The Regulation of Cognitive Enhancement Devices
An Oxford Martin School Policy Paper
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Executive summary

A major challenge facing EU regulatory bodies is how to regulate devices intended for cognitive enhancement. Whilst there have been a number of calls from groups such as the British Medical Association for more policy debate on enhancement technologies, few specific recommendations have been made.

This regulatory gap is made particularly concerning by the fact that some of these potentially risky devices, which alter brain function, are being built, bought, and used by individuals with little knowledge and training and in the absence of regulatory safeguards. For example, Transcranial Direct Current Stimulators (tDCS) and neurofeedback devices are currently marketed online as Cognitive Enhancement Devices CEDs without the particular models on sale undergoing comprehensive clinical evaluation.

We suggest that the similarities between CEDs and therapeutic medical devices are sufficient to create a presumption in favour of extending the existing risk-benefit model for regulation to CEDs. In this model, the acceptable level of risk for a particular device is determined in part by the likely benefit that it offers. Moreover, concerns regarding the objectivity and measurability of the benefits of CEDs do not, in our view, warrant ignoring the likely level of benefit in determining the acceptable level risk. Attempts should be made to ascertain typical benefits even if these assessments will necessarily be uncertain. They could be based on measurable improvements to cognitive functions and capacities along with assessments of the typical value of those functions and capacities. In some cases, it may be possible to evaluate cognitive functions and capacities using tools that have been developed to measure the value of different health states for health economic assessment.

Consideration should also be given to incorporating a low-risk exemption, whereby devices that fall under a given threshold level of risk would be approved regardless of likely benefit. This would allow consumers a degree of discretion to conduct their own assessment of risk and benefits. The case for this exemption would, in our view, be strongest for (i) devices (therapeutic, diagnostic or enhancing) that are not intended for use in severely unwell individuals, and (ii) devices suitable for use without medical involvement. In severely unwell individuals there may be legitimate concerns about patient vulnerability impairing risk-benefit assessments. Similarly, in cases where medical professionals would be involved in the provision of a device, their involvement might be taken to signal a favourable risk-benefit profile. We remain agnostic on whether these concerns would count decisively against including a low-risk exemption for devices intended by used in the severely unwell or with medical professional involvement.
One factor that would, in our view, count decisively against including a low-risk exemption is the likelihood that a device will be used on children or non-competent individuals. This is most likely to be the case for devices that can be used in an unmonitored setting. Another factor that might count against a low risk exemption is that a device is likely to be used in ways that have substantial knock-on costs for the health system, as is the case with some cosmetic implants.

It is important to note that the case for a low-risk exemption would be stronger for at least some CEDs than for invasive or implantable cosmetic devices. These devices are in most (but not all) cases more risky than, for example, tDCS and neurofeedback devices, and most (but not all) require the input of a medical professional, whereas tDCS and neurofeedback devices do not.

A 'low-risk exemption' would allow competent individuals to make their own assessments about the risks and benefits of CEDs. The role of regulation would be in ensuring that consumers have access to the right kind of information on which to make these assessments.
The Regulation of Cognitive Enhancement Devices

A major challenge facing EU regulatory bodies is how to regulate devices intended for cognitive enhancement.

Whilst there have been a number of calls from groups such as the British Medical Association (2007) for more policy debate on enhancement technologies, few specific recommendations have been made. The regulation of technologies can occur at many points from the research and innovation stages, through placing a technology on the market, to the use of the technology by private individuals. Whilst the EU has a clear regulatory framework for medical devices, it is yet to develop anything comparable for cognitive enhancement devices (CEDs). These are devices which, though similar to medical devices in their mode of action, can be sold and used not to treat disease, but to augment typical cognitive capacities.

Definitions

We refer to cognitive capacities as human abilities ranging from basic sensory abilities to higher cognitive functions, such as motor and sensorimotor skills, vision, decision-making and problem solving, mathematical cognition, language, memory, learning, and attention.

tDCS is a non-invasive technique in which a device sends a small Direct Current across the scalp to modulate brain function.

Neurofeedback is a type of biofeedback that uses realtime displays of electroencephalography to illustrate brain activity, often with the goal of enabling regulation of central nervous system activity.

This regulatory gap is made particularly concerning by the fact that some of these potentially risky devices, which alter brain function, are being built, bought, and used by individuals with little knowledge and training and in the absence of regulatory safeguards. For example, Transcranial Direct Current Stimulators (tDCS) and neurofeedback devices are currently marketed online as CEDs without the particular models on sale undergoing comprehensive clinical evaluation.

In order for a regulatory body to set standards for a particular technology, it first has to identify the technology as something that requires regulation. One problem with current EU legislation is that products intended for enhancement are not identified by any of the existing directives other than those covering general product safety - the General Product Safety Directive (GPSD). The GPSD, however, only sets general requirements and does not make provision for pre-market assessment. Devices such as used for enhancement purposes are therefore not held to the rigorous standards set for medical devices since they do not fall within the definition of a medical device set out in the Medical Devices Directive (MDD).

The possibilities for the regulation of CEDs can be identified according to (1) the regulatory instruments that could be employed, and (2) the stringency of the standards the CEDs could be required to meet. CEDs could be regulated under the same legislation as medical devices (the Medical Devices Directive), they could be regulated by a new regulatory body/under new legislation specifically for CEDs, they could be prohibited, or the status quo could be maintained. Adopting either of the first two options would allow CEDs to be held to a higher regulatory standard than medical devices, to the same standard or to a lower standard. This therefore generates eight options to consider. We discuss these options in section 2.2; The eight regulatory options.

If CEDs were to be regulated under the same legislation as medical devices, the simplest option would be to extend the definition of a medical device to cover CEDs or add a section to the directive that separately deals with CEDs. Such an amendment, designed to include some devices without a primary therapeutic purpose, has recent precedent. The Medicines and Healthcare products Regulatory Agency (MHRA) has just closed its public consultation on the revision of European legislation on medical devices. Amongst the proposed revisions was an extension of the current definition of a medical device to cover some implantable or other invasive products without a medical purpose. Examples of such devices include non-corrective contact lenses and implants for aesthetic purposes. However, this amendment would not include non-invasive CEDs, such as tDCS devices.

Through exploring the regulatory options, this policy paper argues that a similar amendment should be made to the definition so that a wider range of CEDs fall within the current regulatory framework for medical devices. In presenting this argument, the paper highlights potential challenges and suggests solutions.

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2 Directive 2001/95/EC
3 Directive 93/42/EEC
1. The Medical Devices Directive

1.1 Which devices does the Medical Devices Directive cover?

The various devices regulated under the Medical Devices Directive are diverse in their purposes and modes of application, and exhibit varying degrees of complexity. Simple examples include medical thermometers and pregnancy tests; more complex devices include implantable cardioverter defibrillators and x-ray equipment. The importance of holding these sorts of devices to high standards of safety and accuracy is clear. However, there are devices – often very similar or even identical in mechanism, and motivating similar concerns about safety and accuracy – which are not covered by the MDD. For example, tDCS devices used for brain stimulation to achieve cognitive enhancement are not classified as medical devices when marketed for this purpose, but can be bought online by already healthy individuals hoping to augment their capacities. Similarly, neurofeedback devices are marketed as devices that, amongst other benefits, can effect improvements in concentration, attention and creativity. Notably, the individuals purchasing such devices do not have any training and, in the case of tDCS, lack sufficient knowledge of how to provide optimal or even safe stimulation. Cohen Kadosh and collaborators (2012) explain that the apparatus is relatively inexpensive (some forms of transcranial electrical stimulation (TES) devices can be purchased for less than £500 and can be built using off-the-shelf components) (for example http://www.diytdcs.com/). Consequently, they suggest that there is a danger that these devices could be tried out ad hoc on adults and children before enough is known about the potential physiological or psychological side effects, about the appropriate method of stimulating (for example, the optimal duration and location of stimulation) and about how psychological training protocols can be designed that are selective for the desired effects. More recently, people lacking formal training have begun to offer treatment using tDCS.

1.2 Why are CEDs not covered by the MDD?

Cognitive enhancement devices, despite often raising safety and effectiveness concerns comparable to those raised by medical devices, are not covered by the MDD because the definition the directive employs excludes

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5 Directive 93/42/EEC
7 Recently, trade-offs have been identified following enhancement of one brain function [Iuculano, T., & Cohen Kadosh, R. (2013), ‘The mental cost of cognitive enhancement’, The Journal of Neuroscience 33, 4482-4486.]. It has been shown that depending on the stimulated brain region, cognitive enhancement in one domain is associated with a cognitive cost in another domain.
them. The current definition of a medical device specifies that the device must be intended by the manufacturer to be used for diagnostic and/or therapeutic purposes. Since CEDs are neither diagnostic nor therapeutic, they are not identified as devices for medical regulation. The definition is as follows:

Article 1(2) (a) MDD defines a medical device as:

Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

It might be argued that the definition in its current form in fact does cover CEDs: devices used for tDCS or neurofeedback modify physiological processes in the brain, as per the third indent of the definition. However, if this criterion were considered individually sufficient, the definition would then problematically extend to anything that alters the brain: books, DVDs and computer games would arguably become medical devices, as interacting with them to some extent modifies neuronal connections.

Further, the consensus amongst the European Commission, Member States and stakeholders is reportedly that having a specific diagnostic and/or therapeutic purpose is the primary criterion for a medical device, and that the purpose of ‘investigation, replacement or modification of the anatomy or of a physiological process’ is amongst the secondary criteria once a general medical purpose has been recognised. A working document published by the European Commission during the recent consultation on the MDD explains:

It is currently not clear whether implantable or other invasive products for which the manufacturer does not claim a medical purpose, but e.g. an aesthetic or cosmetic purpose, are covered by the AIMDD or MDD or not. Some argue that the third indent of the ‘medical device’ definition in Article 1(2)(a) of the MDD covers any device which pursues the purpose of ‘investigation, replacement or modification of the anatomy or of a physiological process’, regardless of whether the manufacturer attributes to it a medical or a non medical (e.g. aesthetic) purpose. However, according to the prevailing interpretation of the Commission, Member States and stakeholders, a device falls within the definition of a medical device when it pursues a medical purpose. The question is currently pending before the European Court of Justice for a preliminary ruling.

The result is that CEDs, despite modifying physiological functions, are not identified by the definition as devices for regulation. Note that the current definition also excludes any device intended to be used for both cognitive enhancement and therapeutic purposes, again, because its usage would then not be considered specific for therapeutic purposes.

2. Possible approaches to CED regulation

2.1 What proposals for CED regulation have there been?

The present lack of a regulatory framework for CEDs – and for enhancement technologies more generally – has motivated large-scale working groups to consider the ethical and social implications of the increasing production and

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11 Ibid
use of these technologies. For example, the British Medical Association published a report in 2007 on the ethical aspects of cognitive enhancement; the European Commission funded a 7th framework programme on Ethics in Public Policy Making: The Case of Human Enhancement (EPOCH)\textsuperscript{12}; the Academy of Medical Sciences, in collaboration with the British Academy, the Royal Academy of Engineering and the Royal Society, published a report based on their workshop investigating Human Enhancement and the Future of Work\textsuperscript{13}.

Notwithstanding the various important outputs of these and similar projects, there has not yet been a paper providing overt guidance to lawmakers and regulatory bodies on the regulation of cognitive enhancement technologies. As summarized by Outram and Rachine (2011)\textsuperscript{14}, the report published by the British Medical Association (BMA)\textsuperscript{15} places emphasis on public debate in advance of making recommendations. Whilst it outlines the possible regulatory approaches and discusses their implications, it does not argue for the adoption of any particular course of action. The express aim of the BMA report is to facilitate informed debate amongst doctors, scientists, policymakers, and members of the public about the future development and use of cognitive enhancements. The BMA states that it ‘does not have policy or recommendations to put forward on these issues but would welcome informed public debate about how, as a society, we should respond to these developments’\textsuperscript{16}.

The aim of the EPOCH project was to broaden and deepen knowledge of the role of ethics in the governance of science and technology, focusing on ethical aspects of new and emerging bio-, neuro- and nano-technologies and specifically related to the topic of human enhancement. Although regulatory challenges were a focus of the project, the central aim was to generate new insights into the role of ethical expertise in European policy making on science and technology, coherent with national and other European projects. Overt recommendations to lawmakers were thus not the goal.

The recent report from the joint academies had a narrow focus on human enhancement in the workplace. The report suggests that the greatest immediate challenges for regulators and other policy-makers will arise from the use of drugs, brain stimulation, and digital devices that enhance cognition and concludes that dialogue with potential users and the wider stakeholder community, as well as studies and commissioned research, will be required to balance the risks and benefits of these technologies in the future workplace. The report does go some way towards suggesting particular regulatory approaches, but these recommendations are specific to employment contexts. As the report notes, ‘in many ways, work represents a unique context, within which a cautionary regulatory approach is desirable, with the primary objective of protecting employees’\textsuperscript{17}. We should not assume that the regulatory approach appropriate for work contexts will also be appropriate for other contexts.

So, whilst there has been preliminary exploration of

\textsuperscript{13}The Academy of Medical Sciences (2012), Human Enhancement and the Future of Work.
\textsuperscript{15}British Medical Association (2007), Boosting your brainpower: ethical aspects of cognitive enhancements.
\textsuperscript{16}ibid, at 1.
\textsuperscript{17}The Academy of Medical Sciences (2012), Human Enhancement and the Future of Work, at 51.
regulatory questions, there is no precedent for recommending a particular approach for CEDs, nor for how any such approach should be implemented. The remainder of this paper will examine eight possible regulatory options and argue that the best approach is one in which medium and high-risk CEDs are regulated in the same way as medical devices, with low risk devices held to a less stringent standard.

2.2 The eight regulatory options

The authors see eight options for the regulation of CEDs, as follows:

1) The status quo could be maintained.
2) CEDs could be regulated via a new process specifically for CEDs, to:
   - ...a higher regulatory standard than medical devices,
   - ...a lower regulatory standard than medical devices, or
   - ...the same regulatory standard as medical devices.
3) CEDs could be regulated under the same legislation as medical devices, to:
   - ...a higher regulatory standard than medical devices,
   - ...a lower regulatory standard than medical devices, or
   - ...the same regulatory standard as medical devices.
4) CEDs could be prohibited.

Arguments can be made to reject options 1) and 8) at the outset.

From the reasons stated so far, maintaining the status quo is not a defensible option. The devices currently marketed for cognitive enhancement are most often devices that are also being tested in clinical research trials, with the hope that ultimately they will be used to treat patients. For example, to date, a number of clinical studies have reported some promising effects of TDCS when treating patients with depression, chronic pain, schizophrenia, dementia, Parkinson’s disease and cerebral stroke. Whether used in research, for treatment or for enhancement, the devices modify brain activity via similar mechanisms and with similar physiological effects. They can thus be expected to impose similar risks; and there seems little reason to suppose that CEDs offer greater benefits. Given this, the careful regulation of the same or similar devices in one context but not in others appears arbitrary. At the opposite end of the spectrum of policy options, there does not seem to be a convincing argument for a complete prohibition of CEDs. Although devices will present some risks, these are not greater than the risks posed by many medical devices that are considered safe enough to be placed on the market.

Some authors have argued that using biotechnologies for cognitive enhancement, or indeed to enhance other human capacities, is morally problematic for example because it invariably expresses an objectionably desires to ‘master’ the human body and mind, or because it can be expected to have net harmful individual or social consequences. Such arguments could be taken to support a universal prohibition on CEDs, among other enhancement technologies. However, these arguments have been strongly contested. Moreover, even if CED use is always morally problematic, this may not justify legal or regulatory prohibition. A concern to protect individual autonomy would militate against such a prohibition, and it might also be argued that CEDs ought to be permitted in order to help forestall unregulated illicit use. As noted by Cohen Kadosh et al., devices can be built from off-the-

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shelf components; it is preferable that, if individuals choose to pursue enhancement, they purchase devices that are held to a strict level of safety, appropriate for the particular use intended. Finally, while other forms of biomedical enhancement, such as cosmetic surgery, remain permitted, there is an argument from consistency for allowing the use of CEDs as well.

The remaining two groups of options require more detailed discussion. CEDs could be regulated separately from medical devices by a new regulatory process. Alternatively, CEDs could be regulated in the same way as therapeutic medical devices, for example by extending the definition of a medical device to include devices with enhancement purposes. These two options will be examined in turn, with the authors arguing that the latter should be pursued by existing regulatory bodies, such as the Medical and Healthcare products Regulatory Agency (MHRA) in the UK.

2.3 Option one: establish a new regulatory process of CEDs

Establishing a new regulatory process would allow CEDs to be regulated to the same standard, to a lower standard, or to a higher standard than medical devices. An argument for doing this would most likely maintain that CEDs categorically differ from medical devices raising qualitatively differently regulatory issues or that the standards to which CEDs must be held are so high that their regulation must proceed in a significantly different way (bearing in mind that there is already variation of standards within the directive). As a way of regulating CEDs separately from medical devices, the BMA suggests as a possibility ‘the establishment of a new regulatory body to approve the use of particular techniques and to issue guidance for their use – the Regulatory Authority for Cognitive Enhancements (RACE) perhaps?’

However, there are practical arguments against establishing a new regulatory process, particularly if this were to involve the creation of new government agencies. Indeed, the BMA point out the EU’s problem with the proliferation of regulatory bodies:

This practical concern, however, is not the only argument against regulating CEDs independently from medical devices: there are also strong theoretical reasons to resist a separate regulatory process. First, CEDs are not categorically different from medical devices; in fact, the very same device may be used both for therapeutic and enhancement purposes, and to issue guidance for their use – the Regulatory Authority for Cognitive Enhancements (RACE) perhaps?

CEDs, as devices that modify brain function to improve cognitive performance are, in important respects, the same sorts of devices that the MDD covers: they intervene to modify physiological processes and present varying degrees of physiological risks and side effects. Whilst in some cases there is no categorical distinction to be made between CEDs and medical

22 British Medical Association (2007), Boosting your brainpower: ethical aspects of cognitive enhancements, at 34.
23 Ibid, at 34.
devices, it is true that the purpose of CEDs is enhancement and not therapy. However, the proposed revision of the MDD to cover (principally cosmetic) devices without a medical purpose sets a precedent for non-therapeutic devices to be regulated in the same way as medical devices. It could even be argued that aiming to improve cognitive function is closer to our traditional understanding of medical purpose than is aesthetic enhancement, and it is certainly not further from therapy than is cosmetic surgery. If cosmetic devices are not wildly out of place within the MDD, then neither are CEDs.

There is also a philosophical reason to place CEDs within current medical regulatory regimes. Many philosophers have denied that there is a morally relevant difference between treatment and enhancement. Both therapy and enhancement aim to improve a human being’s biology or psychology. The two most important ethical considerations in regulating such interventions are the risks that are involved and considerations of distributive justice when such interventions are publicly funded. Thus the critical issues in the evaluation of any new technology, whether for treatment or enhancement, are what the benefits in terms of increment in well-being and what are the risks. The balance of benefit over risk should be one important determinant in deciding whether such an intervention should be admitted to the market place, restricted or publicly funded.

Finally, the worry that CEDs should be held to a higher standard than medical devices does not preclude regulation under the MDD. In fact, different medical devices are already held to different standards within the directive. Further, the MHRA proposal intends implantable or other invasive products without a medical purpose to be held to a different (more stringent) standard than many of the regular medical devices, requiring that they present zero or minimal risk. There is therefore the possibility of setting an appropriate standard for CEDs within the MDD (see below for discussion of weighing the risks and benefits of CEDs).

The above arguments find further support from the European Commission’s discussion of the policy options for extending the medical devices definition to cover some implantable or other invasive products without a medical purpose. While the European commission does think there may be merit in considering products with a medical purpose separately from those without such a purpose, it also sees theoretical value in retaining a homogenous definition and assessment framework, and practical value in having legislation that can more easily be extended in the future. Ultimately, the Commission consider the costs of separate legislation to be too high:

The negative impact of a separate legislation would be that manufacturers which produce same or similar products with and without a medical purpose (e.g. corrective and non-corrective contact lenses without medical purpose) would be subject to two different product-related legislations which, in particular for [small and medium sized enterprises], would be more burdensome and increase compliance costs.

Moreover, it would not appear logical to submit products which have the same features and the same risk profile to different requirements. In addition,
If the aim is merely to ensure that the Directive is applied to CEDs, then it may be preferable to include an ancillary ‘positive list’ of CEDs that are to be included within the legal definition of a medical device.

The MHRA’s proposal for inclusion of a positive list of implantable or other invasive products without a medical purpose takes the first of these two approaches: the devices share the feature that they are implantable or invasive, and the purpose of cosmetic enhancement is thus not the categorising factor.

The practical question to be considered alongside these conceptual issues is how the regulators are best able to ‘keep control’ of what the Medical
We suggest that a further necessary condition be included in any regulatory framework: that regulation is only appropriate on grounds of potential risk. Only technologies which involve more than minimal risk should fall under regulatory purview.

Amending the definition of a medical device would be that new CEDs would be held to the required standards from their emergence on the market (indeed, their emergence on the market would be dependent on meeting the standards). A positive list that was reactive to CEDs already in use creates the risk that untested devices might be used for some time before being subject to regulation.

Whether a purposive or device-based definition is used, it is important that such an approach is not overly inclusive, for example catching educational training software inappropriately. We suggest that a further necessary condition be included in any regulatory framework: that regulation is only appropriate on grounds of potential risk. That is, whether regulation is purpose- or device-based, it should be risk-oriented. Only technologies which involve more than minimal risk should fall under regulatory purview.

Amending the definition presents two significant challenges which would need to be resolved: 1) how the purpose of a device is identified; 2) how risks are quantified and how any risks and side effects should be weighed against the benefits of enhancement, essentially setting the stringency of the regulatory requirements for CEDs. We explore these challenges in turn.

2.4.1 Challenge one: Identifying purpose (enhancement is often a secondary purpose)

If the definition of a medical device were to be amended to include (or cease to exclude) CEDs by including devices with an enhancing purpose, thought would have to be given to how the enhancing purpose of a device is identified. The principle justifications being:

- Enhancement and medical devices are similarly-acting technologies which can have similar risks – there is thus arguably no morally relevant distinction between treatment and enhancement.
- Parsimony in regulation is always preferred where possible.
- The implantable and other invasive products without a medical purpose included on the positive list primarily have cosmetic purposes – this is arguably further from medical purpose than is enhancement purpose and thus sets a precedent.
- Enhancement should be considered a legitimate goal of healthcare.

If the purpose of a device is identified; 2) how risks are quantified and how any risks and side effects should be weighed against the benefits of enhancement, essentially setting the stringency of the regulatory requirements for CEDs. We explore these challenges in turn.

2.4.1 Challenge one: Identifying purpose (enhancement is often a secondary purpose)

If the definition of a medical device were to be amended to include (or cease to exclude) CEDs by including devices with an enhancing purpose, thought would have to be given to how the enhancing purpose of a device is identified. The current wording of the directive provides that medical devices are devices intended by their manufacturer to be used specifically for diagnostic and/or therapeutic purposes. In some cases, this means that the very same device is identified for regulation as a medical device when marketed as such, but not when it is marketed ‘off-label’ as a cognitive enhancement device.

Crucially, the wording of the definition suggests that what comes to be regulated under the directive depends on the explicit claims manufacturers make about their products. A guidance document published by the European Commission elaborates on how this purpose is identified.
Medical devices are defined as articles which are intended to be used for a medical purpose. The medical purpose is assigned to a product by the manufacturer. The manufacturer determines through the label, the instruction for use and the promotional material related to a given device its specific medical purpose.

Given that the medical purpose of a device is identified in this way, if the definition were to be extended to include (or to cease to exclude) the enhancing purposes of various devices, enhancement purposes might be derived from the manufacturer’s labels and instructions, and so forth. However, there might be a difficulty in identifying purpose when a device is marketed for both therapy and enhancement, generating a need to adjudicate between primary and secondary purposes.

It might be possible to avoid these difficulties by identifying and including CEDs not on the basis of their purpose, but rather by their mode of interaction with the body. For example, all devices that electrically stimulate the brain might be classed as medical devices, regardless of the purpose of that stimulation. However, there might still be reasons to identify the purpose of brain stimulation devices. For example, adjudicating between purposes might be significant for determining the level of safety required: if the benefits of a device used for enhancement would typically be less than the benefits of the same device used for therapy, then it might be appropriate to require a lower level of risk in order for the device to be approved for its enhancement purpose. How to weigh risks against the benefits of enhancement is considered in the next section.

2.4.1 Challenge two: risk-benefit assessment (how measurable are the risks and benefits of enhancement?)

If cognitive enhancement technologies were regulated within the existing definition, they would be subject to the general requirements emphasizing safety and effectiveness, requiring risks to be weighed against benefits. Whilst the risks and side effects of CEDs could be assessed in a similar way to the risks and side effects associated with medical devices, it is less clear how the benefits of CEDs should be measured. It could be argued that unlike medical devices – which either succeed or fail in improving or maintaining health to a measurable degree – CEDs confer benefits that are more subjective. Parallels might be drawn with the difficulty of assessing the benefits of cosmetic enhancements: a nose might be made smaller or straighter in a way that we can measure, but how beneficial this is will vary from person to person.

It is certainly possible to measure the size of any improvement to cognitive performance. For example, the improvement in learning speed or capacity of an individual using tDCS will be something determinable through laboratory tests that assess the respective skill acquisition. However, whilst we can measure the size of improvements to cognitive functions, it could be argued that the value of enhancement is something that varies between people to a greater extent than the value usually attached to health. Intuitively, the degree of subjectivity in the value of cognitive enhancement sits somewhere in between the close-to-objective value of health and the more subjective value of the physical traits produced by cosmetic surgery and medicine. The value of these traits is arguably

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A significant issue to resolve when extending the Medical Devices Directive to cover CEDs is how the benefits of the devices are to be estimated and weighed against any risks or side effects.

Devices shall achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose, taking into account the generally acknowledged state of the art. They shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

Further instruction on what should be fed into the risk/benefit assessment is found in the European Commission’s guide to clinical evaluation, for manufacturers and notified bodies30. There it is stated that combined clinical data must show that:

Any risks associated with the use of the device are acceptable when weighed against the benefits to the patient. Such considerations should take into account the number of patients exposed to the device, the type and adequacy of patient monitoring, the number and severity of adverse events, the adequacy of the estimation associated risk for each identified hazard, the severity and natural history of the condition being diagnosed or treated. The availability of alternative diagnostic modalities or treatments and current standard of care should also be taken into consideration.

The emphasis on an assessment of the severity and natural history of the condition being diagnosed or treated implies that the EC holds the view that the more severe the condition, the greater the benefits that can be expected of the device, and thus the higher the level of risk that can be tolerated. This approach is similar to that used by the Human Fertilisation and Embryology Authority in regulating the use of preimplantation genetic diagnosis for non-medical purposes such as sex selection. The corresponding idea – that the less severe the condition, the lower the tolerable level of risk – suggests that, as devices move closer towards enhancement than treatment, the number and/or magnitude of the risks tolerated will decrease. It seems that the European Commission took such

an approach when proposing the amendment for implantable and other invasive devices without a medical purpose. Qualifying the general requirements pertaining to performance and safety, it is suggested:

For devices listed in Annex XV for which the manufacturer does not claim a medical purpose, the general requirements set out in Sections 1 and 5 shall be understood that the device, when used under the conditions and for the purposes intended, shall not present any risk or only the minimum acceptable risks related to the product’s use which is consistent with a high level of protection for the safety and health of persons.

Echoing this, the MHRA’s consultation document explains:

Weighing up the risks and benefits of a product which does not have a medical purpose is different than for medical devices. Therefore Annex I, which sets out the safety and performance requirements of devices, requires manufacturers of implantable or invasive products without a medical purpose to ensure that these products present either no or the minimum acceptable risk which is consistent with a high level of protection for the safety and health of persons.

This qualification has the result that devices without a medical purpose – even when they have the same risk-profile as analogous devices with a medical purpose – will be held to more stringent standards than devices with a medical purpose: requiring zero or minimal risk is more cautious than requiring that risks are acceptable when weighed against the benefits to the patient. Further, the more stringent requirement makes no mention of weighing risks against benefits at all, possibly because it was considered that the devices for which no medical purpose is claimed do not confer (relevant, measurable) benefits on their users. The purposes of the devices included in the ‘positive list’ are principally cosmetic, and as suggested above, it might be thought that, as cosmetic benefits are subjective, they cannot be relevant to a risk/benefit assessment. This sentiment is found in one of the consultation responses from the German trade association representing the National and International Companies of Contact Lens (and Lens Care) Manufacturers:

Since non-corrective lenses for cosmetic/aesthetic purpose, have the same risk profile but no medical benefit, the risk-benefit principle cannot apply as for regular medical devices. Therefore for quasi-medical devices, the principle of keeping the risk as low as reasonably possible (ALARP) should apply. Quasi-medical devices should be classified the same way as medical devices under the principles of Annex IX of Directive 93/42/EC to ensure a conformity assessment route that is equivalent to the risk associated with the device.

It is not obvious, however that less objective or quantifiable benefits should be given less weight than more objective or quantifiable ones. Moreover, the benefits of cognitive enhancements are arguably more objective and more quantifiable than those of cosmetic interventions. Thus, even if the benefits of cosmetic procedures should be given no weight, the same may not be true of the benefits produced by CEDs. In fact, as medical need falls, consumer freedom-to-choose should rise, other things being equal. This is principally because decline in health puts people in a vulnerable position where they are more likely to accept any treatment on offer. Enhancement devices, however, are not something people will feel compelled by natural circumstances to make use of. For therapeutic medical devices, there is a good case for imposing strict risk-based restrictions in order to protect vulnerable patients. By contrast, for CEDs there may be an argument for placing decisions about the level of acceptable risk primarily in the hands of the consumers who will use them.

It should be noted, however, that this argument would not apply to CEDs intended for use on children.

32 MHRA (2012), The revision of European legislation on medical devices, at 10.
33 SPECTARIS, Response to Public Consultation Recast of the Medical Devices Directives. Unit ENTR F/3. Cosmetics and Medical Devices. (SPECTARIS is the German trade association representing the National and International Companies of Contact Lens (and Lens Care) Manufacturers), at 2.
who are arguably always a vulnerable group. For these CEDs, stringent risk-based restrictions might be appropriate. Moreover, even CEDs not intended for use in children might in some cases be offered to children. If such devices are freely available, parents could use them on their children without the child’s valid consent. So while respect for liberty may speak in favour of relaxed regulation of enhancement devices, those which can spill over to be used on children would need to subject to stringent risk-based restrictions.

In addition to level of risk, there are two further factors that will moderate the degree of choice that should be offered to consumers: first, whether a medical professional is required to be involved in order for the device to be used properly and, second, how high the indirect costs to the healthcare system are likely to be if faulty devices are used or if devices are misused. These factors should be weighed against the resources that would be saved if low risk devices were not subject to ongoing regulation under the Medical Devices Directive.

3. Points of comparison with proposal to extend the MDD to include some implantable or other invasive products without a medical purpose

3.1 Point one: unreasonable broadening of the remit of the MDD

One concern raised by the European Commission when discussing how to extend the MDD to cover some implantable or other invasive products without a medical purpose was to ensure that the remit of the MDD was not unreasonably broadened. If the directive were extended to cover all implantable and invasive products, then things such as earrings and other body piercings would then fall within its remit.

Similarly, if a category of ‘cognition improving’ or ‘brain modifying’ devices were to be added to the definition, it would be very difficult to justify the inclusion of tDCS devices but the exclusion of, for example, educational software. To avoid this unreasonable broadening, either particular mechanisms of action would have to be specified (e.g. electrical stimulation), or a positive list identifying specific devices would have to be drawn up. For the implantable and other invasive products, the European Commission proposed to solve this by generating a positive list of devices:

With the suggested two-step approach, the incorporation of a general provision regarding implantable or other invasive nonmedical products in the medical device regulation would not have any immediate impact on these products. Only the inclusion in a ‘positive list’ would trigger the application of the legal requirements regarding a given type of products. This would have the advantage that the concrete impacts on specified products could be assessed once a type of product should be added to the positive list.

We believe that given these benefits of a positive list, this approach is preferable to regulating CEDs by reference to their mechanism of action.

3.2 Point two: implications for manufacturers

In relation to implantable and other invasive products, the European Commission also considered the implications for manufacturers, particularly of the more demanding requirements the MDD makes for pre-market clinical assessment. When a manufacturer markets a device for both medical and non-medical purposes, the impact will likely be negligible, as they will already be complying with...
the requirements of the medical device legislation. However, those that only manufacture devices for nonmedical purposes will begin to be subject to onerous requirements and additional costs. In the case of non-corrective contact lenses:

Manufacturers of only noncorrective contact lenses would have, among others, to draw up a technical documentation (incl. clinical evaluation), be subject to a conformity assessment procedure by a Notified Body and set up a system to respond to incidents (vigilance) which would lead to additional costs. In the case of responsible manufacturers which already today apply an internal quality management system and follow-up of incidents, the additional costs would be limited to the involvement of a Notified Body. Manufacturers which place decorative contact lenses on the market without prior internal quality control and incident follow-up would have to adapt or lose Europe as a market place which would be a desired consequence of this policy option and increase consumer safety.

As expressed here, the outcome that manufacturers who do not implement internal quality control and incident follow-up strategies would lose Europe as a market is actually desirable. Similarly, the manufacturers making CEDs should have to meet the required standards and incur the costs of doing so in the interests of consumer safety.

However, there may be some concerns about what exactly is required for adequate clinical assessment, especially when devices are in early stages of innovation and have not yet been subject to many clinical trials. In the case of the cosmetic implantable and invasive devices:

The application of the medical device legislation to implantable or other invasive products without a medical purpose may force some products out of the market in case that the manufacturer cannot demonstrate conformity with the essential requirements based on clinical data. In particular, those manufacturers who cannot rely on clinical data obtained for medical devices of the same category would, for ethical reasons, unlikely be allowed to conduct a clinical investigation with a product that does not have a medical purpose. Such effect, however, would ensure that only those non-medical products would be allowed on the EU market for which the demonstration of the conformity with the essential requirements by means of clinical data is required by law.

Again, to the extent that the devices are already being tested for medical purposes, an adequate assessment of clinical data should be possible. Where devices are being developed purely for enhancement purposes, holding them to these requirements may stifle innovation as ethical approval for clinical investigation may be withheld. Altering the legislation to include CEDs may therefore have ramifications backwards, to the regulation of innovation and clinical research. However, this should not be a concern as, in our view, quality control pre-market assessment should be the same for CEDs as for medical devices if the theoretical risks are similar. Whether the existing research ethics requirements are reasonable is a question that can be posed in relation to both CEDs and medical devices and is beyond the scope of this paper.

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4. Summary of our recommendations for the regulation of CEDs

Based on the above discussion, we recommend the following for the regulation of CEDs:

- CEDs should be regulated within the Medical Devices Directive: the justifications for this are that CEDs have similar risk-profiles to some medical devices, they are often essentially the same as devices with a medical purpose, parsimony in legislation is desirable, and the inclusion of some cosmetic implantable and invasive devices sets a precedent for broadening the remit of the directive in this way.

- A ‘positive list’ of ‘cognition improving or facilitating devices’ should be drawn up: although this means that the legislation has to react to the emergence of hitherto unregulated devices as they come on to the market, the extension of the directive to all cognition improving or facilitating devices would generate huge difficulties for regulators in keeping the purview of the directive appropriately narrow.

- The devices that should be included on the initial positive list are: transcranial electrical stimulation (e.g., tDCS, transcranial random noise stimulation, transcranial alternating current stimulation); transcranial magnetic stimulation; neurofeedback equipment.

- The benefits of CEDs should be identified and weighed against risks in the same way as they are for medical devices. Unlike cosmetic enhancement, the improvements elicited by CEDs are quantifiable. Whilst there may be differences in opinion concerning how valuable enhancement is, objective benefits will principally include improvements in cognitive capacities. In some cases it may be possible to evaluate these improvements using standard tests. Comprehensive information about the risks and benefits will be required to allow consumers to make informed decisions.

- Where CEDs are deemed to be low risk, do not require the involvement of a medical professional, and are unlikely to generate large indirect costs to the healthcare system, there would be a case for exempting them from continued regulatory evaluation, thus promoting consumer choice. Neurofeedback devices would be an example of a low-risk CED unlikely to require ongoing evaluation. In our view this should also be the preferred approach for low risk medical devices.

- The exception to our proposal is where devices are easily applied to non-competent third parties such as children. This is most likely to be the case when the device is likely to be used in unmonitored settings or is intended for use on