on transplantation of kidneys from living donors who are not genetically related to the recipient

(Adopted by the Committee of Ministers on 26 March 2008 at the 1022nd meeting of the Ministers’ Deputies)

The Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia,¹

Considering that the aim of the Council of Europe is to achieve greater unity between its members and that this aim may be pursued, inter alia, by the adoption of common action in the health field;

Taking into account its Resolution (78) 29 on the harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances and the final text of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987);

Having regard to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine – ETS No. 164), and in particular to Article 19 (General rule) and Article 20 (Protection of persons not able to consent to organ removal) thereof;

Having regard also to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning the Transplantation of Organs and Tissues of Human Origin (ETS No. 186);

Recalling its Recommendation Rec(2001)5 to the member states on management of organ transplant waiting lists and waiting times;

Recalling its Recommendation Rec(2004)7 to the member states on organ trafficking;

Recognising that, in facilitating the transplantation of organs in the interests of patients in Europe, there is a need to protect individual rights and freedoms and to prevent the commercialisation of parts of the human body involved in organ procurement, exchange and allocation activities;

Recalling the principle that organ removal can be undertaken on a living donor only in the case where a suitable organ from a deceased donor is not available and only when no alternative therapeutic method of comparable effectiveness is available;

Considering that there is a shortage of kidneys for transplantation to patients having reached the end stage of renal failure;

Taking note that the increasing number of transplantations of organs from living donors is one way of reducing the increasing gap between the growing number of patients waiting for kidney transplantation and the limited number of organs procured from deceased donors;

Stressing that transplantation of a kidney from a living donor to a genetically related recipient is a well-established practice in most of the States Parties to the Convention and that in some countries living donor kidney transplantations account for a large proportion of the transplants performed each year;

¹ States concerned: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Republic of Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, “the former Yugoslav Republic of Macedonia”, Turkey and United Kingdom.
Knowing that there is very good evidence that living donor kidney transplants, even if the donor is not genetically related to the recipient, lead to similar or better clinical outcomes than with kidneys transplanted from deceased donors;

Stressing that living donor kidney transplants allow for the optimum treatment of receiving a transplant before going on to dialysis (pre-emptive transplant);

Taking into consideration that the removal of a kidney from a carefully selected, healthy individual carries a low risk of complications and has not been shown to have long-term effects on the health of such a donor;

Recalling that no organ removal may be carried out on a person who does not have the capacity to consent,

Recommends to the governments of States Parties to the Convention to take note of the general principles and measures listed in the attached appendix when they draw up the regulations and procedures relating to the donation of a kidney in view of transplantation by a living donor non genetically linked to the receiver:

Appendix to Resolution CM/Res(2008)6

1. States Parties to the Convention may permit the transplantation of kidneys from non-genetically related living donors on condition that:

   - the living donor and the recipient have a relationship as required and defined by law; the donor has been given appropriate information as to the purpose and nature of the removal as well as on its consequences and risks. The donor has also been informed of the rights and the safeguards prescribed by law for his or her protection, in particular of the right to have access to independent advice about such risks by a health professional having appropriate experience and who is not involved in the organ removal or subsequent transplantation procedures;
   - the living donor has given free, informed and specific consent, either in written form or before an official body; the donor may freely withdraw consent at any time;
   - no pressure is exerted on the living donor into donation;
   - the organ does not, as such, give rise to financial gain or comparable advantage;
   - the living donor has been properly screened to identify any physical or psychological contraindications; the removal may not be carried out if there is a serious risk to the life or health of the donor;
   - long-term medical follow-up is provided to living donors. This includes the monitoring of short-and long-term effects of organ removal on the health of the living donor notably by the establishment of officially recognised registries.

2. States Parties to the Convention may require that persons waiting for such transplants be placed on a national waiting list during the period of approval of the potential donor for donation.

3. Any States Parties to the Convention allowing for non-genetically related living kidney donation should establish a register for such transplants which includes a donor register and donor follow-up procedures in line with those existing for transplantations of kidneys removed from genetically related living donors.

4. States Parties to the Convention may permit or prohibit by law non-directed living kidney donations – i.e. “good Samaritan” donors, truly altruist donors or donors involved in a “paired exchange” donation for the purpose of transplantation from a person with no established close personal relationship with the recipient. (This type of donation is in contrast to donation where the donor and the recipient are in close personal relation called “directed donation”). In the States Parties to the Convention authorising donations from non-related living donors, national regulations and appropriate management must be put in place in view of prohibiting and preventing organ trafficking, namely by clearly defined rules for non-residents.
5. States Parties to the Convention should establish an independent mechanism for approving non-genetically related living kidney donor transplants in compliance with Article 10 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning the Transplantation of Organs and Tissues of Human Origin. It is also recommended that States Parties to the Convention establish such a mechanism for all cases of non-directed donation. Particular attention should be given to cases where the donor is not a resident of the member state concerned. Within the requirements of data protection legislation, registered activities should be reported on a regular basis to the national health authority.