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Draft Consultation Document on Predictivity, Genetic Testing and Insurance

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INTRODUCTION

Background

1. In 1996, the Committee of Ministers instructed the Steering Committee on Bioethics (CDBI) "to draw up a Protocol to the *Convention for the Protection of Human Rights and Dignity of the Human* Being *with regard to the Application of Biology and Medicine* (thereafter the *Convention on Human Rights and Biomedicine*) concerning the problems relating to human genetics (…) taking also into account questions relating to the use and protection of the results of predictive genetic tests for purposes other than health or scientific research linked to health."

2. The *CDBI* decided to prepare separate instruments dealing with genetic testing for health purposes and genetic testing for employment and insurance purposes. The first pillar of the work has been completed with the adoption on 7 May 2008 by the Committee of Ministers of the *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes*.

3. The CDBI then began its work with a view to the development of a framework regulating the use of genetic testing for non health purposes starting with the field of insurance. To that end, a seminar on "Predictivity, Genetic Tests and Insurance" was organised on December 3-4 2007. Furthermore, in order to collect information on existing regulation with respect to the use of results from genetic tests and medical examinations in the insurance context, a questionnaire was sent to CDBI delegations.

4. At its 33rd plenary meeting (5 December 2007), the CDBI agreed to set up an exploratory group which would be entrusted with identifying the main issues that the future Group of Specialists would have to address as well as the types of expertise needed. The exploratory group was also asked to consider the advisability of including in the future legal instrument, medical examinations providing predictive health information other than genetic tests.

5. The exploratory group held a meeting in April 2008 at the end of which it recommended not to limit the scope of the future work to genetic testing proper, and to also consider other medical examinations providing predictive health information. In that context, it agreed that the notion of "predictivity" would need to be further discussed. It noted that the issues raised concerned scientific aspects on the one hand and legal questions on the other. On this basis it identified a number of types of expertise which would be needed to examine all of these issues. As for the methodology, the exploratory group proposed that the CDBI set up a Group of Specialists with a small core composed of the Chair and another member of CDBI, who should preferably have complementary expertise in the fields of law and medicine/science. The other members would be experts who would participate in the work of the Group of Specialists as appropriate, depending on the questions addressed at each meeting.

6. At its 34th plenary meeting (June 4-6 2008) the CDBI endorsed the recommendations formulated by the exploratory group as a whole. Dr Mark BALE (UK), with a background in the scientific field, and Prof. Carlos ROMEO CASABONA (Spain), a lawyer, were elected members of the core group[1], the latter also acting as Chair. At a later stage, considering his significant medical expertise, Prof Jacques MONTAGUT (France) was integrated in the core group.

7. The membership of the Group of Specialists is set out in Appendix 1. The Group of Specialists would like to thank all those experts who assisted it in its work.

[1] In January 2010, Dr Mark Bale due to a change of his responsibilities within the Department of Health, has announced his departure from the British delegation to the CDBI and the Group of Specialists.

The context and objectives of the Consultation Document

8. The Group of Specialists entrusted with "elaborating a draft legal instrument[2] concerning genetic tests in the field of insurance" first examined the notion of predictivity. When considering the issues raised by the use of predictive genetic test results for insurance purposes, the Group of Specialists concluded that the notion of predictivity was relevant not only for genetic examinations but also for other medical examinations. On the basis of this conclusion, and in agreement with the CDBI, it therefore widened the scope of its work to include all predictive information relating to health.

9. Next, the Group studied the risk assessment (underwriting) techniques of insurance companies. To this end, three representatives of the insurance sector, one representative of consumers and one representative of a mediation body have been heard by the Group. These hearings enabled the Group to note that some of the issues raised in that context were of a general nature and concerned the very functioning of the system of insurance, including in particular the processing of personal data for insurance purposes and the criteria for lawfully performing it. This led to the identification of a more general problem preceding the one concerning the use of predictive data for insurance purposes: the collection and processing, in the field of insurance, of health-related data.

10. The hearings and the ensuing discussions enabled the Group of Specialists to identify a certain number of issues and relevant principles. They also led to some proposals. The Group also noted that these issues were mostly complex and transversal, requiring analysis through multidisciplinary expertise (including ethics, law, medicine/science, but also technical and social aspects).

11. Preliminary research also revealed a broad spectrum of approaches among the Council of Europe's member States in regard to the use of genetic data in the context of insurance, ranging from absence of a regulatory framework, restriction on insurers' freedom to underwrite associated with financial caps, to outright legal prohibitions. Moreover, in some countries, insurance companies opted for voluntary moratoria on the use of genetic data.

12. On that basis, the Group of Specialists considered that before starting the proper elaboration of a legal instrument, it would be appropriate to carry out a more thorough analysis of the issues raised and to consider different options within the framework of the fundamental principles for the protection of human rights. In that light, it proposed to prepare this Consultation Document which examines the different problems identified, discusses them and presents the different options which could be envisaged with pro and con arguments. In doing so, the Consultation Document aims to generate comments from all the stakeholders, in particular with regard to different options envisaged as well as to form the basis for the future legal instrument.

Structure of the Paper

13. Given the highly technical nature of private insurance, the Paper begins with a preliminary chapter describing the functioning of private insurance, including its governing rules and principles. It then examines the general problems surrounding the collection and use of health related data for insurance purposes (Chapter 1), followed by an analysis of those specific to the use of predictive health data in the same context (Chapter 2). In a third chapter, it addresses social and legal aspects of the questions raised.

[2] The status of the legal instrument (legally binding or not) remains to be determined.

PRELIMINARY CHAPTER: THE FUNCTIONING OF PRIVATE INSURANCE

1. Private insurance and social welfare schemes

14. In contemporary societies, healthcare costs and financial losses associated with mortality and morbidity are usually covered by social welfare schemes or by private insurance. At one end of the spectrum are the social welfare schemes, based on the principle of social solidarity. In this model, the risks associated with health are spread among all or a significant proportion of members of a community. The level of coverage and the associated rules are established for everyone and cover is financed through broad contribution-based mechanisms such as income tax. In principle, there is no underwriting and contributions do not reflect each person's individual risk profile. In contrast, under a private insurance model, risks are classified and grouped together in homogenous groups. This risk classification process is known as "segmentation". The private insurance model uses the segmentation technique to select and assess the risks presented by individuals and adjust insurance enrolment rules and premiums accordingly. Stringent selection takes place upon application to join a scheme. Under this system, insurers may consider that some individuals present too high a risk to be insured (coverage is refused) or agree to insure them only with certain exclusions (particular illnesses or disorders may be excluded). They may also charge higher premiums. Lastly, insurers may make coverage subject to additional conditions, such as the application of a waiting period or an excess fee.

15. Private insurance and social welfare schemes do not necessarily exclude each other. Private insurance may offer complementary coverage (voluntary) to the one provided by social security, for example with regard to medical expenses not or only partially covered by the social welfare scheme. Legislation may require private insurance companies to contribute to a social solidarity-based system ("subsidising solidarity"). This is the case for complementary insurance schemes that are made compulsory, in which the underwriting policies are strictly regulated by the state. In such contexts, insurance companies are in competition concerning the quality of the services provided.

2. Private personal insurance: principles and rationale

16. Private personal insurance is based on **underwriting** which requires applicants to give an accurate and complete description of the risk characteristics to be covered, in particular the individual's health history insofar as this may impact on the assessment of the risk. Here the "**good faith**" concept plays a very important role. Each party to the contract must comply honestly and fairly with the commitments entered into under the contract.

17. In accordance with the **principle of the mutualisation** of risks, policyholders are categorised in homogenous groups and pay the average premium corresponding to the recognised level of risk. This classification system is often referred to as "**actuarial fairness**" by the industry since the price of the insurance reflects, as accurately as possible, the level of risk presented by the policyholder (pure premium) plus administration and marketing costs (commercial or market premium).

18. Generally speaking, people who are aware that they present significant health risks could have a greater incentive to take out insurance and request more extensive coverage. Some people, because of their risk level, may also be tempted to make false declarations in order to pay lower premiums or have broader coverage. In such cases, the actuarial calculation establishing the premiums will be inaccurate and the amount of premiums collected will not be sufficient to cover the claims. As a result, prices may rise (making it more difficult for people

on low incomes to afford insurance) and there may no longer be any coverage for the higher risks. Where insurers are no longer certain of being able to correctly assess risks, certain products may be withdrawn from the market. This is termed **adverse** or **anti-selection** by insurers.

19. The private insurance policies offered to the general public are usually in the form of an **adhesion contract**, which sets out the general conditions that apply. An individual has virtually no alternative other than to accept or refuse the contract. The margin for negotiation is therefore extremely small, if not non-existent. As in the case of other types of adhesion contracts, national legislation usually imposes some limits on the contractual freedom of the party offering the contract (i.e. insurer) with a view to re-establishing a balance in the relationship between the parties and protecting the insurance applicant.

3. General concepts and insurance categories

a. Reinsurance

20. An insurance company may conclude a reinsurance agreement (treaty) in order to share or transfer risks in the event of there being a higher claim rate than anticipated, which could threaten its financial capacities. This treaty will stipulate the conditions under which the reinsurer will pay for the insurer's losses.

21. The person who has taken out the insurance policy is a third party in respect of the reinsurance contract. He or she, in most cases, will be unaware of the existence of the reinsurer and will have no dealings with the latter.

b. Co-insurance

22. Co-insurance is an operation in which a policyholder spreads the risk or set of risks between several insurers. In such cases, the risk is shared based on percentages between the insurance companies, with, unless there is a clause to the contrary, each one guaranteeing only that part which it has agreed to cover.

23. In contrast to reinsurance, in which there is a vertical sharing of risks, co-insurance operates via the horizontal spreading of risks between each co-insurer. In this arrangement, the policyholder has a contractual relationship with each of the co-insurers.

c. Individual and group insurance

24. Unlike individual insurance, in which there is a relationship between one individual and an insurer, group insurance is taken out by an individual to cover a specific group. It covers all members of that group irrespective of their individual risk profiles, which is why it is generally less expensive than individual insurance (for example, an employer may take out a group insurance policy for his or her employees). A common feature in group insurance is that the premium cost is based on the characteristics of the group (e.g. size, industry sector, occupational risk profile, locality and previous mortality experience). Most personal insurance (e.g. health, life, disability, and critical illness insurance) can be taken out in this way.

d. Compulsory/mandatory insurance (by law or contract)

25. Taking out an insurance policy may be made compulsory by law (for example, statutory health insurance in Germany and the Netherlands). The obligation to take out an insurance policy may result from a commitment stipulated in another contract (for example, the obligation to take out life insurance when obtaining a mortgage, or a tenant’s obligation to take out rental insurance policy as part of a lease agreement).

4. Types of personal insurance coverage

a. Health insurance

26. Health insurance commonly provides coverage for medical expenses incurred by the policyholder, such as the purchase of medicines, visits to the doctor, hospital stays, etc. The policies available vary considerably (the amount of excess or patient contribution, limitations of coverage, treatment options available to the policyholder, etc.). Even in countries that provide universal health services under the social security scheme, the emergence of parallel (complementary or supplementary) private insurance regimes creates a multi-level system for covering healthcare costs.

b. Critical illness insurance

27. Critical illness insurance is purchased to protect against potential financial difficulties should an individual become seriously ill. It guarantees the payment of a fixed sum upon the occurrence of any of a specified list of serious conditions detailed in the policy. Critical illness insurance coverage is an important component of insurance portfolios in the USA and the United Kingdom. In recent years, it has also gained popularity in Canada.

c. Long-term care/dependence insurance

28. Long-term care insurance covers long-term care resulting from the policyholder's loss of autonomy because of age or chronic illnesses such as dementia and strokes. It may also cover assistance and care provided to the dependent person in his or her home or in a care home, as well as technical aids and adaptations to the individual's home.

d. Life insurance

29. Life insurance is a long term product that guarantees a fixed sum, the amount of which is unaffected by the foreseeable contingency, payable on the death of the policyholder or if he or she lives beyond a certain age.

e. Disability insurance

30. Disability insurance is meant either to provide the policyholder with a replacement income in the event of an accident or sickness preventing him or her from working over an extended period or, in similar circumstances, to reimburse various fees and expenses (for example, accommodation) in which case the claim may be paid directly to a third party. The amount guaranteed may be a fixed sum or a compensatory payment.

CHAPTER 1: COLLECTION AND USE[3] OF HEALTH-RELATED DATA FOR INSURANCE PURPOSES

1. General practice of the insurance industry

31. Insurers collect data from insurance applicants with a view to evaluate their risk and decide whether, and at what conditions to offer insurance (underwriting). When it comes to insurance contracts where health risks play a significant role (e.g. life, disability, health, critical illness, long-term care, retirement), data collected by the insurers concern mainly the applicant's health status as well as factors that can affect the health status (lifestyle, diet).

32. If he/she does not provide data requested by the insurer, the insurance applicant might end up being refused coverage.

a. How are health-related data collected?

33. Health-related data can be collected through several ways and only with the valid consent of the insurance applicant by requiring :

- the applicant to fill in an application form (including questions pertaining to his/her health status), a lifestyle and/or health questionnaire (including questions about family history of diseases)
- a medical examination (performed by the applicant's doctor or by an independent medical practitioner)
- access to data (e.g. medical record, medical test results) kept by third parties to the contract (e.g. family doctor, general practitioner).

b. What is the scope of data requested?

34. The scope of data requested for underwriting depends on several factors such as the type of risk to be covered (e.g. life or critical illness), the sum to be insured, the sex, age and lifestyle of the applicant. Hence, in some cases, a written declaration from the applicant or the filing of a self-reported "simple" health questionnaire attached to the application form will suffice. In other cases, in particular when the responses of an applicant highlight areas for further investigation, a more comprehensive health questionnaire may be used. This could also involve the disclosure of an additional amount of personal data, including family and past history of disease, lifestyle factors, medical test results, etc.

c. Who is collecting and processing the data?

35. At the point of sale of the contract by the insurance company, the applicant fills out the application form and receives the list of documents, if any, to be submitted to the company for underwriting. Once completed, the documentation is given to the front office which then sends it to the head office of the insurance company for processing.

36. The underwriting papers are examined at different stages according to the sum to be insured and the health condition of the applicant:

- Stage I: the front office of the company handles those files in which the health questionnaire in the application form provides sufficient data;
- Stage II: the underwriting department of the head office of the company where underwriters examine the health-related data of the insurance applicant autonomously in their capacity as underwriters.

[3] Given the different nature of issues they raise, it was considered appropriate to distinguish between collection and processing of data. Since the term "processing" is highly technical and leads to confusion as to its scope (does it cover collection or not?) the term "use" has been preferred for the title of this Chapter. However, the rest of the document refers to the term "processing" with a view to ensure the coherence with relevant legal instruments. This term must be understood as covering all operations concerning health-related data for insurance purposes except for collection.

- Stage III: medical doctors working for the company, either as full time employees or external consultants, also examine the risks independently and give an assessment in agreement (or not) with the senior underwriter.
- Stage IV: the underwriting department of the reinsurer of the insurance company itself then also examines the risks over the underwriting independence of the company.

d. What are the possible outcomes of underwriting?

37. The underwriting is based on the knowledge and experience of underwriters and medical doctors who give their evaluation on the basis of ratings suggested in the underwriting manuals. Underwriting manuals are up-to-date, evidence-based rating guidelines suggested for the assessment of different risk factors. These guidelines are usually produced by reinsurers using data from clinical and insurance literature, as well as the findings of experience studies analysis[4].

38. At the end of the underwriting process, on the basis of the risk presented by the insurance applicant, the insurer establishes if and at which conditions the latter can be covered. The following alternatives may be considered:

- the risk is acceptable at standard conditions (with a standard premium);
- the risk is acceptable but with the application of an extra premium;
- the risk is acceptable with specific exclusion clause(s) (e.g. the insurance company may exclude coverage for any asthma-related breathing problem for an asthmatic, or for certain types of long-term illnesses such as Parkinson Disease, Multiple Sclerosis);
- the risk is deferred for a reconsideration after a certain period of time;
- the risk is declined.

2. Issues raised

39. In relation to the general practice of the insurance industry, in particular with regard to the collection and processing of health-related data, some issues that have been identified as being potentially problematic with regard to fundamental principles (see point 3.a) are listed below (from a to d). This list is complemented with issues raised by the internationalisation of the insurance market and those that may result from potential abusive conducts (points e and f).

a. With regard to the way data are collected

i. Health questionnaires

40. Health questionnaire is one of the tools to collect information from the insurance applicant. The content of the questionnaires varies among the different insurance companies and this variability is considered by insurers to be part of the freedom of competition. Notwithstanding the content of the questionnaires, the ultimate objective is to collect information that is relevant for the insurance contract (and not just any information) with a view to assess the risk of the insurance applicant. In parallel, in most European countries, the insurance applicants have the broad legal duty to provide insurers with all information about the circumstances of their health which are relevant for the insurance contract. If the insurance applicant fails to disclose the relevant information, then the insurer might withdraw the contract. Considering in particular the sensitive nature of health-related data, this legal duty should however not put the applicants in a position where, for example through open-

[4] Studies that compare real experience with expected experience for the period covered by the study.

ended[5] questions, they end up disclosing information that are not relevant to the insurance contract.

41. Hence, it seems both in the interest of insurers and insurance applicants that questionnaires meet certain criteria so that they are an appropriate tool for providing accurate information strictly relevant to the insurance contract, without interfering disproportionately with the private life of the applicant. In this context, consideration should be given in particular to the clarity of questions ; vague or complex questions can be misunderstood by applicants who are generally not familiar with medical terminology, and who may thus end up providing inaccurate and/or irrelevant information. The order in which the questions are asked can also have an impact on the overall coherence and comprehension of a questionnaire.

ii. Medical examinations

42. A medical examination may be requested by an insurance company to identify the presence of the main risk factors and/or pathologies potentially afflicting an applicant. The nature of a medical examination may vary from country to country and will also depend on the type of risk to be covered. Like all medical examinations, a medical examination taken for insurance purposes can be physically invasive. Moreover, its results can have implications in terms of right to respect for private life and in particular, the right not to know in so far as they may reveal information not only on the current health status of the insurance applicant but also with regard to his/her future health.

43. Finally, medical practitioners who perform examinations requested by the insurers are bound by frame of references/evaluation criteria suggested in the underwriting manuals. One can raise doubts as to whether such references/criteria influence the accurate and objective evaluation of examinations' results concerning the persons health.

iii. Communication of data by third parties to the contract

44. The principle of medical confidentiality is the bedrock of the physician-patient relationship. It is a strict legal duty of the physician and can only be lifted for a very limited number of exceptions, such as by law (e.g. mandatory reporting obligations) or by obtaining the consent of the patient.

45. Hence, as such, the practice of accessing health-related data kept by a family doctor and other healthcare providers with the consent of the insurance applicant is not in conflict with the duty of medical confidentiality of the healthcare providers. However, such practice may negatively impact the open, trusting nature of the doctor-patient relationship, as well the accessibility to healthcare in general by affecting the public trust in the medical establishment.

46. Moreover, it should not be forgotten that in some countries (e.g. France), only the patient, not the physician, may communicate the relevant information from his/her medical file to the insurer as the physician is not allowed to communicate to the insurer information from the patient's medical file even with his/her consent.

b. With regard to the scope of data obtained/ received

47. The data received by the insurer can end up being greater in terms of content than needed for the risk assessment. This issue has already been raised concerning health questionnaires (see point 2 a.i), but is also relevant for other ways of collecting information for insurance purposes. Indeed, a medical examination can reveal data that are not sought for in connection with the insurance contract in question. This type of situation could also manifest itself if the applicant or a third party (e.g. the applicant's physician) in order to save time sends the content of the applicant's entire medical file to the insurer.

[5] It was noted that some insurance company questionnaires include open questions as a way to ensure that applicants do not forget to disclose any medically relevant information needed for underwriting (e.g. "Please indicate any disorders or illnesses, deformities or problems that are not explicitly mentioned above")

48. The fate of such information that is not relevant for underwriting should be addressed taking into consideration the right to respect for private life and ensuing data protection principles.

49. In the same context, consideration should be given to situations where the applicant provides information on the medical history of relatives. In such situations, names and date of birth of relatives are not asked, but even without these elements, the person concerned could be personally identifiable by the insurer or a third party on the basis of his/her pathology or his/her relationship to an applicant/policyholder. This situation raises the question of the privacy of familial data (family history) obtained from an applicant.

c. With regard to access to and storage of data

50. Along with access to health-related data – be it from the questionnaire form, medical records or insurer-financed medical examination – comes the responsibility to protect the applicant's privacy. More persons that have access to medical data in the personal file, the greater the risk that confidentiality could be compromised. In this context, given the sensitive nature of health-related data, consideration should also be given to the filing practices of the insurers and in particular to the possible consequences of filing health-related data together with other personal data.

d. With regard to underwriting process and its possible outcomes

51. The underwriting is a complex process which requires important technical knowledge. In addition to this technicality, there is little information about the underwriting rules applied by insurers. In particular, the criteria for determining what data are to be obtained from insurance applicants are opaque, and how the information collected is translated into the actuarial language that serves as a basis for calculating the risk and the premium is unclear[6].

52. The lack of transparency and clarity with regard to the rules governing the underwriting process raise issues. In this context, given in particular the sensitive nature of the data requested by insurance companies, it would be important to ensure that, to be deemed relevant, data requested for risk calculation meet certain objective criteria.

53. Moreover, on a purely individual stand, considering the possible negative outcomes of underwriting and given the limited room for manoeuvre for the insurance applicant, it would be important to ensure the transparency and the clarity of this pre-contractual phase as well the fairness of the process, re-establishing henceforth a certain balance between the insurer and the insured.

e. Issues raised by the internationalisation of the insurance market

54. The insurance business is becoming increasingly international in nature. Indeed, individuals may hold insurance policies from various jurisdictions. Their medical history, as well as the results of their medical examinations, could be processed or stored in different countries. Same wise, in cases where the reinsurer is involved with the risk evaluation (see above, under 1.c), if the latter is a foreign one (i.e. if the insurer purchased reinsurance from a foreign reinsurer), this would involve processing and storage of health-related data outside the country where the applicant purchased insurance.

55. Each of these possibilities raises the spectre of how confidentiality rules play out in international industry practices.

[6] In this respect, the Group of Specialists noted that the assessment of the same risk could lead to the imposition of widely differing additional premiums, depending on the insurance company. According to one example supplied by the German private health insurance Ombudsman, the same person seeking insurance and presenting back problems was asked by two different companies to pay additional premiums of, respectively, 200% and 30%.

f. Issues that may result from potential abusive conducts

56. Nowadays, internet repositories (e.g. personal blogs, facebook pages) can provide information in relation to the health status of people, or their lifestyle. In addition to issues they may raise with regard to the right to respect for private life, this type of information is open to doubt when it comes to its genuineness, in particular when they come from third parties.

57. Moreover, once obtained, the relevant health-related data collected from an insurance applicant can theoretically be stored longer than necessary (to the realisation and execution of the contract) and used for example, in combination with health data found in other applications made by this person or his relatives or, information obtained from other sources (for other purposes), without the knowledge and consent of the applicant. Such potential abusive conducts would also raise issues with regard to the right to respect for private life.

3. Legal principles and possible options

a. Relevant legal instruments

58. In Europe, health-related data are protected both by general human rights instruments and more detailed normative documents on data protection.

i. General human rights instruments

- European Convention on Human Rights and the Case-law of the European Court of Human Rights

59. Article 8§1 of the European Convention on Human Rights (ECHR) stipulates that "*Everyone has the right to respect for his private and family life, his home and his correspondence".* According to the case-law of the European Court of Human Rights, health-related information touches upon the very core of the right to private life and the processing of such data falls within the realm of Article 8 ECHR[7]. Likewise, respecting the confidentiality of such data is, according to the Court, "a vital principle in the legal systems of all the Contracting Parties to the Convention."[8]

60. The Court made an extensive interpretation of this duty to protect confidentiality. In fact it consistently held that the right to private and family life does not merely compel States to abstain from arbitrarily interfering with private and family life; in addition to this primarily negative undertaking, there may be positive obligations inherent in an effective respect for private life. These obligations may, according to the Court, involve the adoption of measures designed to secure respect for private life even in the sphere of the relations of individuals between themselves[9]. Effective respect for private life may therefore require States to make regulations compelling those operating in the private sector, including insurers, to respect the confidentiality of health-related information.

- Convention on Human Rights and Biomedicine *(ETS 164, Oviedo, 04.04.1997)*

61. Article 10§1 of the Convention on Human Rights and Biomedicine establishes the right to respect for private life in relation to information about health, thereby reaffirming the principle introduced in Article 8 of the ECHR. The second paragraph lays down that individuals are entitled to know any information collected about their health, if they wish to know. The right to know goes hand in hand with the "right not to know", which is provided for also in the second paragraph. Patients may have their own reasons for not wishing to know about certain aspects of their health. A wish of this kind must be observed.

[7] ECtHR 26 March 1987, *Leander v. Sweden*, no. 9248/81, § 48 and ECtHR 4 May 2000, *Rotaru v. Rumania* (GC), no. 28341/95, § 43.
[8] ECtHR 17 July 2008, *I. v. Finland*, no. 20511/03, § 38
[9] ECtHR 26 March 1985, *X and Y* v. *the Netherlands* no. 8978/80, § 23

ii. Specific instruments on data protection

- Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data *(ETS No. 108, Strasbourg, 28.01.1981)*

62. The Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (Data Protection Convention) requires States to take 'the necessary measures in their domestic law' to give effect to the basic principles for data protection, including health-related information. The latter principles are particularly concerned with data quality, namely.

- data must be obtained and automatically processed[10] fairly and lawfully;
- data must be recorded for specified and legitimate purposes;
- data must not be used in a way incompatible with those purposes;
- data must be stored only for as long as is required for these purposes;
- data must be recorded in an adequate, relevant and non-excessive (proportional) manner vis-à-vis the said purposes; and
- data must be accurate

63. It should be pointed out that, under Article 6 of the Data Protection Convention, personal data concerning health constitute a special category of data the automated processing of which is prohibited unless domestic law provides appropriate safeguards.

64. The Data Protection Convention also provides for the free flow of personal data between Parties to the Convention. This free flow shall not be restricted for the purposes of data protection. However, parties can derogate from these provisions in two cases: the first enables a Party to derogate if its legislation includes specific regulations for certain categories of data of a special nature (unless the other Party provides equivalent protection); the second covers a situation where data are transferred by a Party to the territory of a non-contracting State through the intermediary of another Party and where such transfer may result in circumvention of the originating Party's legislation.

65. In this connection, according to article 2 § 1 of the **Additional Protocol to the Data Protection Convention regarding supervisory authorities and transborder data flows**, transborder flows of data to a recipient which is not subject to the jurisdiction of a Party are subject to the condition of an adequate level of protection in the recipient country. In this context, it should be noted that the **Safe Harbour Privacy Principles** established between the European Union and the United States provides some guidance to insurers on how to control transborder flow of health data.

- Recommendation No. R (2002) 9 on the protection of personal data collected and processed for insurance purposes (adopted by the Committee of Ministers on 18 September 2002)

66. This recommendation is intended to strike a balance between the interests of insurance companies on the one hand, and the protection of privacy on the other hand. In particular, it establishes principles concerning the collection and processing of personal data for insurance purposes[11]. Accordingly, such collection and processing should be carried out fairly and lawfully and for specified and lawful purposes and data must be:

- adequate, relevant and not excessive in relation to the purposes for which they are collected or for which they are to be further processed;
- accurate and, if necessary, kept up to date.

[10] According to Article 2 c) of the Convention, the automatic processing of data includes storage of data, carrying out of logical and/or arithmetical operations on those data, their alteration, erasure, retrieval or dissemination.
[11] Health-related data is considered sensitive data by the recommendation

67. **Principle 3.2** stipulates that persons involved in insurance activities who have access to personal data must respect confidentiality in accordance with domestic law and practice, possibly complemented by codes of ethics approved by the industry. It also makes it clear that medical data, in particular, can only be collected and processed by health professionals or persons subject to confidentiality requirements laid down in domestic law that are comparable or equally effective.

68. **Principle 4.2** stipulates that personal data must in principle be collected from the data subject or his/her legal representative. In practice however, data are not necessarily collected from the data subject, but from a third party. In such situations, the data subject must be informed of the collection.

69. The recommendation also introduces the notion of *Controller*[12] which refers to the concept of "controller of the file" as set out in Article 2 of the data protection Convention.

70. The Recommendation requires the deletion of personal data once they are no longer necessary for the purposes for which they were collected and processed. This principle also applies where a decision is taken to refuse insurance coverage. If they must nevertheless be conserved for purposes of scientific research or statistics, or other purposes provided for by law, they should be conserved separately and be accessible only for these purposes subject to appropriate safeguards.

iii. Other relevant instruments

71. The Data protection Convention was a source of inspiration in the elaboration of European Union **Directive E95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data** which attempts to harmonize the privacy laws of EU member States[13].

72. **Recommendation No. R (97) 5 on the protection of medical data**, adopted by the Committee of Ministers of the Council of Europe on 13 February 1997 provides that the protection of privacy should apply, by means of the appropriate safeguards, to all medical data, whether processed by a doctor or by another person. It protects any information which might give an idea of a persons' medical situation, such as for insurance purposes, for example data of his or her behaviour, sex life, lifestyle, drug consumption or alcohol or tobacco abuse. The Recommendation contains also specific provisions concerning genetic data.

b. General applicable principles

73. The principles set out below are based on the relevant data protection instruments. They are general principles applicable to the collection and processing health-related data in the insurance sector, which means that they constitute the preconditions for any process of collecting and processing data for insurance purposes.

74. In the first place, sensitive data can only be collected and processed with the free and informed **consent** of the data subject. In the insurance context, this means providing the insurance applicant with appropriate information on the possible consequences of such collection/processing on his/her insurability (including the modalities and purposes of the collection/processing). Furthermore, in cases where the data is collected using a medical examination, the insurance applicant must be informed in advance of any information about his/her health that might result from such an examination. If the information is collected from third parties, the data subject must be informed of such collection and of the content of the information collected (access by individuals to information concerning them).

[12] The natural or legal person, public authority, agency, or any other body which, alone, or in collaboration with others, determines the purposes of and means used in the collection and processing of personal data.
[13] Health-related data is considered as "sensitive data" by the *Directive* (art. 8(1)).

75. Insurance companies must ensure that they only ask for information that is **necessary** for insurance purposes. The principle of necessity requires that health-related data only be sought if the risk presented by the applicant cannot be evaluated without the data in question.

76. The information to be collected and processed should be **relevant**. The principle of relevance requires that there be a clear, well-established link between the health data gathered by the insurer and the risk to be covered.

77. The information to be collected and processed should also be **reliable**. The application of the principle of reliability is particularly relevant when it comes to medical test results (see below).

78. The principle of **proportionality**, complements these requirements by ensuring the adequacy of the means (collecting and processing health-related data) to the aim pursued (risk assessment), with due regard for the legal rights involved (in particular the right to privacy and the closely related right not to know but also other fundamental rights such the right no to be discriminated against). The principle of proportionality would also be relevant for determining the tool to collect data (e.g. questionnaire or medical examination).

c. Possible options

With regard to the way data are collected

- *Questionnaires on health and medical examinations*

Do you agree with the following proposals?

I. Questionnaires and medical examinations as tools for collecting health-related data should comply with certain qualitative criteria:
   a. In general, questionnaires should be clear and comprehensible; in particular, the questions should be relevant, formulated in a clear and easily understandable language and organised hierarchically, allowing the insurance applicant to fully understand the type of information requested. This would avoid any potential resultant difficulties in interpreting questions or disputes, and guarantee that the insurer collected only information relevant for underwriting. Moreover, open or subjective questions such as "do you consider yourself to be in good health?" should be avoided.
   b. Medical examinations should only be requested with due regard to of the principle of necessity, relevance and proportionality.
   c. Only the results of medical tests which form part of established medical practice and meet the criteria of scientific validity and clinical validity can be collected for insurance underwriting.

II. A multidisciplinary body should be set up to ensure the compatibility of questionnaires and medical examinations with the above requirements (see also option IV, chapter II).

III. Insurance applicants should be allowed to obtain clarifications on the meaning of the questions asked in order to be able to reply appropriately.

IV. Given that medical practitioners are subject to reference catalogues when they carry out medical examinations in the insurance context, can the assessment of the results of such examinations be deemed accurate and objective? If not, what measures should be taken to guarantee the accuracy and objectivity of such examinations?

- *Communication of data by third parties*

In countries where communication of existing health-related data by third parties is allowed:

Do you agree with the following proposals?

V. *Third parties should only communicate these data with the insurance applicant's consent [the question arises here whether insurers can be sent information which, for one reason or another, has not been communicated to the insurance applicant but which might be relevant for the insurance contract].*

VI. *Third parties must ensure that they disclose only data which are corresponding to the request (e.g. doctors must not send full medical records or transmit data which do not concern the patient's health).*

VII. *To what extent can the right not to know be fully respected in cases where a medical examination conducted for insurance purposes reveals information that is not already known by the patient?*

With regard to the scope of data obtained

In pursuance of Article 5 of the Data Protection Convention (art. 5):

VIII. *Any data irrelevant for underwriting which are provided by the applicant or, where allowed, by a third party, should be deleted in a timely manner.*

With regard to access to and storage of data

Do you agree with the following proposals?

IX. *Insurers should:*
   a. *establish rules (e.g. privacy codes, good practices, codes of conduct) which protect the security and confidentiality of personal data (in accordance with domestic law). These rules should be made available to the public.*
   b. *have a data controller in charge of enforcement of these rules. Failure to adhere to the rules should lead to appropriate action, including disciplinary measures and, if necessary, legal consequences.*
   c. *handle data responsibly, and only provide access to members of their staff who need to use them in order to underwrite an insurance application. These individuals* should be trained in identifying personal data irrelevant to insurance application documents, so that they can immediately be deleted without being recorded or processed.

X. *Health-related data should only be collected and processed by staff members who are subject to confidentiality requirements that are comparable or equally effective to those laid down in domestic law for health professionals.*

XI. *Insurance applicants should be made aware of the nature of the actual data which are being processed by an insurer, their source and of the purposes for which they are being used. Insurance applicants should also be provided with the identity of the data controller as well as that of possible third party recipients. Applicants should have access to the information required for lodging specific privacy claims and complaints, if necessary.*

XII. *Where the application for insurance coverage is rejected, the data collected for insurance purposes can only be stored for use in the context of a dispute concerning the said rejection, and only for the period of time required to settle the dispute.*

With regard to the underwriting process and its possible outcomes

Do you agree with the following proposals?

XIII. With a view to improving the coherency, transparency and fairness of the underwriting process:

- *a. insurance companies should provide reasons for any higher than standard premium, rejection of an application or exclusion, on request (the right not to know must be taken into account in providing the reasons). This would give the applicant, where relevant, the opportunity to challenge the decision of the insurance company, thus contributing to the fairness of the process.*
- *b. a body should be established to monitor underwriting practices with a view to ensuring some degree of coherency between different insurance companies; what type of body could be set up (an independent authority, a mediating agency, a body coming under the insurance company)?*
- *c. regular communication and meetings should be organised between insurers, consumers and other stakeholders (such as physicians, actuaries, government representatives, etc.) in order to create a collaborative strategy to increase transparency, build trust, and ensure a well-balanced relationship between the contractual parties.*

Issues raised by the internationalisation of the insurance market

XIV. In accordance with the data protection instruments:

- *a. third-party recipients of personal data (e.g. reinsurers, co-insurers etc.) should be bound by the same governing principles as those applicable within the insurance company which originally collected the data;*
- *b. the free flow of personal data should not be restricted for the purposes of data protection. Transborder flows would, however, require the recipient country to possess at least an equivalent level of privacy protection if the sending country has legislation including specific regulations for certain categories of data (e.g. health-related data);*
- *c. transborder flows of data to a recipient which is not subject to the jurisdiction of a Party to the Data Protection Convention are subject to the condition of an adequate level of protection in the recipient country.*

Issues that may result from potential abusive conducts

Do you agree with the following proposals?

XV. Data may not be processed further for purposes incompatible with the original purpose of the collection. (e.g. for other insurance contracts or in order to confirm medical data on relatives of the insured person).

XVI. In view of the issues they may raise with regard to the right to respect for private life and that surrounding their authenticity, data collected from Internet directories should not be used in the insurance field.

CHAPTER 2: SPECIFIC ASPECTS OF GENETIC PREDICTIVE AND OTHER PREDICTIVE DATA

1. Scientific aspects

79. Predictivity is a broad concept which refers to the capacity to know something in advance. In the field of biomedicine, it relates to the capacity to assess the probability of the onset or development of a disease that has not yet manifested itself.

80. Predictivity should be distinguished from concepts such as resistance with regard to a particular disease. It is also different from the individual prognosis of a person affected by a disease which is already expressed.

a. Predictive data from genetic tests

i. Definition

81. Within the meaning of this Consultation Document, and in conformity to Article 2 of the *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes*, genetic tests are understood as being:

> Tests involving analysis of biological samples of human origin and aimed specifically at identifying the health-related genetic characteristics of a person that are inherited or acquired during early prenatal development. Analysis refers to chromosomal analysis, DNA or RNA analysis, and analysis of any other element enabling equivalent information to be obtained, i.e. information that is directly linked to the genetic characteristics sought and thus allows direct information to be obtained concerning the genetic characteristics of the person concerned. This is the case in particular with analysis of gene expression products.

ii. Characteristics of the data resulting from genetic tests

82. A number of characteristics may be emphasised as regards data resulting from genetic tests. This data provides information about the individual genetic characteristics of the person on whom the test was performed, but potentially also characteristics of members of the person's biological family.

83. In the complete absence of symptoms, the results may possibly provide information on the person concerned future health (see section d. below). Their predictive value in relation to the development of diseases nonetheless remains extremely variable and, in the vast majority of cases, limited (see section c. below), owing in particular to the diversity of factors involved, non-genetic ones included, and to the complexity of their mutual interactions.
The capacity to anticipate a possible future health situation at a very early stage (including before birth) before the possible development of a disease should also be added.

84. These characteristics, taken singly, need not be specific to genetic data. However, their aggregation and their importance especially regarding risks to the protection of privacy and risks of discrimination have prompted several states (e.g. Germany, France, Norway, Switzerland) to define a specific legal framework, prohibiting or stringently and precisely limiting the use of the results of genetic testing for non-health purposes.[14]

[14] It is also noted that in its working paper on genetic data published in 2004, the Working Party Article 29 (EU Data Protection Working Party), stated that "the processing of genetic data in the field of insurance should be prohibited in principle and only authorised under really exceptional circumstances, clearly provided for by law." The WP Art.29 based its conclusions on the fact that such processing "could lead to an insurance applicant or members of his family being discriminated against on the basis of their genetic profile."

iii. Technological developments

85. Whole genome studies (WGS) now permit the generation of a very large quantity of data which will help improve scientific knowledge, especially on multi-factorial diseases. But as pointed out in particular by the European Society of Human Genetics, they do not allow/[are not sufficiently specific] for prediction to be made on occurrence of these diseases in the future and may sometimes provide an inaccurate perception of the risk for an individual.

86. It is reasonable to assume that High Throughput Sequencing (HTS) technologies will little by little form an integral part of clinical practice. These technologies will allow on the one hand for complete sequencing of the genome, for instance, to be performed at an increasingly affordable cost and at short notice, but will generate a mass of information the bulk of which will not be relevant to the clinical problem addressed. On the other hand, information may be delivered concerning another health risk, which was not specifically sought initially. This technological progress in clinical practice should definitely be taken into account in examining the potential use by insurers of predictive genetic health data.

iv. Monogenic disorders/ Common multi-factorial disorders

87. Monogenic disorders – either dominant or recessive – are inherited diseases which development is linked to the alteration of a gene (such as a mutation), even if the effect of such alteration may, in certain cases be modulated by other factors. This modulation may even sometimes results in a protection. This is the case for example with cystic fibrosis for which several hundreds mutations have been identified; it has been demonstrated that if some of these mutations are present simultaneously in an individual, the disease will not develop (genes interactions).

88. While therapeutic or preventive methods exist for some of them (e.g. hereditary breast/ovarian cancer, various forms of hereditary colon cancer, hereditary endocrine tumours), for others no effective treatment is currently available (Huntington's chorea, other forms of neurodegenerative diseases, hereditary ataxias, hereditary muscle diseases). To test for a monogenic disorder, the relevant mutation or mutations have to be identified. Then, relatives at risk within a family can be tested for the familial mutation(s).

89. However, monogenic diseases, for which genetic alterations on their own play a decisive part in the development of the disease, are very rare. Diseases are overwhelmingly classed as "multi-factorial". Their onset in a person involves genetic at the same time as "environmental" factors (e.g. life style, diet,…) and interactions between them. These disorders have a highly complex causation in which the genetic factor cannot be used by itself to assess the risk of the disease developing.

90. A growing number of associations between mutations and common diseases have been revealed by association studies on the whole genome. However, for many associations where their confirmation was possible, the predictive value has proved poor, as the European Society of Human Genetics notes in a recent publication[15]. In other words, the risk of the disease developing in carriers of these mutations is not much greater than among the population at large. With the advent of the new sequencing technologies and the association studies that they permit, knowledge is progressing but much research remains to be done before genetic testing can be relied upon to assist with accurate screening for multi-factorial disorders in a clinical context.

v. Diagnostic testing

91. Diagnostic testing is used to diagnose or rule out a specific genetic or chromosomal condition when a particular condition is suspected based on clinical symptoms.

[15] Genetic Testing and common disorders in a public health framework, recommendations of the European Society of human Genetics, C.G.van El and M.C Cornel, European Journal of Human genetics (2011), 1-5.

92. By contrast, predictive testing is used on individuals in apparent good health, to detect genetic alteration(s) associated with a pathology that has(ve) not manifested. These tests can be helpful to people who have a family member with a genetic disorder, but who have no symptoms of the disorder themselves at the time of testing.

vi. Genetic test outside individualised medical examination

- Genetic screening

93. Genetic screening is defined as a health screening program, applied to the whole population or a section of an asymptomatic population. It involves genetic tests whose scientific and clinical validity have been established., Appropriate preventive or treatment measures with respect to the disease or disorder which is the subject of the screening shall be available at the time of screening (*Art. 19 of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes).*

- Genetic testing in a research context

94. Medical research can be defined as any trial and experimentation carried out on human beings, the purpose of which is to increase medical knowledge. In the field of genetics, research may help us better understand the particular genetic and environmental contributions to health and disease. Insurers have sometimes asked to know the results of genetic tests undertaken by insurance applicants in a research context. However, while genetic research results can make an essential contribution to knowledge of diseases, particularly multi-factorial diseases, isolated use of information obtained in this context cannot allow the future development of a complaint in an individual to be forecast. Moreover, in genetic research, new findings may be contradicted by subsequent large-scale studies.

- Over-the-counter tests

95. A small biological sample which can be easily obtained [including without the person's knowledge (e.g. taking his/her teeth brush)] can be sufficient to carry out a genetic test (e.g. a swab). These samples can moreover be sent easily by regular mail without taking special measures. This easy obtention and preservation of the necessary biological material made it possible for a certain number of companies to offer, through the internet, predictive genetic tests for various diseases, directly to the consumer, (e.g. tests for cardiovascular risks, risk of onset of diabetes or osteoporosis, or certain types of cancer, tests on individual sensitivity to therapeutic treatment). The scientific and clinical validity of many of these tests is not established, and the conditions of their performance often do not always meet the criteria of scientific quality needed for their results to be used in a clinical context. Moreover, direct-to-consumer testing raises significant ethical and legal issues (those issues relate to protection of private life, advertising, marketing, applicable law, etc.) whose handling is all the more complex as the companies concerned may not necessarily be based in the countries where they try to market their tests and/or where analysis of samples is carried out.

b. Predictive data obtained from other medical examinations

96. Non-genetic medical examinations (e.g. physical examinations, biochemical, immunological or electrophysiological investigations, imaging, etc.) identify signs which may be more or less specifically related to a particular disease. These signs may have a predictive value with regard to a disease while there are still no symptoms of that disease (for example, in the form of renal cysts and possible development of polycystic kidney disease – a disease which may result in kidney failure, or with the presence of HLA B27, susceptibility factor for ankylosing spondylitis and for certain diseases with similar clinical manifestations).

97. Signs are objective medical findings resulting from the application of a medical investigation technique (e.g. blood pressure measure, X-ray, other imaging technologies, biochemical measures, body mass index, etc.). They may or may not be associated with symptoms. Symptoms (e.g. headache, fever, seizures, etc.) are manifestations that can be

expressed by the patient. It may not always be possible to find signs which could guide towards the cause of the symptoms (etiology).

98. It should be noted that, as in the case of genetic tests, the results of non-genetic examinations in relation to the occurrence of the disease symptoms may greatly vary in their predictive value. This depends particularly on the specifically ascertainable level of correlation between the sign observed and the disease in question (e.g. observation of a renal cyst is not specific to polycystic kidney disease).

2. Relevance of genetic testing and non-genetic examinations for underwriting

a. Reliability of the method

99. The reliability of the method depends on the tool(s) chosen and the way they are applied. It refers to the notions of clinical validity and positive predictive value (PPV).

100. Scientific validity is established by determining the sensitivity, specificity and reliability of a specific test to measure an indicator. As a result, the scientific validity of a medical test may be described as its capacity to adequately detect a particular indicator.

101. The clinical validity of genetic tests corresponds to a measure of precision with which a particular test can identify or predict a clinical disease. It is quite variable. In particular the sensitivity of a test can be weak due to allelic and/or locus heterogeneity (multiple alternative mutations in a single gene and/or more than one gene responsible for the disease) – characteristics which are increasingly becoming the rule rather than the exception for the majority of genetic diseases.

102. The PPV is a general value enabling the predictive capacity of any method to be determined. It indicates the proportion of persons whose tests have proved positive and who will develop the disease being tested for. The PPV depends on the frequency of the disease and, to some extent, on the genotype predisposing to the disease in the general population.

b. Predictive value: timescale and accuracy

103. In general, genetic tests concern elements lying far upstream of the possible development of the disease and provide information on a possible state of health in a sometimes very distant future, before any biological process with may be linked with the disease has even started. This is not the case with non genetic predictive tests which identify elements requiring that a biological process has already started. In general, a genetic test makes it possible to obtain predictive information much earlier with regard to the development of a disease than a non genetic predictive test.

104. However, the results of predictive tests can have varying predictive value depending whether they are genetic or non-genetic tests, as well as within either of these two categories.

105. With genetic tests, the predictive value will depend in particular on the disease concerned. It can significant for monogenic diseases (rare) but very limited for multifactorial diseases (more frequent) (see chapter 1.i.d., below).

106. Similarly, there are variations for the same disease, when comparing predictive genetic and non genetic tests. Thus, the predictive value of a genetic test concerning a multifactorial illness such as Alzheimer's disease will be limited, for example, in the light of an examination disclosing amyloid plaques in the brain. Conversely, a genetic test applied to a monogenic dominant disorder will have very high predictive value. For example, genetic testing for dominant renal polycystosis, as far as the complaint's likely onset is concerned, will have far higher predictive value than echographic observation of a renal cyst.

c. Relevance of the test results

107. The relevance of test results depends on the purpose for which they are used. Some test results are neither relevant for the risk evaluation of a disease, nor for insurance purposes (e.g. test results for multi-factorial diseases). Even if such results were to become significant, they should only be used in conjunction with other factors which point to a risk (e.g. weight, diet, blood pressure, habits, etc.). In the context of insurance underwriting, relevance requires that there be a clear, well-established link between the health data gathered by the insurer (whether by means of a questionnaire or a medical examination) and the risk to be covered.

d. Integration of individual data

108. Integration of different types of predictive data (e.g. genetic test results, family history, exposure to factors in the professional environment, lifestyle, epidemiological data, etc.) is important to increase predictivity.

109. In medical practice, genetic testing is rarely done in isolation. It is generally associated with a non-genetic medical examination, as well as with other medical data. The combination of the results of a person, together with his/her family history and relevant group risk factors, helps refine predictivity with regard to a particular disease. However, interpretation of the results to such an end may be complex and require specific expertise.

3. Issues in relation to potential use of predictive tests and/or their results for insurance purposes

a. Use of predictive examinations for insurance purposes

110. In accordance with Article 12 of the *Convention on Human Rights and Biomedicine*, tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for medical or medical research purposes, and subject to appropriate genetic counselling. Non-genetic predictive examinations are not mentioned in this article.

111. The main principle on which the provision of Article 12 is based is the respect of the right not to know [in particular when it comes to dieses for which no treatment is available]. This principle could also be considered relevant for predictive non genetic examinations, which provide information on the possible development of a future disease which, in the absence of any symptoms, the person is not aware of. Therefore, the issue may be raised as to whether the limitations of purposes defined in the Article should also apply to predictive non genetic examinations.

b. Interpretation of predictive data

112. The results of predictive tests are subject to erroneous interpretations. This situation will likely be more common in the case of complex (e.g. multi-factorial) or novel (e.g. research) tests. Currently the genetic factors linked to multifactorial diseases do not generally contribute to a significant change in disease risk. The scientific and clinical validity of genetic tests for such diseases are still not well established, and are very likely to be quite limited.

c. Overestimation of the predictive value of genetic testing in the underwriting process

113. Carrying a genetic mutation linked to a disease is not a guarantee that the disease will eventually express itself. Most genetic mutations only increase to varying degrees the probability of a given disease affecting one of its carriers. But it may also have the effect of protecting against the onset of a disease. In fact little is currently known about these positive

effects of certain mutations, or about the "compensatory" effects of certain mutations in the onset of a disease (see paragraph i.c above; example of cystic fibrosis).

114. Moreover most conditions are multi-factorial, meaning that environmental factors have an influence on the consequences of any predisposition. In this case, predictivity exclusively in its genetic dimension – even with some additional epidemiological or environmental information remains limited. Thus, apart from a small number of genetic conditions, the capacity to predict cannot be reduced to genetic testing alone.

d. Lack of actuarial data on the effects of therapeutic and preventive treatments

115. Insurers, in pursuing the best possible assessment of the risks which prospective clients carry, are interested in all data likely to provide information on their future health. However, these data may relate to the aggravation of a risk, but also to its reduction. Still, it is difficult to say if current actuarial tables also consider, for example, the positive changes that can follow the disclosure of genetic test results, e.g. change in lifestyle (healthy diet, more active lifestyle etc.) and, where applicable, curative and preventive treatments (regular follow-up, medication). For example, a woman testing positive for BRCA1 could undergo more regular screening.

116. In this connection, it should be emphasised that, in contrast, believing that one is free of all risk factors following a negative genetic test result may induce types of behaviour with a possibly far greater impact on the occurrence of a disorder than the genetic mutation would have had.

117. Furthermore, therapeutic and preventive measures for a particular disease could be developed and made available to reduce or even suppress a risk.

118. The way all these data are taken into account in the definition of actuarial basis for individual risks assessment remains unclear.

e. Exclusion on the sole basis of the results of predictive examinations

119. There is a tendency in the insurance industry to consider predictive health-related data as a self sufficient tool for health risk assessment. Thus, the presence of epidemiological risk factors is sometimes considered as automatically requiring exclusion or an increased rate of insurance. If the same approach was to be followed with results of predictive tests, a growing number of health characteristics might be excluded from the standard rate limiting what counts as "normal and healthy" and having a negative impact on insurability.

f. Use of only negative test results for underwriting purposes

120. There is a certain underwriting practice in some insurance companies whereby premiums are lowered for insurance applicants considered to be a high risk due to family history, if they decide to pass a genetic test to demonstrate the absence of a mutation (or have obtained such results in the past). However, this situation could unduly influence applicants with a strong family history of disease (e.g. Huntington's disease) to take a test in the hope of offsetting the assessment of their risk merely on the basis of family history. These applicants might then feel compelled to take a genetic test for economic reasons at the expense of all psycho-medical considerations.

g. Use of predictive data to underwrite the insurance application of family relatives

121. It would be possible, in theory, for an insurer to use familial information provided to him by an insurance applicant to underwrite future applications from other members of his/her family. This practice is illicit since family members have not consented (and are not aware) of this use of their personal data. It would also go against the bilateral nature of the duty of good faith. Moreover, it should be noted that family members are not always genetically related;

thus, the use of predictive genetic data to assess other family members could also lead to a faulty actuarial assessment.

h. Not undergoing testing – for preventive, therapeutic or research purposes – for fear of its use by insurers

122. Fear of predictive test results being subsequently used for insurance purposes is likely to have a major impact on health care, including its cost, by limiting scope for preventive action or at a very early stage in the development of the disorder. Individuals may abstain from taking a clinically relevant predictive test out of fear of having to disclose the results of such tests and possibly becoming uninsurable in the future or of having to pay higher premiums if they would have to disclose the results of such tests. This outlook could make people reluctant to discuss genetic testing in connection with health care. This feeling could prevent individuals from enjoying the full preventive and curative benefits of predictive medicine.

4. Family history

123. Family history has traditionally been used by insurers to assess risk. This information is deemed particularly relevant for life insurance and complementary insurance policies (especially critical illness). Information about the family of an individual is considered as a source of indication of the genetic and environmental influences affecting his or her health. There are two major disease areas in which family history has been deemed particularly important in risk assessment by insurers: cardiovascular disease and cancer. Furthermore, a growing list of disorders is now recognized as occurring more frequently in some families than others (e.g. blood disorders, early-onset Parkinson's disease, etc.). However, family members may not always be biologically related (e.g. unknown paternity, adoption, gamete donation in a context of an infertility treatment etc.) and this may affect the validity and usefulness of this information in trying to identify inherited risk factors.

124. If family history could remain a relevant factor in measuring environmental and lifestyle influences, this is not necessarily the case when it comes to genetic factors. It should be noted in this context, that some countries have placed restrictions on insurers' use of family history (e.g. Netherlands).

5. Legal principles and possible options

125. It should be noted that the principles referred to in Chapter I also apply and that the options presented are complementing/specifying those already mentioned in the preceding Chapter.

a. Legal principles

i. The right not to know

126. The right not to know is recognized by the *Convention on Human Rights and Biomedicine*, art.10. In the insurance context, this right might be of relevance in two ways:

- Applicants may have their own reasons for not wishing to undergo an examination simply because they do not wish to find out about certain aspects of their health and a wish of this kind must be observed
- Applicants may have undergone an examination in the past and have wished not to know the results thereof; a wish of this kind must also be observed.

ii. Limitation on the use of predictive genetic tests

127. According to article 12 of the *Convention on Human Rights and Biomedicine: "Tests which are predictive of genetic diseases or* which *serve either to identify the subject as a*

carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling."

128. This provision makes a clear distinction between health care purposes for the benefit of the individual on the one hand and for third parties' interests on the other hand. The applicability of predictive genetic testing is limited to health purposes for the individual and to scientific research in the context of developing medical treatment and enhancing the ability to prevent disease. The particular problems related to predictive testing: limit of predictive value of test with regard to the possible future development of a disease, limited therapeutic and preventive measures which are not available for a number of genetically determined diseases, possible implications for members of the family and the offspring of the person who has undergone testing.

129. In this context, the right to know as well as the right not to know are of particular importance. Insofar as predictive genetic testing, in the case of insurance contract does not have a health purpose, it entails a disproportionate interference in the rights of individual to privacy.

130. An insurance company will not be entitled to subject the conclusion or modification of an insurance policy to the holding of a predictive genetic test. Nor will it be able to refuse the conclusion or modification of such a policy on the ground that the applicant has not submitted to a test.

131. It is to be noted that the provision of Article 12 only covers the applicability of predictive genetic testing, and does not address the use of existing predictive genetic data**.**

iii. Non-discrimination

132. Article 11 of the *Convention on Human Rights and Biomedicine* stipulates that*: "Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited"*.

133. Non discrimination is relevant to an individual right established in Article 14 of the Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, ECHR). Under Article 14 of the ECHR, the enjoyment of the rights and freedoms set forth in the Convention must be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.

134. Article 11 adds to this list a person's genetic heritage. The concerns are namely that information of genetic characteristics of a person, in particular those resulting from a genetic test, may become a means of selection and discrimination.

135. The concept of discrimination relates to a difference in the treatment of the person concerned. Yet not all differences in treatment necessarily amount to discrimination. The concept of discrimination has been interpreted with constancy by the European Court of Human Rights in its case law relating to Article 14 according to the following assessment criteria: the relevance and legitimacy of the aim pursued and the reasonable relationship of proportionality between that aim and the means used.

b. Possible options

<u>*Use of non-genetic predictive tests*</u>

I. In view of the predictive nature of certain non-genetic examinations, does the right not to know also apply to this type of examination?

II. *Is the prohibition of the use of predictive genetic tests for insurance purposes as set out in Article 12 of the Convention on Human Rights and Biomedicine also relevant for non-genetic predictive examinations?*

III. *In this context, which approach would be preferable:*
   a. *a global one applicable to all non-genetic predictive tests?*
   b. *a specific one depending on the test in questions? In the latter case, what would be the requisite criteria?*

Access to existing data resulting from predictive genetic tests

IV. *Do the characteristics of genetic predictive data as described in section 1.i.b justify special regulations? If so, should such regulations provide for?*
   a. *prohibiting the use of such data for insurance purposes?*
   b. *making such use subject to strict conditions based, inter alia, on the predictive value of the results of the test in question and/or the type of risk covered?*
   c. *another approach (specify)?*

Reliability and relevance of predictive tests

V. *Should predictive tests which might be used by insurers or the results of which they might utilise, where such use and/or utilisation is/are authorised by national legislation, be restricted to tests which form part of established medical practice and meet the criteria of scientific validity, clinical validity and positive predictive value (PPV)?*

VI. *Should the reliability and relevance of predictive tests be the subject of a reference evaluation before their results can be used by insurers for underwriting? If so,*
   a. *Should this evaluation be entrusted to a pluridisciplinary body representing various sectors, including doctors and geneticists as well as representatives of insurance companies and patients, which would take account of the latest advances and their applicability to the insurance field, particularly in the field of molecular biology?*
   b. *Could this same body act as a reference body to be consulted on other matters, such as the wording of questionnaires to collect information related to the health of insurance applicants (see also Chapter 1)?*

Do you agree with the following proposals?

VII. *The utilisation for underwriting in the insurance field of predictive data obtained in the context of research work should be prohibited, for one or more of the following reasons:*
   a. *because these results, by their very nature, have not yet been sufficiently reproduced to meet the criteria of scientific validity and clinical validity;*
   b. *because taking part in a research project is an altruistic act which is aimed at the common good and should not jeopardise the insurability of those taking part in the research.*

VIII. *The results of the research should be included in a file separate from the patient's medical file (e.g. a research file) inaccessible to insurers*

Actuarial basis

Do you agree with the following proposals?

IX. *Insurers should:*
   a. *remain abreast of the latest scientific developments in the field of predictive medicine;*

b. *gather actuarial data and scientific evidence on which to base their decisions, and refrain from requesting the results of a test if they lack the competences for interpreting them correctly;*
c. *also collect data on factors positively affecting the health risks.*

Do you agree with the following proposals?

X. *Knowledge of predictive information on his or her health can help a person to benefit from curative or preventive measures as well as encouraging them to change their lifestyle in ways that might have a positive impact on the development of the disorder in question.*

- Should such a potential impact be taken into account by insurance and reinsurance companies in defining their criteria for evaluating risks?

Process transparency

XI. *Do you consider that greater transparency and more specific information should be required on the process of evaluating and transposing the relevant data in terms of actuarial risks? If so, how?*

Family history

Do you agree with the following proposals?

XII. *Since it is always possible to make mistakes – in the case of people unaware of their genuine family history – insurers should avoid relying exclusively on family history for underwriting decisions.*

XIII. *While family history can sometimes provide information on the impact of environmental factors, its predictive value is much more limited where genetic alterations are concerned.*

XIV. *The utilisation of such information for insurance purposes should be considered in the light of the reliability and relevance criteria, notably for the evaluation of genetic risks.*

CHAPTER 3: SOCIAL ASPECTS

1. Social risks and their coverage

a. The concept of social risks

136. A certain number of insurable risks are considered in European and other countries as being of a social nature. They exhibit three main characteristics:

- they correspond to perceived basic needs,
- they concern all or a substantial part of the population,
- there is a social consensus that all the persons concerned should have access to appropriate coverage of these risks.

137. It may be the case that the first two conditions are satisfied, but not the third, if it is considered, in a particular country, that it is for the individual and not the community to make the necessary arrangements for such coverage.

b. The most typical examples

138. The most emblematic example of these risks is that of sickness or maternity and the requisite medical care.

139. International and, in particular, European conventions mention other examples[16] :

- loss of income in the event of temporary or partial incapacity for work following sickness or an accident
- loss of income when a person stops working at a certain age (retirement)

c. How these risks are covered

140. Access to the benefits corresponding to the social risks mentioned may be ensured in several ways. If we consider that the public authorities have direct responsibility for implementing measures to make this access effective, the measures in question may take the form of insurance or direct provision of services, or a combination of the two.[17]

141. Where most of these risks are concerned, national legislation in European countries contains provisions designed to ensure universal or virtually universal coverage. In most cases, these are insurance schemes (often referred to as “social insurance” or “social security”) which depart from the principle of contractual freedom in several respects:

- insurance is obligatory (and often linked to gainful employment, whether as a salaried employee or an independent professional)
- there is no possibility of exclusion, in particular on the basis of the insured person’s state of health)
- the level of coverage is the same for all insured persons
- premiums are usually charged at a single rate (principle of solidarity between good and bad risks)

142. This insurance is usually publicly run, but it may also be run by private companies on the understanding that it remains obligatory and that there may be no personalised rates.

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[16] See, for example, the provisions of the European Social Charter and the European Code of Social Security. See also Article 34 of the Charter of Fundamental Rights of the European Union. Article 9 of the United Nations Covenant on Economic, Social and Political Rights contains a very general reference to the right of everyone to social security, including social insurance; Article 12.2.d of this Covenant…

[17] For example, there may be an insurance system for some, usually majority, sections of the population and free access to publicly funded services for those who do not have access to that insurance.

d. Level of coverage

143. The level of benefits may vary considerably from one country to another for the same risk (and sometimes within the same country, depending on what scheme is applicable). Supplementary coverage may be available for risks which are insufficiently insured by the obligatory general coverage, and this supplementary coverage may itself take the form of obligatory group insurance in some cases (this applies, for example, to supplementary sickness and retirement insurance in France for salaried employees), or voluntary individual insurance, or group insurance schemes of which membership is voluntary. This shows that the social or non-social nature of a particular level of coverage is not necessarily linked to the obligatory nature of insurance but rather to the financing capacity of the system or the group in question.

144. The question therefore arises of the justification for possible legislative action to induce private insurance to play some form of social role, and the means employed.

2. State intervention: justification and means employed

145. Intervention by the public authorities in the insurance field generally appears legitimate precisely because of the social nature of certain risks for which insurance coverage may be required.

146. The public authorities have a wide range of means of intervention available to them, and each method of intervention warrants special consideration in the light of the sometimes conflicting interests and principles at stake.

a. Obligatory nature of insurance

147. In many European countries, the State makes it obligatory to insure certain risks which are perceived as essential: these include sickness and maternity (health care), loss of income in the event of temporary or permanent incapacity for work and loss of income in the event of retirement from working life. This obligation to be insured is often linked to gainful employment, whether as a salaried employee or an independent professional, and does not apply to those who have no gainful employment (subject to certain conditions, those not gainfully employed may have access to free medical care in respect of sickness or maternity).

148. Generally speaking, the principle of obligatory insurance is not questioned in Europe[18].

149. Obligatory insurance may be public or private (or a combination of the two). The obligatory nature of insurance does not appear to be inconsistent in principle with the fact of its being private. In fact, the obligation to take out (often private) insurance exists in other fields, in particular those related to civil liability.

b. Non-selection of risks in an obligatory insurance system

150. With regard to the above-mentioned social risks, the rule in Europe is that, provided the insurability requirement (being gainfully employed) is met, there is no selection of risks: hence, no exclusion of persons presenting a high risk, same level of coverage and rate of premium for all insured persons.

151. Non-selection of risks and, in particular, the application of uniform premiums does not appear inconsistent with private insurance provided it is made obligatory. Indeed, the risk of anti-selection is non-existent or negligible where insurance is obligatory for large sections of the population. On the other hand, the application of uniform premiums is more problematical where insurance is voluntary, as stated above.

[18] This principle does seem to have been challenged in the United States, however, and the question is before the courts.

c. Non-selection of risk in an optional insurance system

152. There are two main reasons for having recourse to optional insurance to cover certain social risks:

- only some social risks are subject to obligatory insurance, while certain others are not, or not yet, included in the scope of obligatory insurance. To give two examples, dependency[19] and death are not insured, or are insured only to a very small extent, under social insurance in many countries.
- Some risks are subject to obligatory insurance but coverage remains limited (for example, in some countries, health care is covered only up to a certain percentage of the actual expenditure: 70%, 50%, or even less for some types of care). The portion not covered is the responsibility of the insured person, who can only obtain full coverage by taking out optional private insurance.

153. Insurers seem to consider that as soon as the State decides not to include (totally or partially) certain risks in the mandatory coverage, it does not consider them as social risks for which appropriate protection is required for the entire population. However, mandatory coverage may be only one of the means to achieve that objective. As the financial coverage of social risks is becoming increasingly difficult, States tend to withdraw from the coverage of certain risks which are nevertheless socially important.

154. It seems legitimate for the public authorities to regulate private insurance in these cases. For their part, the insurance companies argue that non-selection of risks and uniformity of premiums make the latter more expensive, and that this has a deterrent effect on the "good risks", who will tend not to take out insurance, and an incentive effect on the bad risks, all of which may jeopardise the system's financial equilibrium.

d. Non-selection of genetic risk in an optional insurance system

155. In some countries, the law (or an agreement promoted by the public authorities) permanently or temporarily prohibits insurers from using or even disclosing the results of a genetic test already undergone by the insured person. This prohibition applies either to all types of insurance (eg in France), or to certain types of insurance, or to certain types of insurance and to others below a certain amount.

156. This prohibition may be seen as partial non-selection of risks. The arguments on which the justification is based can be quite varied in nature.

157. This question is sometimes raised in terms of non-discrimination (for example in United States with the Genetic Information Non Discrimination Act (GINA).

e. Graduated intervention according to the type of risk insured

158. It should however be borne in mind that the same (social) risk may be covered by different types of insurance, some social in appearance, others not. For example, the dependency risk may be covered by insurance designed specifically to cover that risk or by an individual death and disability insurance plan where specific dependency coverage is unavailable on the market.

159. Similarly, it has been observed in some countries that the recent infatuation with home ownership (with homes often purchased by means of a bank loan combined

[19] It should be noted that, according to Article 34 of the Charter of Fundamental Rights of the European Union, "the Union recognises and respects the entitlement to social security benefits and social services providing protection in cases such as… dependency…, in accordance with the rules laid down by Community law and national laws and practices". However, obligatory insurance designed specifically to cover the dependency risk is still fairly uncommon in the member states.

systematically with death and disability insurance) reflects a growing fear among the population of a significant future decrease in pensions.

f. Other interventions of various types

160. It should be noted that the public authorities may take various measures to mitigate the effect of anti-selection. Examples:

- the addition to an optional but widely used form of insurance of an obligatory special premium designed to cover another risk. One example of this is the "natural disaster" coverage which, in some countries, is added on an obligatory, single-premium basis to optional insurance covering damage to property. One could imagine the same method being used to cover certain social risks thought to be less profitable or to entail a risk of anti-selection owing to the small number of persons taking out such cover. A precondition for the viability of this method is that the portion corresponding to the obligatory part of the insurance should be relatively small compared with the voluntary part, failing which people would be discouraged from taking out the voluntary insurance which is the basis for the obligatory insurance.
- the promotion of social dialogue with the aim of setting up obligatory group insurance schemes. Under agreements between labour and management, the entire workforce of some companies has obligatory coverage for some risks supplementing the general social coverage. The larger the membership of the scheme is, the less is the risk of anti-selection.

3. Questions/Possible options

I. Does the social nature of a risk (for example that of illness) justify an intervention by the public authorities to ensure proper coverage?

II. Should it be possible for this intervention to take the form of regulation of private insurance?

III. Which form(s) of regulation would be most appropriate
- *strict regulation?*
- *flexible regulation (eg agreement between stakeholders and public authorities)*

IV. Substantively, should this regulation take the form of a prohibition forbidding insurance companies, when evaluating the risks, to take account of genetic characteristics resulting from a predictive genetic test and which is supposed to[20] *represent an aggravated risk?*

V. Should such a prohibition be
- *limited to insurances in respect of which the risk of adverse selection is nil or virtually nil, particularly compulsory insurances?*
- *applicable also to insurances with optional subscription?*

VI. In the latter case, do you think that the insurance companies
- *are able in present circumstances to bear unaided the possible consequences of adverse selection*
- *would incentives of various kinds be needed (specify which)*

[20] This only concerns data derived from tests meeting the criteria described in chapter 2.2 as to reliability and predictive value in particular.

VII. Having regard to their social character, which are the risks to whose coverage the above prohibition should be applicable:

- *illness*
- *invalidity*
- *death*
- *long-term care/dependence*
- *retirement*

VIII. Should this prohibition be applicable, for each of the above risks, to the total coverage or only up to a certain amount?:

- *illness (limited amount/unlimited)*
- *invalidity (limited amount/unlimited)*
- *death (limited amount/unlimited)*
- *long-term care/dependence (limited amount/unlimited)*
- *retirement (limited amount/unlimited)*