CPME voting recommendations on Medical Devices and In Vitro Diagnostics Medical Devices

European Parliament Plenary vote, 22 October 2013

CPME- the Standing Committee of European Doctors representing National Medical Associations across Europe - reminds that human rights and ethics should not be subject to negotiation. We call on the European Parliament to protect patients in Europe and help avoiding dangerous medical devices like in the PIP breast implant scandal or like the faulty hip replacements and recommends the following, please:

- **Adopt Amendment 42, Recital 49** where 'member states retain the ultimate responsibility for deciding whether the clinical investigation may be conducted on its territory.'

- **Adopt Amendment 44, Recital 51 a (new)** which provides for strict rules to be adopted for persons unable to give informed consent such as children and incapacitated persons.

- **Adopt Amendment 56, Recital 63** which emphasises the respect for protection of personal data, free and informed consent and the European Convention for Human Rights.

- **Reject Amendment 87, Article 2 , Section 1, No. 37a new as it lacks legal clarity** and insert similar legal provisions as foreseen in the case of IVD medical devices: **amendments 168, article 49 a new and amendment 63, article 2 point 48 new**

    - *(48a) 'inspection' means an official review, carried out by a competent authority, of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by that authority to be related to a clinical performance study and that may be located at the site of the trial, at the sponsor's and/or contract research organisation's facilities, or at other establishments which the competent authority sees fit to inspect;*

- **Adopt Amendment 88, Article 2 - paragraph 1 - point 37 b (new), Ammendment 181, Amendment 334 and Amendment 343** regarding the mandatory agreement of the ethics committee before a clinical trial/assesment may take place.

- **Reject Amendment 338, Annex XIV – Part I a (new) – point 1** due to the problematic formulation with regard to incapacitated subjects, where informed consent may be overridden in cases where
  '*– there are grounds for expecting that participation in the clinical investigation will produce a benefit to the incapacitated subject outweighing the risks or will produce only a minimal risk;*'

- **Amendment 339, Annex XIV – Part I a (new) – point 2** is problematic as it defines informed consent *as the explicit wish of a minor who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn from the clinical investigation at any time asks that the investigator takes the minor's opinion into account* without observing the opinion of the legal representative of the minor who is under obligation to ensure the safety of the child under his custody.

With regard to IVD medical devices, we encourage the adoption of the following amendments:

On ethics, human rights of persons participating on clinical trials and the conduct of a clinical trial, please:

Adopt Amendment 162, Article 49 – paragraph 2 – subparagraph 1
Adopt Amendment 166, Article 49 – paragraph 5 a (new)
Adopt Amendment 167, Article 49 – paragraphs 6 a to e (new)
Adopt Amendment 250, Annex XII – part A – point 2.2 – paragraph 1
Adopt Amendment 52, Article 48 – paragraph 4
Adopt Amendment 53, Article 49 – paragraph 6 – subparagraph 2
Adopt Amendment 56, Article 53 – paragraph 1
Adopt Amendment 89, Annex XII – section 1 – point 2 – point 2.2 – paragraph 1

On inspections within members states, please:

- **Adopt Amendment 63, article 2 point 48 new**
- **Adopt Amendments 168, article 49 a new**