



Ministry of Health and Social Affairs

Comments on the Draft Recommendation on the Protection of Health-Related Data (version dated 8 June 2018)

Comments concerning specific articles

Sweden has some comments regarding to specific parts of the Recommendation which are presented below.

3. Definitions

/.../

- The expression “genetic data” means all data relating to the genetic characteristics of an individual which have been either inherited or acquired during prenatal development, as they result from an analysis of a biological sample from the individual concerned, in particular chromosomal, DNA or RNA analysis or analysis of any other element enabling equivalent information to be obtained.

SE Comments: The adding of “during prenatal development” may be unnecessary. It also differs from the definition in GDPR, article 4.13.

5. Legitimate basis of health-related data processing

SE Comments: We suggest changing the wording “defined by law” to permitted by law” in article 5.1 a, b, e and f and the same for 5.3. The word “defined” is too narrow and deviates from how these articles are written in Recommendation No. R (97) 5, e.g. 4.3 b and 7.3. b.

6. Data concerning unborn children

SE Comments: We suggest a change of the heading to “6. Health-related data collected before birth”. It is more in line what the article aims to regulate.

9. Communication of health-related data for other purposes than providing and administering health care

9.1 Health-related data may be communicated to recipients where the latter are authorised permitted by law to have access to the data.

SE Comments: See comment on heading 5 above concerning the word “permitted” which we believe is much better and in line with Recommendation No. R (97) 5.

9.2 Insurance companies and employers cannot, in principle, be regarded as recipients authorised to have access to the health-related data of patients unless law provides for this with appropriate safeguards and if the data subject has consented to it ~~in accordance with the conditions of principle 5.2.~~

SE Comments: We suggest that the last part of the article is deleted as above. Article 5 states that processing is lawful if at least one out of five legitimate basis are fulfilled but the wording now compels employers or insurance companies to rely only on article 5.2.

13. Security

13.2 These security rules, defined by law or other regulation and possibly contained in reference frameworks ...

SE Comments: There may be other forms of regulations that may be used as well when it comes to it-security.

13.4 Guaranteeing integrity requires assumes verification of every action carried out on the data ...

SE Comments: Suggested changes of wording that are more realistic. A regular data system carries out an enormous number of actions where most are of no interest for e.g. follow-up or inspection. To oblige controllers or processor to keep this data may be too burdensome and unnecessary and may also be very expensive.