Presidenza del Consiglio dei Ministri

COMITATO NAZIONALE
PER LA BIOETICA

DECLARATION ON CLINICAL TRIALS AND THE CONFERRAL TO THE EUROPEAN COMMISSIONER FOR HEALTH AND CONSUMER POLICY OF COMPETENCES ON THE EUROPEAN MEDICINES AGENCY (EMA)

24 october 2014

Preamble

At the moment when the European Commission has taken office[1], the conferral to the European Commissioner for Health and Consumer Policy of competences on the European Medicines Agency (EMA) and, more generally, on clinical trials, drugs, pharmaceuticals and devices has been confirmed. At the beginning, such conferral has been called into question, so that it was supposed to move Unit B2 (*Health Technology and Cosmetics*), D5 (*Medicinal Products - Authorisations, European Medicines Agency EMA*) and D6 (*Medical Products - Quality, Safety and Efficacy*) from DG Health and Consumers (DG SANCO) to DG Enterprise and Industry (DG ENTR)[2]. Clinical trials, the placing on the market of new drugs, the report of suspected unexpected serious adverse reactions and EU database could have been, at least in this field, included in the competences of the European Commissioner for Internal Market, Industry, Entrepreneurship and SMEs[3]. This circumstance was already known at a European level. The EMA was set up under Regulation (EC) No. 726/2004 and remained within the portfolio of Industry until 2010, when its sphere of competence moved towards the then-European Commissioner for Health and Consumer Policy. In previous years, many experts in the field and Patients Associations criticized this transfer, for it was considered inappropriate and in opposition with the institutional structure of the most important countries of the European Union.

Declaration

The NBC shares the European decision on the conferral of competences on EMA and, more generally, on clinical trials. In that respect, it considers important to underline the reasons why such institutional structure is highly significant.

Drugs are not, even symbolically, a mere consumer good, otherwise they will lose, or at least lessen, their main meaning as an instrument of health protection in an integrated system. The current situation of the competences has the merit to avoid a highly potential conflict of interest among industry, guarantee authority, triers and patients/ EU citizens, who have the right to see the impartiality and independence of those administrative structures involved in a field of a highly public and personal relevance safeguarded.

The Directorates-General of the European Commission are departments with a total managerial autonomy, while the general and political powers are a question of the Commissioner in charge. A possible repetition of the competences on EMA to the European Commissioner for Internal Market, Industry, Entrepreneurship and SMEs would have given to the latter the definition of priorities and the overall strategy of the European Union on clinical trial of drugs, consistent with its institutional mandate.

Furthermore, this problem became worse due to the recent approval of the Regulation (EU) No. 536/2014 of the European Parliament and of the Council 16th April 2014 on clinical trial of medicinal products for human use, which abrogates Directive 2001/20/EC, though including detailed guarantee

[1] 1st November 2014.

[2] Furthermore, DG ENTR merged with DG MARKT (Directorate General for the Internal Market and Services).

[3] Small and Medium-sized Enterprises.

procedures and calls of ethics. In terms of a necessary perspective aiming at a simplification of the procedure, harmonization and promotion of European competitiveness at international level, the text shows several ethical problems and seems, at least partially, more favourable to industry and market efficiency rather than to the protection of rights, safety, dignity and well-being of patients.

The NBC is aware that health care management is not directly included in the initial EU Treaties, and, therefore, those elements of a European centralisation of health care fall within the perspective of a single European market. However, Article 168 of the EU Treaty in 2010 states that "*a high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities*". Furthermore, developments in the laws and their procedures of the European Union (i.e. the Charter of Fundamental Rights of the European Union), as well as the increasingly strong emphasis placed on the rights of individuals and on the health protection of European citizens, justify the conferral of the competences in the field of clinical trial to the portfolio of Health.

For these reasons, the NBC:

- welcomes the conferral to DG SANCO of competences on EMA and its related activities;
- proposes that industry impartiality will be strengthened further through an EMA prevision of financial autonomy;
- expects the introduction and development of independent studies for the authorization of new drugs or new therapeutic indications;
- recommends that the above-said Regulation (EU) No. 536/2014 will be interpreted and applied in order to put patients' rights at the heart of the EU action.

The document was drafted by Prof. Cinzia Caporale, with the contribution of Prof. Silvio Garattini.

The document, discussed within the plenary, was voted and approved unanimously by those present, Profs. Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Cinzia Caporale, Carlo Casonato, Antonio Da Re, Carlo Flamigni, Paola Frati, Silvio Garattini, Marianna Gensabella, Assunta Morresi, Demetrio Neri, Andrea Nicolussi, Laura Palazzani, Monica Toraldo di Francia, Grazia Zuffa.

The ex Officio members who joined are the following: Dr. Carla Bernasconi, Rosaria Conte, Carlo Petrini.

Among those who did not attend the plenary session, the following members adhere to the Declaration: Carlo Caltagirone, Lorenzo d'Avack, Bruno Dallapiccola, Mario De Curtis, Rodolfo Proietti, Massimo Sargiacomo, Lucetta Scaraffia.