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On 21 February 2013, the CPME Executive Committee adopted the 'CPME Statement on Medical Devices and In Vitro Medical Devices' (CPME 2012/150 REV4).

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## CPME STATEMENT ON MEDICAL DEVICES AND IN VITRO DIAGNOSTICS MEDICAL DEVICES

**CPME Statement on  
the European Commission proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and the European Commission proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices COM (2012) 541 final, 2012/0267 (COD)**

*The Standing Committee of European Doctors (CPME) 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.*

- We believe the best possible quality of health and access to healthcare should be a reality for everyone. To achieve this, CPME promotes the highest level of medical training and practice, the safe mobility of physicians and patients, lawful and supportive working conditions for physicians and the provision of evidence-based, ethical and equitable healthcare services. We offer support to those working towards these objectives whenever needed.*
- We see the patient-doctor relationship as fundamental in achieving these objectives and are committed to ensuring its trust and confidentiality are protected while the relationship evolves with healthcare systems. Patient safety and quality of care are central to our policies.*
- We strongly advocate a 'health in all policies' approach to encourage cross-sectoral awareness for and action on the determinants of health, to prevent disease and promote good health across society.*

*CPME's policies are shaped through the expertise provided by our membership of national medical associations, representing physicians across all medical specialties all over Europe and creating a dialogue between the national and European dimensions of health and healthcare.*



## MEDICAL DEVICES DRAFT REGULATION

The European Commission proposal for a Regulation of the European Parliament and of the Council on medical devices (hereinafter referred to as: the EU MD Regulation), and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, revises the existing legislative framework for medical devices in order to ensure greater patient safety while promoting better access of innovative EU medical devices. The objective of the proposed Regulation is to harmonise the rules for market approval, testing and controls of medical devices within an internal market with 32 participating countries. Additionally, regulatory interpretation concerning certain products (e.g. products manufactured utilising non-viable human tissues or cells; implantable or other invasive products for cosmetic purposes) is furthermore clarified.

### I. GENERAL RECOMMENDATIONS

Overall, the EU MD Regulation provides for a fundamentally new regulation. As a legislative tool, it also aims to eliminate substantial divergences in interpretation and application experienced from previous EU laws.

➤ General recommendation 1.

*In its current form, the EU MD Regulation needs to address patient safety more specifically and in a more comprehensive manner, especially if the regulation is to promote innovation, competitiveness, prompt and reasonably priced access to the market for innovative medical devices.*

The different aims of the proposal for a regulation should altogether as an overarching objective harmonise legislative standards, because uniform standards create the prerequisites for uniform behaviour among Member States. However, an equally high level of protection in all Member States can only be achieved if guidelines are formulated in sufficient detail.

➤ General recommendation 2.

*The EU MD Regulation needs a more balanced degree of detail, especially with regard to clinical investigations and not only sustain the absence of such detail with references to further legislation (e.g. delegated legal documents).*

CPME believes that medical devices are crucial in the practice of medicine and represent one element to ensure patient safety.

The value of medical devices needs to be triggered both by innovation and high quality standards. The patient is central to the practice of medicine but first his/her safety should be ensured with all possible means, as the value of the patient should be the cornerstone of breakthrough innovation. **In this order, i.e., that the patient is key, medical devices are essential for high quality medicine.**

➤ General recommendation 3.

*CPME reminds legislative bodies that it is the intrinsic human value which is to trigger innovation and that in this order, the patient is of higher priority than innovation and only in a second step, medical devices are to be assessed in their value as essential part of high quality of medicine.*



## II. SPECIFIC RECOMMENDATIONS

### II.1 SAFETY OF MEDICAL DEVICES

Device faults before and after delivery, represent one of the main causes of medical device incidents. As demonstrated by the numerous DePuy cases since 2010<sup>1</sup>, the PIP case<sup>2</sup> and even more recently the faulty metallic implants investigation in the UK<sup>3</sup> of the British Medical Journal (BMJ 2012;345:e7090), CPME considers there is urgency for regulatory measures to ensure the safety of medical devices on EU markets and welcomes the proposal for a regulation.

The British Medical Journal case exemplified the necessity of state controls prior to CE marking and the associated certified suitability for marketability within the EU, at least for devices with high risk potential. The freedom to select a notified body anywhere in the EU creates a situation of competitive pricing among notified bodies, which in turn results in the exploitation of any latitude in regulations in favour of the manufacturers, enabling fast market access for new medical devices to the detriment of device safety. High-risk devices in particular, demand higher market-access hurdles, which, as in the USA, include the state licensing of a medical device and an obligatory clinical investigation which must document the effectiveness and safety of the medical device, and not merely its suitability for its intended purpose.

In this sense, CPME welcomes the MD Regulation recognising it as a first step in the right direction. CPME believes that the EU regulation must require the necessary professional documentation and evidence for the effect and patient safety of medical devices.

That means:

- Implants must be thoroughly tested in relation to the strength of the product, the content/substances, alloying, metals, etc.
- Implants, invasive devices and all devices that may pose a direct risk must be clinically tested before approval/certification can be obtained. At the same time, there is a need for a re-evaluation of the existing division of risk classes.
- Regarding single use devices and their reprocessing, the draft MD regulation and in particular Article 15 does not provide at all clarity regarding what is to be reprocessing medical devices, single-use devices and/or reprocessing of single-use devices. CPME recommends training and qualified monitoring as means to reach the most modern scientific and technological standards across member states, so that reprocessing of medical devices may be safe and a distinction between disposable or suitable for reprocessing medical devices is possible to address further.

In view of the recent events, comparability of the EU regime with the US regime in terms of adverse events and after having considered and recognised the value of EU innovation on medical devices, CPME recommends the following measures for patient safety:

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<sup>1</sup> DePuy cases since 2010: multidistrict litigation of the many DePuy cases (<http://www.ohnd.uscourts.gov/home/clerk-s-office-and-court-records/multidistrict-litigation-cases/mdl-2197/>). Additionally the landmark case of the European Court of Justice, Mines de Potasse case gives a choice to either sue in the English court or in the country where the national resides. European Court of Justice 30 November 1976, zK 21/76 NJ 1977,494. However, litigation is very complex.

<sup>2</sup> [CPME call for increased surveillance of medical devices](#), 5 May 2012

<sup>3</sup> <http://www.ca-aixenprovence.justice.fr/index.php?rubrique=10794&ssrubrique=12510>



- *A high quality coordinated approval procedure for high risk medical devices and adequate controls at state level prior to CE marking and the associated certified suitability before entering the EU market.*
- *The burden of proof is to be shifted from the patient to the responsible economic operator.*
- *Product specification requirements should apply to as wide a scope as necessary to ensure patient safety.*
- *The principle of equivalence needs to be upheld at legal level. Improved medical devices and entirely new medical devices should be clearly delimited within law.*

Invasive procedures on clinical trials need to address patient safety by having more stringent and safe measures while verifying and validating the investigation procedures. In this sense, the accompanying risks could be successfully managed in order to ensure the absence of lasting complications and/or minimal problems for the patient.

**CPME reminds of the European Parliament Resolution of 14 June 2012<sup>4</sup> which called on the Commission to shift to a system of pre-market authorisation for certain categories of medical devices, including, at least, high risk medical devices.**

## II.2 ETHICS AND CLINICAL EVIDENCE

‘Clinical investigation’ should include systematic investigations meant to test the effectiveness of a device and not only its safety and performance.

Similarly, the responsibility of ‘sponsors’ of clinical investigations should also include the management, conduct and/or financing of the investigation and not only the initiation of the investigation.

Any clinical research on human beings should be safe, reliable and ethically viable. CPME believes that the ethical principles for medical research involving human subjects documented in the **Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects** needs to be properly reflected where applicable within the EU MD Regulation.

Like the Commission's Proposal for a Regulation on clinical trials on medicinal products, this proposal leaves it to the Member States to define the organisational set-up at national level for the approval of clinical investigations and moves away from a legally required dualism of two distinct bodies, i.e. national competent authority and ethics committee.

- *CPME recommends the legal application within the MD Regulation of the ethics principle of justifiability of clinical investigations judged on a benefit – risk basis. Article 50 par 3 of the draft EU MD Regulation prescribes the benefits of clinical investigations without mentioning the inherent risks to which a test subject participating in a clinical investigation is exposed.*

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<sup>4</sup> <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2012-262>



- *CPME recommends, in agreement with international ethical standards, that planned research protocols must be submitted to an independent ethics committee before the study begins. Whereas, Directive 2001/20/EC on clinical trials on medicinal products for human use clearly specified, 'the sponsor may not start a clinical trial until the ethics committee has issued a favorable opinion' (Article 9, Par. 1, Subpar. 2, Clause 1 of Directive 2001/20/EC), Annex XIV No. 4.2 and Art. 51 Par. 6 are evasive on this point. Hence, it should be required that the start of the clinical investigation is dependent not only on authorization by the competent authority, but also on the favourable opinion of the ethics committee.*

*Effective protection of the interests of study participants requires that ethics committees be independent, not only of the sponsors and investigators but also of state agencies and in particular of agencies which are responsible for the approval of clinical investigation or the licensing of medicines. The personal independence of members of ethics committees also prohibits any assignment to a state agency. The Regulation should be committed to these principles.*

In a sensitive area of medical activity which is associated with special risks, it is not sufficient that researchers continuously measure the project itself against recognised ethical principles for medical research on human beings, they must be supported in that process by an expert body made up of persons who are familiar with day-to-day clinical routines and can properly assess any questions which arise. The formulation of ethical principles and their analysis by an independent body of ethics experts are therefore two pillars of the Declaration of Helsinki which, from the perspective of the medical profession, represents an inseparable unit. *CPME recommends that for clinical investigations, the ethics committee is to be maintained*<sup>5</sup>.

### II.3 TRANSPARENCY, TRUST, CONFIDENTIALITY AND DATA PROTECTION

- The EU MD Regulation should establish an appropriate balance between facilitating the secure use of health data for health purposes and the human right to privacy in all applicable cases for medical devices.
- When the EU MD Regulation makes implicit reference to implementing the right to be forgotten and to erasure in the healthcare context, a qualified assessment of potential consequences needs to become a legal requirement.
- In healthcare and as applicable in the case of medical devices, data protection should establish an appropriate balance between a data subject's rights, and innovative use of information to support research.<sup>6</sup>

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<sup>5</sup>in line with the [CPME Statement on Clinical Trials](#), 24 November 2012.

<sup>6</sup> In line with the [Joint Statement of the Healthcare Coalition on Data protection](#), 29 January 2013 and [CPME Statement on the General Data Protection Regulation](#), 24 November 2012.



## IN VITRO MEDICAL DEVICES

The proposal for regulation on in vitro diagnostic medical devices aims to strengthen the application of a comprehensive regulatory framework which settles divergences in the interpretation and application of rules among 32 participating countries regarding market approval and surveillance, supports research and innovation and benefits patients and healthcare professionals. Further clarification is provided regarding the competences of notified bodies in charge of safety, monitoring and vigilance, the creation of a Unique Device Identification (UDI) and clinical investigation.

Despite horizontal features common to both proposals, there are several differences between this proposal for regulation and the proposal for regulation of medical devices. These refer to specific aspects related to the unique and non-invasive character of in vitro diagnostic medical devices and the designing of a distinct risk-based classification system.

### I. ETHICS AND CLINICAL EVIDENCE

CPME welcomes the mentioning of the **Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects**, especially with regard to clinical performance studies, but encourages more stringent ethical rules. Not enough prominence seems to be given to ethics, when talking about the practical aspects of the studies, especially regarding the ones which involve risks for the subject. Research on human volunteers, human tissues, or identifiable human data must be reviewed **ethically and where applicable in a similar fashion as with medical devices**.

CPME is deeply concerned with the fact that the proposal implies that an actual legal separation between national competent authorities and ethics committees is no longer necessary. Ethics committees should be separated in order to guarantee basic ethical standards. These ethical principles need to be respected during clinical performance studies, especially when the sponsor of the clinical study applies for substantial modifications with a considerable impact or during post market follow-up performance studies.

### II. TRANSPARENCY, TRUST, CONFIDENTIALITY, DATA PROTECTION AND QUALITY MANAGEMENT

CPME underlines the ethical importance of guaranteeing personal data, but also considers that genetic data, as a particular sensible area, should be submitted to an even higher degree of protection for the treatment, storage and transmission of information.

Sharing results from the performance evaluation of in-vitro diagnostic medical devices (e.g. for cerebrospinal fluid sampling) and making them public, whether they are positive, negative or inconclusive is a matter of trust in medical research. All the results, especially the ones concerning genetic data, should be publicly available and any research with human volunteers, human tissues, or identifiable human data must follow legal and regulatory standards.

CPME welcomes the creation of a central database that integrates different electronic systems to collate and process all information regarding in vitro diagnostic devices and believes that Eudamed



should be comprehensively developed to assure the sharing of important information, in parallel with notified authorities.

Regarding quality management, CPME understands that facilities which manufacture devices as defined in Annex 7, Classes A, B and C for use in their own facilities must adhere to a specific system of quality management, but does not recommend the naming of one or another type of quality management. Legal experience has shown that even where the type of quality management standard is not mandatory, but is mentioned as an example specifically within the law, it becomes practice over other quality management standards.

For this reason, there is an urgent necessity that facilities which manufacture in vitro diagnostic devices for their own use should be granted the same freedom of action as those enjoyed by laboratories which are involved in the commercial manufacture of in vitro diagnostic devices.

It should also be noted that DIN EN ISO 15189 was specifically designed for laboratories which are engaged in routine care. The special aspects which may possibly be taken into consideration in the manufacture of in vitro diagnostic devices are not represented in this standard in any way.

#### **Annex I, No. 16**

The annex puts devices which are intended by the manufacturer for self-testing and devices which are used professionally in association with near-patient testing in the same category. This is not appropriate, because it results in members of the health professions being put on the same footing as non-medical persons.