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Elements for the draft Explanatory Memorandum to the Recommendation on the processing for insurance purposes of personal health-related data, in particular data resulting from genetic tests

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Chapter I - General provisions

Object

Paragraph 1

1. This paragraph defines the Recommendation's purpose.

2. The aim of the Recommendation is to guarantee the respect for the fundamental rights of persons in the context of insurance contracts covered by this Recommendation by proposing a number of measures that may be of assistance to the governments of the member States.

3. Fundamental rights, be they related to private insurance or other fields, must be respected both by member States and by private natural or legal persons alike.

4. The principles set out in the Recommendation relate in particular to respect for the privacy and for the protection of individuals with regard to the processing of health-related personal data. Processing of health related data refers to the collection, use, and storage of this data (see Chapter II); including data resulting from genetic tests (see Chapter III).

5. The principles set out in the Recommendation also relate to the inclusion of new scientific knowledge in actuarial basis (see Chapter IV).

6. Insurance policies should also aim at ensuring fair access to insurance contracts for all citizens without discrimination of any kind. The coverage of socially important risks for persons presenting an increased risk is part of an effective non-discrimination policy (see Chapter V).

Scope

Paragraph 2

7. The second paragraph defines the field of application of the Recommendation.

8. The insurance contracts concerned by this Recommendation are personal or group contracts to which subscription is mandatory or optional and in which the principal risk covered is linked to a person's health, physical integrity, age or length of life, such as contracts providing care in the event of illness, disability, accident, retirement, dependence or guaranteeing the payment of a capital sum or an annuity in the event of death or survival.

Paragraph 3

9. Paragraph 3 constitutes a transposition of the principle of wider protection established by Article 27 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Applicatin of Biology and Medicine (Convention on Human Rights and Biomedicine).

10. In pursuance of this paragraph, the member States may apply measures of a more protective nature than those contained in this Recommendation. The text sets out common standards for member States, while allowing them to provide a higher level of protection with regard to the substance of the proposed measures in case they so wish.

Definitions

Paragraph 4

11. The term "insured person" used in this Recommendation refers to the individual concerned by the risk covered by the contract, whether in the process of being drawn up or concluded. The insured person may or may not be the policyholder (for example, in contracts taken out by an employer, the latter is the policyholder while the insured persons are the employees).

12. A "third party" is any natural or legal person other than the insured person. The status of third party is determined in relation to the person concerned by the information and not in relation to the contract. It may be a healthcare professional, an institution or a private individual holding information on the insured person. In certain cases, the policyholder himself or herself may be considered as a third party, for example an employer taking out an insurance contract for his or her employees (who are the insured persons).

13. The term "insurer" refers to both insurance and re-insurance companies.

14. The term "examination" refers to any non-genetic or genetic test and / or examination with diagnostic or predictive value. The results of an examination are of diagnostic value, if they confirm a diagnosis of a disease in a person. The results of an examination are of predictive value, if they indicate a risk of the development of a disease in the future. The reliability of the results of examinations with predictive value is extremely variable from one to another.

15. The term "genetic test" refers to an examination in accordance with Article 2 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes. The analysis undertaken in the context of genetic tests is carried out on chromosomes, DNA or RNA or any other element enabling equivalent information to be obtained. A genetic test can have diagnostic or predictive value (see above). As regards the reliability of results of genetic examinations with a predictive value, again it is extremely variable from one test to another. The predictive value is significant for monogenic diseases only. For polygenic, multifactorial diseases, which present the most cases, other (non-genetic) factors will have a very important role in the development of the disease.

16. The term "health-related personal data" refers to any data related to the health of an individual. It also refers to data which have a clear and close link with health as well as to genetic data (see also Recommendation (97)5 on the Protection of Medical Data).

Chapter II – Processing of health-related personal data

17. The principles set out in this chapter are the manifestation in the insurance field of the principle of fair and lawful processing of data outlined in Article 5 of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data.

Principle 1 – Insurers should justify the collection of health-related data.

Paragraph 5

18. This paragraph calls on member States to take appropriate measures to protect the privacy and to respect the principle of non-discrimination of insured persons by formulating the essential criteria for the collection of health-related personal data for insurance purposes.

19. Relevance refers to the value of the information recognised as appropriate for assessing the state of health of an insured person and evaluating the risks relating to his or her future health. The paragraph also stipulates that the relevance of the requested health-related data has to be duly justified.

20. The principle of proportionality refers to the nature of the health-related personal data requested or resulting from a requested examination in relation to the importance of the risk in question. The insurer should not collect any health-related personal data if the data is either not relevant for the risk or is not proportional to the nature and importance of the risk. The paragraph also stipulates that the respect for the principle of proportionality in relation to the nature and importance of the risk in question has to be justified.

21. The quality of health-related personal data collected for insurance purposes has to meet generally accepted scientific standards. Such data may include already existing health-related data resulting from examinations previously carried out as well as data resulting from examinations requested by insurers. In both cases, the examinations concerned should comply with generally accepted scientific and clinical criteria and be used in clinical practice.

22. A further safeguard relates to the predictive value of the examination. The results of an examination with predictive value do not per se fulfil the criterion of relevance, as the reliability of the results of examinations with a predictive value is extremely variable from one examination to another. In order to fulfil the criterion of relevance (in accordance with Paragraph 5, first indent, of this Recommendation) prove for the high/significant positive predictive value of the requested examination has to be provided. This does not apply to predictive examinations only, but also to examinations undertaken with a diagnostic purpose which produce, inter alia, results with predictive value. Renal cysts are, for example, directly linked to the possible development of polycystic kidney disease. The diagnosis of renal cysts therefore also produces results which are of predictive value.

Paragraph 6

23. The existing practice of including questions on family history in questionnaires has given rise to numerous objections in regard to relevance, proportionality, and data protection. The reliability of family history as a factor in assessing the insured person's risk has in particular been questioned. The paragraph stipulates that the collection of data on family history should in general be prohibited unless provided for by domestic law. If so, the criteria of Paragraph 5 of this Recommendation apply.

24. The conditions for the collection of this information should meet the data protection requirements provided in domestic law.

Paragraph 7

25. The Paragraph relates to the standards of questionnaires used by insurers to collect health-related personal data. The questions should be clear, intelligible, direct and objective and precise:

- Clear drafting of questions is in the interest of both the insurer and the insured person. It allows a more accurate assessment of the risk and prevents needless disputes at a later stage. The insurer as an expert, who can be expected to know how to draw up questions, should not be able to take advantage of the imprecision of the answers given by an insured person when this imprecision is due to the insufficient clarity of the questions.

- Questions should be drafted in a way to be easily intelligible by the insured person. This implies that the terminology used and the complexity of the questions should be comprehensible for the average insured person.

- Questions should be direct in order to obtain information from insured persons on their state of health or lifestyles. They should not include questions liable to prompt subjective answers. For example, questions such as, "Do you consider yourself to be in good health?" should not appear in the questionnaires.

- Questions should be objective and precise. This implies that questionnaires should not include questions which are too general or may give rise to incomplete answers.

26. In addition, insurers should take appropriate measure to verify that questionnaires are correctly understood by insured persons.

27. Requests about health-related personal data must be accompanied by accurate and appropriate information enabling the insured person to assess exactly what information is best to pass on. In order to ensure that requests for the submission of health-related data are correctly understood, the insurer should provide easy access to a contact person or body, having the requisite competence and experience, to address any difficulties of understanding. The contact person should be a physician or, at least, have the proper medical training.

28. The documents should always indicate the contact person or body to ensure the possibility of easy access.

Principle 2 – Insured persons should have control over their health-related personal data.

Paragraph 8

29. Health-related personal data processed for insurance purposes should, in principle, be collected from the data subject who is the insured person (see also Article 4.2 of the Recommendation (2002) 9 of the Committee of Ministers on the protection of personal data collected and processed for insurance purposes). In many cases, the insured persons will submit their own health declaration, and based on this, the insurer may ask the patient's medical doctor to confirm the information provided by the insured person, and / or provide additional information. However, the insured persons should still have control over any data requested from third parties by the insurer to calculate risks or premiums.

Paragraph 9

30. The paragraph specifies that the only admissible third party to transmit health-related personal data are medical doctors or health professionals. It is important that any request for information about aspects of a person's health made by the insurer with a view to calculate risks or premiums should be addressed to the professionals responsible for the insured person's health. A patient's medical record may contain personal information which has no bearing on the calculation of risks and premiums, the case in question, and in particular to the stage of the case. Medical files should therefore not be passed on as such. While technical items in the medical record may be communicated as they stand to avoid having to repeat medical examinations, it is not acceptable to send the entire medical record or large parts thereof without selecting those data which are genuinely relevant and proportional to calculate risks or premiums. In addition the respect for the principle of confidentiality can thus be ensured, as data collected in this way is covered by rules of professional secrecy.

31. In case agreement between parties has been reached that it is more suitable that the data is transmitted directly by the medical doctor or health professionals, the insured person's written consent is a precondition for the transmission of the insured person's health-related data.

32. The insured person's written consent should be free, express and informed. The consent is limited to data that is relevant and proportional at the particular stage of the case. Therefore, insurers should inform insured persons both about the precise content of the data sought from third parties and the reasons for this exceptional procedure and about the impact that the answers given by the third party might have for the insured person.

Paragraph 10

33. The collection of health-related personal data by controllers (natural or legal person, public authority, agency or any other body who is competent according to the national law to

decide what should be the purpose of the automated data file, which categories of personal data should be stored and which operations should be applied to them) from the public domain, such as the Internet, raises serious concerns with regard to the respect for the principle of purpose limitation and compatibility of purposes as set out in Article 5(b) of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. In addition, the reliability of information in the public domain particularly that found on the Internet is questionable. Consequently, such information should not be used to calculate risks or premiums. The public domain also includes social media and internet fora.

Paragraph 11

34. The collection of health-related personal data obtained in a research context also raises serious concerns with regard to the respect for the principle of purpose limitation and compatibility of purposes as set out in Article 5 (b) of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, as consent to the collection and storage of the respective data was given in a research context.

Principle 3 – Insurers should have adequate safeguards for the storage of health-related personal data

Paragraph 12

35. This Paragraph reiterates the principle of purpose limitation and compatibility of purposes as set out in Article 5(b) of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data and the safeguards formulated in Article 13 of the Recommendation (2002)9 of the Committee of Ministers concerning the protection of personal data collected and processed for insurance purpose. For respective safeguards on the period of conservation of data see Article 13(2) of the Recommendation (2002)9 of the Committee of Ministers concerning the protection of personal data collected and processed for insurance purpose.

Paragraph 13

36. The Paragraph specifies measures for protecting the security and confidentiality of the insured person's health-related data in practice. It calls for insurers to adopt internal rules (for example, codes of confidentiality, good practices, codes of conduct) to provide in particular that health-related personal data is stored separately from other data with limited access. The access to health-related personal data should be restricted to persons who need to use the respective data in connection with the calculation of risks and premiums, the acceptance of cover, or the performance of the contract. If the contract has expired, but claims can still be made, the data should not be stored in a live database, but in an intermediate database. The Paragraph also stipulates that data kept for statistical purposes should be anonymised.

Paragraph 14

37. The Paragraph calls for the adoption of internal and external audit procedure to ensure that the rules for the adequate control of the measures set out on Paragraph 13 are enforced. Failure to adhere to the rules should lead to appropriate action, including disciplinary measures and, if necessary, legal consequences.

Chapter III - Specific provisions on genetic tests

38. Chapter II sets out the general criteria applicable to the processing of health-related personal data for insurance purposes. This chapter describes additional safeguards which apply to the request for a genetic test or the use of existing data resulting from a genetic test.

Principle 4 – Genetic tests should not be required for insurance purposes

Paragraph 15

39. Article 12 of the Convention on Human Rights and Biomedicine sets out that, "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 [...]." This article prohibits the carrying out of predictive tests for reasons other than health or health-related research, even with the assent of the person concerned. Therefore, an insurer will not be entitled to subject the conclusion or modification of an insurance policy to the holding of a predictive genetic test. Nor will it be able to refuse the conclusion or modification of such a policy on the ground that the applicant has not submitted to a test.

Paragraph 16

40. This Paragraph stipulates that existing data resulting from a predictive genetic test should in principle not be used for insurance purposes. In case the use of existing data resulting from such a test is authorized by domestic law, the safeguards set out in Paragraph 5 of this Recommendation apply and their respect should be assessed by an independent body composed of experts having the requisite competence and experience.

Paragraph 17

41. Paragraph 6 of this Recommendation stipulates that the collection of data on family history should, as a general rule, be prohibited. The exception formulated in Paragraph 6 regarding possible respective provisions by domestic law does not apply for existing data resulting from genetic tests of family members. This Paragraph stipulates that existing data resulting from a genetic test from a family member should, without any exception, not be used for insurance purposes.

Chapter IV - Provisions on risk assessment

42. This Chapter addresses the requirement to regularley include new scientific knowledge in risk assessment for insurance purposes.

Principle 5 – Insurers should take account of new scientific knowledge

Paragraph 18

43. In order satisfy the criterion of relevance as set out in Paragraph 5 of this Recommendation, the Paragraph calls on insurers to regularly update their actuarial bases in line with any new scientific knowledge.

Paragraph 19

44. In line with the principle of the right to information, this paragraph defines, as a general rule, the obligation for insurers to provide information and justification to insured persons regarding the calculation of the premium, any additional premium or any total or partial exclusion from insurance.

Chapter V – Socially important risks

45. This chapter addresses the aim of ensuring fair access to insurance contracts for all citizens without discrimination of any kind. The coverage of socially important risks for persons presenting an increased risk is part of an effective non-discrimination policy.

Principle 6 – Member states should facilitate the coverage of socially important risks.

Paragraph 20

46. Paragraph 5 of this Recommendation sets out the criterion of relevance for the collection of health-related personal data, which refers to the value of the information recognised as appropriate for assessing the state of health of an insured person and evaluating the risks relating to his or her future health. In case it is already known that a person presents an increased risk due to his or her health status, the regular risk evaluation policy of insureres could lead to a situation that persons presenting an increased risk are excluded from any insurance cover or permiums become unafordable for persons concerned.

47. In international law as well as in European and national law, it is acknowledged that it is of fundamental social importance to cover certain risks. This is the case in particular for insurance contracts relating to a person's health or physical integrity, age or length of life, such as contracts providing care in the event of illness, disability, accident, retirement, dependence or death.

48. Contracts relating to the length of life, such as contracts guaranteeing the payment of a capital sum or an annuity in the event of death or survival, may be considered to be of

varying social importance depending on the country. Access to home ownership (and hence access to the life insurance connected with the loan taken out for the purchase of a home) can be extremely important in countries where the old-age pension scheme is not very well developed.

49. Member States are therfore called on to take, where appropiate, measures to facilitate the affordable subscription of insurance contracts covering socially important risks for persons presenting an increased risk. These measures can either relate to optional insurance contracts which fill gaps or remedy deficiencies in social security schemes or to mandatory contracts covering socially important risks by facilitating access to insurance under affordable conditions.

50. Various measures can be taken to facilitate access to insurance and avoid the exclusion of persons presenting an increased risk. They range from the prohibition of any exclusion where such contracts are subscribed by a large part of the population to the establishment of a fund to bear the cost of any additional premium.

51. Mechanisms to provide for the insurability of persons presenting an increased risk have, in certain countries, enabled those previously unable to take out insurance, to be accepted for cover.

Chapter VI - Mediation, consultation and monitoring

52. Chapter VI addresses mediation, consultation and monitoring procedures for the provisions of this Recommendation.

Principle 7 – Member states should ensure adequate mediation, consultation and monitoring

Mediation in disputes between insured persons and insurers

Paragraph 21

53. The Paragraph calls for setting up of mediation procedures for the fair and objective settlement of individual disputes between insured persons and insurers. In order to guarantee the functioning of mediation, insured persons need to be informed of the existance of such a procedure.

Collective consultation between parties

Paragraph 22

54. The Paragraph calls for setting up of a process of collective consultation between insurers, patient and consumer representatives, heath professionals, and the competent autorities with the objectives of ensuring a well-balanced relationship between the parties by

increasing the level of confidence that insured persons have in the decision-making process of insurers and by improving transparency vis-à-vis the public.

Monitoring of practices

Paragraph 23

55. The Paragraph calls for setting up of an independent monitoring mechanism for the evaluation of compliance of practices in the insurance field with the provisions set out in this Recommendation.