Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

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The committee adopted the report by Peter LIESE (EPP-ED, D) amending the Council's common position under the 2nd reading of the codecision procedure. The key amendments were as follows: - Member States should ensure, rather than merely "encourage", voluntary and unpaid donations of tissues and cells. Donation "must be done out of the donor's free will without payment except compensation". However, detailed rules should be left to each Member State. Member States should report to the Commission every two years (rather than every three years) on the way in which they implement this requirement; - the traceability requirements laid down in the directive for tissues and cells should also apply to all relevant data relating to products and materials coming into contact with those tissues and cells. Moreover, the data required to ensure full traceability in accordance with the directive should be kept for at least 30 years; - Member States should ensure that tissues and cells imported from third countries have been donated, procured and exported in accordance with the laws of those countries and that they can be traced from the donor to the recipient and vice versa; - in order to guarantee full and effective traceability of human tissues and cells, Member States may authorise, although only in exceptional circumstances, the lifting of donor anonymity in the case of gamete donations; - Member States should ensure that there is no trading in unmodified tissues and cells. However, where human tissues or cells are used as source material for manufacturing products for therapeutic use, such activities may be permitted by bodies and organisations operating on a profit basis; - special rules should be required for the procurement of tissues after an abortion, and no abortion should be performed to obtain foetal tissue. Measures should be put in place to ensure that no pregnant woman is put under any kind of pressure to undergo an abortion in order to obtain tissue. The timing of an abortion and the way it is carried out should not be influenced by the wish to obtain foetal tissue; - Member States should encourage the donation of umbilical cord blood for the public; - cloned human embryos should be excluded as sources of material for transplantation; - a separate directive on organ transplants should be published by the end of 2003. The committee added that, once tissues have been retrieved, the deceased donor body should be reconstructed so that it is as similar as possible to its original anatomical shape. Finally, MEPs were opposed to the commitology procedure being used to decide on the conditions for donor selection, evaluation and procurement in the case of cells used for reproduction purposes. They argued that Parliament should be able to scrutinise any rules proposed in this very sensitive area.