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Consultation Document on Predictivity, Genetic Testing and Insurance

Elaborated by the Steering Committee on Bioethics (CDBI)¹

¹ Since 1st January 2012, CDBI activities have been taken over by the Committee on bioethics (DH-BIO) under the authority of which this consultation is being carrying out.

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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 develop a legal framework for the protection of human dignity and fundamental rights with regard to 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 expertises 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 group², 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 the Appendix to this Document. The Group of Specialists would like to thank all those experts who assisted it in its work.

² 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 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 of Specialists 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 were 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 issue 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 addresses the different issues raised by the use of predictive health related personal data, in particular genetic data, for insurance purposes.

13. This Document analyses these issues and presents questions resulting from this analysis as well as proposals, based on already established principles. In doing so, the Consultation Document aims to generate comments from all the stakeholders, which will be taken into account in forming the basis for a future legal instrument.

Structure of the Paper

14. The main focus of the document is the use of predictive health related personal data, in particular genetic data, for insurance purposes. However, as this document is intended to be used for consultation of different stakeholders with various knowledge and expertises, it was considered important to include brief descriptive elements on the functioning of private insurance, including its governing rules and principles in its first part.

15. It was considered important as well, when considering the use of predictive health related personal data, in particular genetic information, to first examine the way such information may be collected for insurance purposes in the light of established principles, in particular data protection principles. Issues raised by the practices for the collection of health related data could be particularly relevant for predictive ones (Chapter 1). The very notion of

predictivity and the analysis of specific issues raised by the possible use of predictive health related personal data are then addressed in Chapter 2. Finally, specific social and legal aspects of the questions raised are addressed in Chapter 3.

16. Going from more general to more specific issues, each chapter is addressing a set of problems that are complementary to each other as illustrated in the presentation of all the questions and proposals submitted for comments and presented in the last part of this document.

PRELIMINARY CHAPTER: THE FUNCTIONING OF PRIVATE INSURANCE

1. Private insurance and social welfare schemes

17. In contemporary societies, healthcare costs and financial losses associated with mortality and morbidity are usually covered by social welfare schemes or by private insurance or a combination of the two. 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 (e.g. professional revenues or 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 admission rules and premiums accordingly. 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.

18. 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

19. 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.

20. 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).

21. People who are aware that they present significant health risks may feel it necessary to take out insurance and request more extensive coverage. Insurance companies may fear inexact declarations in order to avoid paying too high premiums or to have broader coverage. In such cases, the actuarial calculation establishing the premiums being inaccurate, the risk is that 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.

22. 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 ensuring a balance in the relationship between the parties and, where appropriate, protecting the insurance applicant.

3. General concepts and insurance categories

a. Reinsurance

23. 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.

24. 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

25. Co-insurance refers to the joint assumption of risk between various insurers. In this context, a common insurance contract is used and the risk is shared based on percentages between the insurance companies. Often, one insurance company will be responsible for administering the contract.

26. 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, there is a contractual relationship between the co-insurers.

c. Individual and group insurance

27. Contrary to individual insurance which creates a link between a person and an insurer, group insurance is issued by the insurer to a particular group, generally a group of employees of a same company, and covers all members of that group () irrespective of their individual risk profiles. 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 and locality) and previous mortality or morbidity experience. All types of insurance (e.g. health, life, disability and critical illness insurance) can be sold to groups.

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

28. 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. Personal insurance

a. Health insurance

29. Health insurance commonly provides coverage for medical expenses incurred by the policyholder, such as the purchase of medicines, visits to the doctor, hospital stays, and other medical expenses. 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

30. 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

31. 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 or consequences of 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

32. Life insurance is a 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. The performance of life insurance contract may consist not only in the payment of a particular sum, but also in the payment of annuity.

e. Disability insurance

33. 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.

34. When it comes to individual insurance, many of these forms of insurance such as life insurance, critical illness insurance and disability insurance are long term products. Here the insurer is able to assess the risk of the individual applicant at the beginning of the contract but must stand by that decision whatever the duration of the contract regardless of any change in the policyholder's health.

In group insurance, a reassessment of the risk presented by the group is often carried out before a new term in the light of the results of the previous one.

CHAPTER 1: COLLECTION AND USE³ OF HEALTH-RELATED PERSONAL DATA ⁴FOR INSURANCE PURPOSES

1. General practice of the insurance industry

35. Insurers collect data from insurance applicants with a view to evaluating their risk and deciding 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).

36. 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?

37. 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?

38. 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 data, including family and past history of disease, lifestyle factors, medical test results, etc.

c. Who is collecting and processing the data?

39. 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.

40. 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;

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 cover collection for some people not for others) 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.

⁴ Hereafter referred to as « 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.
- 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. Communication of data to other insurers or to reinsurers

41. For certain contracts, the insurer may communicate some health related data to other insurance companies (i.e. co-insurance) or to a re-insurance company.

e. What are the possible outcomes of underwriting?

42. 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 analysis⁵.

43. 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 premium⁶;
- 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

44. 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 below) 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).

⁵ Studies that compare real experience with expected experience for the period covered by the study.

⁶ In the case of annuities, the benefit paid could be increased in recognition of the purchaser's reduced life expectancy.

a. With regard to the way data are collected

i. Health questionnaires

45. 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 these questionnaires, the ultimate objective is to collect information that is relevant for the insurance contract 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 or reduce the payment when a claim occurs. 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-ended⁷ questions, they end up disclosing information that are not relevant to the insurance contract.

46. Hence, it may be both in the interest of insurers and insurance applicants that questionnaires meet certain qualitative criteria so that they are an appropriate tool for providing accurate information 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

47. 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 (e.g. radiography examination with injection of radioactive contrast medium). Moreover, its results can have implications in terms of right to respect for private life and in particular, the “right not to know”⁸ 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 (See Chapter 2).

48. Finally, while possibly guided by references/evaluation criteria suggested in the underwriting manuals, medical practitioners performing examinations requested by the insurers are expected to proceed to an accurate and independent evaluation of examinations’ results concerning the person’s health.

iii. Communication of data by third parties to the contract

49. Health related data can be stored in different settings and kept by different persons. This includes in particular family doctor or other health professionals, health care center such as hospitals, laboratories as well as research institutions or biobanks which can keep

⁷ 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”)

⁸ See section 3.a.i.

identifiable data associated with biological samples. The question is raised as to whether these persons or establishments could be a source of health related data on a particular person for an insurance company, and if so under which conditions.

50. 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, namely when subject to strict legal conditions, it is required or allowed by law and/or after obtaining the consent of the patient.

51. As such, the practice of accessing health-related data kept by a family doctor or other healthcare providers, or health care centers with the consent of the insurance applicant is, according to the law of certain countries, not in conflict with the duty of medical confidentiality of the healthcare providers. However, in other countries it is feared that such practice may negatively impact the open, trusting nature of the doctor-patient relationship, as a consequence the accessibility to healthcare in general by affecting the public trust in the medical establishment.

52. Moreover, it should not be forgotten that in some countries (e.g. France), only the patient 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

53. 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.

54. The fate of such information that is not relevant for underwriting should be governed in accordance with the right to respect for private life and ensuing data protection principles.

55. 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 dates 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 confidentiality of familial data (family history) obtained from an applicant.

c. With regard to access to and storage of data

56. 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. The 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 storage and filing practices of the insurers and in particular to the possible consequences of filing health-related data together with other data. So as to ensure data confidentiality and safety, particular attention needs to be paid to security measures of information systems adopted which should be as up to date as possible from a technical point of view and with regard to measures to regulate access to data.

d. With regard to underwriting process and its possible implications

57. The underwriting is a complex process which requires important technical knowledge. Furthermore, 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 rather 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 unclear⁹.

58. 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.

59. 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 as 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

60. 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, section 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.

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

f. Issues that may result from potential abusive conducts

62. 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.

63. 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 (and communicated 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.

⁹ 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%.

3. Legal principles

a. *Relevant legal instruments*

64. 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

65. 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 of the ECHR. 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.*”¹⁰

66. 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 themselves¹¹. 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)

67. 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.

¹⁰ ECtHR 25 February 1997, *Z. v. Finland*, no. 9/1996/627/811, § 95; ECtHR 27 August 1997, *M.S. v. Sweden*, no. 74/1996/693/885, § 41; ECtHR 17 July 2008, *I. v. Finland*, no. 20511/03, § 38; ECtHR 25 November 2008, *Biriuk v. Lithuania*, no. 23373/03, § 39; ECtHR 25 November 2008, *Armonienė v. Lithuania*, no. 36919/02, § 40; ECtHR 28 April 2009, *K.H. and others v. Slovakia*, no. 32881/04, § 55; ECtHR 2 June 2009, *Szuluk v. The United Kingdom*, no. 36936/05, § 47; ECtHR 2 November 2010, *Gillberg v. Sweden*, no. 41723/06, § 96 (referred to the Grand Chamber, Hearing 28 September 2011, judgment pending)

¹¹ ECtHR 26 March 1985, *X and Y v. the Netherlands* no. 8978/80, § 23; ECtHR 10 January 2008, *Kearns v. France*, no. 35991/04, § 74; ECtHR 17 July 2008, *I. v. Finland*, no. 20511/03, § 36; ECtHR 2 December 2008, *K.U. v. Finland*, no. 2872/02, § 42-43; ECtHR 15 January 2008, *Reklos and Davourlis v. Greece*, no. 1234/05, § 35; ECtHR 6 July 2010, *Grönmark v. Finland*, no. 17038/04, § 41; ECtHR 6 July 2010, *Backlund v. Finland*, no. 36498/05, § 39; ECtHR 27 July 2010, *Aksu v. Turkey*, nos. 4149/04 and 41029/04, § 50; ECtHR 21 June 2011, *Kruskovic v. Croatia*, no. 46185/08, § 28; ECtHR 19 July 2011, *Durdevic v. Croatia*, no. 52442/09, § 106; ECtHR 26 July 2011, *Georgel and Georgeta Stoicescu v. Romania*, no. 9718/03, § 48

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)

68. 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 processed¹² 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 adequate, relevant and non-excessive (proportional) vis-à-vis the purposes for which they are stored; and
- data must be accurate

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

70. The Data Protection Convention also provides for the free flow of 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.

71. 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)

72. This Recommendation, which recall that health-related data are sensitive data, 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 data for insurance purposes. Accordingly, such collection and processing should be carried out fairly and lawfully and for specified and lawful purposes and data should be:

¹² 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.

- 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.

73. Principle 3.2 stipulates that persons involved in insurance activities who have access to data should 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.

74. Principle 4.2 stipulates that data should 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 should be informed of the purpose(s) for which the data will be processed, the identity of the controller as well as any other information which is necessary to ensure the fairness of processing (Principle 5.3).

75. The Recommendation also introduces the notion of "controller"¹³ which refers to the concept of "controller of the file" as set out in Article 2 of the Data Protection Convention.

76. The Recommendation requests the deletion of 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 safeguards¹⁴.

iii. Other relevant instruments

77. 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 States¹⁵.

78. 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

79. The principles set out below are based on the relevant data protection instruments. They are general principles applicable to the collection and processing of 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. Insurance companies, as controller, are responsible for their fulfilment.

¹³ 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.

¹⁴ Other important principles laid down in the Recommendation include the principle of non-communication for other purposes, the principle of security of data, and the principle of prohibition of access by third parties.

¹⁵ Health-related data is considered as "sensitive data" by the *Directive* (art. 8(1)).

80. 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 which may involve the international transfer of the data for reinsurance purposes). Furthermore, in cases where the data is collected using a medical examination, the insurance applicant must be informed in advance of possible additional 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).

81. 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.

82. The data to be collected and processed must 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.

83. The data to be collected and processed must also be reliable. The application of the principle of reliability is particularly relevant when it comes to medical test results (see Chapter 2).

84. 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 not 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).

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

1. Scientific aspects

85. 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.

86. 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*

87. 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*

88. 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.

89. In the complete absence of symptoms, the results may possibly provide information on the person concerned's future health (see section iv. 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 2.b. 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.

90. 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. Austria, Germany, France, Norway, Spain, 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.¹⁶

¹⁶ 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: WP Art.29), 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

91. Whole genome studies (WGS) now permit the generation of a very large quantity of data which will help improving scientific knowledge, especially on multi-factorial diseases. But as pointed out in particular by the European Society of Human Genetics, they 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.

92. It is reasonable to assume that High Throughput Sequencing (HTS) technologies will little by little form an integral part of clinical practice. These technologies, which will allow, for instance, for complete sequencing of the genome to be performed at an increasingly affordable cost and at short notice, 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

93. Monogenic disorders – either dominant or recessive – are inherited diseases in 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 result in a protection. This is the case for example with cystic fibrosis for which several hundred 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).

94. 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).

95. 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.

96. 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 publication¹⁷. 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.

¹⁷ 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.

v. *Diagnostic testing*

97. 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.

98. 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

99. 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

100. 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 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.

- Direct to Consumers Testing

101. A small biological sample which can be easily obtained, including without the person's knowledge (e.g. taking his/her toothbrush), 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 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*

102. 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).

103. 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).

104. 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

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

106. 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.

107. The clinical validity of tests corresponds to a measure of precision with which a particular test can identify or predict a clinical disease. It is quite variable. In the case of genetic tests, 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.

108. 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

109. 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 which 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.

110. 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.

111. With genetic tests, the predictive value will depend in particular on the disease concerned. It can be significant for monogenic diseases (which represent rare cases) but very limited for multifactorial diseases (which are the most frequent cases).

112. 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 disease 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/examination results

113. The relevance of test/examination results depends on the purpose for which they are used. Some test/examination 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

114. 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.

115. 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

116. 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 health purposes or scientific research linked to health purposes, and subject to appropriate genetic counselling. Non-genetic predictive examinations are not mentioned in this article.

117. The main principle on which the provision of Article 12 is based is the respect of the "right not to know", which is particularly important when it comes to diseases 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

118. 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

119. 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 section 1.a.iv above; example of cystic fibrosis).

120. 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

121. 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 not only 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.). While some treatments may be taken into consideration by insurers e.g. mastectomy for BRCA patients, the question remains when it comes to less specific interventions concerning other diseases (for example a person testing positive for specific mutations involved in bowel cancer might undergo regular screening and early treatment thereby reducing the risk of serious disease).

122. 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.

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

124. 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

125. The sole 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 negative test results for underwriting purposes

126. There is a certain underwriting practice in some insurance companies whereby proposed premiums are lowered for insurance applicants considered to be a high risk due to family history, if these persons can demonstrate by a genetic test the absence of a mutation. However, this practice 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

127. 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 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

128. Fear of predictive test results being subsequently used for insurance purposes is likely to have an 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 prospect 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

129. 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.

130. 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. Portugal).

5. Legal principles

131. It should be noted that the principles referred to in Chapter I also apply.

a. *Legal principles*

i. The right to know and the "right not to know"

132. The right to know, which is recognized by the *Convention on Human Rights and Biomedicine*, Art.10.2, goes hand in hand with the "right not to know" which is also provided in this Article. 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

133. 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.*"

134. This provision, which however, only covers the applicability of predictive genetic testing, and does not address the use of existing predictive genetic data, 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 are the limited predictive value of the 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, as well as possible implications for members of the family and the offspring.

135. 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 contracts does not have a health purpose, it entails a disproportionate interference in the rights of the individual to privacy.

136. In accordance with the provisions of Article 12, an insurance company is thus not entitled to subject the conclusion or modification of an insurance policy to the holding of a

predictive genetic test. Nor is it able to refuse the conclusion or modification of such a policy on the ground that the applicant or person insured has not submitted to a test.¹⁸

iii. Non-discrimination

137. 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”.

138. 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 status¹⁹.

139. 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.

140. 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.

141. It is also to be noted in this context that the European Court of Justice, in a judgement in 1 March 2011²⁰, referring to Directive 2004/113/EC²¹, has ruled that in insurance services sector, the derogation from general unisex premiums and benefits, laid down in Article 5(2) of the Directive, was invalid with effect from 21 December 2012.

¹⁸ National law may allow for the performance of a test predictive of a genetic disease outside the health field only for one of the reasons and under the conditions provided for in Article 26.1 of the Convention which reads:

“1. No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.”

¹⁹ It is to be noted that Protocol 12 of the ECHR extends the protection of individuals against any discrimination in applying this provision to the enjoyment of any right set forth by law.

²⁰ Case C-236/09 Association belge des Consommateurs Test-Achats ASBL and Others v. Conseil des Ministres

²¹ Council Directive 2004/113/EC of 13 December 2004 implementing the principle of equal treatment between men and women in the access to and supply of goods and services (OJ 2004 L 373, p.37)

CHAPTER 3: SOCIAL ASPECTS AND INTERVENTIONS OF PUBLIC AUTHORITIES

1. Socially important risks and their coverage

a. The concept of social risks

142. A certain number of insurable risks are considered in European and other countries as having a significant importance for the society as a whole. 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.

143. 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

144. The most emblematic example of these risks is that of sickness or maternity and the requisite medical care.²²

145. International and, in particular, European conventions mention other examples²³ :

- 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)

146. It is to be noted in this context that, some decades ago, the dependency risk was not as relevant as it is now due in particular to the demographic evolution.

c. How these risks are covered

147. 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 the direct provision of state funded services, or a combination of the two.²⁴

148. Where most of these risks are concerned, national legislation in European countries contains provisions designed to ensure universal or virtually universal coverage. In most

²² It may be noted in this respect that the United Nations Covenant on Economical, Social and Cultural Rights requires in its Article 12.2.d that States take steps to create the conditions which would assure to all medical service and medical attention in the event of sickness.

²³ 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 requires that States take steps to create the conditions which would assure to all medical service and medical attention in the event of sickness.

²⁴ 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.

cases, these are insurance schemes (often referred to as “social insurance schemes” or “social security schemes”) which are mainly based on another principle than contractual freedom, which is the principle of solidarity:

- coverage 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 charged by insurers are usually charged at a single rate (principle of solidarity between good and bad risks).

Tax funded schemes are based on the ability to pay, thus higher earners pay more than low earners.

149. 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. However in certain countries, the level of the premium may be individualised while not being higher than the rate applied by the public insurance.

d. Level of coverage

150. 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 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.

151. 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

152. 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.

153. 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

154. In many European countries, the State makes it obligatory to cover 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).

155. Generally speaking, the principle of obligatory insurance is not questioned in Europe²⁵.

156. Obligatory insurance may also operate in tandem with publicly funded services. 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

157. 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.

158. Non-selection of risks and, in particular, the application of uniform premiums (or submitted to an upper limit) 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.

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

159. 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, dependency²⁶ 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.

160. Some may 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, some States may tend to withdraw from the coverage of certain risks which are nevertheless socially important.

161. It seems legitimate for the public authorities to regulate private insurance in these cases so as to facilitate the coverage of these risks. For their part, the insurance companies argue that non-selection of risks and uniformity of premiums make the latter more expensive,

²⁵ This principle does seem to have been challenged in the United States, however, and the question is before the courts.

²⁶ 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.

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

162. In some countries, the law (or an agreement between the insurance industry and the public authorities) permanently or temporarily prohibits insurers from using or an applicant even disclosing the results of a genetic test he/she has already undergone. This prohibition applies either to all types of insurance (e.g. in France), or to certain types of insurance, or to certain types of insurance and to others below a certain amount.

163. 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.

164. This issue of non selection is sometimes raised in terms of non-discrimination (for example in United States with the Genetic Information Non Discrimination Act (GINA)²⁷.

e. Graduated intervention according to the type of risk insured

165. 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.

166. 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 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

167. 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.

²⁷ <http://www.eeoc.gov/laws/statutes/gina.cfm>

168. It should also be noted that the legislator has the possibility to use mechanisms of conventional type. Insurance companies (or credit companies) can also be encouraged to come to an agreement with organisations of health care system users so as to facilitate the application to private insurance contract for the benefit of persons with an increased health risk.

QUESTIONS AND PROPOSALS
[To reply to the questionnaire,
please use the separate document (with active fields)]

The questions and proposals presented in this chapter should be examined in the light of the preceding chapters of the Consultation document.

As in Chapters 1 to 3, the expression « data » when used in this last part of this Consultation Document, refers to « personal data ».

DATA COLLECTION

▪ **QUESTIONNAIRES ON HEALTH AND MEDICAL EXAMINATIONS**

Questionnaire

1. Questionnaires as tools for collecting health-related data should comply with certain qualitative criteria, in particular to avoid any potential resultant difficulties in interpreting questions and prevent disputes, and guarantee that the insurer collects only information relevant for underwriting.

Do you agree with this proposal: Yes No

(Please explain)

- a. Only objective questions should be included and open or subjective questions such as “do you consider yourself to be in good health?” should be avoided.

Do you agree with this proposal: Yes No

(Please explain)

- b. Which are the other key qualitative criteria that questionnaires should comply with to that end?

(Please explain)

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

a. **Do you agree with this proposal: Yes No**

(Please explain)

b. **If so, how should applicants obtain these clarifications?**

(Please specify)

Medical examinations

3. Only the results of medical examinations which meet established scientific and clinical standards and are used in clinical practice should be collected for insurance underwriting.

a. **Do you agree with this proposal: Yes No**

(Please explain)

b. **If so, how can this be ensured?**

(Please specify)

▪ **COMMUNICATION OF DATA BY THIRD PARTIES**

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

4. Third parties should ensure that they disclose only data which correspond to the request and are relevant for the risk evaluation (e.g. doctors should not send full medical records or transmit data which do not concern the patient's health)?

Do you agree with this proposal: Yes No

(Please explain)

5. Third parties should only communicate these data with the insurance applicant's express consent.

Do you agree with this proposal: Yes No

(Please explain)

6. Only data known by the applicant should be communicated by third parties to the insurer.

Do you agree with this proposal: Yes No

(Please explain)

USE OF PREDICTIVE DATA AND TESTS (complementary questions)

▪ **EXISTING PREDICTIVE GENETIC DATA**

7. Do the characteristics of genetic predictive data as described in particular in Chapter 2 section 1.a.ii justify some form of regulation of their use for insurance purposes?

Yes **No**

(Please explain)

If so, should such regulation provide for:

- a. prohibiting the use of such data for insurance purposes?

Yes **No**

(Please explain)

- b. making such use subject to specific conditions based, inter alia, on the predictive value of the results of the test in question and/or the type of risk covered?

Yes **No**

(Please explain)

- c. another approach?

(Please, specify)

▪ **NON-GENETIC PREDICTIVE EXAMINATIONS**

(Please see Chapter 2.1.b. regarding predictivity of non genetic examinations)

8. 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 Biomedicine²⁸ also relevant for non-genetic predictive examinations?

Yes **No**

(Please explain)

²⁸ Article 12 – Predictive genetic tests

"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."

9. In this context, which approach for non-genetic predictive tests would be preferable:

a. A global one applicable to all non-genetic predictive tests?

Yes **No**

(Please explain)

b. A specific one depending on the test in question?

Yes **No**

(Please explain)

c. In the latter case, according to what criteria?

(Please specify)

▪ **RELIABILITY AND RELEVANCE OF PREDICTIVE GENETIC TEST RESULTS**

10. Where the law allows for the use, for insurance purposes, of existing data resulting from predictive genetic tests, this should be restricted to data derived from tests which meet the criteria of scientific validity, clinical validity and positive predictive value (PPV) and are used in clinical practice.

Do you agree with this proposal: Yes **No**

(Please explain)

▪ **PREDICTIVE DATA OBTAINED IN A RESEARCH CONTEXT**

11. Should the use for insurance purposes of predictive data resulting from a test on which a research is carried out be prohibited?

Yes **No**

(Please explain)

12. Should the use for insurance purposes of any predictive data obtained in the context of research activities be prohibited?

Yes **No**

(Please explain)

FAMILY HISTORY

13. While family history may sometimes provide information on the impact of environmental factors, its predictive value is very limited where genetic alterations are concerned.

Do you agree with this proposal: Yes **No**

(Please explain)

14. Not all applicants are aware of their genuine family history (for example, in the case of adoption, assisted procreation with gametes donation or misattributed paternity). Should insurers then avoid relying on family history for underwriting decisions?

Yes **No**

(Please explain)

15. However, if family history were to be used for insurance purposes, should specific criteria be defined (e.g. reliability and relevance criteria for example, similar to those used for the evaluation of genetic risks)?

a. **Yes** **No**
(Please explain)

b. **If so, how can this be ensured?**
(Please specify)

ACCESS TO AND STORAGE OF DATA

16. **Should** insurers:

a. establish rules (e.g. privacy codes, good practices, codes of conduct) which protect the security and confidentiality of data (in accordance with domestic law)?

Yes **No**
(Please explain)

b. make them available to the public?

Yes **No**
(Please explain)

c. ensure that these rules are enforced. Failure to adhere to the rules should lead to appropriate action, including disciplinary measures and, if necessary, legal consequences?

Yes **No**
(Please explain)

d. only provide access to members of their staff who need to use them in order to underwrite an insurance application or assess a claim?

Yes **No**
(Please explain)

17. The insurer should inform the applicant/insured person of any data concerning him/her obtained from a third source.

Do you agree with this proposal: Yes **No**
(Please explain)

18. Which are the arrangements to be made by insurers to make available to the applicant any processed data concerning him or her?

(Please specify)

19. In accordance with general data protection principles, where the application for insurance coverage is rejected, the data collected for insurance purposes shall 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. Are there reasons justifying any possible longer storage of the data?

Yes **No**
(Please explain)

UNDERWRITING PROCESS

20. With a view to improving the transparency and fairness of the underwriting process insurance companies should provide, where appropriate on request, the specific reasons for any higher than standard premium, rejection of an application or exclusion. 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.

Do you agree with this proposal: Yes No

(Please explain)

21. Should underwriting practices be monitored with a view to ensuring adherence to fundamental principles?

Yes **No**

(Please explain)

If so, by what type of monitoring mechanism:

- a. by a mediating body?

Yes **No**

(Please explain)

- b. by a body coming under the insurance company?

Yes **No**

(Please explain)

- c. other?

(Please specify)

22. Which other measures should be taken by insurers to ensure transparency in the process of evaluating and transposing the relevant data in terms of actuarial risks?

(Please specify)

ACTUARIAL BASIS

23. Which are the measures to be taken by insurers:

- c. to remain abreast of the latest scientific developments in the field of predictive medicine?

(Please explain)

- d. to benefit from the appropriate competences to ensure proper interpretation of the data to be processed?

(Please explain)

24. Insurers should also systematically include in actuarial basis, data on factors positively affecting the health risks.

Do you agree with this proposal: Yes No

(Please explain)

25. Insurers should seek individual data on factors that may positively affect the individual risks evaluation.

Do you agree with this proposal: Yes No

(Please explain)

POTENTIAL UNFAIR CONDUCTS

26. According to an established principle, health related data should not be processed further for purposes incompatible with the original purpose of the collection. In accordance with this principle, health related data collected for the purpose of a contract with a person should not be used for a contract with a member of this person's family.

Do you agree with this proposal: Yes No

(Please explain)

27. 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 the internet should not be used for insurance underwriting.

Do you agree with this proposal: Yes No

(Please explain)

COMMUNICATION OF DATA TO OTHER INSURERS OR TO RE-INSURER

28. In accordance with the data protection instruments transborder flows of data should require the recipient country to possess at least an equivalent level of privacy protection, in particular regarding sensitive data such as health-related data. What arrangements should be made by the insurance company to comply with this principle?

(Please specify)

STAKEHOLDERS CONSULTATION

29. As a general policy rule, regular consultations should be organised between insurers, consumers and other stakeholders (such as physicians, actuaries, government representatives, etc.) with a view to ensuring a well-balanced relationship between the interested parties and increasing transparency towards the public.

Do you agree with this proposal: Yes No

(Please explain)

30. In particular, should the following issues be addressed in such consultation process?

a. reliability and relevance of predictive tests before their results, if authorised by national law, can be used by insurers for underwriting?

Yes **No**

(Please explain)

b. health related data and medical examinations requested by insurers?

Yes **No**

(Please explain)

c. the wording of questionnaires to collect data related to the health of insurance applicants?

Yes **No**

(Please explain)

d. any other issues

(Please specify)

31. Would it be appropriate to set up a permanent body within which the various stakeholders and expertises would be represented, to facilitate this consultation process?

Yes **No**

(Please explain)

32. If so, what should be:

a. the composition of such body?

(Please specify)

b. its tasks:

i. specific tasks ?

Yes **No**

(Please explain)

ii. a more general work scope?

Yes **No**

(Please explain)

QUESTIONS CONCERNING SOCIAL ASPECTS AND INTERVENTION OF PUBLIC AUTHORITIES

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

Yes **No**

(Please explain)

34. Which are the risks for which proper coverage should be ensured for all persons concerned:

a. illness?

Yes **No**

(Please explain)

b. invalidity?

Yes **No**

(Please explain)

c. death?

Yes **No**

(Please explain)

d. long-term care/dependence?

Yes **No**

(Please explain)

e. retirement?

Yes **No**

(Please explain)

f. Any other

(Please specify)

35. In order to ensure proper coverage, should it be possible for the public authorities' intervention to take the form of regulation of private insurance?

Yes **No**

(Please explain)

36. If so, which form(s) of regulation would be most appropriate:

a. binding regulation?

Yes **No**

(Please explain)

b. flexible framework (e.g. agreement between stakeholders and public authorities)

Yes **No**

(Please explain)

Genetic predictive testing

37. 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 which is supposed to²⁹ represent an increased risk?

Yes **No**

(Please explain)

38. Should such a prohibition be :

a. limited to insurances in respect of which the risk of adverse selection is nil or virtually nil, particularly compulsory insurances?

Yes **No**

(Please explain)

b. applicable also to insurances with optional subscription?

Yes **No**

(Please explain)

39. In the latter case, do you think that:

a. the insurance companies are able in present circumstances to bear unaided the possible consequences of adverse selection?

Yes **No**

(Please explain)

b. incentives of various kinds would be needed (specify which kinds)?

Yes **No**

(Please explain)

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

a. illness?

Yes **No**

(Please explain)

²⁹ This only concerns data derived from tests meeting the criteria described in chapter 2.2 as to reliability and predictive value in particular.

b. invalidity?
Yes **No**
(Please explain)

c. death?
Yes **No**
(Please explain)

d. long-term care/dependence?
Yes **No**
(Please explain)

e. retirement?
Yes **No**
(Please explain)

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

a. illness? *Limited amount* *Unlimited amount*

b. invalidity? *Limited amount* *Unlimited amount*

c. death? *Limited amount* *Unlimited amount*

d. long-term care/dependence? *Limited amount* *Unlimited amount*

e. retirement? *Limited amount* *Unlimited amount*

APPENDIX

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³⁰ 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. / En janvier 2010, Dr Mark Bale, en raison d'un changement de ses fonctions au sein du Ministère de la Santé, a annoncé son départ de la délégation britannique auprès du CDBI et du Groupe de spécialistes.

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