



THE CATHOLIC CHURCH  
IN THE EUROPEAN UNION

# HEALTH, RESEARCH & BIOETHICS

EU'S COMPETENCES  
CHURCH'S VISION  
COMECE'S CONTRIBUTION

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## EU's competence

The EU does not have any legislative competence in the field of bioethics. In such a context, the principle of subsidiarity means that it is up to the Member States to decide within this area, thus guaranteeing as well the deference to the principles of respect for cultural diversity and for national identity of the Member States.

However, it is clear that, on the one hand, the impact of new developments in biomedical research and bioethical questions in general also encompass a transnational side; and, on the other hand, EU decisions in different policy fields impact upon the bioethical positions of the Member States. The main fields of EU competence where bioethical issues tend to arise are the establishment and functioning of the internal market, public health, research and technological development and development cooperation.

### 1. Internal Market: [Article 114 TFEU](#)

According to this Article, the Council of Ministers together with the European Parliament shall adopt “*measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.*”

A number of legislative instruments with bioethical relevance are based on this Article, for example:

- [Directive 2010/63/EU](#) on the protection of animals used for scientific purposes
- [Regulation \(EC\) No. 1394/2007](#) on advanced therapy medicinal products
- [Directive 98/79/EC](#) on *in vitro* diagnostic medical devices
- [Directive 98/44/EC](#) on the legal protection of biotechnological inventions
- [Directive 93/42/EEC](#) concerning medical devices

### 2. Public Health: [Article 168 TFEU](#)

This legal provision clarifies that Member States have the main responsibility for health policy and provision of healthcare to European citizens, whereas EU action in the field “*shall respect the responsibilities of the Member States for definition of their health policy and for the organisation and delivery of health services and medical care.*”

However, Article 168 establishes that a “*high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.*” Furthermore, it states that the Union “*shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health.*”

Article 168 still provides the European Commission with the mandate to “*take any useful initiative to promote (...) coordination*” between the Member States. And, more

concretely, it provides the EU with the direct competence to adopt “*measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives*”.

A number of legislative acts are based on this Article, in particular:

- [Directive 2011/24/EU](#) on the application of patients’ rights in cross-border healthcare
- [Directive 2010/45/EU](#) on standards of quality and safety of human organs intended for transplantation
- [Regulation \(EC\) No 726/2004](#) laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
- [Directive 2004/23/EC](#) on setting standards of quality and safety for the donation, procurement, testing, processing of human tissues and cells
- [Regulation \(EU\) 536/2014](#) on clinical trials on medicinal products for human use

### 3. Research and Technological Development: [Articles 179-188 TFEU](#)

The Treaty establishes the objective for the EU's research policy of “*strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely, and encouraging it to become more competitive, including in its industry, while promoting all the research activities deemed necessary by virtue of other Chapters of the Treaties*”. The Union’s main instrument for research funding, Horizon 2020, the research framework programme to run from 2014 to 2020, was adopted by means of the [Regulation \(EU\) 1291/2013](#), following the ordinary procedure set forth by [Article 294 TFEU](#).

### 4. Development Cooperation: [Articles 208-211 TFEU](#)

In the field of development cooperation, the competence of the EU is only complementary to the policies pursued by the Member States. Article 208 stipulates that the “*Union shall take account of the objectives of development cooperation in the policies that it implements which are likely to affect developing countries*”. The same legal provision sets out that the EU’s development cooperation policy shall foster “*the reduction and, in the long term, the eradication of poverty*”. Moreover, like all Union’s action on the international scene, it shall be guided by the principles of “*democracy, the rule of law, the universality and indivisibility of human rights and fundamental freedoms, respect for human dignity, the principles of equality and solidarity, and respect for the principles of the United Nations Charter and international law*” ([Article 205 TFEU](#) and [Article 21 TEU](#)). EU cooperation in the so-called ‘sexual and reproductive health’ raises special concern insofar as this ambiguous expression is often wrongly interpreted as including abortion.

Currently, one of the main instruments for development cooperation is [Regulation \(EU\) 233/2014](#) which establishes a financing instrument for development cooperation for the period 2014-2020. However, some problematic, ideological phrasing such as ‘gender identity’ has been introduced in this fundamental instrument.



## Church's vision

The Church recalls the need for respect of human dignity and the inviolability of each human life: modern science, and genetics in particular, has shown that from the moment of conception the life of a new human being starts, with its own capacity for growth, in a *continuum*, going through many developing and ageing stages, culminating with death.

Medical and biotechnological activities have a human being at their very core. A human being is always an agent, not an object. It stems from there the importance of free, informed consent for therapeutic and other medical interventions, and in the ambit of participation in research projects.

Founded in a deep anthropology that indeed arouses the interest of all men of good will, the Church champions human dignity - which nevertheless stems, in the final analysis, from the divine affiliation - and confidently announces the Gospel of Life, proclaiming that each human person must be protected from conception until natural death. Human physical and mental integrity and health are seen as fundamental goods envisaging the integral development of each human being.

Moreover, the Catholic faith has throughout the ages stimulated scientific advances and technological developments as, on the one hand, the knowledge of our surrounding reality, considered a sign of God Himself, was always understood, indeed, as a deepening of the divine mystery; and, on the other hand, human beings are seen as co-creators who imprint a specific dynamic of change on the world. The Congregation for the Doctrine of the Faith, in [Dignitas Personae](#) (§36), professed that in creating new technologies man “*participates in the creative power of God*” and acts as “*the steward of the value and intrinsic beauty of creation*”. Primacy brings responsibility ; as Pope Francis recalls us in [Laudato Si](#) (§116) “*our ‘dominion’ over the universe should be understood more properly in the sense of responsible stewardship*” which includes a protective attitude towards non-human animals.

Other than the [Congregation for the Doctrine of the Faith](#), diverse dicasteries of the Roman Curia – namely the [Pontifical Academy for Life](#), the [Pontifical Council for Health Care Workers \(for Health Pastoral Care\)](#) and the [Pontifical Council for the Family](#) - regularly publish documents addressing key bioethical issues.

Among the major documents of the Church that are a reference in this field, and besides *Dignitas Personae*, of 2008 (which addresses, e.g., abortion, assisted reproductive technologies, cloning), one can mention:

- 1995: [Evangelium Vitae](#) (abortion, organ transplantation, stem cells)
- 1992: [Catechism of the Catholic Church](#) (abortion, euthanasia, human genetics, organ transplantation)
- 1987: [Donum Vitae](#) (abortion, assisted reproductive technologies, stem cells)
- 1968: [Humanae Vitae](#) (assisted reproductive technologies, contraception)
- 1965: [Gaudium et Spes](#) (organ transplantation)



## COMECE's contribution

COMECE strongly supports scientific research and technological development. At the same time, COMECE has voiced its concern towards research conducted compromising sound ethical norms and boundaries, as if what is technically feasible can, or should, be always realized. As it is enshrined in [Article 2](#) of the Convention of Human Rights and Biomedicine of the Council of Europe “*interests and welfare of the human being shall prevail over the sole interest of society or science.*” As a matter of fact, history has taught us that technological innovations do not always promote the common good and true, integral human development. Before the increasing technical possibilities, a responsible, mature ethical reflection and debate should now more than ever take place. A debate needs to be conducted that does not overlook the rights and interests of the most vulnerable, or of the future generations.

Therefore, at the light of [Article 17 TFEU](#), COMECE welcomes political leaders’, but also researchers’ and European citizens’ at large engagement in a open, transparent and regular dialogue over these issues, while calling, as well, on the full enforcement of [Article 1](#) (human dignity), [Article 2](#) (right to life) and [Article 3](#) (right to integrity) of the Charter of Fundamental Rights, which endue a particular significance in the field of the life sciences. This is one of the fields to which, at the light of Article 17, the Church has a clear, specific contribution to make for the EU’s debate.

In this context, the Secretariat of COMECE regularly monitors and analyses EU policy and, in particular, key EU legislative initiatives concerning developments in medicine and biotechnology where bioethical issues may arise. As a result, the Secretariat issues reports, opinions, position papers, and often participates in the public consultations launched by the European Commission. It is advised by a Working Group in Ethics in Research and Medicine, a multidisciplinary team, set up in 1996, composed of experts – theologians, philosophers, lawyers, medical doctors – representing most of the of COMECE’s Bishops Conferences. They meet twice a year, and issue [reports and opinions](#), being the last one on ‘Gestational Surrogacy’ (2015). Other subjects tackled are:

- 2013: Ethical assessment of clinical trials on medicinal products
- 2013: The regulation of medical devices, and *in vitro* diagnostic medical devices in particular
- 2010: The term ‘sexual and reproductive health’ and its meaning at international and European levels
- 2009: State of post-coma unresponsiveness commonly known as ‘persistent vegetative state’
- 2009: Prospects for the human enhancement by technological means
- 2008: Non-commercialization of parts of the human body
- 2007 : Ethical aspects of organ donation
- 2007: The creation of human-animal mixed organisms (hybrids and chimeras) – an opinion on anthropological and ethical issues

- 2006: Ethical issues raised by nanomedicine
- 2006: Patentability of human stem cells
- 2005: Living wills (End of Life arrangements)
- 2004: Ethical and cultural aspects of genetic testing
- 2003: Comments on Opinion No. 18 of the European Group on Ethics (EGE) concerning "Ethical aspects of genetic testing in the workplace"
- 2002: Biomedical Research in Developing Countries
- 2002: Some remarks on the Communication of the European Commission "Life Sciences and Biotechnology – a Strategy for Europe"
- 2001: Medical experiments
- 2000: Reflections on the use of human stem cells
- 1999: Xenotransplantation
- 1998: Biomedical research on human embryos *in vitro*
- 1998: Euthanasia
- 1997: Cloning
- 1996: Convention on Human Rights and Biomedicine of the Council of Europe

Additionally, the Secretariat of COMECE regularly publishes [press releases](#) concerning Health, Research and Bioethics, whereas articles on these fields often appear in its monthly newsletter [europeinfos](#).



## Your contact person

**José Ramos Ascensão**

*Legal adviser*

Tel. +32(0)2 235 05 18

Email: [jose.ramos-ascensao@comece.eu](mailto:jose.ramos-ascensao@comece.eu)