International Federation of
CLINICAL NEUROPHYSIOLOGY

Europe-Middle East-Africa Chapter (EMEAC)

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The European, Middle East, and African Chapter of the International Federation of Clinical Neurophysiology is concerned about an ongoing tightening of regulations on medical products that is hindering brain, peripheral nerve, and muscle research. Whilst we understand and support the necessity of safety measures in the area of patient care, these measures apply to early stage research where new technologies are explored for future patient care. As a result, a vicious circle develops, where new technologies have to pass a lengthy process to be fully CE certified before they are accepted for research exploring their efficacy in healthy subjects, even before patients are involved. This long and expensive process is insufficiently funded by EU grants, causing unnecessary delays that other world regions (such as Asia or North America) do not experience and subsequently, they are writing decisive patents. As such, we are, already, at a material disadvantage when competing with these regions.

Points which require improvement:

- Future manufacturers of devices used for electrical or magnetic brain or peripheral nerve stimulation, must also collect clinical data even when the intended research is on healthy subjects for discovery research. This needs to be simplified. With appropriate technical safety clearance, the regulations need to be modified to allow local ethics committees the ability to approve investigations without the bureaucratic superstructure required for clinical studies and medical product approval.
- At present, devices used in our research, when CE certified, need a dedicated purpose, which in turn requires studies to justify that. It is an unnecessary hurdle, since even if we have available CE certified devices, we cannot use them outside of their dedicated purpose. This restriction again complicates and delays research, aside from the prohibitive costs.
- Equipment intended for non-invasive brain stimulation that applies weak electrical currents, or magnetic or electromagnetic fields, that penetrate the cranium to modify neuronal activity in the brain, are part of the ANNEX XVI of the new MDR which came into European law last year.
- Annex XVI of the MDR is obviously designed for non-medical "neuroenhancements," brain stimulation techniques like consumer stimulation devices which are marketed to enhance intelligence or improvement in mathematical ability. We need clear regulations, distinct from these consumer devices, which cover ethical issues in high grade research and warrant a safe legal basis for ethics committees to allow early stage research with minimal bureaucracy and monitoring.
- In this context, a clearer separation of patient care devices and research devices is requested. Both manufacturers of medical and non-medical devices for Brain Stimulation need now to follow similar processes, demonstrating compliance with the MDR through a technical file and present it for scrutiny to one of the notified bodies, commercial companies accredited by national designating and competent authorities, before being allowed to affix a medical or non-medical CE mark. What we need is a more flexible process for research with non-medical devices. During research, results often lead to adaptation of the devices to new requirements. The present situation then requires completely new certification of a device even for very minor changes.
- Similar problems occur in the software area. Ethics committees should be provided with a legal framework to allow assessment of research with fewer requirements than at present, for example questionnaires.

Unnecessary to mention that of course, finally patient care will benefit from this research.

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