Europese Commissie wijst burgerinitiatief “Eén van Ons” af

European Citizens Initiative: European Commission replies to ‘One of Us’ – Q&A

Europese Commissie, 28 mei 2014

In een lang document met vragen en antwoorden wijst de Europese Commissie het burgerinitiatief “One of Us” van de hand. Financiering van onderzoek met menselijk embryo’s gaat daardoor door.

What was the request of the ECI ‘One of Us’?
The ‘One of Us’ initiative had asked the EU to end the financing of activities which presuppose the destruction of human embryos, in particular in the areas of research, development aid and public health. The ECI requested changes to the Financial Regulation, the Horizon 2020 regulation and the Development Cooperation Instrument (DCI) regulation.

For all details on the initiative, consult the organisers’ website at http://www.oneofus.eu/

1. Research involving human Embryonic Stem Cells (hESC)

What are embryonic stem cells?
Embryonic stem cells, sometimes known as the body’s master cells, are a type of cell that possesses two unique characteristics: they can develop into any of the 200 or so cell types found in the body and, under the right conditions, they are able to multiply indefinitely to form a cell line. These characteristics indicate the potential of these cells for tissue repair after injury or disease. Human embryonic stem cells were first isolated and cultured in 1998.

Why are human embryonic stem cells used in research?
Stem cell research offers hope for serious and/or life-threatening diseases, such as Parkinson’s, which are currently untreatable and where life is at stake. Therapies based on human embryonic stem cells are already being tested in patients. The first clinical trial took place in the US for spinal cord injury repair and the first European study took place in the UK for blindness.

Some biologists also use embryonic stem cells to understand how our tissues are maintained and repaired in health, and how disease develops and might be treated. For example, research based on use of human embryonic stem cells has revealed the molecular machinery controlling development of gut and associated organs, shown how organs develop in three-dimensional culture and helped us understand the genetic control of a very serious rare disease, called fragile-X syndrome.

Where do embryonic stem cell lines come from?
All current human embryonic stem cell lines come from four to five day old blastocysts, which consist of a hollow ball of around 100 cells, left over from in vitro fertilization (IVF).

Each cycle of IVF can produce many such blastocysts, some of which are implanted into the woman, with the rest stored by freezing them. After a couple has completed their treatment, they must decide what to do with any remaining blastocysts. They can continue paying to store them or they can defrost them, which destroys them. One option is to donate the frozen blastocysts for research. Only these donated blastocyts are the source of human embryonic stem cell lines.

Do you need a new embryonic stem cell line for each research project?

No, researchers do not need to start anew for every study they carry out. Cells taken from one 4 to 5 day old blastocyst can be made to multiply in the laboratory to create a 'cell line' that is able to produce an almost infinite number of embryonic stem cells, all with the same genetic make-up. Many cell lines are kept in non-profit stem cell banks that can be accessed by researchers all over the world. Existing cell lines are also exchanged at no cost between laboratories in the context of research programmes, under tight legal controls.

What position do Member States take on human embryonic stem cell research?
There is a diversity of legislative provisions among Member States on human embryonic stem cell research. 18 Member States permit, subject to their oversight and conditions, research involving human embryonic stem cells, three prohibit it (PL, LT, SK) and the rest have no specific legislation1. The EU has no competence to harmonise the legal situation in Member States.

What is the policy towards the use of human embryonic stem cells in EU-funded research?
In view of the different legal situation and practices in EU Member States, the EU has since 2002 had its own clear ethical and legal framework on human embryonic stem cell research funded from the EU budget. The current framework, adopted in 2007 and which has been renewed for the duration (2014-2020) of Horizon 2020, the EU's new research and innovation programme, consists of the so-called triple lock system.

• First and foremost, national legislation is respected – EU projects must follow the laws of the country in which research is carried out;

• In addition, all projects must be scientifically validated by peer review and must undergo rigorous ethical review;

• Finally, EU funds may not be used for derivation of new stem cell lines, or for research that destroys embryos (blastocysts) – including for the procurement of stem cells.

Since one of the principles of EU research is that it operates on a bottom-up basis, the European Commission does not publish calls for proposals specifically for research using human embryonic stem cells. It is for the scientists to propose the methods and materials they need for a particular study. EU research allows for the comparison of different cell types. One of the challenges for research is to find the best cell source for a particular application.

How do you enforce these rules?
All projects involving stem cells go through an ethics review undertaken by independent experts who review proposals for conformity with all the relevant clauses in the Horizon 2020 legislation.

Reporting requirements are set out in the grant agreements and running projects are monitored by the Commission. Any revisions needing authorisation are referred to the Member States.

The ethical panel can recommend a mandatory ethical review be carried out during the course of a project if necessary. Requirements put forward by the review become project contractual obligations. The procedures for the review are based on Opinion 22 of the European Group on Ethics in Science and New Technologies2.

How much has the EU spent on human embryonic stem cell research?
Since 2007, the EU has funded 27 collaborative health research projects involving the use of human embryonic stem cells with an EU contribution of about €157 million. Human embryonic stem cell research projects represent approximately one third of health projects on all forms of stem cells.

In addition, the European Research Council has funded 10 projects for an EU financial contribution of about €19 million and there have been 24 Marie Skłodowska-Curie actions involving human embryonic stem cell research

worth €23 million.

Are there alternatives to embryonic stem cells?
Embryonic stem cells possess certain properties and carry out certain functions that cannot currently be obtained from other cell types.

Induced pluripotent stem cells, whose discoverers were awarded the 2012 Nobel Prize, have many similar properties to embryonic stem cells. They are of most use in drug development, for instance to screen potential new medicines. If they could be produced to clinical standard, which they are not at present, they might be developed for therapeutic purposes in the future. In recent years the number of scientific publications on human embryonic stem cells has held steady, suggesting that this area of research is still active despite the development of induced pluripotent stem cells. Without prior research on human embryonic stem cells, induced pluripotent stem cells would not have been developed.

There are various types of “tissue-specific” or “adult” stem cells; while these cells are useful in specific cases, they are limited in their potential and largely make the cell types found in the tissue from which they are isolated.

What is the EU doing to promote/develop alternatives?
The 27 research projects involving human embryonic stem cells mentioned above represent about a third of the 87 projects in the FP7 health programme on all sources of stem cells; these include haematopoietic, mesenchymal, tissue-derived or adult stem cells and induced pluripotent stem cells. Nearly all of the recent human embryonic stem cell projects also include complementary work on human induced pluripotent stem cells. During the course of FP7 new stem cell sources were developed, and others rejected. The EU approach to stem cell research is to let science decide the best cell source for a particular application, while respecting the safeguards in place.

Where can I get information about EU stem cell research projects?
EU projects set up their own websites. These provide information about their work to other scientists, patients interested in possible treatments and the public in general. Centralised information on all EU research projects is available here: http://cordis.europa.eu/home_en.html

In addition, the EU supports Eurostemcell (www.eurostemcell.org), “Europe’s stem cell hub”, is a multi-lingual website providing reliable, independent information and road-tested educational resources on stem cells and their impact on society.

Does the Innovative Medicines Initiative support human embryonic stem cell research and does it follow the same ethical and supervisory rules and procedures as Horizon 2020?
So far the Innovative Medicines Initiative has not supported embryonic stem cell research. In principle, it could do so, in which case it would have to follow the Horizon 2020 rules and procedures.

Doesn’t the Court of Justice’s “Brüstle” judgement prohibit hESC research and its funding?
The so-called Brüstle judgement of the European Court of Justice (Case C-34/10) was referred to by the organisers when presenting their case. However, the Court noted in that ruling which concerned the Biotech Directive (98/44/EC), that the purpose of the European legislation in question is not to regulate the use of human embryos in the context of scientific research; the ruling was limited to the patentability of biotechnological inventions and did not deal with the question of whether such research can be carried out and whether it can be funded.

Why does the EU still fund such research if, after the Brüstle judgement, its results cannot be patented?

The EU funds hESC research first and foremost because of its societal benefits, namely because such research has great therapeutic potential with respect to a wide range of life-threatening diseases. The use of the results of EU-funded hESC research is not limited to their patenting. Usage can take the form, for instance, of follow-up research or clinical use.

Does the Commission fund, through H2020, patent applications made outside the EU, even if they contravene the Brüstle verdict?
No. Such costs are not eligible for funding under Horizon 2020.

2. EU assistance on health in developing countries

What is the Development and Cooperation Instrument?
The main EU financing instruments for development cooperation are the European Development Fund (EDF) and the Development Cooperation Instrument (DCI). The EDF is technically outside the EU budget and it supports the collaboration with countries in Africa, the Caribbean and the Pacific. The DCI is part of the Headline IV of the EU budget, and provides bilateral support to developing countries not covered by the EDF and thematic support to all partner countries on priority themes such as human rights, democracy and good governance, inclusive and sustainable growth.

In addition to the impact assessment and the internal review of different evaluations, audit and mid-term review reports, the Commission held in 2010-2011 a public consultation on future funding for EU external action. The DCI Regulation was adopted on 11 March 2014 after ratification from the European Parliament and the European Council.

The 11th EDF for 2014-2020 will have a budget of EUR 30.5 billion. The DCI will receive an allocation of EUR 19.7 billion from the EU budget for the period 2014-2020.

Why is maternal health in developing countries an issue of concern for the EU?
This is the current situation: 287,000 women die from pregnancy or childbirth-related complications every year. Some 47,000 mothers die following unsafe abortions every year. Almost exclusively, these occur in developing countries. The EU has committed, along with other partners, to fight this unacceptable scourge.

The Millennium Development Goals (MDGs) were agreed in the year 2000 by almost 190 countries, including all 28 EU member states. They include a goal to reduce the number of maternal deaths (MDG5). It is the worst performing MDG and has not yet been reached: the target was to reduce maternal mortality by three quarters and it has not even been reduced by half until now.

The EU and its Member States have also committed to respect the sexual and reproductive rights of women in the international agreement of the International conference of Population and Development (ICPD) Programme of Action (adopted by 179 countries in 1994), which includes access to safe abortion services where they are legal.

How does the EU support developing countries on health issues?
There are different ways of channelling EU aid on health:

• Through budget support, by providing budget to the partner countries directly, to improve country ownership and sustainability of programmes.

• Through UN agencies active in the health sector and Global Health Initiatives such as the Global Fund to fight AIDS, Tuberculosis and Malaria, and the GAVI Alliance.

• Through civil society organisations (CSOs), particularly where the main target are hard-to-reach populations or operations in contexts of emergency or conflict – groups that have benefitted the least from improved health services in recent decades.

Of the EUR 3.2 billion of development funds that the EU spent between 2008 and 2012 on the health sector, EUR 1.5 billion were spent on maternal, new-born, and child-health. Specifically, EUR 87 million went to reproductive health care, EUR 17 million to family planning, and EUR 95 million to controlling sexually transmitted diseases. Contributions to the Global Fund to fight AIDS, Tuberculosis and Malaria account for another EUR 503 million.

What does the EU do specifically in the area of Sexual and Reproductive Health?
The European Commission allocated in 2012 €321 million for maternal and new born child health programmes, including reproductive health care, family planning and nutrition in developing countries.

• Commission funding is typically allocated for programmes which strengthen partner countries' health systems, such as building and rehabilitating health care facilities, training of health personnel, providing equipment, essential medicines and supplies, as well as providing technical assistance and policy advice to Government and in support of its national health strategy.

• Support is also given to civil society organisations for work on sexual and reproductive health; providing information, education and counselling to young people, prevention of sexually transmitted diseases such as HIV/AIDS, and supporting local civil society organisations to act in these fields.

Since 2004, thanks to the European Commission:

• Almost 17 million consultations on reproductive health have taken place

• Over 7.5 million births have been attended by skilled health personnel

Why does the Commission believe that the existing framework for managing funding is the right one?
Firstly, EU Development cooperation provides comprehensive support to the entire spectrum of health services provided by partner countries. EU funding may, for instance, support building and rehabilitating health care facilities, training of health personnel, providing equipment, essential medicines and supplies as well as providing technical assistance and policy advice to governments. In helping provide safe and quality health services, including good-quality family planning, a broad range of contraceptive methods, emergency contraception and comprehensive sexual education, it contributes substantively to a reduction in the number of abortions.

Earmarking support for certain services only would prevent this comprehensive support to work effectively as it would require the partner country to re-organise its entire health service – something they may not have the means to do. Therefore, in practice, it would jeopardize the financing and support of sexual and reproductive health services in countries where abortion is legal, i.e. practically all developing countries.

Secondly, a funding ban would constrain the EU's ability to deliver on the objectives set out in the Millennium Development Goals, particularly on MDG 5 to reduce maternal mortality by three quarters and achieve universal access to reproductive health. Despite improvements, 47,000 women still die every year as a result of unsafe abortions and the evidence from WHO is that maternal deaths and illness can be dramatically reduced by improving the safety of health services.

Thirdly, a funding ban would also conflict with the EU's international commitment to the Programme of Action of

the International Conference on Population and Development (ICPD), which was recently reconfirmed at both international and EU levels (see below extract of ICPD text) and calls for expanded and improved family planning services to eliminate the need for abortion.

NB. Section 8.25 of the ICPD programme of action states:

8.25. In no case should abortion be promoted as a method of family planning. All Governments and relevant intergovernmental and non-governmental organizations are urged to strengthen their commitment to women's health, to deal with the health impact of unsafe abortion as a major public health concern and to reduce the recourse to abortion through expanded and improved family-planning services. Prevention of unwanted pregnancies must always be given the highest priority and every attempt should be made to eliminate the need for abortion. Women who have unwanted pregnancies should have ready access to reliable information and compassionate counselling. Any measures or changes related to abortion within the health system can only be determined at the national or local level according to the national legislative process. In circumstances where abortion is not against the law, such abortion should be safe. In all cases, women should have access to quality services for the management of complications arising from abortion. Post-abortion counselling, education and family-planning services should be offered promptly, which will also help to avoid repeat abortions.

Does this mean that the EU promotes abortion practices?
EU health programmes do not promote abortion as a method of family planning;

On the contrary, they aim at:

• giving highest priority to the prevention of unwanted pregnancies through expanded and improved family-planning services, thus eliminating the need for abortion;

• ensuring that in circumstances where abortion is legal, such abortion is safe.

It should be noted that the EU fully respects the sovereign decisions of partner countries where health services will be provided and how they are packaged as long as they are in line with agreed human rights principles. According to the United Nations, only six countries and one state in the world prohibit abortions under all circumstances. Source: United Nations; World Abortion Policies 2013; www.unpopulation.org

Is the EU controlling the use of development funds in interventions related to Sexual and Reproductive Health?
The EU contractual terms are strict to ensure that all interventions funded by EU development assistance respect the legislation of the countries where they take place. The Commission monitors the performance of projects and programmes through independent assessments and, where major difficulties are identified, the Commission ensures follow up measures. This independent monitoring is complemented by internal monitoring carried out by Delegations and by evaluation that provide important feedback on impact and results achieved. In addition, financial audits and verifications provide assurance on the legality and regularity of external aid operations.

In case of misconduct all organisations are treated equally. Information of all EU funded projects is public information and the beneficiaries of grants can be found in the database on the Commission website

http://ec.europa.eu/europeaid/work/funding/beneficiaries/index.cfm?lang=en&mode=SM&type

This database has a search function enabling information to be obtained on a year by year basis for all grants awarded to programmes related to, for instance, reproductive health care.

1 : European Science Foundation Science Policy Briefing No. 38.

2 : http://ec.europa.eu/bepa/european-group-ethics/publications/opinions/index_en.htm