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Committee on Social Affairs, Health and Sustainable Development

Minutes

Public hearing on "Combating trafficking in human tissues and cells", held in Paris, on Friday, 13 September 2019

In the framework of the report currently in preparation on "Combating trafficking in human tissues and cells" (Rapporteur: Mr Serhii Kiral, Ukraine, EC), the Committee held a public hearing with the participation of:

- ✓ Mr Jacinto Sánchez Ibáñez, Director – Tissue Establishment and Cryobiology Unit, University Hospital, A Coruña (Spain)
- ✓ Mr Givi Javashvili, Chairman of the National Council on Bioethics of Georgia; Professor and Head of Family Medicine Department – Tbilisi State Medical University (Georgia)

In the absence of the Rapporteur, the **Chairperson** introduced the preliminary draft report, and warmly welcomed **Mr Jacinto Sánchez Ibáñez**, Director of the Tissue Establishment and Cryobiology Unit of the University Hospital in A Coruña (Spain). **Mr Givi Javashvili**, Chairman of the National Council on Bioethics; Professor and Head of the Family Medicine Department of Tbilisi State Medical University (Georgia), was delayed due to the public transport strike, and arrived later on during the exchange of views.

Mr Sánchez Ibáñez pointed out that tissue and cell donations played an important role in health care, research and the pharmaceutical industry. One donor could improve up to 100 lives. An absence of financial gain was paramount. The only area where profits were allowed was the production of medicinal products, because developing such products involved extensive manipulation and was very costly. Donors should give explicit consent for this type of use. In other areas, prices should reflect the operational costs of the tissue establishments, and there should be no profit. Some activities in this area should be criminalised. However, there was no internationally accepted definition of trafficking in human cells and tissues. There were also unethical activities. While it might be questionable whether they should be criminalised, they should be controlled and properly regulated.

There was no data on how much tissues and cells were collected, distributed and used in Europe or imported/exported from/to other countries. Not much official data was available on trafficking in human cells and tissues. Particularities of tissues and cells made trafficking a simple and very lucrative business. Tissues from one donor could be used for the development of more than 200 products. They could be procured up to 48 hours after death (or even longer if there was no concern for quality), and not necessarily in an operating theatre. They could be stored for long periods of time. They could be easily transported without being recognised as human tissues and could also be used in the 'health tourism' sector. Lack of data on imports and exports created opportunities for "laundering" of trafficked tissues and cells. Fraudulent use of cadavers posed a major risk of disease transmission. Prohibition of financial gain should be paramount. Measures to increase availability were needed. Reliable data disaggregated by gender needed to be collected from official sources. There was a need for an international legal instrument, setting out a definition of trafficking in human tissues and cells, measures to prevent such trafficking and protect victims, as well as criminal law measures to punish the crime.

Mr Şahin enquired who the traffickers of human cells and tissues were. **Mr Essl** wondered about the steps in bone cell processing. **Mr Kılıç** asked why the issue of blood was not included in the preliminary draft report.

[1]The minutes were approved and declassified by the Committee on Social Affairs, Health and Sustainable Development at its meeting on 5 December 2019, in Paris.

Mr Sánchez Ibáñez responded that there was no information on criminal networks active in this area. However, it was clear that in many cases consent requirements were not duly respected and that the facilities used were not adequate. Furthermore, human tissues were often used to produce medicinal products which could be used outside the hospital setting (e.g. in dental care). It was difficult to recognise such products as human "material", and they were therefore easy to use in unauthorised ways. The dimensions of the problem were not known. Organs, cells and tissues, and blood were three different issues, and different approaches were required for each of them.

The Chairperson enquired as to whether sperm and oocytes were considered as tissues and cells. **Mr Sánchez Ibáñez** confirmed that this was the case.

Ms Leyte congratulated the expert on his presentation. As a Spanish and Galician politician, she was proud that her country representatives could provide useful guidance on this matter.

Ms Trisse asked about situations where national laws foresaw that every person was presumed to be a donor unless he or she had expressed their will to the contrary. **Mr Sánchez Ibáñez** explained that opting in or out as donor applied only to clinical use of organs, cells and tissues. The most important thing was the public trust in the whole system. Donations and consent must be explicit, and the family of a deceased person should always be informed about any removal of body parts.

Mr Javashvili pointed out that the use of human tissues in research and clinical contexts was growing rapidly. Several scandals related to procurement questioned the adequacy of the regulatory frameworks. The key concerns were non-consensual procurement, inadequate testing, inaccurate or false donor files and trafficking. In the last two decades, several international legal instruments had been developed and put into practice to address these concerns. Soft law instruments were also important, such as the Council of Europe's Guide on how to interpret prohibition of financial gain. There were no reported cases of illicit activities in this area in Georgia. However, review of research projects showed that researchers did not pay due attention to consent procedures. In many cases, for example, residual material obtained during diagnostic procedures or surgery was used for research.

The case of surrogacy provided a good illustration of how detrimental inaction at early stages of medical innovations could be. Surrogacy was not duly regulated in Georgia. Nevertheless, it was widely used, and it seemed to be impossible to stop it at this stage. It was better to regulate such issues in the beginning, and not after they became an accepted practice. Surrogacy also reflected disparities between countries. Most couples looking for surrogate mothers came from rich countries. Developed countries organised procurement from developing countries. Procurement facilities were often located near borders. Financial incentives in this context often took the form of coercion. Lump sum payments for tissues and cells were also an area of concern. Trafficking was becoming a big issue, but it was largely overlooked by society. Public debate was needed to make this problem visible.

Development of soft law instruments was essential, such as the Committee of Ministers Recommendation CM/Rec(2016)6 on research on biological materials of human origin, which provided useful guidance. Furthermore, while legal instruments were important, they provided external motivation to tackle trafficking and were not sufficient. It was important to create intrinsic motivation among professionals concerned to adhere to ethically sound principles. Education and training were needed, in order to support the implementation of the existing standards in this area.

The Chairperson warmly thanked the experts for their contribution and closed the hearing.

Committee on Social Affairs, Health and Sustainable Development
Commission des questions sociales, de la santé et du développement durable

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Dr Givi JAVASHVILI, Chairman of the National Council on Bioethics of Georgia ; Professor and Head of Family Medicine Department – Tbilisi State Medical University / *Président du Conseil national géorgien de bioéthique ; Professeur et Chef de Département de la médecine familiale – Faculté de médecine, Université d'État de Tbilissi*

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