

SEND IN ENGLISH OR IN FRENCH TO
dgI.consultation@coe.int
by 27 April 2012 at the latest



ORGANISATION : Centre for Disability Law and Policy, National University of Ireland, Galway, Ireland.

(association, society, ...)

ACTIVITY SECTOR : Specialists in disability law and policy

(insurance, reinsurance, mutual insurance, doctors, geneticists, consumers, patients, ombuspersons, specialists in human rights, other)

NAME AND SURNAME : Aisling de Paor

OCCUPIED FUNCTION IN THE ORGANISATION : Ph.D. candidate

E-MAIL ADDRESS : aisling.depaor@nuigalway.ie

Do you authorise the publication of your comments and replies? Yes No

QUESTIONS AND PROPOSALS

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) One of the underlying principles of insurance is that the information gathered must be relevant to the risk being covered. In the interests of fairness to the insurance applicant, and in accordance with fundamental human rights such as the right to private life, it is important that the questionnaire only ask questions that are relevant, and directly applicable to the applicant and the risk in question. In accordance with the need to ensure against any interpretative difficulties, it is also important that any questions asked are clear and unambiguous and only relate to health information that is necessary as regards the current health status of the individual.

- 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) It is important that any questions asked are clear, objective and unambiguous. Subjective questions may be vague and and ambiguous and may give rise to confusion and misunderstanding on the part of the insurance applicant. Further, if questions are subjective and open- ended, an insurance applicant might disclose additional information that is not relevant to the risk in question. This additional information might be misinterpreted and used against the appliant in the underwriting process. In accordance with fundamental human rights, and to ensure access to insurance for all individuals, it is important that that questions on questionnaires are clear and unambiguous and in accordance with the principle of relevance.

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

(Please explain) One of the key principles in insurance is that of proportionality, and this is particularly relevant with regard to questionnaires. The collection of data by means of a questionnaire and the subsequent processing of this data for underwriting purposes must have due regard to the insurance applicant's personal rights. These rights include primarily the right to privacy, the right not to know, and the right not to be discriminated against. Additional rights include, the right to access to insurance, in accordance with the social purpose of insurance.

Further, particular attention must be paid to the rights enshrined in the United Nations Convention on the Rights of Persons with Disabilities ("CRPD") and it is important to emphasise the relevance of the CRPD, its impact on this area, and on the area of human rights law generally. There are now 112 ratifications of the CRPD (including ratifications by 31 Council of Europe states). In addition, the European Union has separately ratified the CRPD, representing the first time the EU has ratified an international human rights treaty, and illustrating the dedication to ensuring the fulfillment of fundamental human rights.

Principles of equality and non- discrimination are underlying concepts which animate the Convention, (for example, Article 5 of the CRPD). The CRPD also promotes the right to dignity and integrity of the person. Importantly, the CRPD focuses on the inclusion of persons with disabilities (in employment, education,, political life, health and society). By creating barriers to insurance, whether by devising prohibitively vague questionnaires, or misusing genetic information/ genetic test results, this may result in the unjustified exclusion of certain vulnerable individuals, with undesirable social consequences.

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) To ensure that an insurance applicant does not reveal additional, irrelevant information that may be misinterpreted by insurers and used against him/ her, it is important that there is no confusion or ambiguity as regards the questions asked. This provides that an individual's rights are upheld and ensures fairness of contract between the parties.

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

(Please specify) Insurance applicants should be free to contact the insurance companies to receive clarifications on the meaning of questions. In addition, there could be provision for a helpline for insurance applicant to contact for clarifications.

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) In accordance with privacy and confidentiality requirements, and to ensure against unfair discrimination in underwriting practices, it is important to ensure that only relevant information is taken into account. It is possible that doctors furnishing medical information, for example, a family doctor, may inadvertently provide an insurance company with a vast amount of medical information relating to an individual's entire medical history (including family history of illness). This surplus information may be used negatively by an insurance company in the underwriting process. In addition, with the deluge of medical information being generated today, for example, from the increasing use of genetic testing (particularly the use of Direct - to- Consumer genetic testing), it is possible that some of this information is of limited scientific value and may not reflect the current health status of an individual. As a result, the use of this information for insurance underwriting may result in inaccurate conclusions and unfairly disadvantage for insurance applicants.

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

(Please specify) The provision of clear guidelines that are made available to doctors involved in issuing medical reports and furnishing medical information, detailing the scope of the information that is to be passed on to insurance companies. It is also important to ensure that doctors involved are informed of the requirement to furnish only necessary medical information - for example, to differentiate between genetic and non-genetic information. Further, it is important that an individual's consent is obtained before any information is exchanged with the insurance company.

▪ **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) To ensure fairness in the underwriting process, it is important that only relevant information is disclosed, and only information directly corresponding to the

request made. It is possible that doctors carrying out medical examinations and furnishing medical information, for example, a family doctor, may inadvertently provide an insurance company with a vast amount of medical information relating to an individual's entire medical history (including family history of illness, and other genetic health information). This surplus information may be used negatively by an insurance company in the underwriting process. There is a risk that insurance companies may misinterpret and overestimate any surplus information given, potentially leading to unfair premiums and/or the refusal of insurance coverage.

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) Health data is classified as sensitive personal data (for example, pursuant to European Union data protection legislation - Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data), and in order to protect an individual's privacy, it is necessary to obtain an individual's express, informed consent. Doctors should only disclose information to which the insurance applicant consents (and any information disclosed in the absence of consent constitutes a breach of privacy). It is also important that the fundamental principle of medical confidentiality is upheld and to ensure the doctor - patient relationship is maintained, for the benefit of the patient. The requirement of express consent provides that this principle is respected.

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) If sensitive personal health data related to the insurance applicant is being disclosed from a third party, this should be communicated to the insurance applicant and their express consent is required. This requirement is in accordance with data protection laws and ensures that an individual's right to privacy is upheld.

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) Genetic information (for example, information gleaned from family history of illness) and the results of genetic tests reveals personal and unique information, not only about an individual, but also about that individual's parents, children and siblings. Genetic information may be predictive. Genetic information carries stigma, and the misuse of genetic information has led to eugenics, racism and genocide in the past. Genetic information is regarded as unique by the public. Although none of these reasons by itself singles out genetic information from other types of health information, taken together, they provide a strong reason for regulation of use for insurance purposes.

This information is of interest to third parties (primarily for financial reasons), and therefore is open to misuse and abuse. Potential misuse of sensitive genetic information can lead to a violation of fundamental human rights, such as breach as privacy, and unfair discrimination. In the context of insurance, misuse of genetic data may also lead to an individual being pushed out of insurance pools either as a result of being charged inordinately high premiums or being denied insurance cover. In particular, misuse of genetic information may lead to the further exclusion of persons with disabilities and elderly persons (who may be denied access to insurance or pushed out of insurance

pools). It is also important to have regard to the ethical issues arising as a result of use of genetic predictive genetic data, for example the 'right not to know' and the psychological consequences of knowing one's genetic make-up (for example, when genetic knowledge is not accompanied by the power to prevent or cure).

In addition, the ultimate fear is that the use of genetic predictive data may lead to the creation of a genetic underclass, and the practice of genetic cleansing, not just in the insurance industry, but in other elements of society such as education, employment, political life, sport, and society in general. In light of the the unique nature of genetic information, the potential for abuse and the undesirable potential social implications, regulation of the use of genetic data for insurance purposes is therefore justified.

If so, should such regulation provide for:

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

Yes No

(Please explain) Insurers may potentially use genetic information primarily for financial advantage and as a tool for selecting what they perceive to be low risk customers. This may result in unfair discrimination, and individuals being pushed out of insurance pools through being denied insurance cover or being charged inordinately high premiums. This is undesirable from the perspective of the social purpose of insurance and fundamental human rights, such as the right not to be discriminated against, the right to privacy, integrity and inclusion in the community (as well as a range of other rights contained in the CRPD). There is also the risk of the creation of a potentially disasterous genetic underclass and the relegation of genetically undesirable individuals, if this area is not appropriately regulated.

In addition, it is necessary to refer to the accuracy of genetic testing and the popular perception of such testing. The common misperception that genetic tests can predict completely and accurately whether a person will develop a genetic disease can cause problems with third party use of genetic information and genetic test results. Insurance companies may misinterpret and misuse genetic test results to weed out persons according to their perceived health risks based on a common misunderstanding that having a genetic trait is the same as having the actual disease or condition. In overestimating the predictive value and accuracy of genetic testing, unfair genetic discrimination can occur simply because of insurer ignorance in granting statistical validity to genomic data that is not sufficiently precise for that purpose.

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) Although potentially justifiable from the economic perspective of insurance companies, it is more challenging to justify use of predictive genetic data from a social perspective and in consideration of the need to provide access to insurance and health care. Even if use of genetic test results (based on the positive predictive value of these tests) was permitted, this would be undesirable as it may result in individuals being denied insurance cover or being charged an prohibitively high premium. More importantly, use of predictive genetic data may be undesirable, in light of the potential for abuse, and ultimately the creation of a genetic underclass, with disasterous societal consequences.

It is necessary to refer to the accuracy of genetic testing and the popular perception of such testing. The common misperception is that genetic tests can predict completely and accurately whether a person will develop a genetic disease can cause problems with third party use of genetic information and genetic test results. Insurance companies may misinterpret and misuse genetic test results to weed out persons according to their

perceived health risks based on a common misunderstanding that having a genetic trait is the same as having the actual disease or condition. In overestimating the predictive value and accuracy of genetic testing, unfair genetic discrimination can occur simply because of insurer ignorance in granting statistical validity to genomic data that is not sufficiently precise for that purpose. In addition, a distinction must be made between monogenetic conditions, and multifactorial genetic conditions. Most genetic conditions are multifactorial, whereby manifestation of the condition is a result of a complex interaction between genes and environment (for example, heart disease). These genetic tests have limited predictive value in terms of whether the condition will manifest in an individual, the age of onset of the condition and the potential severity of the condition. It is only in the case of monogenetic genetic conditions that the onset and severity of the condition can be more accurately predicted (for example, Huntington's disease). Generally when an individual tests positive for having the gene for Huntington's disease, the condition is likely to manifest by middle age.

As regards the use of predictive genetic testing, there is also a risk that information may be disclosed concerning another health risk, which was not specifically sought initially by the insurance company, and could be used against the insurance applicant.

c. another approach?

(Please, specify) Another approach could provide for the favourable use of genetic information, to improve the insurability of an individual. In certain cases, it is submitted that genetic testing may improve the insurability of people who have problems obtaining insurance because of family history – for example, family history of Huntington's disease, or breast cancer. Arguably, while positive test results for a genetic condition may hinder someone's insurance application, a negative test result may often make it possible for people who were previously uninsured to obtain insurance. However, it is necessary to have regard to the predictive value of genetic test results in this regard.

▪ **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 Biomedicine¹ also relevant for non-genetic predictive examinations?

Yes No

(Please explain) This question is dependent upon the interpretation of Article 12 of the Convention on Human Rights and Biomedicine. It further depends on the type of test in question and the information it can reveal. If such tests are predictive of genetic disease or identify the individual as a carrier of a gene responsible for a genetic disease.

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

¹ 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."

(Please explain) In consideration of the fact that non- genetic predictive tests vary in terms of what they test for and their predictive value, it is thought that a global approach in these circumstances would not be appropriate.

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

Yes No

(Please explain) In light of the variety of different tests available, the difference in medical and predictive value and the different uses of such tests in a wide range of scenarios, it is submitted that a specific approach dependent upon the test in question is preferable.

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

(Please specify) According to the type of test in question and the use of such test, the information such test reveals and the predictive value of such tests.

▪ **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) Many genetic tests yield limited and uncertain predictive value (and only reveal an increased probability of developing a certain condition). If genetic test results are even to be considered for use for insurance purposes, the scientific and predictive value must be relatively certain and accurate, otherwise such data can be misinterpreted, its value overestimated, and open to misuse. In particular, as regards Direct- To-Consumer genetic testing, the scientific validity may be questionable, and the use of these tests needs to be carefully monitored. The criteria of scientific validity, clinical validity and positive predictive value are therefore in accordance with the fundamental insurance principles of reliability and relevance.

▪ **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) In order to use information (about an individual's health) for insurance purposes, it is necessary to obtain the consent of the individual, to maintain privacy and uphold data protection legislation. Although an individual may have consented to use of their health data for research purposes, this consent cannot be used to justify use of the information for insurance underwriting purposes. Consent must be voluntarily given and fully informed. In addition, although medical research makes a valuable contribution to advancing medicine and understanding disease, it is nevertheless uncertain in terms of predictive value and its use for insurance purposes is not appropriate.

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

Yes No

(Please explain) It should be clarified for what purpose the predictive data is to be used for. It is necessary to obtain an individual's consent for any collection and processing of sensitive data.

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) Family history of illness only indicates a probability of an individual's genetic make-up, and therefore has a limited predictive value. Family history can act as a guide for physicians in determining susceptibility to disease and can point a physician in a certain direction. However, in terms of being used for insurance underwriting purposes, its predictive value is limited (as there is a complex variety of factors which contribute to disease including genes, environment, lifestyle and diet).

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) Family history is merely one element of a person's medical history, and current health status. A person's own genetic make-up, diet, lifestyle and environment are all contributing factors towards a person's health and susceptibility of developing disease. Despite the inaccuracy of family history, insurers may nevertheless use this information to adversely treat individuals in the underwriting practice. Indeed, many individuals may not be aware of their family history. The use of uncertain, inaccurate information may adversely impact upon an individual's premium and/ or insurance cover. In light of the uncertain nature of family history information, and in accordance with the requirement of reliability and relevance, it is preferable that insurers avoid relying on family history in underwriting decisions.

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) Certain diseases have a strong genetic link, for example, Huntington's disease, cystic fibrosis and Parkinson's disease. Other genetic disease are complex multifactorial conditions, and the reliability and relevance of this information is uncertain and in conflict with principles of reliability and relevance - therefore data of family history of these conditions is uncertain. If family history were to be used for insurance purposes, criteria such as certainty and reliability are required.

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

(Please specify) It would be necessary to have regard to the type of risk involved and the type of condition in question. As noted above, certain diseases have a stronger genetic link than others. A medical report may be able to verify the reliability of the genetic link in terms of use of family history.

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) In accordance with data protection legislation and in accordance with the duty of medical confidentiality, it is important that insurers abide by their obligations when collecting and using sensitive health data. Therefore, it is good practice to establish clear

guidelines (for example, indicating the necessity of obtaining consent from the insurance applicant). It is important, when dealing with health data (sensitive personal data), to obtain the applicant's express consent. It is also important to establish clear guidelines in relation to maintaining the security of data and ensuring data is only processed for a specific purpose and retained for the requisite period.

b. make them available to the public?

Yes **No**

(Please explain) For transparency purposes, it is desirable that these rules are made available to the public. This may instill confidence in insurance applicants and the public, and offer assurance of that privacy and confidentiality will be upheld.

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) In order to ensure that data protection laws are upheld and privacy is respected, it is necessary to have strong enforcement mechanisms, and provision for disciplinary measures. In the absence of strong enforcement and disciplinary measures, the effectiveness of the data protection laws may be diluted, leading to the violation of fundamental human rights.

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) To maintain the confidentiality and security of data, any person acting under the authority of the data processor, must not process, except under the instructions of the processor. In addition, to uphold data protection laws, and maintain privacy of personal health data, such data should only be used for specific purpose. In the event that information needs to be disclosed to members of staff, it is necessary to keep the insurance applicant fully informed of any further use of the data and the required consent obtained, if necessary.

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)

In accordance with data protection legislation, the data controller must provide the insurance applicant with information such as the identity of the controller, the purpose of processing and the recipients of the data. If the applicant can be identified by the data in question, then it is necessary to inform the applicant about this data, in accordance with the right to privacy. Further, it is necessary to obtain the applicant's consent if this information is being processed and used for underwriting purposes.

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) There should be a system of transparency whereby the insurance applicant is kept fully informed as to data concerning them, and provision made for the applicant to access such data and to correct the data, if necessary. The insurance applicant should also have the opportunity to object to the processing of the data, if desired.

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) Data protection legislation provides that personal data should only be retained for a certain, limited period and for no longer than is necessary. There are no reasons justifying any further storage of data. It is also necessary for the insurance applicant to be informed as to the purpose of processing. In the event that an insurance company are re- considering a claim, then it may be justifiable to retain data for a longer period (however, in these circumstances, it is important that an individual's consent is obtained, and he/she is kept fully informed of the reasons for retaining the data).

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) In the event that an insurance company unfairly discriminated against an individual (either by refusing insurance coverage or by charging a higher than standard premium), the individual would have an opportunity to challenge such a decision. In accordance with the social purpose of insurance, there should not be any unduly prohibitive obstacles to accessing insurance and health care.

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

Yes No

(Please explain) This would ensure transparency in the insurance underwriting process. It would also promote protection of fundamental human rights, in particular, the right to privacy, by ensuring that insurance companies uphold an individual's rights. Monitoring of underwriting practices would also ensure that insurers conduct their business with fairness, and would ensure against any unfair, inequitable practices, or any discriminatory use of personal information.

If so, by what type of monitoring mechanism:

- a. by a mediating body?

Yes No

(Please explain) Perhaps an independent monitoring body that would oversee transparency in the insurance industry in relation to underwriting practices, ensure compliance with the relevant legislation, and address any issues arising from the perspective of both the insurance company and the insurance applicant.

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

Yes No

(Please explain) It is important to ensure that the monitoring mechanism is independent and objective, having regard to the interests of both the insurance company and the insurance applicant. A body coming under the insurance company would be inappropriate and potentially biased in favour of the insurance company and its interests.

- c. other?

(Please specify) It is important to re- affirm the relevance of the United Nations Convention on the Rights of Persons with Disabilities, and its impact on this area, and on

the area of human rights law generally. Article 33 of the CRPD requires the provision of an independent monitoring mechanism to promote, protect and monitor the implementation of the CRPD.

In light of the individual and societal implications of unfair, insurance practices (in particular, the potential for abuse of genetic technology), there is a risk that this will lead to, not only discrimination against persons with disabilities, elderly persons, and others, but will also lead to the further exclusion of persons with disabilities from education and health services as well as from social and political life. Ultimately there is a risk that individuals will become segregated according to genetic characteristics, potentially leading to the creation of a genetic underclass.

In consideration of the potential for abuse (particularly for persons with disabilities) and the fundamental human rights at stake, it is suggested that an appropriate monitoring body in this context might be one as provided for under Article 33, CRPD.

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) Training courses could be carried out for insurers, to educate as to the rights of insurance applicants and the applicable laws. Particular attention could be paid to the data protection legislation and the importance of ensuring privacy and confidentiality in the underwriting process. Training could also include details on the correct procedures in relation to the collection and processing of health data, particularly taking account of advancing scientific and genetic technology and the increasingly use of the internet (via which personal health data can be easily transmitted).

ACTUARIAL BASIS

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

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

(Please explain) Science and medicine are advancing rapidly, particularly with regard to genetic technology. Regular discoveries are being made in relation to disease, testing and treatment, which may have implications for an individual's health, and consequently, for obtaining insurance. For the purposes of the underwriting process (and in conjunction with the principles of reliability and relevance), it is important that insurers keep up to date with the latest scientific developments in this area, perhaps by engaging in appropriate training and education.

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

(Please explain) Often there is a complex variety of factors that contribute towards ascertaining the current and future health of an individual. Medical tests are open to erroneous interpretation. If data is misinterpreted or overestimated, this may adversely affect the insurance applicant and his/her access to insurance.

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) This would give individuals the opportunity to disclose positive factors that may have a favourable affect on ascertaining health risks (for example, factors such as healthy diet, lifestyle and environment), and may increase their access to insurance and reduce premiums. The consideration and inclusion of these factors may also give the insurance company a more realistic and true insight into an individual's health, thereby reflecting the fundamental principles of reliability and relevance.

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) See 24. above. This practice would give insurance applicants the opportunity to disclose positive risk factors that may increase their insurability and provide a true reflection of their current health status.

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) Firstly, in accordance with data protection legislation, health related data must only be retained for a certain specific period, and for specified, explicit and legitimate purposes. As health related data is sensitive personal data, an individual's express and informed consent is required for any collection or processing of this information. In order to use the health related information to a draw up a contract for a member of an individual's family, it is necessary to obtain the relevant consent. In addition, some family members are not genetically related, and therefore use of such

information may not reliably reflect the status of family members. In the absence of consent, use of health related data is a breach of privacy and confidentiality. Any such use of health data would be in violation of the duty of good faith, which underlies the insurance industry.

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) With the advent of the technological age and increasing use of the internet, there is a vast amount of information (relating to a person's health and other personal matters) that is accessible to third parties. Any use of personal information (derived from any source, including the internet) is a breach of data protection legislation if used in the absence of consent. Use of such information in the absence of consent also violates the right to privacy and respect for private life.

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) Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data provides that each Member State set up an independent national body responsible for the protection of these data. In addition, insurance companies should provide for a system whereby the express, informed is obtained from all insurance applicants. It would also be desirable to have a system in place in relation to the retention of health related data, ensuring that any information is only kept for a certain specified period and in accordance with the specified purpose. These practices would be in accordance with confidentiality requirements and would ensure compliance with the data protection legislation.

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) Such regular consultation would promote further transparency within the insurance industry and amongst key stakeholders. This consultation would also contribute towards instilling and promoting consumer confidence in the insurance industry, which is necessary for the continued viability of the industry. This consultation process would also ensure that insurers are kept up to date with developments in the legal, medical and scientific fields, including their obligations under relevant legislation (for example, data protection legislation). This would also ensure that insurers are educated as to recent medical developments, for example, advancing genetic technology and what this can reveal. In the absence of education, there is a risk that insurers may overestimate the value and certainty of genetic tests, and genetic information. There is also a risk that insurers may misuse sensitive genetic information, leading to discrimination, breaches of privacy, and potential isolation from society for certain vulnerable individuals.

In the context of disability law and the rights of persons with disabilities, the CRPD promotes the active involvement and integration of persons with disabilities in decision making processes. Article 4.3 specifically provides that in decision-making processes concerning issues relating to persons with disabilities, States Parties shall closely consult with and actively involve persons with disabilities.

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) It is important that insurers are educated as to scientific developments, and advances in genetic technology. The majority of genetic tests have limited predictive value, and it is important that insurers are aware of the realities of genetic test results. Reliability and relevance are key considerations in the underwriting process. Although increased reliability and relevance promote the use of predictive tests, we must address the issue of whether use of predictive tests and this information is appropriate by insurance companies, particularly in consideration of the potential for abuse and misuse of predictive tests (particularly predictive genetic tests). We must also have regard to the social purpose of insurance and the desire for all individuals to have unfettered access to insurance.

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

Yes No

(Please explain) There should be discussion and education around the correct collection and legitimate use of health related data and medical examinations. In particular, the issue of segregating genetic and non-genetic information is becoming increasingly important as science advances and genetic information is being increasingly included in medical records. There may be a vast amount of health related information (including genetic information) in an individual's medical records that may not be relevant for underwriting purposes, but if used, may adversely affect the insurance applicant's insurance coverage or premium, leading to a wide range of abuses.

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

Yes **No**

(Please explain) Questionnaires should be clearly worded, avoiding any ambiguity and/ or confusion on the part of insurance applicants. Questions asked should be in accordance with principles of relevance and proportionality. Vague questions may result in additional, irrelevant information being disclosed that may negatively impact upon access to health insurance.

d. any other issues

(Please specify) The consultation process should provide for updates and education in relation to legal developments (for example, legislative developments, case law) relevant to the insurance industry, in particular, legal advances in the area of data protection and privacy).

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) A permanent body dedicated to facilitating this consultation process would oversee the coordination of the various stakeholders and ensure that the relevant topics are open to discussion. In particular, any proposals in this regard should have consideration of Article 33 of the CRPD and the requirement of an independent monitoring mechanism to promote, protect and monitor the implementation of the CRPD.

32. If so, what should be:

a. the composition of such body?

(Please specify) Insurance company representatives, consumer group representatives, government representatives, actuaries, legal and human rights experts, physicians/ scientists/ geneticists. Importantly, such a body should also include persons with disabilities and their representative organisations, in accordance with the overall objective of the CRPD to promote inclusion and active involvement of persons with disabilities, and specifically in accordance with Article 4.3 of the CRPD.

b. its tasks:

i. specific tasks?

Yes **No**

(Please explain) Specific tasks might include: review of underwriting practices in different jurisdictions, review of data collection processes, review of relevant law and latest developments applicable to the insurance industry, guidance in relation to advancing science/ genetic technology/ predictive medicine.

ii. a more general work scope?

Yes **No**

(Please explain) For clarity and to ensure a structured consultation with the necessary stakeholders, it would be preferable to assign specific tasks to this body.

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) The social purpose of insurance provides that insurance is an important and necessary social good for all individuals. In particular, it is recognized that health care is such an important social good that access to it should be guaranteed to everyone.

The importance of recognizing insurance as a key social good therefore adds merit to the hypothesis that the area of insurance ought be regulated to prevent misuse of genetic information and to ensure that individuals are not pushed out of insurance pools through being denied insurance or being charged inordinately high premiums. In this context, it is also necessary to have regard to the need to uphold the integrity of and ensure the inclusion of persons with disabilities in society, in accordance with the CRPD.

In this regard, it is also important to have regard to the European Code of Social Security and the European Social Charter which provide for the right to social security, and specifies a number of risks that should be covered for all individuals.

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

- a. illness?

Yes No

(Please explain) It is widely recognized that health care is such an important social good that access to it should be accessible to everyone. In accordance with the social purpose of insurance, there should not be any prohibitive obstacles to obtaining health care.

- b. invalidity?

Yes No

(Please explain) In the event of invalidity, an individual may temporarily or partially lose the ability to work and participate actively in the community. This may result in poverty, exclusion and isolation, together with a wide range of social implications (particularly for persons with disabilities, and elderly persons).

- c. death?

Yes No

(Please explain) On death, life insurance can provide peace of mind and security for individuals and their dependents in that event that one dies. The benefits from life insurance are intended to tide survivors over until they can become financially self-sufficient. In this respect, it has been observed that life insurance is perceived as serving a need rather than being a mere commodity, and therefore ought to be universally available, without barriers. In addition, in countries in which there is a requirement to purchase life insurance as a prerequisite to obtaining a mortgage, life insurance is further viewed as essential in securing fundamental human rights and ensuring an individual has access to owning property. Insurance coverage may therefore be seen as important for one's full membership in society (as property ownership is generally accepted as an important social good that many individuals strive to obtain).

- d. long-term care/dependence?

Yes No

(Please explain) The same principles of universal access to health care can be applied to long- term care/dependence insurance. For those who need the benefits which long- term care/ dependence insurance affords, their participation in society relies to a certain degree on having unfettered access to this insurance product.

e. retirement?

Yes **No**

(Please explain) On retirement an individual may suffer a loss of income. This may have subsequent implications on an individual's inclusion in the community in making a fruitful contribution to society. It is important that all individuals have the security of financial provision on retirement from employment.

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) To ensure the achievement of universal access to insurance, and to facilitate the coverage of the above- mentioned risks, regulation of private insurance may be a preferable approach. Some risks are only partially covered (or in some cases, not covered at all) under social insurance, thereby creating obstacles to access to insurance.

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

a. binding regulation?

Yes **No**

(Please explain) Binding regulation would have the advantage of certainty and uniformity. Such regulation would also have strong enforcement mechanisms.

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

Yes **No**

(Please explain) It may be more difficult to enforce a more flexible framework. In addition, the strength of such an approach may not be enough to deter prohibited actions by insurance companies.

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 to² represent an increased risk?

Yes No

(Please explain) In light of the potential for abuse (insurance applicants may suffer unfair disadvantage, unjustified discrimination, and breaches of privacy, as a result of use of genetic information and genetic test results), it is submitted that insurance companies be forbidden from taking account of genetic characteristics. Consideration of genetic characteristics can also act as an unjustified obstacle to insurance and healthcare. This may result in the exclusion and isolation of certain vulnerable individuals from society (particularly persons with disabilities and elderly persons).

This submission is in line with the EU Charter of Fundamental Rights, Article 21.1 which prohibits discrimination on the basis of, inter alia, genetic features. It is also in accordance with European Union data protection legislation, as well as the Article 8 of the European Convention on Human Rights providing for the right to respect for private and family life. In addition, the Council of Europe's Convention on Human Rights and Biomedicine (Chapter IV, Article 11) prohibits any form of discrimination against a person on grounds of genetic heritage. In an effort to avoid discrimination in the insurance context, Article 12 of the Convention on Human Rights and Biomedicine states that "tests which are predictive of genetic diseases...may be performed only for health purposes", which implies that an insurer is not entitled to ask for a predictive genetic test to be carried out as a precondition for concluding an insurance contract.

This submission is also in line with the overall tenor of the CRPD. Specifically, it is necessary to have regard to principles of equality, dignity, integrity and inclusion, which animate the CRPD.

Importantly, in addition to the potential risk of unjustified discrimination, breaches of privacy and exclusion from society, the ultimate fear is that advances in genetic science (and its misuse by insurers and other social actors) could potentially signal the creation of a genetic underclass and the relegation of genetically undesirable individuals, if not appropriately regulated. This may lead to the practice of genetic cleansing, not just in the insurance industry, but in other facets of life such as education, employment, political life and society in general.

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) Any such prohibition should be applicable to all types of insurance. Further, insurance companies have methods of addressing the risk of adverse selection by engaging in risk classification and adjusting overall premiums accordingly.

b. applicable also to insurances with optional subscription?

Yes No

(Please explain) Any such prohibition should be applicable to all types of insurance.

² This only concerns data derived from tests meeting the criteria described in chapter 2.2 as to reliability and predictive value in particular.

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) Insurance companies address adverse selection by engaging in the underwriting process and adopting risk classification when ascertaining insurance coverage and premiums. Therefore, insurance companies will adjust their overall premiums if the risk of adverse selection arises.

A further submission can be made to the effect that knowledge of one's genetic characteristics and potential future health may motivate individuals to plan their lifestyle, diet, and treatment plans to maximise their health care. The end result may be that individuals are healthier and therefore less likely to require the benefits of insurance. On balance therefore, the risk of adverse selection as a result of knowledge of genetic characteristics is not as problematic as some may argue. In addition, at present, relatively few insurance applicants are availing of genetic technology benefits (however, in the future, use of genetic technology is likely to increase).

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

Yes No

(Please explain) The promotion of obligatory group insurance schemes may appeal to both the insurance applicant and the insurance company. This may be financially more attractive to insurance applicants, and premiums may be lower and therefore more accessible. For the insurance company, the larger the membership, the lower the risk of anti- selection is.

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) See 34 (a) above.

b. invalidity?

Yes No

(Please explain) See 34 (b) above.

c. death?

Yes No

(Please explain) See 34 (c) above.

d. long-term care/dependence?

Yes No

(Please explain) See 34 (d) above.

e. retirement?

Yes No

(Please explain) See 34 (e) above.

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*