



PRESS RELEASE

Physicians are worried over the newly agreed clinical trials regulation

Brussels, 3 April 2014

On Wednesday 2 April 2014, the European Parliament gave the green light to the agreement reached with Council on the Clinical trials regulation.

Although the regulation has seen a number of positive amendments, which we have argued for and we gratefully acknowledge, this agreement highly weakens the basic ethical principle of informed consent. The new provisions introducing a “broad consent” in Article 28(2a) and “simplified means for informed consent” in Article 30, are contrary to all internationally agreed ethical standards, such as the WMA Declaration of Helsinki. According to Dr Katrín Fjeldsted: “the assumption that a broad or simplified consent equates a truly informed consent is biased. We have been raising this issue since the very beginning, but it seems unfortunately that other interests take precedence over medical ethics.”

CPME and WMA represent physicians that are directly and on a daily basis involved in the testing of medicinal products on human beings all over the world. The medical community will feel obliged by the stricter ethical rules of the WMA Declaration of Helsinki. “The informed consent has been one of the greatest achievements of the 20th century in making ethical research acceptable. For secondary use of research data or materials, smart solutions can be found. Broad consent for secondary use is only an invitation to circumvent informed consent.” Concluded Dr. Margaret Mungherera, President of the World Medical Association.

Our organisations will continue to advocate for medical law and ethics to be fully respected and will systematically object the weakening of informed consent. As such, we will pay particular attention to the data protection regulation which contains a section on medical research.

For further information, please contact:

Dr Otmar Kloiber
WMA Secretary General
+33 4 50 40 75 75
wma@wma.net
www.wma.net

Birgit Beger
CPME Secretary General
+32 27 32 72 02
secretariat@cpme.eu
www.cpme.eu