CPME/AD/EC/17092013/088_Final/EN

On 17 September 2013, the CPME Executive Committee adopted the " CPME Response to the EMA public consultation on the "Publication and access to clinical-trial data" Policy" (CPME 2013/088 FINAL)

CPME Response to the EMA public consultation on the "Publication and access to clinical-trial data" Policy

The Standing Committee of European Doctors (CPME)[1] represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

CPME is thankful to the European Medicines Agency (EMA) for opening a public consultation on its *"Publication and access to clinical-trial data"* policy paper.

Transparency of clinical-trial data and results is essential to the good conduct of medical research and for the amelioration of public health outcomes. CPME welcomes the general approach of the Agency to guarantee better transparency of clinical-trial data together with the highest level of patients' data protection. These transparency endeavors are all the more necessary when society expects the Agency's evaluation of medicines to be free of any undue influence.

CPME would like to comment on two issues highlighted in the EMA policy:

- Informed consent:

CPME agrees with the statement made on lines 44 to 48. According to all international standards on bioethics and research on human beings, the conduct of a study cannot start before the patient gives his full informed and express consent[2]. The data can only be used for the case for which the consent has been given. Further processing of the patient's data without due consent, e.g. for

[1] CPME is registered in the Transparency Register with the ID number 9276943405-41.

[2] World Medical Association's Declaration of Helsinki, 2008, Articles 24 and 25:
http://www.wma.net/en/30publications/10policies/b3/index.html
Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo Convention), 1997, Article 5:
http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm
Charter of fundamental rights in the European Union, 2000, Article 3:
http://www.europarl.europa.eu/charter/pdf/text_en.pdf
International Ethical Guidelines for Biomedical Research Involving Human (CIOM Guidelines), 2002, Guideline 4:
http://www.cioms.ch/images/stories/CIOMS/guidelines/guidelines_nov_2002_blurb.htm
Universal Declaration on bioethics and human rights, UNESCO, 2005, Article 6:
http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

epidemiological or translational studies, may be possible in exceptional situations where consent would be impossible or impracticable to obtain but must be subject to very strict scrutiny including consideration and approval of a research ethics committee. CPME highly welcomes that the Agency foresees the use of patient's data for any other purposes than the one for which it has been collected as overstepping *"the boundaries of informed consent"*. Indeed, one cannot claim that the patient will be fully informed of the risks and benefits of a study that does not yet exist and for which no protocol has even been defined at the time when he gives consent. The principle of informed consent as defined in the World Medical Association's Declaration of Helsinki must always apply.

- Data of clinical-trial personnel:

CPME agrees that the data of the personnel taking part in a clinical investigation should be made public. Considering the high responsibilities that professionals involved in trials have towards patients, society and public health as a whole, these data should be accessible to anyone. CPME therefore agrees with the categorisation as "open data" foreseen by the Agency for point 16.1.4. of the Clinical Study Reports' ICH guidelines[3] and suggests the following: *"The list of principal investigators; ~~individual investigators' names, addresses, appointments and clinical duties; similar information of other persons carrying out observations of primary or other major efficacy variables, such as a nurse, physician's assistant, clinical psychologist, clinical pharmacist or house staff physician~~; the author(s) of the report, including the biostatistician(s)"* should be published.

[3] Point 16.1.4 concerns the "list and description of investigators and other important participants in the study, including brief (1 page) CVs or equivalent summaries of training and experience relevant to the performance of the clinical study"