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Consultation concerning direct-to-consumer genetic testing services – response from the Swedish National Council on Medical Ethics
Final version

The Swedish National Council on Medical Ethics (SMER) has studied the draft paper entitled "A Common Framework of Principles for direct-to-consumer genetic testing services". We would like to respond to the consultation as follows. We have previously submitted a draft version of our response. This is the final version which contains only minor changes compared with the previous one.

General aspects

We find this document very interesting, ground-breaking and important as a way of dealing with the problems that will arise as a result of people's growing concern for their own present health situation as well as their state of health in the future. The concept of genetic testing at the initiative of the individual consumer fits very well into that perspective. It is important that a regulatory framework of some form is established as soon as possible.

Due to the mobility of people within the European Union and to the impact of the possibility of ordering genetic tests on the internet, it is also important to take steps to achieve a Framework of Principles which can hopefully be agreed upon at international level. The testing procedure is also facilitated by the ease of taking DNA samples and sending them to any laboratory offering to perform a test around the world.

The need for a framework or regulation is also highlighted by the fact that the testing services in question are not, in Sweden at least, covered by the jurisdiction of medical supervision. This is because the individual is primarily regarded as a consumer, not a patient in the health care services.

Another point of discussion is the role of the Oviedo Convention and its additional Protocol concerning Genetic Testing for Health Purposes. Though many European countries have not ratified this Convention they nevertheless follow its main principles. For this reason the Convention and its additional protocol seems well suited as a basis for further initiatives in the field of medical ethics, such as the framework.

In Table 1, we would like to include prenatal diagnosis as one option to be included among the first three tests. The reason for this is that this kind of document should aim to be ahead of development instead of behind it. There is good reason to believe that in a couple of years it will be possible to perform prenatal diagnosis on blood samples from the pregnant mother. Samples are simple to take and may consist of only a drop of blood from the pregnant woman on a piece of blotting paper. One important reason for inclusion of this kind of test is the aggressive attitude among some of the commercial companies with their intention to offer this kind of genetic test as soon as it is available. This standpoint could be presented in a section dealing with future developments.

Responses to the consultation questions

1. Yes, we believe that recommending individualised pre- and post-test counselling to accompany genetic tests in the context of inherited or heritable disorders is the right approach. The reason for this is simple: the possible information received may have important implications for the person's health or for members of the family. Our opinion is that an individual in this position should be given as much information as requested to begin with. The difficulty then becomes striking the right balance in the information given between the right not to know and knowing enough to make an autonomous decision. To be able to strike this balance, in our opinion it is necessary to have two-way communication in which it is possible to meet the individual seeking a genetic test face to face. This process of genetic counselling will enhance the possibilities for the individual to make an autonomous decision. It is obvious that this is best done in a health care setting.

Another issue is the impact that these genetic tests may have on publicly funded health care and what resources need to be mobilised.

2. Due to the demands on genetic counselling mentioned in the first question, we feel that the first three tests in Table 1 should not be offered direct-to-consumers. Moreover, in accordance with Article 14 of the Oviedo Convention, genetic tests for the sole purpose of choosing a future child's sex should not be offered.

3. In our opinion the distinction between pre-symptomatic and susceptibility/pre-dispositional health test is not clear enough and we

therefore recommend the approach suggested under question 5 in your document. If penetrance (impact of genetic factor) is between 5-10 % the test should be considered pre-symptomatic.

4. Yes, our opinion is that the Principles should recommend that pharmacogenetic tests should only be provided to consumers with individualised pre- and post- test counselling. As you have indicated under question 4, the result of a pharmacogenetic test and the action taken by the individual might interfere with a prescription or an intervention recommended by a health care professional. Perhaps this kind of test should only be provided for in a health care setting and be included among the first three tests listed in Table 1.

We believe that pharmacogenetic tests should be regarded as a category of their own and should not fall into the category of genetic tests in the context of inherited or heritable disorders.

5. Yes, we believe that the impact criteria listed in Principle 10.1 are a helpful additional way of stratifying genetic tests. It is not necessary to include a list of tests in the Principles that determines to which genetic tests the application of principle 10.1 is relevant. We regard this way of dealing with the matter as more flexible.

6. No, we believe the amount of information as described under question 6 is applicable to all tests.

7. Yes, we believe that principle 5.10 should be included in the framework. It is important to protect the autonomy of the future adult for the reasons stated in your second paragraph under question 7.

8. A “reasonable step” could be to demand that every customer show his or her identity card to the staff performing the genetic test. With regard to distance agreements, the taking of samples could be witnessed by another person. However, to be honest, this is a weak point when it comes to the need for total reliability. It is also important to establish safe routines, for example concerning the marking of samples.

9. The principle stating that “a test provider must take whatever measures are necessary and appropriate to ensure that an individual has provided informed consent and has capacity to provide that consent for a genetic test” is a kind of general fundamental rule or obligation for the test provider and, as such, important. For that reason we think that this principle should be included.

10. There is no act in force in Sweden regarding these matters in detail, for example the various situations in which consent from the consumer is

required. For that reason the Principles do not contravene any Swedish legislation.

On a more general level, Directive 97/7/EC on the protection of consumers in respect of distance contracts and Directive 2000/31/EC on electronic commerce have resulted in Swedish legislation as well as legislation in other European countries. This EC-based legislation states, for example, that the consumer shall be provided with information about the main characteristics of the services in question in good time prior to the conclusion of any distance contract.

Directive 2006/123/EC on services in the internal market is also of some interest in this matter. Although this Directive only applies to requirements which affect the access to, or the exercise of, a service activity, it also contains recommendations concerning professional liability insurance for service providers and actions taken by the Member States to encourage the establishment of codes of conduct by professional bodies, organisations and associations. Public health and consumer protection may also justify the application of authorisation schemes and other restrictions in the Member States' national legislation.

The existing Swedish legislation concerning obligations for health care providers and health care professionals is not applicable to the situations described in these Principles.

11. If establishing legislation at national or international level (for example at EU level) will be difficult to achieve or will take a long time, countries ought to consider whether the test providers should sign up to the Principles as a demand for accreditation to perform genetic testing, or at least as a voluntary agreement within the trade.

On behalf of the Swedish National Council on Medical Ethics,

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