Consumer Voice

Newsletter on food safety, health and consumer policy
from the European Commission's Health and Consumer Protection DG

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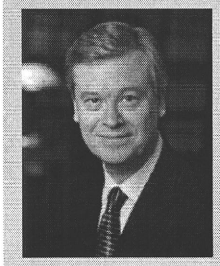


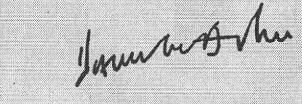
◀ *David Byrne, Commissioner for Health and Consumer Protection*

Quality and safety essential

Who, seventy years ago, could have imagined the great strides medical treatments would take in that time? Corneal and bone marrow transplants belonged then in the realms of science fiction and yet we now take these treatments for granted. In that period of time constant and rapid development of new therapies became the norm and it is now commonplace to use human tissues and cells for transplant. Further, we have recently entered a new phase with a quantum leap into the new science of biotechnology.

Despite the great benefits apparent in the therapeutic use of human tissues and cells, it has not been plain sailing all the way. There are difficulties to overcome before we can have full confidence in the technology. Substances of human origin can transmit disease. All of these medical interventions - whether proven or still at the stage of being potential future treatments - need a good regulatory environment to make sure of their quality and safety.

That is what our proposal for a Directive on Tissues and Cells, adopted by the Commission on 19 June, is about. It responds to a call to meet "the urgent need to regulate the conditions under which human tissues circulate within the European Market". Intense and wide debate at institutional level confirmed the need for this proposal. It brings us one step further on our quest to achieve the best possible conditions for the health of our citizens in the EU.

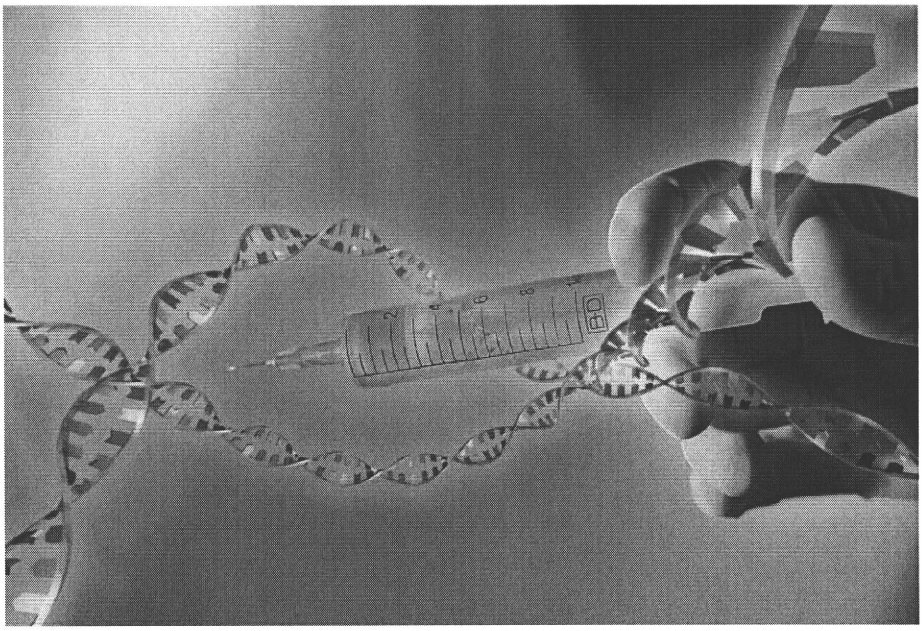


Commission proposes new rules on the quality and safety of human tissues and cells

Thousands of Europeans undergo some form of therapeutic treatment based on the use of human tissues and cells, each year. From hip replacements to the products derived from biotechnology, the therapeutic value of many of these medical applications has been recognised for several decades. However, the steady increase in demand for human tissues and cells, for both established and experimental use, demands that requirements ensuring their quality and safety for clinical use should apply throughout the EU.

The proposal for a new Commission Directive on tissues and cells, adopted by the Commission on 19 June, aims to establish rules that would make sure of that high level of quality and safety throughout the "tissue and cell transplantation chain" in all the Member States. At the same time, the proposal fully acknowledges the right of each Member State to organise and deliver health services and medical care, bearing in mind the principle of subsidiarity.

Binding ethical rules are strictly the responsibility of the Member States. While the proposal fully respects ethical principles cited in texts from both the Council of Europe and the European Group of Ethics, a future Directive could not impose them. But the proposal can and does recommend that specific rules governing ethical considerations – taking these texts into account – should become a fundamental requirement of the high standards demanded under the Directive.



Legal position in the Member States

While most Member States have adopted legislation to control the ethical aspects of donor protection (mainly in the area of organ transplantation), many have yet to agree on rules covering quality, safety or the use of tissues and cells. An informal survey on existing regulations in the EU Member States, carried out in 2000, confirmed that there are considerable discrepancies in the coverage although nearly all Member States have addressed those aspects related to donor protection.

Some types of tissues and cells, in particular germ cells, foetal cells and tissues, and embryonic stem cells, pose particular ethical concerns that can only be tackled by the Member States. The Member States need to decide whether to use them or to prohibit their use. Once that decision is made, the proposed Directive can then cover the quality and safety of permitted tissues and cells.

Safeguards to apply from donor to patient

The proposal covers the first three steps of the application of human tissues and cells to the human body: donation, procurement and testing. It includes starting materials for tissue and cell derived manufactured products, except when the product is used to treat the donor of those cells – a procedure known as an autologous graft. Processing, preservation, storage and distribution are also covered if the tissues and cells are intended for transplantation.

The aim of the proposal, is to ensure that use of these human substances is contained by comprehensive and binding quality and safety rules, and that these rules should cover the entire tissue and transplantation chain from donor to patient. "No matter where a donation comes from," Commissioner David Byrne stresses, "the guarantee of quality and safety must apply across the board."

The new Directive would mean that for the first time there would be a register of entities operating in the field of tissues and cells throughout the EU. All of them would have to apply minimum quality and safety systems and have the necessary professional qualifications and training. All of them would have to meet the high standards of quality and safety required by the proposed Directive. And, the proposal specifies the measures through which the necessary standards can be achieved. The proposal respects the authority of the Member States to grant accreditation to those establishments involved in tissue procurement.

Council of Europe Recommendations on tissue banks

- Tissue banks should be officially licensed by national health administrations or recognised by the competent authorities.
- They should ensure that tissues are tested for transmissible diseases and stored safely.
- Records of all tissues retrieved and issued should be kept.
- Distribution should permit optimal use based on equal access.
- Close cooperation should be ensured between all recognised exchange and tissue banking organisations.

Provisions are set out for Member State inspections and for the mandatory minimum standards that would apply, as well as procedures for the tissues and cells chain from donation, testing, procurement, processing, storage and distribution, through to preservation. Comparable national inspection and accreditation structures are to be set up along with equivalent training for the personnel involved in all parts of the chain. The training, being specific, will not prejudice the legislative requirements concerning mutual recognition of diplomas.

An essential component of the new Directive is the requirement for an EU-wide traceability system to follow all tissues and cells from donor to patient and back again. In addition, the Directive will also require a system that would monitor any bad reactions or adverse event associated with the procurement, processing and use of tissues and cells in any part of the EU.

The proposed Directive provides a coherent approach and set of rules for authorisation of imports and exports. Imports of tissues and cells from third countries are increasing and the same standards of quality and safety must apply to them to protect the health of EU citizens.

Ethical considerations are of paramount importance for donor and patient

The Commission considers it of paramount importance to protect the dignity and identity of the donor and prevent parts of the human body – as such – from being used for tissue and cell procurement or from the exchange and allocation activities that give rise

to financial gain. The proposal states that the use of human tissues and cells should take place under conditions that protect the rights and health of all parties from donors and potential donors to recipients. Human tissues and cells could not be removed from the body of a deceased person without consent, or until any authorisation required by law has been obtained. It could not be carried out if the deceased person had objected to it.

These are commonly accepted principles with different national regulations in place in the Member States to govern what are usually very difficult circumstances. They range from presumed consent law to other regulations where consent from the relatives is needed. The Directive would leave it to the Member States to decide how this general principle should be applied in practice.

Tissue banks

Tissue banks are responsible for processing and preserving tissues and cells, for internal quality control and storage, and finally, for distribution of the procured human tissues and cells. The proposal insists they must ensure the quality and safety of the entire process. It takes on board the full 1994 Council of Europe recommendation relating to the banking of human tissues (and cells).

All EU Member States accept that tissue and cell donation should be voluntary and unpaid. However, this principle does not always apply in the current practice of germ cell donation. The Commission proposal would require that Member States encourage voluntary and unpaid donation of tissues and cells.

Many applications for tissues and cells

Tissues are a functional group of cells. They can be transplanted or implanted as viable cells or preserved, fixed or altered. They include bone and musculo-skeletal elements such as cartilage and tendons, cardiovascular tissues such as arteries and heart valves or ocular tissues such as cornea. Nerve cells, brain cells, skin, foetal tissue, reproductive cells and stem cells are all materials that can be used in medical therapies and procedures.

Tissues and cells are used in the treatment of diseases such as cancer and diabetes, and increasingly, in reproductive medicine. Advances in biotechnology have also resulted in engineered structural tissues and constituent parts of medical devices. These would be governed by the same minimum standards as conventional tissues and cells. Donation, procurement and testing of biological starting materials for medical devices are also covered in this proposed Directive. Tissues and cells used for research purposes are to be covered under this Directive when administered to the human body, but not when used for research in vitro or in animal models.

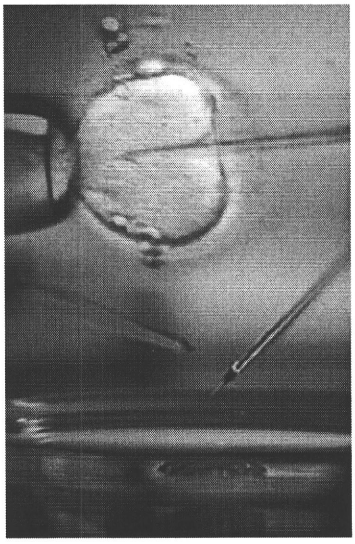
All of these tissues or cells come from donors who may be living or deceased. They are often acquired through cross border exchanges. They can transmit disease and they raise ethical questions. A considerable number of complex and interrelated activities are involved from donor-suitability evaluation to the implantation of the graft, or the manufacturing of a product. The proposed legislation takes all of these factors into account.

Not all human tissues and cells used in medical procedures are included in the proposed Directive. For example, autologous graft tissues and cells are human substances that are not covered. As this medical procedure involves taking tissues and transplanting them back into the same person during the same surgical procedure, the quality and safety considerations associated with the process are completely different to those taken into account in this proposal.

■ Amsterdam Treaty obligations for public health

Article 152 of the Amsterdam Treaty provides the EU with an opportunity as well as an obligation, to implement binding measures laying down high standards of quality and safety for the use of blood, organs and substances of human origin.

The specific requirement of the Amsterdam Treaty to ensure a high level of public health protection for substances of human origin must fully respect subsidiarity. The Amsterdam Treaty states that EU action "shall not affect national provisions on the donation or medical use of organs or blood".



Different legislation needed for different uses of tissues and cells

The technology of tissue and cell transplant and its other medical and research applications is highly complex. The proposed Directive can set clear quality and safety standards to apply to donation, testing and procurement of human tissues and cells regardless of their final use, whether for human transplants or for related medical applications.

However, different specific rules apply to some tissue and cell applications. Blood and blood products are not covered in this proposal as they come under a different set of rules. Specific legislation is also planned for transplants of human organs. Different policy approaches are needed when human tissues and cells are to be used for other purposes, such as industrial applications or medicinal products and treatments. Tissues and cells for use in in-vitro diagnostic medical devices, for example, are covered under different specific legislation. New legislation is also planned for tissues and cells of animal origin to be used for human therapy.

Additional detailed requirements are needed to cover manufacturing and pre-market approval of such complex products. New legislation is planned that will take account of the public health aspects of manufacturing and pre-market approval and also of the need to harmonise market access and ensure free movement within the EU.

Keeping pace with scientific progress

The proposal also contains measures to ensure that technical requirements and standards keep pace with scientific progress. A new Regulatory Committee of Member States representatives is proposed to deal with this aspect. The Committee will regularly update the technical annexes of the Directive taking particular account of technical and scientific progress, and, of emerging risks of transmission of communicable diseases.

Following on from the work of the Committee, the Commission will prepare regular updated standards working closely with the Council of Europe, the World Health Organisation and other relevant international bodies.

Wide and informed input to the proposal

Over a number of years, in-depth consultations on all aspects of the use of human tissues and cells have taken place on an expert and institutional level. Attention was drawn also to the urgency of dealing with the ethical questions posed by the technology in 1994 by the Council of Europe and by the European Group on Ethics in Science in 1998.

A conference held in Malaga in 2002 to investigate the issue in detail was co-organised by the Commission and the Spanish Presidency of the Council, with technical support from the Spanish National Transplantation Organisation. Participants included experts in the field and official representatives from the Member States. The conclusions of this conference were welcomed by the Health Council in June 2002, supporting the idea of a Directive that would set high standards for the quality and safety of human tissues and cells in order to ensure a high level of human health protection in the EU.

For more details on tissues and cells, blood and blood products, and medical devices:
– *http://europa.eu.int/comm/health/ph/others/human_tissues/index_en.htm*
– *http://europa.eu.int/comm/health/ph/others/safety_blood/index_en.htm*
– *http://europa.eu.int/comm/enterprise/medical_devices/index.htm*

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The views expressed in Consumer Voice do not necessarily reflect the opinions of the European Commission.

Chief Editor: Jacques Gennatas. **Editor:** Helen Kinghan, in cooperation with the Directorates of the EC Health and Consumer Protection DG. **For further information:** Rue de la Loi 200, B-1049 - Bruxelles/Wetstraat 200, B-1049 Brussel-Belgium –Office: B232/1/06. **e-mail:** sanco-newsletter@cec.eu.int **web site:** http://europa.eu.int/comm/dgs/health_consumer/newsletter/