Policy paper proposes regulatory model for cognitive enhancement devices

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Researchers from the Oxford Martin School, University of Oxford, are calling for the regulation of a new breed of devices designed to enhance the brain's performance. Cognitive enhancement devices (CEDs) offer the tantalising prospect of potentially making users' brains work faster, more effectively, and more creatively, and are now being marketed for gaming and education. But current European legislation subjects these devices to nothing more than basic product safety requirements, despite them directly modifying the electrical activity of the brain.

A new Oxford Martin policy paper proposes a regulatory model to help oversee this expanding industry. Authored by Hannah Maslen, Thomas Douglas, Roi Cohen Kadosh, Neil Levy and Julian Savulescu, Mind Machines: The Regulation of Cognitive Enhancement Devices provides a comprehensive overview of the types of devices available, assesses the regulatory weaknesses, and provides a practical pathway to designing a regulatory model for CEDs. In the EU, these products are not covered by the Medical Devices Directive because they are neither diagnostic nor therapeutic. So while the same kinds of devices are being trialled by scientists to treat conditions such as depression or Parkinson's disease, when the manufacturer makes no claim to therapeutic effect – either treatment or diagnosis – they are unregulated, with no system in place to guarantee their safety. With the market for enhancement technologies expanding and devices already crossing international borders, controlling which products are approved for sale is a global issue, potentially requiring international regulatory harmonisation.

Professor Julian Savulescu, Director of the Institute for Science and Ethics within the Oxford Martin School, comments: "CEDs open up a range of possibilities in increasing cognitive abilities, but are not risk-free. This paper's proposed regulatory model is directed at both policymakers and manufacturers, and seeks to ensure that consumers can be confident in their choices when purchasing a CED."

The commercial market for these devices is as yet unmeasured, with no sales figures available. The paper's lead author Dr Hannah Maslen, Research Fellow in Ethics on the Oxford Martin School Programme on Mind and Machine, says that this makes it the right time to act: "The market for these devices is still in its infancy, so now is the right time to address gaps in regulation to ensure their safety."

The paper's authors recommend that:

- CEDs should be regulated within the EU Medical Devices Directive, as they possess similar mechanisms and risk profiles to some medical devices. This approach would allow for efficiency in legislation, with a precedent already set by the inclusion in the Directive of some non-medical (cosmetic) implantable and invasive devices.
- High-risk devices must be prohibited; comprehensive and objective information from the manufacturers about mechanisms, safe use and risks and benefits must be provided for moderate-risk devices; and low-risk devices should be exempt from continued regulatory evaluation.
- This model could be adopted in other jurisdictions across the world and, given the online market for these devices, international regulatory harmonisation is potentially required.
- Criminal sanctions should be applied if CEDs intended for use on adults are used on children by individuals lacking adequate training.

- CED manufacturers must exercise best practice in anticipation of regulatory oversight.

More information: The policy paper is available online: www.oxfordmartin.ox.ac.uk/down … gs/Mind_Machines.pdf

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