception of a number of strictly delimited exceptions in relation to the subsequent processing of data for historical, statistical or scientific purposes, the storage and later use of the collected data in Belgium is forbidden by law, namely by the Belgian law on the protection of privacy. This is also the case in other countries with similar legislation (especially the countries of the European Union, see Article 6.1.b. of the aforementioned European directive 95/46/EC).

D.2. Protection of the public

There is also the fear of a certain exploitation of the public's incomplete knowledge and fear of genetic tests. Some people could fall victim to commercial campaigns promoting genetic tests, which would make them receptive to a generalisation of their use, with all the consequences described above. Furthermore, as a result of this assumed lack of knowledge and in the case of a lack of reliable susceptibility indicators, some people could believe themselves to be less vulnerable and could therefore endanger the principle of collective solidarity.
There is also a risk of free access to the tests leading to serious violations of confidentiality of the genetic data, for example in situations where the purchaser of the test subjects a third party to a genetic examination without the latter's knowledge in order to find out his genetic characteristics.
The demand for genetic tests carried out on people who are not in a position to give their consent is not dealt with in this opinion, but will be discussed in a subsequent opinion.

E. Ethical standpoints

The members note that the current practice of genetic self-tests is still extremely limited. This opinion gives rather prospective standpoints on situations that could arise in the future but the possibilities and limitations of which are not yet clear.

Within the Committee two positions became apparent. They show some common ground, but differ fundamentally on the question as to whether genetic self-tests should or should not be made available to the public.

E.1. Common standpoints

E.1.1. All members of the Committee fear that **the market will become flooded** with genetic self-tests which are only made available **out of pure desire for profit**. Consequently they all agree that the public **should be informed in a suitable manner**. They are of the view that the population should be informed of the possibilities and limitations of genetic tests.
They are of the opinion that the population at the moment still only has a limited idea of the possibilities offered by genetic tests. This could result in high hopes being created among the population as a result of which people could be tempted to accept commercial incentives. Effective information calls for effective health information from a young age. That can also be fostered by health education at school and preventive medicine where the emphasis is placed on the problems involved in the correct interpretation of the results and the uncertainties usually surrounding these tests.

E.1.2. The members are of the view that the current **basic training in medicine is insufficient** in the field of knowledge of genetics and the psychosocial aspects involved in it. The same applies for permanent training and the information provided on an ongoing basis on this subject.

E.1.3. The importance of making adequate genetic counselling available

Of course the guaranteeing of genetic counselling before the test is carried out – which the genetic centres regard as essential – is well-nigh impossible in the case of freely available genetic tests. All members of the Committee stress the quality of the procedures for genetic counselling which are currently available via a multidisciplinary approach in the recognised centres for genetics. However, some members are of the view that as a result of the probable rise in the number of requests for genetic tests, that can be expected in the future, genetic counselling cannot be limited to the genetic centres but could also be given by other health workers. This of course is on the assumption that the latter have received the necessary training for this.

E.1.4. Guarantees for the quality of genetic tests

The members of the Committee feel that it is essential to avoid at all costs a situation in which the genetic tests that come onto the market fail to meet the required quality standards. They formally oppose practices leading to the possibility of people freely bringing genetic tests onto the market without any quality guarantee or monitoring procedures preceding the marketing of such tests. All members are of the view that a genetic test should at least bear a CE label before it is brought onto the market.

E.1.5. The rights and obligations of the people concerned

All members of the Committee feel that it is important to point to the well-founded respect for the right to find out one's genetic constitution or not to do so. This means that in the case of a self-test being carried out, the right of the persons concerned by the result of the test to know or not to know, must be respected.

E.1.6. The banning of tests carried out on third parties without them being aware

The members of the Committee draw attention to the danger of carrying out tests on third parties without them knowing. They are unanimous in their opinion that this form of operation is unacceptable and liable to legal sanctions2.

E.1.7. Storage and later use of personal data

The members of the Committee are unanimous in judging that in the case of self-tests, both the samples and the genetic data stemming from them should immediately be destroyed

[2] This opinion does not deal with the question of carrying out genetic tests on people who are not in a position to give their consent, as in the case of minors, for example.

after the test is carried out. The storage and later use thereof for purposes other than the original purpose are not permitted.

E.2. Divergent standpoints

Despite the fact that there were quite a number of common standpoints, the members of the Committee are divided as to whether or not it is expedient to make genetic tests freely available to the population.

E.2.1. According to the first position, the free availability of genetic self-tests should be prohibited

These members think that genetic tests should always take place in a medical professional relationship in the framework of which sufficient information is provided and counselling is guaranteed. They also stress the great importance of effective training of the professionals involved. The most important ethical arguments put forward by these members are, *inter alia*, that the autonomy of the person in the case of genetic self-tests is only an illusion, given the difficulties of correctly interpreting the results of these tests and the risk of negative emotional and psychological consequences for the user in the event of an unfavourable test result. They are also of the view that a need is wrongfully induced in the population and that people then fall victim to commercial practices with a purely profit-oriented objective, without any social added value. The same members think that a reliable test result with a reliable interpretation and sensible instructions for the parties concerned presupposes that these tests take place within a professional relationship. A number of these members cite the danger of misuse of genetic self-tests, for example to obtain information on the genetic make-up of another person than the person requesting the test result, or the obtaining of information on genetic make-up by insurance companies or employers. These members are also of the view that an adequate protection of third parties involved in the test results can only be guaranteed via the filter of a medical professional relationship. All members arguing in favour of a ban on the free distribution of self-tests think that genetic tests that are carried out in the context of a medical consultation, and thus within a professional relationship, should be reimbursed by the social security. For that matter, these members feel that the limitation of access to genetic tests on a doctor's orders would prevent an excessive commercialisation of the tests. They also fear an undermining of the principle of solidarity that underpins our social security system.

The fact that they know some of their hereditary characteristics could encourage certain people to demand that the statutory social security system take account of this information, and this could result in the latter operating more like a private insurance scheme than in the form of a general social protection based on the principle that everyone is equal vis-à-vis the consequences of risks that are inherent to life.

Some of the members advocating a blanket ban think that genetic tests should be reserved for genetic centres, since they feel that only these offer the necessary know-how and

supervision for adequate patient care and support. They feel that the current practice whereby genetic tests are carried out by the genetic centres on medical orders and at the request of the patient, the GP or the specialist practitioner, with the patient's explicit consent, offers the best guarantees for the tests being carried out correctly and for the counselling of those involved. This group also argues in favour of adequate consultation and coordination between all genetic centres involved, *inter alia* via the High Council for Anthropogenetics.

Other members, still amongst those advocating a complete ban on the free distribution of genetic self-tests, feel that genetic tests always belong in a professional relationship and should therefore be carried out on medical orders, but feel that limiting these tests merely to the genetic centres is not feasible or desirable in the future. These members are of the view that GPs could perfectly handle genetic tests provided sufficient attention were paid to genetics in basic medical training. These members also think that the general practitioner is perhaps the person best suited to support these patients and give them advice, since he is best placed as regards knowledge of the family context and the living conditions and lifestyle of the people concerned.

E.2.2. **According to the second standpoint, genetic self-tests can be made available to the public subject to the fulfilment of a number of minimum conditions concerning the quality of the test and the information provided to the user**

These members are of the view that real autonomy of the user presupposes that he himself can judge whether or not he wishes to purchase this test and what he wishes to do with this genetic information. If he so wishes, in a second phase the user can even attend a professional consultation if he has further questions about the relevance of the test result and the measures to be taken. This is comparable to the practice in the case of pregnancy tests which are also supplied to the public without medical prescription. In addition to the arguments of autonomy, an important argument cited is that of the discretion and confidentiality in the practising of self-tests. The person concerned can indeed come to a decision wholly on his own as regards a particular test result and then subsequently call on counselling if necessary. Another important argument advanced by these members is that every practice that is banned is made more attractive and tempting by the creation of an aura of secrecy and inadmissibility of these practices. In this way a reverse effect can be created, whereby the ban in fact causes an indirect promotion of the banned practice. The same members cite the danger of an illicit circuit being formed, with the parallel development of a black market. Moreover they think that the use of genetic tests will not drop when these can only be obtained on doctors' orders. A professional will not necessarily reduce use, since some doctors will accede to their patient's request. Some also fear that a ban could curb scientific developments in this field. This could result in a population being deprived of the possible favourable effects of genetic tests for a long time, even if these are not yet known at the moment. According to the members backing this second standpoint,

this consequence in the scientific field must be avoided at all costs. The members of this group also raise questions about the financing of these self-tests. They are aware of the fact that a reimbursement of these self-tests by the social security system is possibly not a feasible option. The same members feel that solidarity will continue to be guaranteed provided sufficient information is given on the multifactoral determination of most genetic disorders and the predictive value of these tests.

F. Recommendations

The members of the Advisory Committee agree on a number of joint recommendations concerning free access to genetic tests. Free access to genetic tests is understood as meaning that these tests are available outside the framework of a medical professional relationship, the pertinent element being the absence of the doctor as intermediary.

All members agree that absolute priority should be given to ensuring that the population is given adequate and comprehensive information. Various channels can be used for this, in particular the media. Health information at school should also play an important role, as well as the provision of information by the GP and other first-line health workers. This of course implies genetics in all its facets forming part of the basic training of general practitioners and other health workers. The possibilities and limitations of developments in genetics should form part of the permanent training and refresher courses. All members stress that effective provision of information and an adequate basic training should place the emphasis on the importance of genetic counselling.

All members agree that the tests, irrespective of whether or not they are freely made available to the public, should meet quality guarantees as stipulated in Belgian legislation and in the European directive on the subject (CE label). This implies that all these tests are reliable and are subject to the appropriate product checks. All members are of the view that the processing of the test results should comply with the requirements of the legislation on the protection of personal privacy. All members are of the view that the storage and later use of genetic data collected in the framework of self-tests should be prohibited.

Although the Advisory Committee unanimously agrees on the above recommendations, opinions are divided on the need to recommend a general ban on the distribution of these genetic self-tests.

A first group of members is of the opinion that the public should not be given free access to these tests. These members therefore recommend that use be made of the possibilities provided for in the implementing decree of 7 May 2003 enforcing the law of 11 March 2003 on services for the provision of information via electronic means, whereby the federal

Department for Economic Affairs can take specific measures to limit the free distribution of these tests insofar as they are made available by a legal entity established within the European Union. Tests made available by legal entities established outside the European Union fall outside the scope of this law, although the products offered on the Internet do need to meet the product requirements stipulated in Belgian legislation in cases where there is a point of sale or an Internet provider established on Belgian territory. These members recall that the law on the protection of personal privacy is applicable and place the emphasis on the minimal respect for the legal condition according to which the test results should be processed under the responsibility of a professional in the healthcare sector. Among the supporters of this standpoint, a first subgroup wants these tests to continue to be the reserve of the genetic centres and also lay this down as a condition for reimbursement of the cost of these tests via the social security system. A second subgroup of the aforementioned members is less restrictive and is of the view that it ought to be sufficient for these tests to be requested in the framework of a medical relationship in order for them to be eligible for reimbursement by the social security. These members think that tests that are not carried out on medical orders are not eligible for reimbursement by the social security.

A second group of members thinks that a blanket ban on free access is not desirable and at the same time is not feasible. They feel that the tests should be provided with an information leaflet containing at least the following details:

- the aim of the test;
- the limitation in the interpretation of the results;
- information in which it is recommended that people receive genetic counselling;
- the contact details of the eight recognised genetic centres in Belgium.

This instruction leaflet should moreover recall:

- that the results of the test can be important for the relatives of the person requesting the test;
- that the right to know as well as the right not to know should be respected vis-à-vis these people, too.

This leaflet should be written in easily understandable language.

These members feel that it should be possible in the future for these tests to be made freely available to the public provided that the tests meet all required quality guarantees, the information provided is clear and comprehensive, and people can call on genetic counselling. The user would then himself be able to decide whether or not to proceed with a professional consultation after the test. These members therefore think that the public should be given free access to these tests provided they bear a CE label. They are of the opinion that tests that do not have all these guarantees should not be allowed to be made freely available to users.

The opinion was prepared by select commission 2004/1, consisting of:

Joint chairpersons	Joint reporters	Members	Member of the Bureau
G. Lebeer	G. Leunens	M. Abramowicz	M. Roelandt
G. Evers-Kiebooms	S.Friart	A. André	
		J. Colaes	
		E. De Groot	
		A. Duchaîne	
		J. Herremans	
		R. Lambotte	
		J.-A. Stiennon	

Member of the secretariat
B.Orban

External experts
F. Gosselinckx, director at the Pharmaceutical Inspectorate (Directorate-General for the Protection of Public Health: Medicines) of the federal Department for Public Health, Safety of the Food Chain, and the Environment, retired.
S. Louveaux, assistant advisor at the federal Department for Justice, Human Rights division, "Privacy" unit.

The working documents of select commission – the question, personal contributions of the members, minutes of the meetings, documents consulted – are kept on file at the Committee's Documentation Centre where they are available to be consulted and copied.

The opinion is available to be consulted at **www.health.belgium.be/bioeth**

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Annex 1 to Opinion no 32 of 5 July2004 on the free availability of genetic tests

STEERING COMMITTEE ON BIOETHICS
(CDBI)

WORKING PARTY ON HUMAN GENETICS
(CDBI-CO-GT4)

Report of the 10th meeting
Strasbourg, 13-15 October 2003

Preliminary draft Protocol on Human Genetics (articles 1 to 18)

Preliminary draft Protocol on human genetics[3]
Chapter I - General provisions

Article 1 - Object and purpose

Parties shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to such applications of genetics to the human being as specified in Article 2.

Article 2 - Scope

1. This Protocol extends to the applications of genetics in the field of health, including research, as well as in the fields of employment and insurance, which involve an intervention concerning the human genome, carried out on living persons or on the body of deceased persons.

This Protocol also extends to the applications of genetics in the field of health, excluding for research purposes, as well as in the fields of employment and insurance, which involve:

[3] Chapters I and II were revised by the Working Party at its 9th meeting (16-18 October 2002), and published as a working document for comments.

- an intervention on identified or identifiable human biological material, or
- the collection, processing or communication of personal genetic data.

2. This Protocol does not extend to the applications of genetics to the human embryo and foetus or any biological material derived from them.

Article 3 - Primacy of the human being

In the application*s* of genetics covered by this Protocol, the interests and welfare of the human being shall prevail over the sole interest of society or science.

Article 4 - Non-discrimination

Any form of discrimination against a person, either as an individual or as a member of a group, on grounds of his or her genetic heritage is prohibited.

Article 5 - Professional standards and obligations

In the applications of genetics covered by this protocol, relevant professional obligations and standards shall be respected.

Chapter II - Applications for health purposes

Section I - General provisions

Sub-section A - Information, consent and authorisation

Article 6 - Information to be given prior to consent or authorisation

1. Prior to consent or authorisation to an application of genetics, appropriate information shall be given to the person concerned or, where appropriate, to the person, authority or body whose authorisation is requested. This information shall include, when relevant to the application concerned:

On the intervention:
- the purpose and the nature of the intervention;
- risks arising from the intervention;
- as appropriate, the consequences of not undergoing the intervention;

On the consequences of the intervention:
- the diagnosis and prognosis for the person concerned;
- the implications for the person concerned;
- the possible consequences for future reproductive choices;
- the implications for other family members;

On support:
- the forms of support available.

2. Information shall also be provided on any foreseen potential further uses of biological material removed during the intervention and of any personal genetic data derived from that material.

3. The information shall be given in a comprehensible and non-directive manner.

Article 7 - General rule on consent

1. An application of genetics to human beings may only be carried out after the person concerned has given free and informed consent to it.

Additional conditions as to the form of consent may be required depending on the nature of the application and its implications.

2. The person concerned may freely withdraw consent at any time.

Article 8 - Persons not able to consent

1. Subject to Article 17 paragraph 2 of the Convention on Human Rights and Biomedicine and Article 16 paragraph 1 of this Protocol, an application of genetics may only be carried out on a person who does not have the capacity to consent for his or her direct benefit.

2. Where, according to law, a minor does not have the capacity to consent to an application of genetics, that application may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

However, genetic tests shall be deferred until the attainment of legal capacity unless that delay would be detrimental to the minor's health or well-being.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

3. Where, according to law, an adult does not have the capacity to consent to an application of genetics because of a mental disability, a disease or for similar reasons, that application may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The individual concerned shall, as far as possible, take part in the authorisation procedure.

4. The authorisation referred to in paragraphs 2 and 3 above may be withdrawn at any time in the best interests of the person concerned.

Sub-section B - Genetic services

Article 9 - Quality of genetic services

Parties shall take measures to ensure that preventive, diagnostic or therapeutic genetic services are of appropriate quality, and in particular to ensure that:

a. a quality assurance and monitoring programme for services, including quality control of laboratory procedures, is in place;

b. professional staff involved in genetic services have appropriate qualifications and training to enable them to perform their role within the services in accordance with professional obligations and standards;

c. genetic tests provided within such a service meet professional standards of scientific and clinical validity.

Article 10 - Equitable access to genetic services

Parties, taking into account health needs and available resources, shall take

appropriate measures with a view to providing, within their jurisdiction, equitable access to preventive, diagnostic and therapeutic genetic services.

Article 11 - Genetic counselling

Genetic counselling and support appropriate to the application of genetics and its implications for the person concerned or the members of the person's family shall be offered to the person who may receive the application.

Article 12 - Respect for private life and access to the results of an application of genetics

1. Everyone has the right to respect for his or her private life, in particular with regard to his or her personal data derived from an application of genetics.

2. Everyone undergoing an application of genetics is entitled to know any information collected about his or her health derived from this application. The information shall be accessible to the person concerned in an understandable form.

Information derived from a genetic application and not related to health shall be made available to the person concerned, subject to the conditions and procedures determined by law.

3. The wishes of individuals not to be informed shall be observed.

4. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 and 3 in the interests of the person concerned.

Article 13 - Storage of biological materials and personal genetic data

The conditions and duration of the storage of human biological materials and personal genetic data shall be regulated, in particular to ensure security and confidentiality.

Section II - Individual genetic test on living persons

Article 14 - Scope of Section II

The provisions of this section apply to genetic tests on a living person or materials removed from a living person performed in order to diagnose a genetic disease or disorder and/or to determine whether the person possesses one or more genetic traits which may

lead that person to develop a disease or a disorder in the future or may result in a disease or disorder if transmitted to that person's progeny or which are relevant to medical treatment.

Article 15 - Purposes of predictive genetic tests

Tests which are predictive of genetic diseases or disorders or which serve either to identify a person as a carrier of a gene responsible for a disease or disorder, or to detect a genetic predisposition or susceptibility to a disease or disorder may be performed only for health purposes or for scientific research linked to health purposes.

Article 16 - Exception for family members

1. Exceptionally, a genetic test can be carried out on a person not able to consent for the health benefit of family members, only if the following conditions are met:

a. the purpose of the test is to allow the family member or members to obtain an important preventive, diagnostic or therapeutic health benefit, or to allow them to make an informed choice with respect to procreation;

b. the implementation of such a test is essential to obtain the benefit envisaged;

c. the importance of the benefit envisaged has been independently assessed;

d. the risk and burden of the intervention, and risks to private life that may arise from the collection, processing or communication of the results of the test are minimal for the person who is to undertake the test;

e. the person undergoing the test does not object;

f. the authorisation of their representative, or an authority or a person or body provided for by law has been given.

2. If the person tested has expressed the wish not to be informed of the result of the test, this wish shall be observed.

Article 17 - Genetic tests on biological materials

1. A genetic test shall only be carried out on biological material previously removed from a human body if this is done in conformity with appropriate information and consent or authorisation procedures.

2. To that end, to obtain the consent or authorisation, reasonable effort shall be made to contact the person concerned.

Article 18 - Tests directly sold to the public

Alternative A

Genetic tests shall not be directly sold to the public.

Alternative B

The provisions of Chapter I and Sections I and II of Chapter II of this Protocol shall apply to genetic tests directly sold to the public.

Alternative C

Where the law permits direct sale of genetic tests to the public, there shall be adequate regulation, in particular to ensure proper information and understanding of the implications of the test by the person concerned.

…….

(January 2004)

Annex 2 to Opinion no 32 of 5 July 2004 on the free availability of genetic tests: list of the legally recognised centers of human genetics in Belgium

V.U.B. Dienst Medische Genetica V.U.B. Laarbeeklaan 101 1090 BRUXELLES Tel. 02/477.60.71 Fax: 02/477.58.00	**U.L.B.** Centre de Génétique U.L.B. Campus Erasme Route de Lennik 808 1070 BRUXELLES Tel. 02/555.41.69/41.15 Fax: 02/555.42.12
K.U.L. Centrum voor Menselijke Erfelijkheid K.U.L. Campus Gasthuisberg Herestraat 49 3000 LEUVEN Tel. 016/34.59.03 (secrétariat) Fax: 016/34.59.97	**LIÈGE** Centre Wallon de Génétique Centre Hospitalier Universitaire du Sart Tilman Bâtiment B23 Etage – 1 4000 LIÈGE Tel. 043/66.81.45 (secrétariat) Fax: 043/66.81.46
GENT Centrum voor Medische Genetica Universitair Ziekenhuis Gent – 0K5 De Pintelaan 185 9000 GENT Tel. 09/240.36.03 Fax: 09/240.49.70	**LOVERVAL** Institut de Pathologie et de Génétique Allée des Templiers 41 6280 GERPINNES – LOVERVAL Tel. 071/47.30.47 Fax: 071/47.15.20
U.C.L. Centre de Génétique de l'U.C.L Tour Vésale 5220 Avenue Mounier 52 1200 BRUXELLES Tel. 02/764.52.20 Fax: 02/764.52.22	**U.I.A.** Dienst Medische Genetica Universitaire Instelling Antwerpen Wilrijkstraat 10 2610 EDEGEM Tel. 03/820.25.70 Fax: 03/820.25.66