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# Combating trafficking in human tissues and cells

**Report**[1]
Committee on Social Affairs, Health and Sustainable Development
Rapporteur: Ms Reina de BRUIJN-WEZEMAN, Netherlands, Alliance of Liberals and Democrats for Europe

*Summary*

Human cells and tissues are routinely used for medical purposes, transplantation and research. This includes corneas, heart valves, skin, stem cells, sperm and oocytes. New technologies help save lives, improve quality of life and help individuals to become parents. However, such use raises ethical and legal questions.

The principles of prohibition of financial gain, free and informed consent and the prevalence of the interests of the human being over those of society are enshrined in the international legal framework. However, cases of procurement without consent, inadequate testing, false donor files, irresponsible allocation and illegal trade have been reported. The absence of an internationally accepted definition of "trafficking of human tissues and cells", cross-border situations, differences in national legislation and the rapid evolution of technologies make it difficult to prosecute illicit activities.

The Council of Europe has a mandate to protect human rights as well as expertise on human tissues and cells. It is therefore well placed to support decision making on what activities should be criminalised and ensuring that these decisions are respected. The Parliamentary Assembly should thus call on the Committee of Ministers to take the lead and develop a binding legal instrument on combating trafficking in human tissues and cells.

1. Reference to committee: Doc. 14357, Reference 4320 of 13 October 2017.

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## A. Draft recommendation[2]

1. Advances in technology in human tissue and cell transplantation can save lives, restore essential bodily functions, improve quality of life and help individuals to become parents. Today, human substances, ranging from musculoskeletal, cardiovascular and ocular tissues, to many types of cells and gametes, are used routinely for medical purposes, therapy and research. Within the European Union alone, over 2 million human tissue and cell units were distributed for medical use in 2016. At the same time, the use of substances of human origin for transplantation and research raises many ethical and legal questions.

2. The Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention, CETS No. 164) stipulates that the "human body and its parts shall not, as such, give rise to financial gain", that an "intervention in the health field may only be carried out after the person concerned has given free and informed consent to it" and that the "interests and welfare of the human being shall prevail over the sole interest of society or science." Today, these principles are in danger of being bypassed and watered down.

3. In contrast to the field of organs, limited attention has been paid to illicit and unethical activities associated with the procurement, processing and clinical use of human tissues and cells. This is perhaps because society is less familiar with tissue and cell transplantation compared with organ transplantation, although the latter happens far less often.

4. When illicit and unethical activities involve donors, they frequently relate to recently deceased persons. Illicitly obtained tissues from one deceased person can reach up to 90 recipients. Various ethical and safety-related scandals have been reported, such as procurement without consent or authorisation, inadequate testing, inaccurate or false donor files, irresponsible allocation and illegal trade. Hearings, lawsuits, resignations and closures of tissue establishments have followed. However, knowledge about the true extent of these illicit activities remains limited. Little information is available from official sources.

5. Furthermore, there are activities that, in addition to their illicit and unethical component, could seriously jeopardise the quality and safety of tissues and cells, and thus the recipients' health.

6. When illicit and unethical practices occur in the form of financial inducement to donors (or their families), there may be a risk of potential living donors not adequately considering the risks related to the donation procedure or the families of deceased donors not disclosing relevant medical or behavioural information that would, under normal circumstances, preclude donation. This can also motivate intermediaries to withhold information for fear of losing fees.

7. Excessive compensation for donation may endanger the health of vulnerable donors who may be enticed to donate driven by financial need. This may be of particular concern in the case of oocyte donors, where financial inducements can prompt women to provide multiple donations in different clinics without proper follow-up and medical care, and thus risks for their health and fertility. The risk of excessive donation is increased in the case of cross-border donations, where financial disparities between countries may render originally appropriate compensations in one jurisdiction into real inducements for donation for donors from less affluent countries.

8. Desperation may also lead patients to search for alternative therapies for various diseases, including cell-based experimental treatments promoted without clinically demonstrated safety and efficacy.

9. Illicit and unethical practices undermine public trust and support. Scandals related to such practices cause a drop in confidence in all types of donor-derived substances and result in reluctance among the general population to donate bodily materials. Ultimately, this will affect the availability of tissue and cell grafts, and can jeopardise the availability of organ and blood donors as well.

10. The existing international legal framework – developed by the World Health Organization, the EU and the Council of Europe – includes ample provisions to ensure the quality and safety of tissues and cells, by specifying the principles of consent, prohibition of financial gain and authorisation requirements. These principles, however, are not fully implemented and their violations are not systematically prosecuted. The prohibition of financial gain, which is a universally accepted principle for such donations, is not always easy to uphold. Income disparities between and within different countries, together with the fact that tissues and cells can be easily stored and shipped, create opportunities for profit-making and abuse.

2. Draft recommendation adopted unanimously by the committee on 3 December 2019.

11. Most importantly, the absence of an internationally agreed definition of what constitutes trafficking in tissues and cells on the one hand, and the diversity of legal provisions within the EU, Council of Europe member states and third countries, on the other hand, make it difficult to prosecute illicit and unethical activities.

12. The Assembly recalls that in its Recommendation 2009 (2013) on "Towards a Council of Europe convention to combat trafficking in organs, tissues and cells of human origin", adopted in 2013, it suggested that the issue of trafficking in human tissues and cells was different from trafficking in human organs, and that the two issues had to be addressed through two distinct legal instruments. The Assembly thus called upon the Committee of Ministers to decide on a roadmap for the preparation of an additional protocol on trafficking of human tissues and cells to the proposed Convention against Trafficking in Human Organs.

13. Since then, the Council of Europe Convention against Trafficking in Human Organs (CETS No. 216) has been opened for signature and ratification. It has been ratified by nine countries and signed (but not yet ratified) by 15 further countries. It entered into force in 2018. The committee of the parties will be convened following the 10th ratification. As foreseen, this Convention does not address the issue of tissues and cells.

14. With respect to the trafficking in human cells and tissues, the Assembly welcomes the work of the European Committee on Organ Transplantation, and in particular its report on "Illicit and unethical activities with human tissues and cells: addressing the need for the elaboration of an international legal instrument to protect donors and recipients" prepared in 2018. The report identified gaps in international legal frameworks, reiterated the Committee's concern with respect to lack of agreement on what constituted illicit activities in this area and stressed the need for a new legal instrument to address such activities.

15. The Assembly takes note of the progress made so far, as well as of the remaining challenges. It is convinced that stronger action is needed in this area on the part of the Council of Europe member states.

16. In the light of the above, the Assembly recommends that the Committee of Ministers:

16.1. initiates the drafting of a legally binding Council of Europe instrument against trafficking in human tissues and cells, possibly in the form of an additional protocol to the Convention against Trafficking in Human Organs (CETS No. 216);

16.2. ensures that such a legal instrument:

16.2.1. provides a definition of illicit activities in this area, and is based on a comprehensive approach covering crime prevention and repression, victim protection, promotion of appropriate policies, as well as national and international co-operation;

16.2.2. includes mechanisms for regular data collection and analysis on trafficking in human cells and tissues, in compliance with democratic governance structures, as well as transparent, authoritative and effective monitoring and implementation;

16.3. calls on the Council of Europe member states that have not yet ratified the treaties related to this area, such as the Convention on Human Rights and Biomedicine (Oviedo Convention; ETS No. 164), the Convention on Action against Trafficking in Human Beings (CETS No. 197) and the Convention against Trafficking in Human Organs (CETS No. 216), to do so as a matter of priority, and as a contribution to the UN Agenda for Sustainable Development Goal 3: Good health and well-being and Goal 16: Promote just, peaceful and inclusive societies.

## B. Explanatory memorandum by Ms Reina de Bruijn-Wezeman, rapporteur

### 1. Introduction

1. Today, human tissues and cells are routinely used for medical purposes, therapy, plastic surgery and research. Within the European Union, more than 2.1 million human tissue and cell units were reported to have been distributed for medical use in 2016.[3]

2. Advances in technology in human tissue and cell transplantation can save lives (e.g. haematopoietic stem cell transplantation), restore essential bodily functions and improve quality of life (e.g. restoring sight with cornea; transplantation of muscles, bones, joints, tendons, and/or ligaments in patients with musculoskeletal disorders that require orthopaedic surgery) and help individuals in their desire to become parents (e.g. through gamete and embryo donation). However, this is a relatively little-known area of medicine, and the public remains largely unaware of the opportunities and the risks that it entails. At the same time, an efficient system of tissue and cell donation depends heavily on public trust. It is essential to ensure that this trust is not blind and is based on reliable information.

3. While a lot has been done to address illicit activities in organ donation, much less attention has been given to donation of other substances of human origin. Regretfully, as of today, there is no internationally agreed definition of what constitutes “trafficking in human tissues and cells” and therefore what practices should be considered illegal and prosecuted in this context. What is considered illegal in one country can be perfectly legal in another. Official information on trafficking in human tissues and cells is very limited, most of what we know comes from estimates or investigative media reports.

4. So, what exactly is trafficking in human tissues and cells? To what extent is this a problem in Europe today? And how can we make full use of the unprecedented developments in medical science and practice, without compromising public interest and respect for human dignity? With these questions in mind, I will explore the past and current challenges in the use of human tissues and cells, the existing international standards and remaining gaps, as well as possible ways of strengthening relevant policy frameworks.

5. I would like to mention that the preparation of this report was initiated by Mr Serhii Kiral (Ukraine, EC), who had been an active member of the Committee on Social Affairs, Health and Sustainable Development for many years. A fact-finding visit by Mr Kiral to the French National Agency for Medicines and Health Products Safety (ANSM) was useful for discussing the perspectives of relevant authorities. Valuable information was received at an exchange of views held in Paris on 13 September 2019, with the participation of Mr Jacinto Sánchez Ibáñez, Director of Tissue Establishment and Cryobiology Unit in the University Hospital, A Coruña (Spain), and Mr Givi Javashvili, Chairman of the National Council on Bioethics, Professor and Head of Family Medicine Department in the Tbilisi State Medical University (Georgia). Substantial written feedback was received from Mr Fewzi Teskrat, expert on human tissues and cells products (Malta). Following the elections in Ukraine in July 2019, Mr Kiral left the Assembly, and I was subsequently appointed rapporteur for this report on 2 October 2019.

6. In the preparation of this report I looked at media reports, academic literature and documents of the EU competent authorities and Council of Europe bodies, such as the European Committee on Organ Transplantation.

### 2. Definitions and scope

7. First of all, and, bearing in mind the rather technical nature of this subject, I would like to clarify what exactly “human tissues and cells” are and what is generally understood by “trafficking” in this context.

8. The “cell” is the smallest transplantable and functional unit of life (for example: a haematopoietic stem cell, a hepatocyte, a sperm or an oocyte). “Cells” means individual human cells of a collection of human cells when not bound by any form of connective tissue. Today, the isolation of cells from almost all body tissues represents new therapeutic opportunities. “Tissue” is an aggregate of cells joined together by, for example, connective structures and performing a function (for example: corneas, heart valves or skin). “Tissue” means all constituent parts of the human body formed by cells. Different types of cells and tissues can be removed either from living or deceased donors.[4]

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3. https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/2017_sare_tc_summary_en_0.pdf.
4. Council of Europe (2017), Guide to the quality and safety of tissues and cells for human application.

9. As previously pointed out, there is no internationally agreed definition of trafficking, illicit, illegal and fraudulent activities in human tissues and cells. For the purposes of this report, I will consider that such activities include any practice performed in violation of one or more guiding principles as set down in international legal instruments. These principles include: 1) consent, 2) non-violation of bodily integrity beyond the necessary, 3) licensed processing, 4) respect of legal requirements, 5) altruistic donation and prohibition of financial gain; 6) promotion of experimental treatments without evidence of safety and efficacy.[5] While acknowledging that there is no agreed definition, I will use the terms "trafficking in human tissues and cells" and "illicit activities with human tissues and cells", when talking about such practices in this report.

10. Furthermore, a distinction needs to be made between trafficking in human beings and trafficking in human organs, tissues and cells.[6] The two crimes overlap, but differ in scope. "Trafficking in human beings" means "the recruitment, transportation, transfer, harbouring or receipt of persons, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of exploitation".[7] Trafficking in human beings is a combination of three elements – action (taking someone away), means (coercion) and purpose (exploitation). The exploitation of an individual is the central aspect of such trafficking.

11. Some cases of trafficking in organs, tissues and cells result from trafficking in human beings. Only when organs, tissues and cells are removed from living donors can these cases relate to trafficking in human beings (but not when they are removed from deceased persons). However, trafficking in human organs, tissues and cells does not necessarily involve trafficking in human beings. For example, when human tissues are procured from a deceased person without due consent on the part of the family members, this is considered as an occurrence of trafficking in human tissues.

12. While currently there are no official statistics on trafficking in human tissues and cells, experts believe that the largest instances of tissue trafficking occur with respect to deceased donors.

13. With respect to the scope of my report, I would like to point out that I will focus primarily on the trafficking in human tissues and cells for the purposes of transplantation and research. While the use of tissues and cells in the development of medical products can be a highly lucrative area, and important ethical concerns are currently raised by researchers on this subject,[8] this is a highly complex issue, which is very different from transplantation and research. It will require a different type of policy response and deserves a separate report by the Assembly.

14. Finally, this report will not cover the issue of trafficking in blood and its derivatives, as this issue is also substantially different and also requires a different approach.

## 3. Ethical and safety scandals – a thing of the past?

15. In the past, a lack of relevant legal frameworks or their weak enforcement and insufficient oversight have led to a number of high-profile scandals across the world. I include below some of the most striking examples of the last 40 years,[9] which show the scale of the damage caused, be it in pursuit of profit, due to lack of diligence, or in the name of science and based on the paternalistic assumption that "doctors know best".

*Alder Hey hospital, United Kingdom, 1988-1995*

16. In 1999, an inquiry was launched into the allegations that the Alder Hey Children's Hospital was involved in the unauthorised removal, detention and disposal of body parts of their patients in 1988-1995, for the purposes of research. The 540-pages enquiry report published in 2001 discovered the long-standing

5. https://www.edqm.eu/sites/default/files/position_paper_-_illicit_and_unethical_activities_with_human_tissues_and_cells_-_november_2018.pdf.
6. Council of Europe / United Nations (2009) Trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs, Joint Council of Europe / United Nations Study, available on the Internet at: https://rm.coe.int/16805ad1bb.
7. The Council of Europe Convention on Action against Trafficking in Human Beings, available at: https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168008371d.
8. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4428037/pdf/embr0016-0557.pdf.
9. Indeed, illegally procuring bodies for scientific purposes has a much longer history, reaching its heyday in the UK, for example, with the "resurrection men" of the 19th century/Victorian era, who dug up corpses in graveyards to sell to medical schools for anatomy studies.

practice of organ retention without consent from the next of kin of the deceased children. It was found that other hospitals were involved as well.[10] This approach was assumed to be in the best interest of the parents. This was aggravated in the case of the Alder Hey hospital, where pathologist Dick van Velzen had ordered the "stripping of every organ from every child who had had a post-mortem" during his time at the hospital, even for children whose parents specifically stated that they did not want a full post-mortem.[11] Following the inept handling of the return of organs after the scandal erupted, some parents received their children's organs piecemeal and third or fourth burials had to be held. The enquiry report made detailed recommendations on different aspects of this case.[12] The 1961 Human Tissue Act was subsequently reviewed. The Human Tissue Act 2004 created the Human Tissue Authority. In 2005, Dick van Velzen was found guilty of serious professional misconduct by the General Medical Council and struck off the UK medical register.

*New-York body snatching scandal, 2000-2004, US*

17. In late 2005, a "New-York body snatching scandal" gripped the United States (US). For almost four years, Biomedical Tissue Services (BTS) supplied bones and other tissue illegally "harvested" from 1,077 corpses to RTI Donor Services (a nonprofit subsidiary of the Regeneration Technologies, Inc. (RTI), which is a Florida-based processor of orthopedic, cardiovascular and other biologic implants) and four other US companies. During this period the company earned around 4.7 million dollars. Bodies were dissected in funeral parlors in New York, Rochester, New Jersey and Philadelphia. Consent forms and personal records were falsified.[13] In the scandal that followed, partner tissue banks recalled 25,000 products – 2,000 of which had been sold to Australia, South Korea, Turkey, Switzerland and other countries.[14] The perpetrators were charged with 122 counts of stealing bodies, illegal dissection, enterprise corruption, grand larceny, and forgery, among other crimes. Michael Mastromarino – the mastermind behind the plot – was sentenced to 15 to 30 years in prison and agreed to pay $4.6 million, to be distributed among the victims' relatives.[15]

*Illicit practices in human reproduction, Cyprus and Romania, 2005*

18. In 2005, the European Parliament condemned the practice of the US-Israeli GlobalART Clinic in Romania, which provided oocytes to the UK, the US and Israel. Romanian donors received 100-250 US dollars as financial compensation. At least 2 Romanian women suffered from acute ovarian hyper stimulation syndrome and did not receive the necessary medical care. Around the same time, Petra Health Clinic in Cyprus sourced oocytes from women from Eastern Europe (who were flown to Cyprus for 500 Euros), and recruited oocyte donors among immigrants who live in Cyprus.[16]

19. Since then, some countries have developed or improved their legal frameworks and put in place monitoring procedures. But have all the problems been resolved?

## 4. Progress achieved at the national level: case study – France

20. Many European countries have developed comprehensive legal frameworks and set up safeguards against trafficking in human tissues and cells in the past decades. Within the European Union, strict control measures were introduced to ensure quality and avoid illicit activities. Mr Kiral was advised that a fact-finding visit to France would be a good way for him to become familiar with the current situation in this field.

21. In June 2019, Mr Kiral met representatives of the French National Agency for Medicines and Health Products Safety (ANSM), to discuss the latest developments in processing human tissues and cells. This Agency took part in a project on "Vigilance and surveillance of substances of human origin" (SoHO V&S, 2011), co-funded by the EU, which developed the Guidance on the detection and investigation of suspected

10. For example, the Birmingham and Liverpool hospitals had also given thymus glands, removed during heart surgery from live children, to a pharmaceutical company for research in return for financial donations.
11. https://www.theguardian.com/society/2001/jan/30/health.alderhey1.
12. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/250934/0012_ii.pdf.
13. https://www.theguardian.com/world/2006/apr/02/usa.features.
14. https://www.icij.org/investigations/tissue/body-brokers-leave-trail-questions-corruption/.
15. https://www.psychologytoday.com/us/blog/shadow-boxing/201307/death-body-snatcher.
16. https://books.google.fr/books?id=wMfeCwAAQBAJ&pg=PT250&lpg=PT250&dq=european+parliament+globalART+romania&source=bl&ots=JeCxP0gLJr&sig=ACfU3U1X06MK2vKp8d9tvs0bkfEOFK3P4g&hl=en&sa=X&ved=2ahUKEwjkndvCmO_lAhVFzIUKHdwuDOcQ6AEwC3oECAgQAQ#v=onepage&q=european%20parliament%20globalART%20romania&f=false.

illegal and/or fraudulent activity (IFA) related to tissues and cells. During his visit, he discovered that today the use of human tissues and cells for transplantation and research is well-established and thoroughly regulated in France.

22. The EU Directives 2004/23/EC[17], 2006/17/EC[18], 2006/86/EC[19] and 2015/565/EC[20] provide a common European framework for the donation, procurement, testing, processing, storage and distribution of human cells and tissues. These standards are transposed in the national French legislation.

23. The French Ministry of Solidarity and Health (Directorate General on Healthcare) oversees policies and their implementation. Procurement is the responsibility of regional agencies under the Ministry of Solidarity and Health. The Agency for Biomedicine supervises, accompanies, evaluates and informs other relevant bodies with a view to improving access to care and quality of life for patients in several areas, including organ and tissue collection and transplantation. The ANSM gives authorisation starting from procurement to distribution of tissues and cells, including import and export. Regular inspections are organised, and meetings are held with relevant law enforcement agencies.

24. In France, there are about 70 establishments, half of which are tissue banks (22 of which are public and 9 are private) and the other half – cells banks (all of which are public). Private tissue banks export a lot of tissue outside of Europe, mainly to the Middle East and North Africa. Nevertheless, their work is oriented primarily towards the national market. Registries are maintained in accordance with relevant regulations. Public tissue banks aim to meet the public need. The trend is that public needs remains stable, while exports are growing. A lot of innovation takes place in the private sector.

25. The ANSM interlocutors felt that there was little margin for illicit and fraudulent activities in France, as the regulations were strict, and it was impossible to pay for human tissues and cells. Furthermore, autologous donations (from the patients themselves) were given precedence to the allogenic ones (from a donor to the patient) whenever possible. While imports were common in the past, today they are no longer needed, except for reasons of compatibility between donors and recipients. France was therefore largely self-sufficient and, in most cases, did not depend on other countries (which could have lower levels of protection against abuse). Co-operation within the EU allowed to work with countries with a similar level of quality assurance.

26. It is possible for the ANSM to co-operate with entities outside of the EU. In this case, relevant documentation needs to be submitted by such partners. A system of assessment of the relevant processes is established, including the possibility of inspections.

27. Public awareness plays an important role in promoting public trust in donations and ensuring national self-sufficiency in this area. National awareness campaigns are organised by the Agency for Biomedicine. The National Day of Reflection on Organs and Tissues Donation and Transplantation, and Donor Recognition is held annually on 22 June.[21]

## 5. Progress achieved at the European and international level

28. Inequalities among different countries and regions provide opportunities for illicit and fraudulent activities. Tissues and cells of human origin can be easily transported (without being recognised as such), and people can travel for the purposes of transplantation. Thus, high moral and ethical standards should be ensured not only for tissues and cells procured and used in one jurisdiction, but also for those brought in from (and exported to) other countries.

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17. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004. Official Journal of the European Union. L102, 7.4.2004, p. 48.
18. Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells. Official Journal of the European Union. L38, 9.2.2006, p. 40.
19. Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells. Official Journal of the European Union. L294, 25.10.2006, p. 32.
20. Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells Text with EEA relevance. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.093.01.0043.01.ENG.
21. https://www.agence-biomedecine.fr/Journee-nationale-de-reflexion-sur,1259.

29. It is therefore of utmost importance to ensure that basic common approaches and rules are agreed upon and respected in practice. While international standards have been developed on trafficking in human organs, trafficking in human tissues and cells has proved more difficult to tackle. Nevertheless, a number of important steps have been taken in this direction.

30. The World Health Organization (WHO) sets out international standards in its Guiding Principles on human cell, tissue and organ transplantation, which include consent requirements; prohibition of financial gain; allocation guided by clinical criteria and ethical norms; self-sufficiency of countries; altruistic donation; equal access to grafts; and efficiency, safety and quality.[22] Although these Guiding Principles are not legally binding, they influence national legislation and professional codes of practice.

31. The Charter of Fundamental Rights of the European Union (EU) sets out the principle that making the human body and its parts, as such, a source of financial gain must be prohibited (Article 3). The three previously mentioned European Commission Directives provide the legal framework for tissue donation, banking and usage in the EU. While these Directives provide useful guidance and have significant influence on the development of national legislation, it is up to the member States to put them into practice.

32. The Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention; ETS No. 164), opened for signature in 1997, reaffirmed the principle that the human body and its parts should not give rise to financial gain, defined consent requirements, and introduced a requirement for public debate. To date, 29 member States are bound by it. With respect to financial gain, it is worth mentioning a recent publication of a "Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors", which was prepared to support the implementation of the Oviedo Convention.[23]

33. An Additional Protocol to the Oviedo Convention on Transplantation of Organs and Tissues of Human Origin (ETS No. 186) was opened for signature in 2002. To date, 15 member States are bound by it. The Protocol covers transplantation (but not research or development of medical products). It covers both tissues and cells. However, the Additional Protocol is not a criminal law instrument and it does not provide clarity on which practices constitute trafficking in human cells or tissues and should be criminalised. The Protocol is to be regularly re-examined to ensure that it reflects relevant scientific developments. The Steering Committee on Bioethics (CDBI), which was initially responsible for re-examinations foreseen in the Convention and its Additional Protocols, was replaced by the Committee on Bioethics (DH-BIO).

34. The Council of Europe Convention on Action against Trafficking in Human Beings (CETS No. 197) was adopted in 2005 and entered into force in 2008. It is ratified by all Council of Europe member states except for the Russian Federation (and is also in force in Belarus). The forms of exploitation covered by the Convention include the removal of organs. GRETA – the Group of Experts on Action against Trafficking in Human Beings – is responsible for monitoring the implementation of this Convention. It is not entirely clear to what extent trafficking in human tissues and cells could be addressed under this Convention, and in the context of trafficking in human beings more generally.[24]

35. In 2009, the Council of Europe and the United Nations produced a joint study, which stressed the need to distinguish clearly between trafficking in human beings and trafficking in organs, tissues and cells. It provided an overview of the legal and factual situation and made recommendations (e.g. to pass legislation in conformity with the prohibition of financial gains, to promote organ donations and to collect reliable data).

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22. https://www.who.int/transplantation/Guiding_PrinciplesTransplantation_WHA63.22en.pdf, accessed on 6 March 2019.

23. https://rm.coe.int/guide-financial-gain/16807bfc9a.

24. It might be worth noting that the inclusion of tissues and cells was considered during the drafting of the Legislative Guide to the Palermo Protocol to the UN Convention on Transnational Organised Crime, but was ultimately rejected. This Protocol provides the international legal definition of trafficking in human beings (replicated in the Council of Europe Human Trafficking Convention). Similarly, in 2011, a draft report presented to the Working Group on Trafficking in Persons, which called on States Parties to apply the laws and other measures relating to trafficking in persons to trafficking for the removal of tissues and cells, had to be subsequently rewritten to limit the scope to organ removal. Further, the Legislative Guide states that organ trafficking will fall under the Protocol, for example, where victims are coerced into entering an arrangement to sell their organs. Alternatively, victims may be deceived about the benefit or compensation they will receive, or they may not be fully informed about the procedures and health consequences of organ removal. Another method involves luring the donor abroad under false promises, such as employment opportunities. What would not be covered by the Protocol is mere trafficking in separated organs for profit or any trafficking in tissue, cells, or body parts that are not organs.

Furthermore, the study pointed out the need for an international legal instrument setting out a definition of "trafficking in organs, tissues and cells" and "the measures to prevent such trafficking and protect the victims, as well as the criminal-law measures to punish the crime".[25]

36. A report[26] on illicit and fraudulent activities prepared under an EU funded project entitled 'Vigilance and Surveillance of Substances of Human Origin' (SoHO V&S)[27] aimed at providing to the EU Member States National Competent Authorities responsible for tissues and cells, guidance for detecting, investigating, managing and communicating on such activities. A questionnaire was sent to all National Competent Authorities. The report noted, *inter alia*, that there was significant diversity throughout the EU with respect to the management of suspected illicit and fraudulent activities in the context of tissues and cells and that there was a lack of specific training dealing with how to identify and handle such activities.

37. In 2013, the Assembly adopted two texts related to the draft Convention against Trafficking in Human Organs and recommended that, "[…] at this stage, it has not been considered advisable to prepare an additional protocol against trafficking in human tissues and cells, largely due to the absence at both national and international levels of complete and harmonised regulation of the removal and use of tissues and cells."[28] Instead, it proposed a step-by-step approach and suggested that the Committee of Ministers decide on a roadmap for the preparation of the additional protocol.[29]

38. The Council of Europe Convention against Trafficking in Human Organs (CETS No. 216) was opened for signature in 2015 and entered into force on 1 March 2018. This Convention is a criminal law instrument and provides a definition of trafficking in human organs as well as clarity on which practices need to be criminalised. However, this Convention does not address the issue of tissues and cells. To date, nine countries are bound by it and 15 countries have signed but have not ratified it. The Committee of Parties, which is the body responsible for overseeing the implementation of this Convention, is yet to be established (it requires 10 ratifications).

39. In the Council of Europe framework, a comprehensive Guide to the quality and safety of tissues and cells for human application was published first in 2013 and in its fourth edition in 2019, partly funded by the European Union, provides healthcare professionals with a comprehensive overview of recent advances in the field as well as with technical guidance on ensuring the quality and safety of human tissues and cells applied to patients.[30]

40. Trafficking in human cells and tissues has also been addressed by the European Court of Human Rights. In the case of *Elberte v. Latvia*, body tissue was removed from Ms Elberte's deceased husband, without her knowledge or consent. Tissue from her husband's body was sent to a pharmaceutical company in Germany for the creation of bio-implants, in accordance with a State-approved agreement, and as part of a wide scale method of operation. The domestic authorities did not establish any elements of a crime in this case. The European Court of Human Rights, however, concluded that the removal of tissue from a deceased man's body without the knowledge or consent of his wife amounted to degrading treatment.[31]

41. In October 2018, the European Committee on Organ Transplantation (CD-P-TO) adopted a report on "Illicit and unethical activities with human tissues and cells: Addressing the need for the elaboration of an international legal instrument to protect donors and recipients".[32] This report takes stock of the existing

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25. Council of Europe / United Nations (2009), Trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs, page 8, available at https://rm.coe.int/16805ad1bb.
26. Project Report on SOHO V&S Guidance for Competent Authorities: Communication and Investigation of Serious Adverse Events and Reactions associated with Human Tissues and Cells, available at: https://www.notifylibrary.org/sites/default/files/SOHO%20V%26S%20Communication%20and%20Investigation%20Guidance.pdf.
27. Grant Agreement Number: 20091110. Funded under the EU Second Programme of Community Action in the Field of Health. Further information is available at: https://www.notifylibrary.org/content/vigilance-and-surveillance-substances-human-origin-project-sohovs.
28. PACE Recommendation 2009 (2013) on "Towards a Council of Europe convention to combat trafficking in organs, tissues and cells of human origin", and Opinion 286 (2013) on the Draft Council of Europe Convention against Trafficking in Human Organs.
29. The Committee of Ministers did not reply to this specific recommendation of the Assembly.
30. Council of Europe (2019), Guide to the quality and safety of tissues and cells for human application, available at: https://www.edqm.eu/en/organs-tissues-and-cells-technical-guides.
31. See *Elberte v. Latvia* (judgment of 13 January 2015) before the European Court of Human Rights, https://www.echr.coe.int/Documents/FS_Health_ENG.pdf, accessed on 6 March 2019.
32. https://www.edqm.eu/sites/default/files/position_paper_-_illicit_and_unethical_activities_with_human_tissues_and_cells_rev_-_november_2018.pdf.

international treaties, identifies the gaps, and calls on the Council of Europe decision-making bodies to develop an additional protocol to the Council of Europe Convention against Trafficking in Human Organs on combatting trafficking in human cells and tissues.

## 6. Concerns remain

42. While substantial progress has been achieved, important concerns remain. Indeed, the EU Directives have established a common European framework in this area and play an essential role in ensuring quality and developing public trust. However, these Directives leave ethical issues aside, which are relegated to a great extent to the EU member states.

43. The issue of compensation of tissues and cells donors is quite different from that in the field of organ donors. For example, the Organs EU Directive states: "Member States shall ensure that donations of organs from deceased and living donors are voluntary and unpaid", while the Tissues and Cells EU Directives state "Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells". In the latter Directive it is also stated that "donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation." The calculation of the financial compensation for such inconveniences is the responsibility of national competent authorities. To what extent the safeguards against possible abuse are in place? What are the mechanisms for the oversight and how effective are they?

44. More generally, how can one ensure that altruistic donations are not used by private actors for financial gain? And how can one be sure that such donations are used to meet public health needs rather than for making profit?

45. Differences in legislation and regulations in different parts of the world create loopholes for illicit activities in this area. What mechanisms could be used to support harmonisation of relevant standards? From the Council of Europe perspective, how could co-operation be facilitated between EU and non-EU member States that are members of the Council of Europe?

46. In the current context of growing poverty in some parts of the world and in Europe in particular, how can one prevent exploitation of vulnerable people for the purposes of trafficking in human tissues and cells? Are the existing mechanisms sufficient to protect them from coercion, fraud and abuse? Not only are such illicit activities human rights violations, they are also a threat to public health, as quality and safety requirements are often not respected in this context, which might lead to the transmission of infectious diseases and other serious adverse reactions for the patients.

47. Many occurrences of trafficking in human cells and tissues are related to the issue of consent and importation. For example, it is not uncommon in some countries that residual material obtained during diagnostic procedures or surgery is used for research without the patients' consent. In other cases, tissues collected for the purpose of research are used for military research purposes or cosmetics research and diagnosis (without this being specified when consent is provided). The Committee of Ministers Recommendation CM/Rec(2016)6 on research on biological materials of human origin[33] includes detailed guidelines on this topic, including with respect to persons not able to give their consent (which can be done exceptionally under certain circumstances). It is important to ensure that the principles underlying these guidelines are applied in practice by means of solid and systematic oversight procedures.

48. The WHO principle is that the distribution of tissues and cells should be guided by clinical criteria and ethical norms, and distribution rules should be equitable, justified and transparent. How effective are we at respecting this principle?

49. Currently, in many countries there are long waiting lists for medically assisted reproduction treatments involving oocytes and sperm. Medically assisted reproduction might not be available for all the population (often it is only married heterosexual couples who are given access). This creates a great demand for such treatments, leading some patients (who can afford to) to travel to other countries for this purpose. Furthermore, there are websites where sperm can be purchased by private individuals from companies in Europe and third countries and shipped by post directly to the final user. In the absence of appropriate monitoring, traceability and follow-up, all these possibilities create risks for both donors and recipients and need to be addressed.

33. https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff.

50. Another area of concern is the promotion of experimental treatments without clinically demonstrated safety and efficacy. While haematopoietic progenitor cell transplantation has been used for many years without controversy, and research is underway to apply progenitor-cell treatments for neurodegenerative diseases and conditions such as diabetes and heart disease, among others, some health agencies also promote the use of these cells for the cure of Parkinson's disease, autism, dementia, depression, multiple sclerosis, cerebral palsy, traumatic brain injury, heart disease, macular degeneration, chronic kidney disease, osteoarthritis, and strokes. Anti-aging treatments are also advertised. In most cases, there is not sufficient evidence on the benefits of such treatments.

51. The absence of a binding international legal instrument on trafficking in human tissues and cells, which would include a definition of what falls within the scope of illicit activities in this area, makes it difficult to combat and prevent such activities.

## 7. Conclusions and recommendations

52. Medical use of human cells and tissues is a rapidly evolving area, which creates new opportunities and challenges for our societies. A lot of progress has been achieved at national, European and global levels, with respect to developing standards for quality and safety and ethically sound medical procedures and research. Nevertheless, important challenges remain.

53. At present, there is little official information on trafficking in human cells and tissues. Most of what we know about this phenomenon is based on estimates or on investigative media reports. Reliable data on the trafficking of human cells and tissues needs to be collected at a national and European level, to allow for an in-depth understanding of the latest challenges and possible solutions.

54. Discrepancies in legislative frameworks as well as in economic development in different countries (within the EU, in the Council of Europe geographical area and in third countries) provide opportunities for illicit activities in this area. Harmonisation of relevant policies and practices across Europe, including outside of the European Union, is an important element of combating trafficking in human cells and tissues. In those instances where tissues and cells travel, equivalent quality and ethical standards should be ensured. To the extent possible, national (and European) self-sufficiency should be further promoted in order to meet the need of the patients.

55. When preparing this report, I was struck by how little we know about the advances in science and medicine in this area, about the scale of their current application and about both benefits and challenges that they can create. It is important to ensure that there is a broad public awareness about this issue in our societies. Furthermore, it is important to ensure that health and other relevant professionals are duly trained and intrinsically motivated to care about vulnerable persons, who are patients or research participants, identify masked forms of coercion and avoid incentives offered to them which may undermine their judgment.

56. While the absence of a common definition of trafficking in human cells and tissues is a major challenge for successful combating of illicit and fraudulent activities in this area, biomedicine is developing very fast, and it is difficult to anticipate the possible forms of such activities. This means that such a definition, ideally adopted in the framework of an international legal text, should then be applied to specific cases, and further interpreted with respect to the relevant developments in science, research and health-care services.

57. There is clearly a need for strengthening international co-operation in this area. A reputable international body needs to be entrusted with systematic monitoring of the member states' activities in this area, in order to allow for on-going standard setting and implementation and exchange of good practice. Such an international body could produce "case-law" on what falls within the scope of trafficking and should therefore be prosecuted. This would facilitate significantly the development of relevant national policies, as well as the work of law-enforcement bodies. It would be important to ensure that the members of such a body have no conflict of interest in the domain of human cells and tissues.

58. The Council of Europe has the advantage of already possessing a binding treaty in the related field of organ trafficking, as well as the necessary expertise in the criminal law area, and technical expertise through the European Directorate for the Quality of Medicines & HealthCare. As a regional organisation, its reach is necessarily limited by geography, a drawback which can, however, be overcome by opening any legal instrument to be developed to non-member States.

59. Based on the above-mentioned considerations, the Parliamentary Assembly should invite the Committee of Ministers to consider the drafting of a binding legal instrument on combating trafficking in human tissues and cells, possibly in the form of an additional protocol to the Convention against Trafficking in Human Organs (CETS No. 216).

60. Furthermore, the Parliamentary Assembly should invite the Council of Europe member states that have not ratified the important Council of Europe legal instruments related to this area – such as the Convention on Human Rights and Biomedicine (Oviedo Convention; ETS No. 164), the Convention on Action against Trafficking in Human Beings (CETS No. 197) and the Convention against Trafficking in Human Organs (CETS No. 216) – to do so as a matter of priority. This would also be an important European contribution to the UN Agenda for Sustainable Development Goal 3: Good health and well-being and Goal 16: Promote just, peaceful and inclusive societies (with respect to human trafficking).