IP/03/969

Brussels, 9 July 2003

European Commission proposes strict ethical guidelines on EU funding of human embryonic stem cell research

Today the Commission adopted a proposal for guidelines on EU-funded human embryonic stem cell research. The EU 6th Research Framework Programme (FP6 2003-2006), as adopted by the Council of Ministers and the European Parliament in 2002, allows for the funding of human embryonic stem cell research in relation to the fight against major diseases. Such research, in particular when it involves the derivation of stem cells from human supernumerary embryos, can only take place within a framework of clear and strict ethical guidelines. The EU research programme includes ethical provisions related to sensitive areas of research. In light of the sensitive nature of human embryonic stem cell research, the Council and the Commission agreed at the time of the decision-making process on FP6 that further ethical guidelines would be adopted before the end of 2003 for deciding on and for monitoring the EU funding of human embryonic stem cell research. Today's proposal presents a coherent set of strict ethical guidelines that will apply to the EU funding of research projects involving the derivation of stem cells from human supernumerary embryos. In parallel, the Commission is publishing a call for proposals for the set-up of a European registry of stem cells and for contributing to the establishment of public stem cell banks. In this way, the EU will contribute to an optimal access to and use of stem cells, ensuring that the results of research ultimately become more quickly available to all patients across Europe.

Research Commissioner Philippe Busquin said : « The decision to fund human embryonic stem cell research from the Sixth Framework Programme was already taken by Council and Parliament last year. By funding this research and by setting strict ethical rules for such funding, the EU contributes in a responsible way to advancing this science for the benefit of patients across the world, while at the same time ensuring that it takes place within a clear ethical framework. »

Stem cell research

Stem cells are basic cells that multiply and differenciate into specialised cells, tissue and even organs. Stem cell research is a promising area of biotechnology for human health. It offers the prospect of developing new methods to repair or replace tissues or cells damaged by injuries or diseases and to treat serious chronic diseases such as Parkinson's or Alzheimer's as well as more common diseases such as diabetes. Stem cell research is expected to provide a better understanding of human life and of disease development. It will lead to the development of safer and more effective drugs. It does, however, raise ethical questions when stem cells are derived from human supernumerary embryos.

The scope of the Commission proposal

The Commission proposal does not aim to set universal ethical principles, which is not a role for the EU. It does not aim to provide guidelines for EU Member States either, since every Member State must decide for itself on this issue. The Commission proposal only sets out the conditions for EU (FP6) research involving the derivation of stem cells from human supernumerary embryos. The proposal is fully in line with the various opinions of the European Group on Ethics (EGE), in particular opinion n°15 of November 14, 2000, "Ethical aspects of human stem cell research and use". The Framework Programme respects national rules and values as no funding is made available for a specific research activity in a Member State where that research is forbidden.

The stem cell debate

Funding for human embryonic stem cell research has always been possible under previous Framework Programmes and any project related to this issue was subject to an ethical review by a broad group of experts in the field. In the decision-making process on the Specific Programmes implementing FP6, the Council and the Commission agreed that additional guidelines on human embryonic stem cell research would be put in place before the end of 2003. During that period, no projects involving derivation of new stem cell lines from human supernumerary embryos would be funded. The Commission committed itself to submitting a legislative proposal identifying these guidelines, on which the European Parliament will be consulted. The three Institutions agreed to reach a decision on this issue before the end of 2003.

The opinion of the European Group on Ethics

The EGE identified the following principal requirements regarding human embryonic stem cell research and the procurement of embryonic stem cells from supernumerary embryos:

- Free and informed consent from the donating couple or woman.
- Approval of the research by an authority.
- No financial gain for donors.
- Anonymity of the donors and protection of the confidentiality of personal information of the donors.
- Transparency regarding research results.

Guidelines for human embryonic stem cell research at EU level

The Commission proposal deals with a very precise research topic, namely the derivation of stem cells from supernumerary embryos with no parental project. These embryos, maximum 5 to 7 days old and of a microscopic dimension, are frozen as a result of in-vitro fertilisation (IVF) treatment and are donated by parents for research. They will, at some point, be disposed of without being used either for IVF or for research purposes. The proposal does not aim to create human embryos for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer, (commonly referred to as therapeutic cloning). The creation of human embryos for research is explicitly excluded from the scope of FP6 funding. To meet a concern that EU funding would provide indirect incentives for the production of more embryos than needed for IVF, the Commission proposes that only

supernumerary embryos can be used that were created before 27 June 2002, the date of adoption of the EU 6th Research Framework Programme.

FP6 funding for the derivation of new stem cells will only be made available if proposals successfully pass a rigorous scientific peer-review and an ethical review, for which this proposal suggests the criteria. The derivation of stem cells from supernumerary embryos is only one element in the broader EU approach to stem cell research, which also includes funding for adult (somatic) stem cells, training of researchers in this field, etc.

What exactly is the Commission proposing?

The Commission's proposal acknowledges that this issue is controversial, with many open questions, but also recognises the potential it offers for curing diseases and principle of freedom of research which is enshrined in the European Charter of Fundamental Rights. It proposes the following guidelines:

- The EU will not fund human embryonic stem cell research where it is forbidden by a Member State;
- Human embryonic stem cells can only be derived from supernumerary embryos that are donated for research by parents and that were created before 27 June 2002, the date of the adoption of the Framework Programme. These embryos are destined to be destroyed at some point in time;
- Potential research project partners applying for EU funding must seek ethical advice at national or local level in Member States where the research will take place, even in countries where obtaining such ethical advice is not mandatory;
- Research will be funded only when it is demonstrated that it meets particularly important research objectives;
- Research will be funded only when there is no adequate alternative available. In particular, it must demonstrated that one cannot use existing embryonic or adult stem cell lines;
- Supernumerary embryos will be used only if informed consent has been given by the donor(s);
- Embryo donor(s) will not be permitted to make any financial gain;
- Data and privacy protection of donors must be guaranteed;
- Traceability of stem cells will be required;
- Research consortia will be required to engage in making available new human embryonic stem cells to other researchers.

The Commission intends to fund the creation of a European registry, an initiative advocated by nearly all Member States. Such a registry at European level should reduce the need for derivation of stem cells from human supernumerary embryos in the future.

Collaborative research at EU level should contribute to a reduction of the use of human embryos. By sharing resources and results within a European project, duplication of research activities will be reduced. Furthermore, more rapid scientific progress can be achieved by bringing together multidisciplinary teams.

Fabio Fabbi : 02.2964174
Lone Mikkelsen : 02/2960567