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Draft
Additional Opinion
of
the Steering Committee on Bioethics (CDBI),
the European Committee on Crime Problems (CDPC),
the European Committee on Transplantation of Organs (CD-P-TO),
identifying the main elements that could form part of a binding legal instrument
against the trafficking in organs, tissues and cells (OTC)

I. Background:

1. At its meeting on 16 November 2010, the Group of rapporteurs of the Committee of Ministers, on legal cooperation (GR-J), examined the opinions adopted by the Steering Committee on Bioethics (CDBI), the European Committee on Crime Problems (CDPC), the European Committee on Transplantation of Organs (CD-P-TO) and the Group of Experts on Action against Trafficking in Human Beings (GRETA) on the recommendations made in the Joint Council of Europe - United Nations Study on Trafficking in Organs, Tissues and Cells and Trafficking in Human Beings for the purpose of the removal of organs, in particular on the elaboration of an international legal instrument setting out a definition of trafficking in organs, tissues and cells (OTC) and the measures to prevent such trafficking and protect the victims, as well as the criminal law measures to punish the crime.
2. In this context, and following a proposal by the Deputy Secretary General, the CDPC, the CDBI and the CD-P-TO were invited to "identify the main elements that could form part of a binding legal instrument and report back to the GR-J by next April."
3. In reply to the request of the Committee of Ministers, representatives of the three Committees (CDBI, CDPC, and CD-P-TO) met on 9 – 10 February and 31 March – 1 April 2011, to prepare the present additional opinion, which was adopted by the aforesaid three Committees on ..., ... and ... April 2011, respectively.

II. Introductory remarks

4. As demonstrated in the joint Council of Europe/United Nations Study on trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs from 2009, the trafficking in human organs, tissues and cells is a problem of global proportions that violates basic human rights and constitutes a direct threat to individual and public health.
5. Despite the existence of two international legal instruments (see paragraph III. 1. below), important loopholes, that are not sufficiently addressed by these instruments, continue to exist in the international legal framework.
6. The three Committees acknowledge the transnational dimension of trafficking in organs, tissues and cells and the need to combat the criminal acts related thereto at international level.

III. Scope of a binding instrument:

III. 1. The scope of criminalization and the concept of “trafficking”

7. The three Committees note that the trafficking in persons for the purpose of removal of organs is already criminalized in international law through the trafficking protocol¹ of the 2000 UN Convention Against Transnational Organized Crime (“Palermo Convention”) and the 2005 Council of Europe Convention on Action against Trafficking in Human Beings² respectively. However, the three Committees consider that the trafficking in human organs, tissues and cells is a broader concept than trafficking in human beings for the purpose of removal of organs.
8. In fact, the aforesaid international legal instruments only address the scenario where recourse is had to various coercive or fraudulent measures to exploit a person in the context of the removal of organs, but do not sufficiently cover scenarios, in which the donor has – adequately – consented to the removal of organs or – for other reasons – is not considered to be a victim of trafficking in terms of the above mentioned conventions.
9. For example, the scenario where an organ is transplanted, and the donor has knowingly and willingly agreed to have the organ removed for financial gain or comparable advantage, and/or where this takes place in breach of applicable domestic legislation, is presently not criminalized at international level, although posing equally serious threats to human rights and individual and public health.
10. In the view of the three Committees, a separate draft convention should be negotiated in order to address, inter alia, the removal of organs with consent, but for financial gain or comparable advantage and/or outside of the approved domestic systems in order to close the current loopholes in international law.
11. Against this background, it is the opinion of the three Committees that a certain level of overlap in the proposed criminalization of acts related to the trafficking in human organs, tissues and cells with provisions of the existing international instruments against trafficking in human beings does not pose a legal problem and is unavoidable, as the three Committees recommend that a possible future binding instrument against trafficking in human organs, tissues and cells should be a stand-alone instrument, cf. paragraph IV below, open not only to the member states of the Council of Europe, but to all states,

¹ Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, supplementing the United Nations Convention Against Transnational Organized Crime, Articles 3 (a) and 5.

² Council of Europe Convention on Action against Trafficking in Human Beings (CETS No. 197), Articles 4 (a), 18 and 19.

some of which may not be Parties to the two existing international anti-trafficking instruments.

12. The three Committees have discussed the feasibility to include in the proposed scope not only human organs but also tissues and cells. While the risk to public health as well as to the health of the recipient posed by unauthorised and uncontrolled activities in these fields is essentially the same, the risks to life and health of the donor are often more limited in the case of removal of tissues and cells than is the case for removal of organs.
13. The three Committees note that, at present, important differences exist in the regulatory and institutional frameworks governing the removal and transplantation of human organs on the one hand, and the removal, distribution and subsequent use of human tissues and cells for transplantation and/or other purposes, on the other. In fact, the domestic regimes governing the latter are extremely diverse (if at all existing) and cannot be compared to the regimes governing the removal and transplantation or other use of human organs.
14. Hence the three Committees recommend that the experts that may be tasked with the drafting of a binding legal instrument should further look into the feasibility – at the current stage – of including human tissues and cells under the scope of a possible binding instrument and discuss in more depth – and taking into account the relevant legislation of all member states – the possibility to criminalize certain conduct also in respect of tissues and cells.
15. The three Committees further recommend, that a possible binding instrument be focused on the illicit removal, obtention, trading, distribution and subsequent use of human organs, tissues and cells as such (i.e. in an unprocessed form), whereas the legal trade in medicinal products such as highly innovative and complex advanced therapy medicinal products based on human organs, tissues and cells should be excluded from the scope of such an instrument.
16. Even though cells as such cannot, at present, be extracted directly from the donor, but are always subject to a secondary extraction from tissues, the three Committees are of the opinion that, in so far as the inclusion of human tissues and cells under the scope of a future binding legal instrument is considered feasible by the experts that may be tasked with drafting it, human cells should be covered in their own right and not merely be considered as "tissue". The Committees further suggest that human blood and the related issue of transfusion should be excluded from the scope of a binding instrument. There are strong arguments for such a proceeding, mainly the specific regulations or specific standards for this field such as the respective EU Directives and Recommendation R(95)15 on the Preparation, Use and Quality Assurance of Blood Components that resulted for instance in the exclusion of the issue from the Additional Protocol concerning the Transplantation of Organs and Tissues of Human Origin (ETS No. 186).
17. Also, questions remain as to the inclusion under the scope of a possible future instrument of other types of tissues and cells, such as cord blood cells and gametes, to name just two examples. These issues should be looked into by the expert group that may be tasked with the drafting of a binding legal instrument.
18. The term "trafficking" has long been used in international criminal law instruments (e.g. on trafficking in drugs or trafficking in human beings) and is immediately recognizable. However attempting to lay down a legal definition of "trafficking in human organs tissues and cells" for use as a constituting element for criminalization may prove impractical and may not be necessary or appropriate for realizing the aim of a possible binding instrument. The three Committees recommend further discussions in the framework of the expert group that may be tasked with the drafting of a binding legal instrument in order to achieve a consensus on what conducts and practices are to be targeted and constitute "trafficking" within the framework of a new binding legal instrument in this field.

19. The Committees consider the notion of financial gain or comparable advantage to be central to the concept of “trafficking” and propose that a number of specific acts related to the removal and transplantation of human organs as well as to the obtention, trading and distribution of human tissues and cells could be criminalized. In general terms these could cover three types of situation which may warrant criminalization of certain conduct:

- providing **financial gain or comparable advantage** for the removal, obtention, trading, distribution and subsequent use of human organs, tissues and cells
- removal, obtention, trading and distribution and subsequent use of human organs, tissues and cells **without the appropriate consent** of the donor
- removal, transplantation, obtention, trading, distribution and subsequent use of human organs, tissues and cells **outside of approved domestic systems**.

III. 2. Financial gain or comparable advantage:

20. The three Committees propose to criminalize certain conduct, if a financial gain or comparable advantage is requested, offered or taken³ for removal, distribution and use of organs, tissues or cells as such, either from a living or a deceased person. A legally binding instrument may need to specify the term “financial gain” (where criminalization should be foreseen) as opposed to providing or taking of an acceptable “compensation” in line with the principles laid down in Article 21 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (CETS No 186) from 2002.

III. 3. Consent:

21. The absence of an appropriate consent by the donor to removal of organs, tissues and cells, or the use of removed organs, tissues and cells for other purposes than those covered by the consent of a donor are key components of the description of a number of the proposed criminal acts (see above). The term “consent” should be understood as “free and informed consent” (cf. the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (CETS No. 164) and its Additional Protocol concerning Transplantations of Organs and Tissues of Human Origin (CETS No. 186)). A new legally binding instrument will need to address the concept of “consent” in case of removal of organs, tissues or cells from a deceased person. In such a case, specific consent may have been given by that person prior to his death. If not, such consent by the donor may be replaced by authorisation given by the family of the deceased. Or, as an alternative, states may choose to apply a concept of “presumed consent”.

III. 4. Outside of approved domestic systems:

22. While most states, as far as the removal and transplantation of organs are concerned, appear to have approved domestic systems (officially approved, regulated and controlled institutions, procedures etc), this does not necessarily hold true for the removal of tissues and cells from bodies of deceased persons and/or the removal of organs, tissues and cells for purposes other than transplantation.

23. The three Committees believe that in case a legally binding instrument will be elaborated, drafters should look at the need/feasibility to have the instrument address the advisability of establishing such systems where they do not yet exist.

³ The expert group tasked with drafting a possible new instrument could examine to which extent donors should be exempt from criminalization based on the requesting, offering or taking of financial gain or comparable advantage.

24. As to criminalization, the three Committees believe that a legally binding instrument should foresee criminalization of removal of organs, tissues and cells, obtaining and distribution thereof outside of the approved domestic systems, if such systems exist, since the very existence of a parallel “black market” for organs, tissues and cells in itself constitutes a serious threat to human rights and to public health, eventually risking to undermine public confidence in the approved domestic systems.
25. However, taking into account the potential broad spectrum of possible conduct in non-compliance with applicable legislation regulating the removal, transplantation, storage, import, export etc. of human organs, tissues and cells, any requirement to “criminalize” should allow for states to respond by the imposing of administrative fines rather than criminal sanctions strictu sensu, cf. paragraph V. 2. “Criminal and administrative sanctions” below.
26. Furthermore, it should be noted that not any act in breach of any rule governing an approved domestic system is necessarily to be subject to criminalization/administrative sanctions under a possible new binding legal instrument, but only such conduct as is related to the trafficking in organs tissues and cells.
27. In so far as the possible unauthorised manufacturing of medicinal products on the basis of illegally removed human organs, tissues and cells is concerned, the three Committees find that it should fall outside the scope of a possible new binding instrument, since such acts are already criminalized under Article 8 of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (“Medicrime Convention”).

IV. Main elements related to substantive criminal law:

28. More specifically, the three Committees recommend that a group tasked with drafting a possible new binding instrument should examine the feasibility of criminalizing the following conduct:
29. In case of organs:
- The offering and the receipt of financial gain or comparable advantage in the context of the removal, distribution and use of human organs
 - Removal of human organs from living or deceased donors for purpose of transplantation or other purposes without the appropriate consent of the donor or authorisation substituting such consent.
 - The recruitment of donors and solicitation of recipients outside of the approved domestic transplantation systems.
 - The performance of transplantations outside of the approved domestic transplantation systems.
30. In case of tissues and cells (if included under the scope of a binding legal instrument, cf. paragraph 14 above):
- The offering and the receipt of financial gain or comparable advantage⁴ in the context of the removal and subsequent distribution and use of tissues and cells as such from living or deceased donors.
 - The removal of tissues and cells from living or deceased donors without the appropriate consent of the donor or authorisation substituting such consent.

⁴ Other than fees for medical and technical services performed and linked to costs of retrieval, transport, preparation and storage.

- The obtention, trading and distribution of tissues and cells as such outside of the approved domestic systems, where such systems exist.
- The obtention, trading and distribution of bodies and body parts for the purpose of removal of tissues and cells outside of the approved domestic systems, where such systems exist.
- The use of tissues and cells removed from living or deceased donors outside the approved domestic systems or imported in non-compliance with the applicable domestic legislation on importation of tissues and cells.

V. Other criminal law provisions

V. 1. Criminal intent, aggravating/mitigating circumstances, aiding, abetting, attempt:

31. The three Committees consider that the focus of a possible binding legal instrument should be on criminal intent as a precondition for applying sanctions. However, it recommends that an expert group that may be tasked with the drafting of a binding legal instrument should also consider the possible need for applying the concept of criminal negligence in certain cases.
32. Furthermore, the three Committees suggest addressing such issues as aggravating and mitigating circumstances, aiding, abetting and attempt. As regards an example of a possible aggravating circumstance, the three Committees point to the perpetration of certain of the above listed possible offences by healthcare professionals. A mitigating circumstance, on the other hand, could be the special vulnerability of an organ recipient.

V. 2. Criminal and administrative sanctions:

33. Whereas the three Committees agree that the most serious criminal acts listed above should as a starting point be subject to criminal sanctions, they note that depending on the domestic legal systems of States Parties, the application of administrative sanctions for lesser crimes could be an option. The three Committees recommend that this issue be looked into in detail by the expert group tasked with the drafting of a binding legal instrument in particular in respect of the criminalization of removal, transplantation, subsequent distribution and use of organs, tissues and cells outside of approved domestic systems, cf. paragraph III. 4. "Outside approved domestic systems" above.

V. 3. Other sanctions:

34. Given the clear financial incentives to commit these types of offences, the three Committees strongly recommend that a binding legal instrument will oblige States Parties to permit the seizure and confiscation of proceeds stemming from offences. It should also be possible for States Parties to ban the exercise of a professional activity by a person sentenced for having committed one of the possible offences listed above, if the professional activity is directly related to his/her ability to commit that offence. Finally, the three Committees note that a number of both public agencies and private companies are active in the field of obtention, trading and distribution of in particular human tissues and cells. In order to ensure an efficient protection in the entire field, it is considered necessary to also introduce corporate liability.

V. 4. Jurisdiction

35. In terms of jurisdiction, the three Committees recommend that in addition to the obligatory jurisdiction based on the territorial principle, jurisdiction based on the nationality and passive nationality principles (with possibilities to enter reservation) should be included.

36. In addition to the principles of jurisdiction to be applied by the Parties to a possible binding legal instrument, a provision on the principle of “extradite or prosecute” (aut dedere, aut judicare) should be included. In accordance with this principle, a Party is obliged to establish jurisdiction over, and prosecute, an alleged offender, present on its territory, whom it has declined to extradite to another Party having so requested, solely on the basis of the nationality of the alleged offender.
37. In the view of the three Committees, a possible group of experts to be tasked with the drafting of a new binding legal instrument should examine the phenomenon of “transplantation tourism” with a view to identifying possible solutions.
38. As in the case of the Council of Europe Convention on the Protection of Children against Sexual Exploitation and Sexual Abuse (CETS No. 201), where the specific purpose was to combat the phenomenon of “sex tourism”, eliminating the normally applicable principle of “double criminality” (i. e. making the establishment of jurisdiction over a criminalized act dependent on the criminalization of the act in the place where it was performed and not only in the focal state), could be considered.
39. Finally, the jurisdiction provisions should include a safeguard clause to the effect that a possible binding instrument would not exclude any criminal jurisdiction exercised by a Party under its national law.

V. 5. International cooperation on criminal matters

40. The three Committees note that in the framework of the Council of Europe cooperation on criminal law matters, the issues of mutual legal assistance and extradition are governed by a number of horizontal instruments, namely the European Convention on Extradition (ETS No. 24) from 1957 and the European Convention on Mutual Assistance in Criminal Matters (ETS No. 30) from 1959 together with their Additional Protocols and the Convention on Laundering, Search, Seizure and Confiscation of Proceeds from Crime (ETS No. 141) from 1990.
41. A possible binding legal instrument should as a minimum contain a general provision enabling a Party to process a request for legal assistance or extradition from a Party with which it has not concluded mutual legal assistance treaty, by considering the possible binding legal instrument as the proper legal basis for mutual legal assistance and extradition in respect of offences established under that instrument.
42. However, since the three Committees recommend that a possible binding legal instrument should be open to non-member states of the Council of Europe, a group of experts tasked with the drafting of a possible legal instrument may also look into the need/feasibility of including provisions based on the aforesaid Council of Europe conventions.

V. 6. Victims

43. In line with the recent practice of the Council of Europe, the three Committees propose to include provisions on the protection and standing of victims in criminal proceedings against alleged perpetrators of the aforesaid proposed offences. Taking into account the particular nature of the crimes which may be covered by a possible binding instrument, the three Committees note that there is a need to define in more detail which persons could be covered by provisions on victims, as in some instances not only donors, but also recipients, might be considered as victims.
44. Moreover, the experts that may be tasked with drafting a binding legal instrument should examine the issue of compensation to victims, including for subsequent damages.

V. 7. Protection of witnesses

45. Given the organised nature of the crime of trafficking in human organs, tissues and cells, a group of experts tasked with drafting of a possible binding instrument may examine the need/feasibility of providing protection to witnesses.

VI. Main elements not related to substantive criminal law:

46. The three Committees also propose that a binding legal instrument could address a number of issues not related to substantive criminal law, including the following.

VI. 1. Prevention

47. A possible binding legal instrument should contain provisions calling on Parties to ensure equitable access to transplantation services for patients, in particular through the adoption of relevant legislation and the establishment of transparent approved domestic systems for transplantation and removal of organs, and for the obtention, trading, distribution and subsequent use of tissues and cells along the lines laid down in the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (CETS No 186).
48. The criminalisation of acts related to the illicit removal of, and trade in, human organs, tissues and cells will only be effective in so far as States Parties have established regulatory systems at national level for transplantation and removal of organs, and for the obtention, trading, distribution and subsequent use of tissues and cells. Whereas most member states of the Council of Europe have such systems in place at least in respect of the transplantation of organs, these systems may vary considerably. The three Committees propose that an expert group tasked with the drafting of a binding legal instrument should examine this issue in depth in particular in view of the removal, subsequent distribution and use of organs, tissues and cells for purposes other than transplantation. Also, such an expert group should look into particular issues that may arise in this respect in case of import of organs, tissues and cells from third states.
49. Furthermore, the three Committees recommend that a provision calling on Parties to carry out awareness raising measures, directed both at the general public and at healthcare professionals, is included.

VI. 2. International cooperation in the prevention of such crimes

50. The three Committees strongly recommend that a possible binding legal instrument should contain provisions on international cooperation for the purpose of crime prevention with a view to enhancing the ability of the various domestic health and other competent authorities involved to detect and combat the trafficking in human organs, tissues and cells in the most efficient way. Such international cooperation may include the establishment of a system for information exchange and early warning, e. g. through dedicated national contact points. In line with the recommendations of the joint Council of Europe/United Nations study, the three Committees agree that collection of data and the exchange of information are key elements in the fight against trafficking in human organs, tissues and cells.

VI. 3. Cooperation at domestic level

51. Similarly, the three Committees propose that a group of experts tasked with drafting a possible binding legal instrument could examine the need/feasibility of obliging Parties to ensure proper information exchange at domestic level between their competent authorities in order to improve the capacity of these authorities to tackle the many challenges posed by trafficking in human organs, tissues and cells.

VII. Form of a legally binding instrument

VII. 1. Stand-alone instrument or additional protocol

52. Finally, the three Committees suggest that a possible binding legal instrument should be elaborated in the form of a stand-alone convention in its own right, and not as an additional protocol to an already existing instrument. The main reasons for this recommendation are that the scopes of the two instruments in question, namely the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (CETS No. 164) and the Council of Europe Convention on Action against Trafficking in Human Beings (CETS No. 197), are not easily compatible with the aforesaid proposed scope of a new binding legal instrument.

VII. 2. Participation of non-member states of the Council of Europe

53. Given the global character of the criminal phenomena related to the trafficking in human organs, tissues and cells, it would in the view of the three Committees be desirable to open up a new binding legal instrument for participation by non-member states, as has also been the case of the Convention on Cybercrime (CETS No. 185) and the recently adopted Medicrime Convention. Such participation may however be hampered, if as a prerequisite non-member states would also have to sign a “mother convention”, and the three Committees consider this to be an additional argument for elaborating a possible binding legal instrument in the form of a stand-alone instrument.
