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Ethical aspects of nanomedicine: opinion presented to the Commission by the European Group on Ethics in Science and New Technologies

Following the request made by President Barroso on 10 November 2005, the European Group on Ethics in Science and New Technologies (EGE) chaired by Swedish philosopher Göran Hermerén yesterday handed the President its Opinion on the ethical aspects of nanomedicine.

In its Opinion the EGE acknowledges that nanomedicine offers the possibility of new diagnostic, treatment and preventive methods that may open up promising areas of medicine. The Opinion focuses on ethics issues arising from nanomedicine but also discusses a number of problems raised by nanotechnology insofar as they concern primarily health-related issues.

The EGE underlines the vital importance of addressing concern for safety with respect to nanomedical developments (and, in fact, nanotechnology in general) and therefore advocates the need to establish measures to verify the safety of nanomedical products and to ensure that nanomedical devices are properly assessed with regard to public health. The Group proposes that institutions already operating at European and national level to protect the safety of patients and citizens should be charged with the additional task of overviewing the safety and security aspects of new tools and devices in nanomedicine. The Group then underlines the need to properly address risk assessment at national and EU level and invites relevant stakeholders to devote adequate efforts to understanding and preventing risks that may be linked to nanomedicine.

As far as public participation is concerned, the Group argues that transparency (including openness about uncertainties and knowledge gaps) is essential for public trust in nanotechnology. The Group therefore proposes that initiatives should be taken at national and European level to prepare surveys of public perception of the benefits and risks of the applications of nanotechnologies, with special reference to medical sectors. The Group also calls for initiatives to be taken to organise academic and public debates on problems and possibilities of present and near-future nanomedicine.

Additionally the Group underlines the need for: prospective technology assessment, including consideration of social effects (also in developing countries); interdisciplinary research on the Ethical, Legal and Social Implications (ELSI) of nanomedicine; the establishment of a European Network on Nanotechnology Ethics; and enhanced information exchange between research ethics committees in different Member States or among competent bodies in particular on toxicity studies, ELSI-related aspects of nanomedicine and informed consent procedures with regard to safety.

As far as the legal implications of nanomedicine are concerned, the EGE does not propose any new regulatory structures specifically dealing with nanomedicine at this point, and argues that any changes should be made within existing structures (with focus on implementation of existing regulations). The Group proposes, however, that possible cases of nanomedicine applications where there might be overlap between regulations, which could create uncertainty as to which regulations should be applied, should be explored by the relevant authorities so that the existing regulations can be implemented in an unambiguous way. In addition the EGE calls for comparative research on intellectual property rights and nanomedicine and advocate the needs to look further into the balance between knowledge protection and information dissemination.

Background

In finalising its work the EGE received inputs from a number of hearings with experts in the field, decision makers and relevant stakeholders, as well as a public round table that took place in Brussels, in March 2006. These meetings were organised by the Bureau of European Policy Advisers (BEPA), which acts as the Group's Secretariat.

The EGE is an independent, multidisciplinary and pluralist advisory group composed of 14 members. Its role is to advise the European Commission on how ethical values should be taken into consideration in the preparation and implementation of Community legislation or policies.

Nanomedicine is an area of nanotechnology which raises high expectations with regard to its potentials in diagnostics, drug development and delivery, imaging and other health- related applications. It is a major research sector covered by the EU Research and Development Programme.

Under the 6th EU Framework Programme for research (FP6) the Commission has invested more than €1.36 Billion in nanotechnology (550 projects financed) and under the 7th Framework Programme for research (FP7) some €3.5 billion should be allocated to this research sector.

The first FP7 call for proposals on nanotechnology has been launched and it has been estimated that €300-400 million could be allocated to nanotechnology in 2007. Around €100 million per year is expected to be allocated to nanomedicine project proposals.

Like other research sectors, however, this new area of nanotechnology needs a proper analysis of its ethical implications.

For more information:

BEPA homepage: http://ec.europa.eu/dgs/policy_advisers/index_en.htm

EGE homepage: http://europa.eu.int/comm/european_group_ethics/index_en.htm

FP7 calls: http://cordis.europa.eu/fp7/dc/index.cfm

Nanotechnology homepage: http://cordis.europa.eu/nanotechnology