REGULATORY HORIZONS COUNCIL

Neurotechnology Regulation

The Regulatory Horizons Council

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Foreword

From Parkinson's to Alzheimer's, depression to stroke rehabilitation, rheumatoid arthritis to cardiac illnesses, neurotechnology is an umbrella term that encompasses a wide range of devices that have the potential to significantly improve the lifestyle of thousands of people suffering from different kinds of health conditions in the UK and worldwide. Clinical interventions have seen a completely paralysed man with amyotrophic lateral sclerosis (ALS) type on a screen using his thoughts alone, a man with a severed spine walk again, and a blind woman recognise forms and letters, all capturing the imagination of the scientific community and wider society.

Neurotechnology has already had a significant impact on patients with otherwise intractable conditions. For example, cochlear implants have now restored functional hearing to an estimated 1 million patients worldwide. Thanks to continued research advances, across many engineering and scientific disciplines, there is great potential for further clinical and societal impact. However, neurotechnology also presents challenges**.** The brain is the basis of consciousness and the last resort of privacy and interventions raise questions of safety, effectiveness and data security. Moreover, in recent years, an increasing number of applications have been developed in the non-medical space that could redefine how we interact with one another and our environment in future. This includes devices that could enhance or optimise human performance in educational, work, and recreational settings.

The UK is very well placed to deliver on the potential of neurotechnology. Its thriving research ecosystem, recognised ethical research frameworks and centralised health service provide a valuable platform to develop, launch and assess new neurotechnologies. Nonetheless, almost **60% of respondents of a survey conducted by the Knowledge Transfer Network (KTN) rated 'difficulty navigating the regulatory pathway' as a moderate or major barrier to commercialisation.**

We therefore very much welcome this report by the Regulatory Horizons Council (RHC) on neurotechnology regulation. **Regulation does not necessarily have to be a barrier to innovation. It can also be a key enabler**. By addressing early on the challenges neurotechnology could pose in the future, the UK government has an opportunity to guide the development of the sector and unlock the potential of neurotechnology, on an equitable basis, so that it can benefit society as a whole.

With its report, the RHC builds upon the vision outlined by KTN in its '*Transformative Roadmap for Neurotechnology in the UK.'* We think **the RHC's recommendations will help establish a proportionate regulatory framework across medical and non-medical neurotechnologies that will encourage their rapid and safe development and commercialisation in the UK.** We also welcome the RHC's proposals for the

establishment of an anticipatory and agile governance system that aims to effectively address the challenges neurotechnologies may pose in the future.

We expect this report to provide a valuable framework that guides future conversations on neurotechnology regulation and governance. We therefore call on government departments to consider and implement the proposals outlined in this report.

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Co-chairs of Knowledge Transfer Network's Neurotechnology Innovation Network Advisory Board

1. Executive Summary

1.1. Why neurotechnology?

The human brain comprises over 100 billion neurons, and associated cell-types, that interact in a highly complex fashion to allow information from the outside world to be processed and behavioural responses to be coordinated. But this 'input-output machine' description ignores perhaps the most mysterious and important aspect of the brain's function: it is the organic seat of *consciousness*, of all the sensations, emotions and thoughts that characterise minds and make life worth living. Inevitably, brain-talk attracts attention.

Neuroscience research is gradually improving our understanding of the brain and nervous system and their inner workings. 'Neurotechnology' refers to a wide range of devices and techniques that have been developed to allow activity in the nervous system to be measured or directly altered (modulated) by the delivery of energy. Such devices – neurodevices – which can be implanted in neural tissue or worn (such as a headset), show great promise in treating a range of diseases and disorders of the nervous system. But their use is not restricted to medicine: neurotechnology uses in recreation, education, the workplace and to promote wellness/well-being have been described and devices are increasingly available in the direct-to-consumer space. The neurotechnology industry is growing and its future impact on our lives may be pervasive.

1.2. About this study

This Regulatory Horizons Council (RHC) report is a response to a Cabinet Office commission to make recommendations for regulatory reforms that could facilitate the rapid and safe development of neurotechnology. This commission reflects the belief that a thriving neurotechnology innovation sector offers considerable economic, health and social benefits. Over 10 months, the Council interviewed 66 stakeholders from diverse areas (Annex III) to create an evidence base for its recommendations. The scope of the investigation includes devices that *directly* measure or modulate brain and nervous system activity but excludes a whole host of activities and associated accessories that could be said to do so *indirectly*, such as use of apps on smart phones and tablets. The report makes fourteen recommendations for the regulation and future-facing governance of neurotechnology and also aims to add clarity to the diverse landscape of neurotechnology and its regulation.

1.3 Main findings and recommendations

The report begins with an in-depth survey of the neurotechnology terrain: of the kinds of uses of neurotechnology that exist in medical and non-medical settings and how these are

often classified, including a proposed taxonomy of applications (Figure 1) that can be used to guide future thinking about risk profiles and governance of neurotechnologies.

1.3.1 Establishing a proportionate regulatory framework for both medical and non-medical neurotechnologies

The report then considers how neurotechnology use is regulated in the medical and non-medical sectors and how this could be amended to be more agile, proportionate and innovation friendly.

Stakeholders interviewed identified the following 3 barriers to commercialisation: (1) unclear and difficult-to-navigate regulatory pathways to market, and insufficient pre-submission advice and guidance, (2) lack of capacity of regulators and Approved Bodies (ABs) and (3) onerous requirements to generate clinical evidence.

The Council would like to see the below actions taken by the Medicines and Healthcare products Regulatory Agency (MHRA) and ABs to facilitate the commercialisation of medical neurotechnologies. These recommendations reflect the RHC's commitment to ensuring that safe and effective devices are available to patients that need them, whilst recognising that regulation can set up and ossify unnecessary impediments to beneficial innovation.

Recommendation 1: The MHRA should build an enhanced culture of dialogue and early engagement between regulators and innovators.

Recommendation 2: The MHRA should supplement existing guidance on medical device regulation to incorporate specific neurotechnology challenges, explaining in more detail how the existing regulatory framework should be applied to these devices.

Recommendation 3: The MHRA should establish a dedicated sub-group of neurotechnology specialists, to advise on future regulatory adaptation for neurotechnologies.

Recommendation 4: The Department of Health and Social Care (DHSC) should 1) increase funding to the MHRA to sufficiently expand its capacity in neurotechnology device regulation and 2) consider options for increasing the capacity of Approved Bodies to deal with approval demands for neurotechnology devices.

Recommendation 5: The MHRA should consider options for facilitating generation and presentation of clinical evidence and avoiding unnecessary repetition of clinical trials to avoid negatively impacting innovation.

Recommendation 6: The MHRA, Approved Bodies and the NHS should work together to establish a sandbox programme for neurotechnology devices in the UK.

Stakeholders have argued that the distinction between medical and non-medical use cases is often merely linguistic and that manufacturers have some leeway to frame the intended purpose of a device so as to avoid medical device regulations. This can be particularly

concerning given that there is no regulator or government Department that explicitly oversees the regulation of non-medical use cases. As a result, under-regulation in non-medical use cases could lead to issues around safety (e.g. involving modulation of brain function), security, privacy, misleading claims and accessibility.

The RHC taxonomy (Figure 1) indicates that, in contrast to devices that only measure/record neural activity, uses of neuro*modulating* devices which *directly* deliver energy to neural tissue in order to alter neural activity raise questions of safety (including impacts on neuroplasticity) that apply whether the purpose is medical *or* non-medical. In this regard:

Recommendation 7: All brain modulation devices (invasive and non-invasive) should be regulated under the medical devices framework, irrespective of the purpose for which they are marketed, as proposed by the MHRA. This recommendation should also extend to devices that modulate all neural tissue, and not just the brain.

Recommendation 8: Non-invasive devices that *only record* neural information (i.e., neurorecording wearables) for non-medical purposes should not be regulated by the MHRA but should be compliant with general consumer protection, security, product safety, privacy and sectoral regulations, according to their use cases

1.3.2 Developing an anticipatory and agile governance framework that fosters responsible development and commercialisation of neurotechnologies in the UK

Of course, the risks and potential benefits associated with neurotechnology extend beyond the direct impact of a device on the human nervous system. Recording neurodevices entail the unprecedented collection of highly personal neurodata:

Recommendation 9: The Information Commissioner's Office (ICO) should clarify how the data protection framework would be applied to neurodata. The Council would like ICO's work on neurodata regulation to lead to the publication of guidance, drafted in collaboration with the neurotechnology community.

Recommendation 10: In reforming the UK Data Protection Framework, the Department for Culture, Media and Sport (DCMS) should (1) consider creating a new special category for neurodata to ensure their processing is limited under Article 9 of the GDPR and (2) assess whether existing protections are proportionate to the risks posed by different kinds of neurodata.

In respect of questions of accessibility:

Recommendation 11: DHSC should consider adopting policies to ensure that neurotechnologies are available to a wide patient base regardless of their personal characteristics.

The RHC acknowledges concerns expressed by stakeholders about the issue of support for implantable devices over the long-term.

Recommendation 12: As part of its plans to amend the UK Medical Devices Regulations to clarify and strengthen the requirement for manufacturers to implement a post-market surveillance and vigilance system, the MHRA should consider requiring manufacturers to present a plan describing how they intend to manage long-term implants installed in patients, as part of their submission to Approved Bodies.

The RHC has chosen a pragmatic approach in this report, focussing on near- to medium-term challenges and recommendations for existing regulatory structures, encouraging greater anticipation, agility and proportionality. It also recognises the need for structures that meet the future needs of this dynamic, fast-moving area of technology development:

Recommendation 13: HMG should ensure that senior accountability is set out to drive forward and coordinate thinking on neurotechnology regulation across government to enable its transformative potential by addressing existing leadership gaps and avoiding the risks of regulation that is disproportionate or fragmented. As part of this, the establishment of a cross-governmental network of regulators and government departments, including (but not limited to) the MHRA, ICO, Office for Product Safety and Standards (OPSS), DHSC, DCMS, the Department for Business, Energy and Industrial Strategy (BEIS) and the Ministry of Defence (MoD), allied to wide-ranging expertise from industry, academia, patient/user perspectives and medicine, could be considered.

At an international level, several organisations have started holding discussions on the future challenges of neurotechnology with the aim of developing an international governance framework.

Recommendation 14: HMG should play an active role in international initiatives on neurotechnology and proactively collaborate with other countries to develop an international governance framework that takes account of UK values in the future development of neurotechnology.

2. Introduction and Background

Neurotechnologies are already being used to treat conditions affecting the human brain, spinal cord (central nervous system (CNS)) and peripheral nervous system (PNS), including devastating diseases such as Parkinson's, amyotrophic lateral sclerosis (ALS) and dementia. The last example is a reminder that neurological disorders can disrupt not only sensory functions and motor skills, but also cognition (including memory) and mood. The incidence of neurobehavioural/neuropsychiatric disorders, including depression, anxiety, autism spectrum disorder and schizophrenia is thought to be increasing.[1] In 2001, the World Health Organisation (WHO) estimated that one in four people will be diagnosed with a neurological or mental disorder at some point in their lives.[2]

Devices based on neurotechnologies are also being used to treat conditions such as paralysis following trauma and complex, multi-factorial conditions caused by a combination of genetic and environmental factors, including diseases of ageing, where much research remains to be done to identify basic mechanisms in their aetiology.

The neurotechnologies designed to treat such conditions are becoming more effective and widespread. For example, neurotechnological interventions – both invasive (involving brain or spinal cord implants) and non-invasive (involving wearable devices) - have been reported for the treatment of stroke[3], Parkinson's disease[4], and epilepsy[5]. Indeed, recent examples of using neurotechnologies, several involving so-called brain-computer-interfaces (BCIs), have caught the attention of the media and the wider public imagination due to the extraordinary impact they have had on the lives of those they treat. One case study involved implantation of miniature electrode arrays into the brain of a completely paralysed man with ALS, enabling him to communicate by typing on a screen using the power of his thought alone.[6] Another described use of electrodes in the spinal cord to restore the ability to stand, walk, cycle and swim in three individuals with complete

[1] Vervoort et al (2021) A multifactorial model for the etiology of neuropsychiatric disorders: the role of advanced paternal age. *Pediatric Research* **volume 91**, pages 757–770

[2] World Health Organisation (2001). *Mental Disorders Affect One in Four People*, Vol. 180, 29–34.

[3] Micera et al (2020) Advanced Neurotechnologies for the Restoration of Motor Function. *Neuron* Volume 105, ISSUE 4, P604-620

[4] Arlotti et al (2021) A New Implantable Closed-Loop Clinical Neural Interface: First Application in Parkinson's Disease. *Front. Neurosci*. https://doi.org/10.3389/fnins.2021.763235

[5] Jarosiewicz & Morell (2021) The RNS System: brain-responsive neurostimulation for the treatment of epilepsy. *Expert Rev Med Devices* 18(2):129-138.

[6] Chaudury et al (2022) Spelling interface using intracortical signals in a completely locked-in patient enabled via auditory neurofeedback training *Nature Communications* volume 13, 1236 (https://doi.org/10.1038/s41467-022-28859-8) & Kelly Servick (2022) In a first, brain implant lets man with complete paralysis spell out thoughts: 'I love my cool son.' *Science.org* https://www.science.org/content/article/first-brain-implant-lets-man-complete-paralysis-spell-out-thoughts-i-love-my-cool-son

sensorimotor paralysis.[7] The small scale of these case studies indicates that much work is required to ensure such interventions are generally effective and widely applicable; but they are hugely promising.

Neurotechnology is predicted to become a significant market with the potential to generate substantial economic benefits, valued at US$17.1 billion globally by 2026, with the largest segments being neuromodulation, neuroprosthetics and neurosensing.[8] Growth potential is also reflected in the number of patents being filed. An Organisation for Economic Co-operation and Development (OECD) 2019 report found that more than 16,000 patents had been filed between 2008 and 2016 in health-related neurotechnologies across 10 key worldwide priority filing locations, with a significant upwards trend.[9]

The growth of the sector is currently driven by both private and public investment. The scale of government investment in neurotechnology can be difficult to ascertain. The Council is aware of significant government-driven investment in the United States, European Union, China, South Korea, Australia, Japan and Canada, with the US being the largest investor in absolute terms.[10] There is also increasing evidence of private investment in neurotechnology.[11] The *Crunchbase* database lists 757 neurotechnology start-ups, companies and organisations at the time of writing,[12] compared to the 400 listed in 2019.[13]

In the UK, UKRI invested a modest £9 million per year in neurotechnology-related research between 2011 and 2020.[14] The scale of investment and patent filing in the UK is generally smaller, both in absolute and relative terms, when compared with other countries.[15] Despite this, the UK is well positioned to drive forward the development of the sector and become a key international player in this space. Considerable progress has

[7] Rowald et al (2022) Activity-dependent spinal cord neuromodulation rapidly restores trunk and leg motor functions after complete paralysis. *Nat Med* 28**,** 260–271 https://doi.org/10.1038/s41591-021-01663-5 & Pallab Ghosh (2022) Paralysed man with severed spine walks thanks to implant. *BBC* https://www.bbc.co.uk/news/science-environment-60258620

[8] Neurotech reports (2022) The Market for Neurotechnology: 2022-2026 https://www.neurotechreports.com/pages/execsum.html

[9] Garden, H., et al. (2019), Responsible innovation in neurotechnology enterprises, OECD Science, Technology and Industry Working Papers, No. 2019/05, OECD Publishing, Paris, https://doi.org/10.1787/9685e4fd-en. Priority filing locations include: US, China, Korea, Japan, Patent Co-operation Treaty, Russia, Germany, European Patent Office, UK and Australia.

[10] KTN (2021) A transformative roadmap for neurotechnology in the UK https://ktn-uk.org/news/a-transformative-roadmap-for-neurotechnology-in-the-uk/#:~:text=%E2%80%9CThis%20roadmap%20sets%20out%20the,innovation%20in%20the%20coming%20decades.

[11] Royal Society (2019) iHuman: Blurring lines between mind and machine https://royalsociety.org/topics-policy/projects/ihuman-perspective/

[12] https://www.crunchbase.com/hub/neuroscience-companies Accessed 18.07.22

[13] Royal Society (2019) iHuman: Blurring lines between mind and machine

[14] KTN (2021) A transformative roadmap for neurotechnology in the UK

[15] Garden, H., et al. (2019), "Responsible innovation in neurotechnology enterprises", https://www.oecd-ilibrary.org/science-and-technology/responsible-innovation-in-neurotechnology-enterprises_9685e4fd-en

been made to establish an innovation infrastructure that can accelerate the commercialisation of neurotechnologies.[16] According to a survey from the Knowledge Transfer Network (KTN), 39% of UK respondents expect that it will take between 1 and 3 years to bring their neurotechnology devices to market.[17] However, the expected regulatory scrutiny of medical devices may well challenge this projected timescale.

Many of these devices will treat conditions that affect tens of thousands of people living in the UK, including Parkinson's, Alzheimer's, depression, heart and circulatory diseases, arthritis, strokes, etc.[18] Moreover, the UK's thriving research ecosystem and centralised health service provide a valuable platform to develop, launch and assess new neurotechnologies. Regulation, as argued throughout this report, can also play a very important role in removing unnecessary obstacles to the development and flourishing of the neurotechnology sector.

Nevertheless, uses of neurotechnology also raise difficult questions. Are they safe?[19] The human brain is arguably the most complex organ in the human body[20] - the ability of humans to think, speak, feel, see, walk and a host of other cognitive, sensory and motor functions depends on a delicate neurological system comprising over 100 billion neurons across the brain and spinal cord - and our knowledge of how its structure translates into function and how interventions may affect performance is significantly limited compared to other sites in the body. What of non-medical applications? Direct-to-consumer (DTC) non-medical neurodevices – which claim to improve wellness, well-being and quality of life[21]; performance during, and enjoyment of, gaming[22]; or focus during work- or education-related tasks[23] - are all increasing in profile and availability. Should they be regulated in a similar fashion to medical applications? Finally, the brain is an organ like no other: neural activity is the basis of consciousness, intentionality, personal identity, agency and free thought. Might neurotechnology negatively impact our mental privacy and freedom to choose? Might human augmentation through neurotechnologies become widespread? The

[16] KTN (2021) A transformative roadmap for neurotechnology in the UK

[17] KTN (2021) A transformative roadmap for neurotechnology in the UK

[18] KTN (2021) A transformative roadmap for neurotechnology in the UK

[19] Safety, and the importance of the patient voice, are key issues for medical devices regulation that are addressed further in the Independent Medicines and Medical Devices Safety Review chaired by Baroness Julia Cumberlege https://www.immdsreview.org.uk/Report.html and the RHC's report on Medical Devices (https://www.gov.uk/government/publications/regulatory-horizons-council-report-on-medical-devices-regulation).

[20] Aazmi A, Zhou H, Lv W, Yu M, Xu X, Yang H, Zhang YS, Ma L. Vascularizing the brain in vitro. iScience. 2022 Mar 17;25(4):104110. doi: 10.1016/j.isci.2022.104110. PMID: 35378862; PMCID: PMC8976127.

[21] Jen French (2020) Is Neurotech a passive or active tool for Wellness? https://medium.com/neurotech-network/is-neurotech-a-passive-or-active-tool-for-wellness-9ec5b79fa99a

[22] Lewis Gordon (2020) Brain-controlled gaming exists, though ethical questions loom over the tech. The Washington Post. https://www.washingtonpost.com/video-games/2020/12/16/brain-computer-gaming/

[23]Alleynah Veatch Cofas (2022) Energizing the brain: Combating worker fatigue using wearable neurotechnology. Medical Press. https://medicalxpress.com/news/2022-01-energizing-brain-combating-worker-fatigue.html

discipline of ‘neuroethics’, including ‘neurorights’ framings, has evolved in response to such questions.[24]

In this report, we focus on the regulation of neurotechnology, specifically the need for regulatory reform in this area, whilst acknowledging the exceptional nature of the brain and nervous system, and the broader issues raised. It develops an approach to the regulation of neurotechnology in the UK over the next 5-10 years that would allow this promising group of interventions to develop rapidly in the interests of patients and of consumers of non-medical applications, while ensuring high standards of safety, quality and efficacy.

2.1 Motivation

The RHC is an independent expert committee that identifies the implications of technological innovation, and provides the UK government with impartial, expert advice on the regulatory reform required to support its rapid and safe introduction. It is supported by civil servants from the Better Regulation Executive in the Department for Business, Energy and Industrial Strategy (BEIS). The Council was established as a result of the White Paper ‘Regulation for the Fourth Industrial Revolution’ published in June 2019.

Recent reports have identified the importance of neurotechnologies and associated opportunities. The 2020 report ‘*Towards a UK Neurotechnology Strategy*’[25] by KTN identifies the need to develop a UK ecosystem to accelerate commercial and economic opportunities from neurotechnology science and engineering research, one which can also make a valuable contribution to international leadership in this space. It recommends that the commercial sector, alongside regulatory bodies and the NHS, should be integrated at the earliest stages to ensure that translation to application and societal benefit are at the fore. The Royal Society’s 2019 report *iHuman*[26] also recommends accelerating the development of neurotechnologies in the UK, involving a multi-disciplinary collaboration across industries, an ‘early and often’ approach to addressing societal and ethical issues, potential use of regulatory sandboxes and a role for public dialogue in shaping the future of neurotechnology.

Against the backdrop of these reports, and in recognition of the fact that they did not make recommendations concerning UK regulation, the RHC was commissioned by the Cabinet Office to make recommendations for regulatory reform to facilitate the rapid and safe development of neurotechnology, reflecting the recognition that a thriving neurotechnology innovation system has potential to offer considerable economic, health and social benefits.

[24] For further information see Box 3 on neuroethics and https://www.humanbrainproject.eu/en/social-ethical-reflective/about/neuroethics-philosophy/
[25] KTN (2020) Towards a UK Neurotechnology Strategy
[26] Royal Society (2019) iHuman: Blurring lines between mind and machine

There is a high level of interest across government, following the UK's departure from the EU, in delivering UK regulatory systems that support the development of innovative technologies that safely meet human needs and desires and facilitate trading relationships within and beyond the EU. The UK therefore has the opportunity (and challenge) of leveraging its new freedoms to change how it approaches regulation, whilst avoiding additional layers of red tape that could result from regulatory divergence. This report will address questions about whether and how regulations for neurotechnology products, both medical and non-medical, will need to be adapted to enable safe and effective innovation, including: a) how to classify different uses of neurotechnology in order to highlight the aspects most relevant to their regulation; b) the regulatory landscape for medical applications of neurotechnology and any necessary changes; c) the regulatory landscape for non-medical applications of neurotechnology and recommendations for improvements to enable safe development of all neurotechnologies; and d) wider issues of governance for the responsible development of neurotechnologies over the longer term ensuring better coordination between policymakers and regulators.

The Council has relied on evidence acquired during stakeholder interviews to inform its recommendations (see Annex III). In making recommendations, the Council has sought to be:

Strategic – adopting a systemic, evidence-based approach to take account of interactions between innovators, regulators and stakeholders;

Focused - on high-impact recommendations that could aid safe development of the technology;

Innovative – identifying novel approaches to solving challenges;

Targeted – identifying the owners of recommendations and associated expectations, and implementation timelines;

Pragmatic – considering resource constraints and the wider political context within which government operates.

This report focuses on the near- to medium-term – the next 5-10 years. Beyond that timescale it becomes increasingly difficult to distinguish between likely scientific fact and fiction and making regulatory decisions based on very uncertain technology futures risks creating intractable regulatory problems for an innovative sector. There is no doubt that neurotechnologies are here to stay and in future they may radically transform clinical practice and human activities in ways that are difficult to accurately predict. The Council's response to this challenge has been to highlight the importance of new structures, systems and associated competencies to ensure ongoing agile and adaptive oversight in this continually developing area.

2.2 Classifying neurotechnologies to guide future discussions around regulation and governance

The RHC defines neurotechnologies as devices that can be placed inside, on or in close proximity to the human body and used for medical and non-medical purposes to *directly* record and/or modulate the activity of the nervous system. The inclusion of the word 'directly' in the definition means that devices that might *indirectly* record or modulate neural/neurobehavioural activity – including tablet computers, smart phones, watches, wristbands and computer interfaces (keyboards, track-pads) are excluded from the report's consideration. The Council acknowledges, however, the important roles that such devices may play in supporting the use of the devices that *are* the main focus of the report's recommendations.

2.2.1 Neurotechnology case studies

Stakeholder interviews and supporting research has revealed a growing market in neurotechnology applications, at various stages of development, as summarised below.

Implantable medical devices, in the CNS or PNS, can perform real-time recording or stimulation of neural activity. The aim of neural recording is to identify 'biomarkers' or 'signatures' of neural disease states through the use of common tools of clinical neuroscience such as signal processing and machine learning. 'Closed loop' devices can also directly modulate neural activity in real-time using electrical stimulation, in response to detection of such biomarkers, to return activity to a healthy state. The company *Bioinduction* has developed a miniaturised Deep Brain Stimulator that has been implanted in patients to help control Parkinson's disease and in future may be used to treat diseases of cerebrovascular origin such as resistant hypertension, stroke, Alzheimer's disease and vascular dementia.[27]

Real-time recording may also assist in understanding the mechanism and impact of a drug and support patient stratification. Companies operating in this space include *BIOS Health,* developing its Autonomic Therapy Initiative (ATI) for neural-cardiac therapy,[28] and *Galvani Bioelectronics,* developing an implant with the aim of treating rheumatoid arthritis through stimulation of the splenic nerve to drive immuno-modulation.[29] Record-only medical devices include those being developed by *Braingate*,[30] using intra-cortical microelectrode arrays with the aim of supporting early detection of epileptic seizures[31] and to record brain

[27] https://bioinduction.com/

[28] https://www.bios.health

[29] https://galvani.bio

[30] braingate.org

[31] Y. S. Park et al., "Early Detection of Human Epileptic Seizures Based on Intracortical Microelectrode Array Signals," in IEEE Transactions on Biomedical Engineering, vol. 67, no. 3, pp. 817-831, March 2020, doi: 10.1109/TBME.2019.2921448.

information from patients with tetraplegia to allow them to control a computer cursor and other assistive devices with their neural signatures.[32]

Several companies are also aiming to develop non-invasive medical neurotechnologies. *Neurovalens* is developing wearable devices (headsets) that electronically stimulate the hypothalamus and the associated autonomic nuclei of the brainstem. These areas are responsible for metabolic control, stress response and circadian regulation and *Neurovalens* is thus aiming to target treatment for Type 2 diabetes, obesity, insomnia, anxiety and PTSD.[33] *Flow Neuroscience* has developed a headset that delivers electrical stimulation to the dorsolateral prefrontal cortex of the brain's frontal lobe to allow at-home treatment for depression.[34] *Actipulse* is using transcranial, wearable neuromodulation devices that generate high frequency magnetic pulses with a view to treating neurodegenerative disorders such as major depressive disorders, tobacco addiction and Alzheimer's disease.[35] *Cumulus* is developing a home-usable electroencephalogram (EEG) headset paired with tablet-based functional assessments for the identification of biomarkers to support clinical trials in neurodegenerative and neuropsychiatric disease, which is a record-only wearable.[36]

Non-medical (consumer neurotechnology) wearables are being developed that can record and modulate. On its website, *Omnipemf* markets headsets that use pulsed electromagnetic field (PEMF) technology to expose the brain to electromagnetic waves and claims that these can help with meditation, sleep, relaxation, focus, and improved physical wellbeing[37]. By contrast, *Kernel's Flow* headsets aim to support functional neuroimaging (recording changes in brain blood oxygenation as a proxy for neural activity) using time-domain functional near-infrared spectroscopy (TD-fNIRS) imaging technology, intended for use in a wide range of applications such as meditation, gaming, learning and performance.[38] *Emotiv* markets its EEG headsets for similar lifestyle applications.[39]

Non-medical invasive applications are far less developed than wearables and the likely consumer appetite for such devices in future is unclear given the associated risks. US-based company, *Neuralink*, claims it is developing implants that will record electrical signals in the brain to help people with paralysis regain their independence and provide new kinds of neural information that could help treat a wide range of neurological disorders. However, the company's ambitions appear to cross over to the non-medical

[32] Simeral JD et al. Home Use of a Percutaneous Wireless Intracortical Brain-Computer Interface by Individuals With Tetraplegia. IEEE Trans Biomed Eng. 2021 Jul;68(7):2313-2325. doi: 10.1109/TBME.2021.3069119. Epub 2021 Jun 17. PMID: 33784612; PMCID: PMC8218873. Also see: https://www.braingate.org/clinical-trials/
[33] https://neurovalens.com/pages/technology
[34] https://flowneuroscience.com/home/treatment/
[35] https://actipulseneuroscience.com
[36] https://cumulusneuro.com/index.html#platform
[37] https://omnipemf.com
[38] https://www.kernel.com
[39] https://www.emotiv.com

space. In 2021, *Neuralink* famously shared the video of a macaque (an Old World monkey) playing the game Pong with its mind alone and it hopes its devices will eventually "expand how we interact with each other, with the world, and with ourselves."[40] The Council was not aware of any invasive neuromodulating devices being developed in the non-medical space at the time of writing.

It is, of course, possible that devices developed primarily for the consumer neurotechnology (non-medical) market might also have medical applications, and vice versa.

[40] https://neuralink.com/

Neurotechnology Taxonomies (BOX 1)

Notwithstanding existing legal provisions, there is no consensus on how best to classify medical and non-medical neurotechnologies and there was a perceived need among stakeholders consulted for a taxonomy to support classification of neurotechnologies for future regulatory purposes. Existing approaches include, but are not restricted to, technology-based, procedure-based, outcome-based and function-based taxonomies. A brief outline of these is given below.

Technology-based approaches classify according to the type of technology used by the device. Examples of technological categories suggested by stakeholders include brain-computer interfaces (BCIs), electroencephalography (EEG), functional near-infrared spectroscopy (fNIRs), transcranial electric stimulation (tES), deep brain stimulation (DBS), etc. The Council of Europe reviewed the different technologies used by neurodevices in its 2021 report[41], as did the OECD in 2018[42]. Most stakeholders engaged, however, were not satisfied with this overall approach, because it can fail to keep up with rapid technological advances or because its descriptions are too specific, requiring many more classes to capture existing (and anticipated) devices.

Procedure-based approaches focus on how the procedure impacts on the human body: such as whether it is invasive or non-invasive, long-term or short-term, reversible or non-reversible, etc. Outcome-based approaches classify according to outcome achieved, such as optimisation, enhancement, degradation or restoration. The latter approach has supporters in the Ministry of Defence (MoD)[43], but it is less clear whether it is useful in common civilian contexts, and some of the terms it uses, especially ‘enhancement’, were criticised by neuroethicists, given definitional issues, potential negative connotations for public perception and because it can be difficult to establish a biological baseline for the general population. Finally, function-based taxonomies, such as suggested by IBM[44], focus on what the device actually does, e.g., records neural activity, or modulates neural activity, or both.

[41] Ienca, Marcello. (2021). Common Human Rights Challenges Raised By Different Applications Of Neurotechnologies In The Biomedical Field. https://rm.coe.int/report-final-en/1680a429f3
[42] Garden, H. and D. Winickoff (2018), "Issues in neurotechnology governance", OECD Science, Technology and Industry Working Papers, No. 2018/11, OECD Publishing, Paris, https://doi.org/10.1787/c3256cc6-en.
[43]Development, Concepts and Doctrine Centre (2021) Human Augmentation – The Dawn of a New Paradigm https://www.gov.uk/government/publications/human-augmentation-the-dawn-of-a-new-paradigm
[44] IBM (2021). Privacy And The Connected Mind. https://fpf.org/blog/how-neurotechnology-can-benefit-society-while-leading-with-privacy-and-ethics/

These classification criteria have echoes in other innovative technologies. For example, in life sciences, the emphasis is often on two alternatives: (a) a 'process-based approach' where regulation is based on the technologies (genetic modification, genome editing, engineering biology) used to develop a range of innovative products; or (b) a product-based approach where regulation is based on the properties of the product itself and how it is used, particularly its risks and benefits. Of the above four taxonomies, the first (technology-based) can be seen as equivalent to a process-based approach, and experience in the genetic technologies area has seen a need for frequent and time-consuming revision of the regulatory system as new scientific and technical advances open up new innovation opportunities.[45] Some neurotechnology stakeholders wished to avoid a similar scenario. The other three taxonomies can be seen as product-based, focusing on the properties of the final product, as is the case for the RHC's proposed taxonomy.

2.2.2 The RHC's proposed taxonomy for neurotechnologies

There was widespread agreement amongst stakeholders regarding the value of a common neurotechnology taxonomy that is suitable for discussions on governance and potentially guiding future discussions on regulatory classification. 'Neurotechnology' is a broad term that needs to be broken down for conversations about its regulation to be meaningful but, as noted above, the taxonomies suggested so far present some limitations. Medical device classification rules, specified in the Medical Devices Regulation[46], are necessary for assessing the risks and requirements associated with an individual device but they were not considered to be as helpful by stakeholders for non-medical use cases or for guiding broader conversations on governance of the sector.

With future regulatory oversight its main concern, the RHC proposes the taxonomy below (see Figure 1), which focuses on primary properties of the end-products: whether the neurodevice is *invasive* (implantable) or not, and then whether it is used to directly *modulate* neural activity or not. The rationale in choosing these main decision points relates to the potential for organic, physiological or functional harm. The first distinction (invasive or not) acknowledges that any device that penetrates the body, either through an orifice or through the surface of the body, will cause damage to existing structures upon invasion and generates risks (of surgery to complex, sensitive tissue, of immune rejection, secondary infection, etc.) not raised by wearables. The second distinction (direct modulation of neural activity or not) acknowledges that the direct delivery of energy (electromagnetic, infrared, etc.) to neural tissue may have unpredictable consequences for

[45] Regulatory Horizons Council (2021). Regulatory Horizons Council report on genetic technologies. https://www.gov.uk/government/publications/regulatory-horizons-council-report-on-genetic-technologies

[46] European Commission (2015) Guidance document - Classification of Medical Devices - MEDDEV 2.4/1 rev.9 https://ec.europa.eu/docsroom/documents/10337.

its function, locally or more generally, potentially impacting on neural plasticity[47] and/or long-term activity trends. Other potential harms include the misuse of neurodata, which is not in an individual's (or society's) interest, and inappropriate or excessive use of a wearable device, even if it only records neural data, especially in vulnerable individuals. Other taxonomies highlight these to a lesser or greater extent. To capture these concerns, each category in the proposed taxonomy is associated with an additional set of questions: Is there a history of safe use? Does the use aim to enhance or optimise some function? Is the target tissue in the CNS or PNS? Is the use a case of concern? What is the duration of the intervention? Is it irreversible? What is its spatial and temporal resolution? These questions were viewed by stakeholders as the most important ones in assessing the risks of individual applications.

The Council proposes that this framework can be used to help regulators, policymakers, manufacturers, clinicians, patients and the wider public to think more broadly about the regulatory implications and risks posed by different *kinds* of neurotechnology application. The taxonomy is *not* intended to replace individual risk assessments, or the existing qualification and classification rules for medical devices embedded in legislation. Instead, it is offered as a framework to guide future conversations on how to regulate and govern the sector, with the aim of ensuring regulatory interventions are proportionate to the risks/benefits posed by different kinds of application, irrespective of whether their purpose is medical or non-medical.

[47] Neural plasticity can be defined as 'the ability of the nervous system to change its activity in response to intrinsic or extrinsic stimuli by reorganizing its structure, functions, or connections...this phenomenon is involved in learning and memory, brain development and homeostasis, sensorial training, and recovery from brain lesions.' See: Mateos-Aparicio, P., & Rodríguez-Moreno, A. (2019). The impact of studying brain plasticity. Frontiers in cellular neuroscience, 13, 66. https://www.frontiersin.org/articles/10.3389/fncel.2019.00066/full

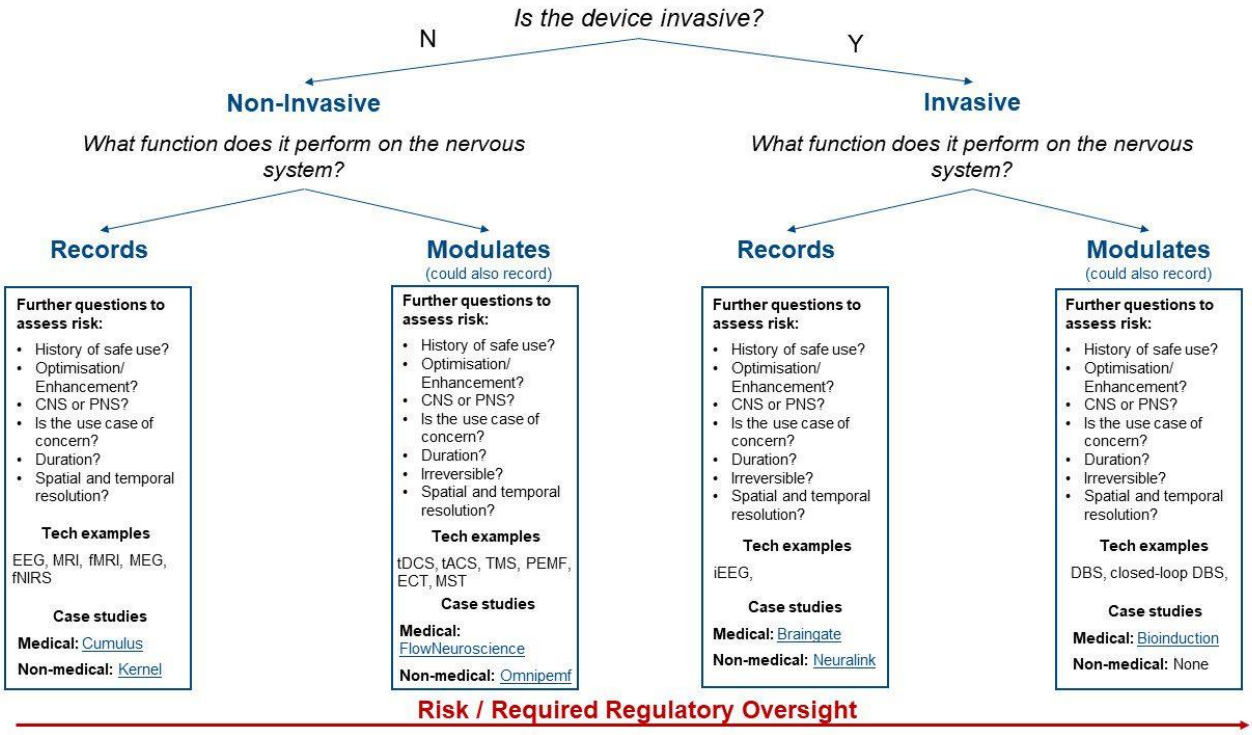

Fig 1. RHC suggested taxonomy to classify neurotechnologies according to their associated level of risk.

The following points are relevant to this taxonomy:

1. The taxonomy does not intend to capture every single device (now and in the future), but rather aims to provide a general framework to guide government and others in their approach to neurotechnology governance and future regulation, based on the nature and hazards of the product or application rather than the precise technology used to develop it.
2. The taxonomy should be understood as a dynamic document that can and should be amended or supplemented (if necessary) as neurotechnologies develop.
3. Even though the taxonomy suggests a general correlation between the identified categories and their associated level of risk (in Fig. 1, these are shown to increase from left to right), the correlation is not perfect. For example, it does not imply that, in future, there will not be modulating wearables that present a greater risk to the user than implantable devices that only record; or that modulation by implantable devices is always riskier than modulation by wearables. Rather, at a general (probabilistic) level, recording implantables are likely to be riskier than modulating wearables, and so on.
4. The boundaries between the categories can be blurred. Recording wearables can also modulate brain function through 'neurofeedback', even though this is not done through the *direct* provision of energy.[48]. For instance, the company *Brainboost* pairs the insights provided by EEG wearables with an activity programme

[48] 'Neurofeedback' is a closed loop approach which uses self-governed or volitional neuromodulation, the resulting change or alteration in brain function overlapping with operant conditioning and human learning.

comprising virtual reality, movies, music/sounds and games to 'train' the brain.[49] As this kind of neuromodulation relies on visual and/or audio training programmes, not dissimilar to normal human learning, it is considered to pose fewer and different risks from the direct provision of energy through electric or magnetic currents, hence the distinction between the two categories. Nonetheless, certain neurorecording technologies, such fNIRS, rely on the provision of energy to record neurodata. However, it remains unclear whether their impact on brain plasticity is comparable to that caused by other modulating technologies and there is no consensus within the scientific community on how to classify them. Further investigation is needed to determine whether such devices can be considered to modulate brain function and, if so, require classification as such.

One implication of this *single* proposed taxonomy for classifying all neurotechnologies is clear: whilst the existing regulatory framework draws a sharp distinction between medical and non-medical use cases, the Council believes that some devices intended for non-medical uses may pose similar risks to those intended for medical application and are therefore deserving of similar regulatory oversight.[50]

[49] https://brainboost.de/en/

[50] For further information on how to regulate medical vs non-medical neurotechnologies see recommendations 7 and 8 of the report.

3. Methodology

The findings and recommendations of the RHC report have been informed by stakeholder engagement and a literature review initiated in October 2021 following Cabinet Office's commission. The Council engaged with 66 stakeholders in three phases:

1. **Scoping –** between October and November 2021, the Council undertook literature searches and engaged with leading UK neurotechnology experts identified through Knowledge Transfer Network (a part of UK Research & Innovation, a non-departmental public body) and other government bodies to discuss the main regulatory challenges and approaches to removing any unnecessary impediments to the development of neurotechnology, and to define the scope of the report.
2. **Evidence gathering –** between November 2021 and April 2022, the Council probed further the areas of focus identified as part of the scoping exercise by organising interviews and roundtables grouped according to the kind of stakeholder (businesses, academia, clinicians and ethicists). A roundtable was also held to discuss the regulatory implications of the public dialogue on neural interfaces commissioned by the Royal Society in 2019.[51] The interviews followed a semi-structured approach and the Council then undertook a thematic analysis of the readouts produced to identify the main findings.
3. **Testing findings and recommendations –** between April and July 2022, the Council finalised its draft recommendations to government, based on associated harm/benefit considerations and the 5 criteria outlined on page 12 of this report. Many of the recommendations were based on stakeholder suggestions and the Council held a workshop to rank these according to their impact, ease of implementation and how innovative they were, to allow prioritisation. The draft recommendations were shared with regulators and government departments that would be responsible for implementing them and with a small group of external stakeholders, and their comments are reflected in the final report. However, responsibility for the recommendations should be attributed to the Council and they do not necessarily represent the views of the stakeholders consulted.

The stakeholders engaged included government Departments and regulators, businesses, clinicians, patient organisations, investors, Approved Bodies (ABs), neuroscientists, neuroethicists, learned societies such as the Royal Society and international organisations such as the OECD and the Council of Europe. A full list of stakeholders and acknowledgments can be found in Annex III.

[51] Further information on the RHC's approach towards public engagement can be found in Annex I.

4. Establishing a proportionate regulatory framework for both medical and non-medical neurotechnologies

4.1 Regulating medical neurotechnologies

Broadly, a medical neurotechnology device is defined as a product whose purpose is to diagnose, prevent, monitor, treat or alleviate neurological disease or injury. Currently, medical devices in the UK are regulated under the Medical Devices Regulation 2002.[52] The existing regulatory framework establishes four classes of general medical device (I, IIa, IIb and III), depending on the risk posed, and sets out the corresponding level of regulatory oversight.[53] The class to which a medical device belongs depends on a series of factors, including treatment duration, invasiveness, chemical activity, etc. In the UK, wearable neurotechnologies generally fall under class IIa or IIb, and invasive neurotechnologies fall under class III.[54]

Medical devices that fall under classes IIa, IIb or III must undergo a conformity assessment process managed by an Approved Body (AB), organisations designated by the MHRA to assess whether manufacturers and their medical devices meet the regulatory requirements for obtaining the UKCA marking.[55] As part of the designation process, the MHRA reviews an AB's systems and procedures, its structure and governance, Quality Management System, resources and processes. The MHRA may also sample client files for review during Annual Surveillance Audits, observe an AB's audit of a manufacturer, or undertake a direct audit of the manufacturer if they have cause.

Almost sixty percent of respondents in a survey conducted by KTN rated 'difficulty navigating the regulatory pathway' as a moderate or major barrier to commercialisation.[56]

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[52] The Medical Devices Regulations (2002) https://www.legislation.gov.uk/uksi/2002/618/contents/made

[53] In vitro diagnostic devices (IVDs) are classed differently. For further information see: MHRA (2020). Medical devices: how to comply with the legal requirements in Great Britain. https://www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements

[54] Based on European Commission (2015) Guidance document - Classification of Medical Devices - MEDDEV 2.4/1 rev.9 https://ec.europa.eu/docsroom/documents/10337. However, the EU Commission has outlined a proposal to class brain modulation devices as class III devices under the new EU MDR. For further information see: Draft Implementing Regulation laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12972-Medical-devices-reclassification-of-products-without-an-intended-medical-purpose_en

[55] MHRA (2020). Medical devices: how to comply with the legal requirements in Great Britain.

[56] KTN (2021) A transformative roadmap for neurotechnology in the UK

These concerns were echoed by many of the stakeholders interviewed by the Council. On the other hand, findings from the public dialogue on neural interfaces commissioned by the Royal Society show that the public is broadly very supportive of neurotechnologies used for medical purposes[57] and some patients were particularly frustrated by the slow speed of regulatory processes and thought that much could be learnt from the experience of more rapid approvals during the COVID-19 pandemic. Several attendees at the RHC public engagement roundtable thought that there would be merit in streamlining regulatory processes to accelerate the development and commercialisation of neurotechnologies (whilst ensuring safety) given the positive public attitude towards them. In making these proposals, stakeholders aimed to make regulations easier to navigate, understand and comply with in order to accelerate access to market without necessarily eliminating or reducing regulatory requirements.

Nonetheless, many stakeholders spoke positively about the work of the MHRA and their relationship with the regulator. The Council recognises the MHRA's commitment to developing innovation-friendly regulation, as exemplified by the rapid approval of the COVID-19 vaccines. However, this report focuses on identifying and addressing the regulatory barriers that are impeding the development and commercialisation of new and potentially beneficial neurotechnologies in the UK. The stakeholders interviewed identified the following barriers in the conformity assessment process for achieving UKCA marking.

4.1.1 Unclear and difficult-to-navigate regulatory pathways to market, and insufficient pre-submission advice and guidance

Under the existing regulatory framework, a neurodevice is classified as a medical device if it will be used to diagnose, prevent, monitor, treat or alleviate neurological disease or injury.[58] However, many of the businesses interviewed argued that it can be unclear what counts as a medical purpose, especially when the same device can serve different purposes depending on context. For example, some devices used to influence performance and optimise lifestyle (promote exercise, better sleep, concentration) can also be used for diagnostic and therapeutic purposes in certain scenarios.

Similarly, manufacturers sometimes struggle to identify the regulations and processes that apply to their device. Generally, the highest risk class should be applied to a device that is made of individual components that fall under different regulatory classes.[59] However, submissions can become more complicated when components are subject to different standards and regulations and could be treated as independent devices, but nonetheless form part of the same treatment. For instance, an innovator was asked to submit separate

[57] Anita van Mil et al. (2019) From our brain to the world: views on the future of neural interfaces. Hopkins Van Mil. https://royalsociety.org/-/media/policy/projects/ihuman/public-engagement-full-report.pdf?la=en-GB&hash=5B6417E1881961853318F4CD570CA07A

[58] MHRA (2021). Borderlines with medical devices and other products in Great Britain. https://www.gov.uk/government/publications/borderlines-with-medical-devices

[59] COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices. Annex IX. Implementing Rules.

applications for a treatment that combined optogenetics and neuromodulation and thought that a 'combinational product' category could be helpful to accommodate such case. Some manufacturers also reported difficulties when dealing with software in combination with a physical product.

Most manufacturers commented that neither the MHRA, nor the ABs offer sufficient pre-submission guidance and advice on these matters. However, the MHRA has published many guidance documents on what counts as a medical device and the relevant regulatory pathways to market.[60] Similarly, the British Standards Institution (BSI) has a Compliance Navigator web-based platform that helps manufacturers search for and interpret relevant regulations for their device.[61] Innovators commented that, while these resources helped them to navigate the relevant expectations, they did not provide enough advice on how to meet them. The perceived lack of guidance could also be a result of the lack of awareness of available resources amongst manufacturers. For instance, MHRA has an Innovation Office, but most of the stakeholders interviewed did not know of its existence.[62]

Researchers and manufacturers clearly expressed a desire for more tailored advice and dialogue, on a case-by-case basis, on top of the generic guidance documents and services currently available and described above. This is especially important in a complex area such as neurotechnology, where general guidance may be insufficient due to the lack of previous case studies and the number of borderline cases.

The need for advice on a case-by-case basis could be addressed by ABs given their role in assessing and approving medical device applications as part of the conformity assessment process. Indeed, by its very nature, the conformity assessment process involves engagement between ABs and the manufacturer. It is rare for a technical file to be completed on a first pass and often the necessary information is gathered as part of an iterative process; but it can also be the case that the application is rejected if the manufacturer fails to provide sufficient information.

However, ABs do not currently answer the more fundamental question that manufacturers ask at the beginning of the development process: "what information do I need to generate that will be sufficient to satisfy an Approved Body assessment?" Receiving support in answering this question early on in the development process could reassure manufacturers that their strategy for generating data to support market access is sufficient,

[60] UKRI has compiled a list of all the guidance documents available for medical devices. See: https://www.ukri.org/councils/mrc/facilities-and-resources/find-an-mrc-facility-or-resource/mrc-regulatory-support-centre/developing-healthcare-products/medical-devices-and-in-vitro-diagnostics/. Moreover, MHRA also has the following email address available for consultations: Devices.regulatory@mhra.gov.uk.

[61] https://compliancenavigator.bsigroup.com/

[62] The Innovation Office is also referred to as the Innovation Accelerator. For further information please see: https://www.gov.uk/government/publications/innovation-accelerator/innovation-accelerator

provide certainty that can help attract investment and reduce the risk of having to perform additional clinical trials further down the line.

Nevertheless, current device designation rules do not contemplate this function[63], and BSI argues that paragraph 1.2.3(d) of Annex VII of the EU Medical Devices Regulation (EU MDR)[64] applies in this context and prevents them from providing this kind of service in the UK. Indeed, tailored advice on individual applications, including on the kind of information that is needed to gain approval, could undermine the function of ABs in the approval process by giving rise to conflicts of interest.

The lack of support in this context is an example of what some refer to as 'the innovation gap' and many manufacturers reported dedicating a lot of resources and time to consultants, in order to understand how to meet regulatory expectations. Addressing this gap could help encourage investment in the sector. Knowing how long it will take to approve a new device, how likely it is to be approved and how much the entire process is likely to cost are key factors that investors identified as being critical to inform investment decisions. Notwithstanding these points, stakeholders also highlighted the importance of advice and engagement going beyond matters related to regulatory compliance. Too many products 'limp' over regulatory hurdles and manufacturers then face the challenge of persuading purchasers/commissioners to use their product. It is therefore important that manufacturers seek advice not only on the available regulatory pathways, but more broadly on their routes to market.

> **<u>Recommendation 1:</u> The MHRA should build an enhanced culture of dialogue and early engagement between regulators and innovators** by (1) providing non-binding feedback on partial submissions before submission of a full application to an AB, (2) producing guidance on how and when to engage with regulators, (3) engaging more and earlier with innovators to increase awareness about available support resources and (4) enabling the innovator to make technical changes to the product to increase the likelihood of its achieving regulatory approval.
>
> MHRA currently provides high-level advice to manufacturers on matters such as whether their device is a medical device, its likely classification and where

[63] MHRA (2020). Guidance: Approved bodies for medical devices. https://www.gov.uk/government/publications/approved-bodies-for-medical-devices/approved-bodies-for-medical-devices#guidance

[64] 1.2.3(d) of Annex VII REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC: "The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not: (d) offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of devices or processes under assessment."

additional support and resources can be found. However, MHRA does not currently provide the tailored scientific advice that is needed to close the 'innovation gap' described above and that ABs cannot address as part of the conformity assessment process. This contrasts with medicine license applications for which MHRA currently offers scientific advice to guide the approval process.[65] The MHRA's ability to provide the desired advisory services was limited when it formed part of the EU's conformity assessment system, since its advice could not diverge from that provided by other national competent authorities across the EU. Following the UK's departure from the EU, the MHRA has an opportunity to increase the attractiveness of the UK market by offering the required advice and support to manufacturers seeking to commercialise and develop their products in the UK.

When considering different options for increasing the levels of advice and support it provides to manufacturers, the MHRA could build on the experience of the US Food and Drug Administration (FDA) Q-submission program, which was praised by many of the stakeholders interviewed. This programme allows manufacturers to send their pre-submissions to the FDA for comments on specific questions, in preparation for their application, with responses due within a time frame of 75 to 90 days. Manufacturers can also schedule a follow-up meeting with FDA representatives to discuss the feedback provided.[66]

These services could be provided as part of the newly established MHRA Innovation Office, which seeks to provide innovators and developers with greater access to MHRA scientific expertise, regulatory guidance and enhanced advice and signposting.[67] As part of this programme, the MHRA is planning to establish 'innovation surgeries' that provide steers to manufacturers through shorter and sharper interactions. The Council welcomes this initiative but believes there is room to provide more specific and bespoke scientific advice on individual applications, in a manner similar to that currently provided for medicines and as described above. This would be particularly helpful to smaller companies that are less likely than larger companies to have legal departments with the necessary regulatory expertise.

MHRA argued that there is an appetite to provide more support and advice to manufacturers, but their ability to implement this programme could be limited by: (1) perceived conflicts of interest, since those offering specific advice cannot be the same individuals that regulate the product; (2) limited resources, since it is a time-

[65] MHRA (2014). Medicines: get scientific advice from MHRA. https://www.gov.uk/guidance/medicines-get-scientific-advice-from-mhra#:~:text=You%20can%20ask%20for%20scientific,for%20a%20variation%20to%20an

[66] See FDA guidance documents: Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program and FDA slides

[67] See https://www.gov.uk/government/publications/innovation-accelerator

intensive process, and the market is rapidly growing; and (3) risk of liability, as the advice could have legal implications and MHRA could be sued as a result.

The Council recognises that this proposal is resource-dependent. ABs such as BSI have approximately 10 times the number of staff of MHRA working on medical devices.[68] Even though the MHRA would not have to replicate AB capacity to provide more tailored advice and support to manufacturers (since they would not have to emulate the functions of a Conformity Assessment Body to do so), the Council recognises that the MHRA would still likely have to increase the size of its organisation and/or partner with ABs to leverage their pre-market assessment expertise and capacity in some form. Advice provided through the USA's Food and Drug Administration's (FDA) Q-Submission programme is free of charge, but the MHRA could also consider charging larger manufacturers for the tailored advice provided, whilst establishing a fee waiver for Small and Medium Enterprises (SMEs), to mitigate the potential resource implications. Indeed, the MHRA is already permitted to charge for scientific advice provided on medicines applications and has set up a fee waiver for SMEs in this context.[69]

Conflicts of interest would be less likely than if ABs were providing the tailored advice, since MHRA is normally not directly involved in the approval of medical devices as part of the conformity assessment process. Liability concerns could be mitigated through the establishment of appropriate disclaimers and by ensuring that MHRA staff received adequate legal training and support. The Department for Health and Social Care (DHSC) is also expected to have a role in supporting the MHRA in establishing this new service by ensuring that they are adequately resourced and able to provide the necessary legal advice.

Recommendation 2: The MHRA should supplement existing guidance on medical device regulation to incorporate specific neurotechnology challenges, **explaining in more detail how the existing regulatory framework should be applied to these devices.** This could include clarifying the distinction between medical and non-medical use cases, highlighting the regulatory requirements that may apply to different neurotechnologies and outlining the recommended steps and factors that need to be considered by any newcomers seeking to place their product on the market, as well as signposting resources for getting further advice and support. It is important that the guidance is future-

[68] If compared to the number of staff MHRA has working on medical devices regulation. Nonetheless, it is important to highlight that BSI is the largest UK Approved Body and EU Notified Body. BSI's resources are not solely focused on the EU and span across all the global schemes that it operates under, principally as an EU Notified Body.

[69] Medicines: get scientific advice from MHRA

oriented, considering present neurotechnologies, but also signposts potentially significant opportunities and likely challenges arising in the next 10 years.

In developing new guidance, the MHRA should work closely with the stakeholder community to establish multidisciplinary partnerships and consult different institutes and companies to receive feedback. Stakeholders praised the MHRA's guidance on Software as a Medical Device[70] and FDA's guidance on Brain Computer Interfaces (BCIs)[71] as good examples from which a new document could take inspiration.

Recommendation 3: The MHRA should establish a dedicated sub-group of neurotechnology specialists, to advise on future regulatory adaptation for neurotechnologies. The group would provide the MHRA with the necessary expertise to ensure regulations are proportionate to the potential benefits and risks posed by different uses of neurotechnologies and work with ABs to implement measures to facilitate the approval process. Some of the questions considered in this report are technical and will require further clarification and periodic review as the applications, risks and potential benefits of neurotechnology are better understood. This includes questions around blurred boundaries between medical and non-medical purposes, the cybersecurity challenges of medical neurotechnologies, the impact of 'neurofeedback' on brain plasticity, blurred boundaries between recording and modulating devices or how medical device regulations should be applied to non-medical use cases (given the report's 7th recommendation to class all neuromodulation devices as medical devices irrespective of their purpose). There are also many future uncertainties given the nascent stage of the technology. It is therefore important that the MHRA is able to remain agile in updating the regulatory framework and issuing tailored advice and guidance, providing clarity to innovators in light of the latest evidence, to support the development of the sector.

The group could comprise a core membership, with co-opted members to address specific requirements depending on decisions to be made, along with input from neurotechnology specialists, experts in regulation of emerging technology, patient representatives, and representatives from industry and neuroethics. It is also important that the group remains outward-facing and that innovators can easily engage with it to highlight issues in navigating the regulatory framework or ask questions that require clarification. Ensuring that there is strong patient representation in discussions over medical uses regulation is also critical to its development.

[70] MHRA (2014). Medical devices: software applications (apps). https://www.gov.uk/government/publications/medical-devices-software-applications-apps

[71] FDA (2021). Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations

Given the sensitive and potentially transformative nature of neurotechnology, the RHC thinks it merits its own dedicated subgroup. However, the Council recognises that the MHRA, or another relevant organisation, may also wish to consider establishing similar specialist sub-groups for other potentially transformative technologies that could challenge the existing regulatory framework. The work of such groups could be coordinated by an Emerging Technologies Board with a horizon scanning function.

4.1.2 Lack of capacity of regulators and approved bodies

As first noted by stakeholders in the RHC Medical Devices report[72], ABs and the MHRA are under-resourced to deliver on current commitments. These capacity issues were acknowledged by BSI and MHRA, especially in relation to high-risk medical devices. In the EU, the number of Notified Bodies has also dropped from around 80 to 50 since the European Commission adopted stricter rules to control and oversee their designation process in 2013. [73] The number dropped even further following the implementation of the EU MDR and has now slowly increased back to 30 as of July 2022, although stakeholders still complain about the designation process being very slow.[74] BSI is one of the few ABs that can provide services across the board in the UK and it is the only AB at the time of writing that can process the approval of Class III medical devices in the UK and, therefore, of invasive neurotechnologies.

Capacity issues may be mitigated by the large number of EU Notified Bodies that are seeking to be designated as an AB in the UK. However, this is a long process and MHRA is introducing additional requirements to assess and designate ABs, following its consultation on the future regulation of medical devices in the United Kingdom.[75] According to the MHRA, their aim is to ensure that ABs in the UK are subject to the same high standards as in the EU and that EU Notified Bodies seeking to provide services in the UK have increased their capacity before being designated as an AB. In other words, they do not want the designation process for new ABs to become a 'rubber stamping process.' However, some stakeholders doubt whether MHRA has the necessary capacity to process all the applications and audit an increasing number of ABs in the UK. Oversight of the EU Notified Bodies is split across 28 national competent authorities, whilst MHRA would have to oversee by itself all the ABs that operate in the UK.

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[72] Regulatory Horizons Council (2021). Report on medical devices regulation. https://www.gov.uk/government/publications/regulatory-horizons-council-report-on-medical-devices-regulation

[73] Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0920 & MEDCERT. EU: Notified Body Numbers continue to fall.

[74] Nando Database. (Accessed 07.22)

[75] MHRA (2021) Consultation on the future regulation of medical devices in the United Kingdom. https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom

Even if the number of ABs is increased, it is unclear whether this will successfully address capacity concerns in processing approvals. Stakeholders told the RHC that prior to the introduction of the EU MDR, the EU Commission was concerned about the large number of very small Notified Bodies that had been established across the EU, as this made the regulatory landscape of medical devices extraordinarily complex and difficult to manage for regulators. It may therefore be more effective to increase the capacity of the sector by focusing the available resources and expertise on a few larger ABs, rather than spreading them across many smaller ones. However, the lack of competition between ABs could lead to higher prices and monopolistic practices, as predicted by some of the stakeholders interviewed. This issue deserves further consideration but falls outside the scope of this report on neurotechnology regulation.

Recommendation 4: The DHSC should 1) increase funding to the MHRA to sufficiently expand its capacity in neurotechnology device regulation and **2) consider options for increasing the capacity of Approved Bodies** to deal with approval demands for neurotechnology devices.

The RHC made a similar recommendation in its Medical Devices report published in 2021.[76] The Council would like to re-emphasise the importance of investing *now* in the capacity of the MHRA/ABs to address the demand, specifically, for removing unnecessary obstacles to progressing through the regulatory pathway for emerging technologies such as neurotechnology.

Whilst recognising other demands on the public purse, such targeted investment would be expected to provide significant benefits for the health and wealth of the nation in the medium and longer term through the promotion of responsible innovation and patient safety and by attracting commercial investment in companies developing neurotechnology products.

The Council also expects that the MHRA and ABs will adopt approaches to regulation that chime with those highlighted in the recent report from the RHC, 'Closing the Gap'[77], recognising how regulation can erect unnecessary barriers to beneficial innovation and acknowledging the need for collaborative, proportionate, adaptable, outcomes-focused and future-facing ways of working. Indeed, the costs of ensuring that regulatory systems are agile and proportionate will likely be amply repaid in benefits to the UK economy.

[76] Regulatory Horizons Council report on medical devices regulation (2021). https://www.gov.uk/government/publications/regulatory-horizons-council-report-on-medical-devices-regulation

[77] Regulatory Horizons Council (2022). Closing the gap: getting from principles to practice for innovation friendly regulation. https://www.gov.uk/government/publications/closing-the-gap-getting-from-principles-to-practice-for-innovation-friendly-regulation

As noted in the RHC Medical Devices report,[78] the Council does not seek to advise on the specific funding models that would best suit the MHRA and ABs, but notes that such models could include private sector funding. However, any review of funding should consider the issue of public trust. The Independent Medicines and Medical Devices Safety (IMMDS) Review reported that the role of industry funding in organisations responsible for advice and regulation is a major concern for patient groups.[79] It is clear that there is a need, on the one hand, to ensure that the regulatory system is adequately funded, whilst on the other to ensure that the mechanism for doing so protects the independence of the regulators, so that patients can be confident that their safety takes precedence.

4.1.3 Addressing onerous requirements to generate clinical evidence

Some academics argued that there is a risk of new and beneficial neurotechnologies failing early in the development process because companies are required to test their devices in the worst affected patients, who are also those least likely to benefit from the intervention.

Currently, healthcare institutions that manufacture general medical devices for use within that institution do not have to comply with medical regulations.[80] However, some manufacturers have complained about not being able to build a complex device within a healthcare institution unless they are associated with a university with manufacturing capability. The RHC welcomes MHRA's proposal to include, as part of the Healthcare Institution Exemption (HIE), academic institutes working with a healthcare institution to conduct a proof of concept or early feasibility study. This involves limited clinical investigation of a device early in development, typically used to evaluate the device design concept with respect to initial clinical safety, without any input from industry, and with no intention to place the device on the market. [81]

Many businesses reported not being able to reference in their submissions the regulatory documentation already submitted and approved for other, similar devices. In most cases, each test had to be repeated. For example, one company claimed that they were asked to provide a full technical file for their product, midway through the development process, even though they simply wanted to carry out a feasibility study. Their product was a non-

[78] Regulatory Horizons Council (2021). Report on medical devices regulation. https://www.gov.uk/government/publications/regulatory-horizons-council-report-on-medical-devices-regulation

[79] Independent Medicines and Medical Devices Safety Review chaired by Baroness Julia Cumberlege https://www.immdsreview.org.uk/Report.html

[80] MHRA (2020). In-house manufacture of medical devices in Great Britain. https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices/in-house-manufacture-of-medical-devices & MHRA (2021) Consultation on the future regulation of medical devices in the United Kingdom.

[81] MHRA (2021) Consultation on the future regulation of medical devices in the United Kingdom. Chapter 7, Section 46.

invasive device that had already been used in other research studies and in very similar contexts.

The Council also discussed with some of the companies interviewed the use of equivalence claims to facilitate market access for neurotechnologies that are similar to devices that have already been approved. *Flow Neuroscience*, a company that markets a brain-stimulation headset combined with a behavioural therapy app to allow at-home treatment for depression[82], gained market approval for its device prior to the implementation of the EU MDR by establishing equivalence to other devices that were already on the EU market. They argued that the technology on which their device relies, transcranial Direct Current Stimulation (tDCS), has been used for over a decade as an in-clinic treatment for depression.[83] In order to obtain the CE mark, they therefore had to establish equivalence to devices whose design focus was based on use in the clinic, whilst adding additional safety features to mitigate the risks associated with using their device outside the clinic. However, *Flow Neuroscience* argued that they would potentially not have been able to pursue the equivalence route under the more stringent requirements now included in the EU MDR. Without equivalence, they would have had to undertake expensive clinical trials at the beginning of the manufacturing process, which would have made it difficult to attract investment and would have seriously challenged the viability of the company.

In the UK, as part of its consultation on the future regulation of medical devices in the United Kingdom, the MHRA is planning to move beyond the equivalence requirements captured in the EU MDR by introducing requirements on ‘entire equivalence’ on a biological, technical and clinical basis.[84] The MHRA is also planning to add additional requirements for applicants seeking to claim equivalence to a device marketed by another manufacturer, including an obligation to have a contract in place to ensure that they have access to all necessary technical documentation and to generate data, post-market, for their medical device (except if the device is a Class I device).[85] In the case of implantable and Class III devices, the MHRA is also planning to add additional requirements for manufacturers, including an obligation to include data from their own clinical investigation unless the medical device has been designed by minor modifications of an entirely equivalent medical device already marketed with a sufficient clinical evaluation, already marketed by the same manufacturer, or when the medical device is on an exempt list of medical devices and the clinical evaluation is based on sufficient clinical data.[86] The

[82] https://www.flowneuroscience.com/product/overview/

[83] https://www.flowneuroscience.com/what-is-tdcs/

[84] MHRA (2022) Government response to consultation on the future regulation of medical devices in the United Kingdom. Chapter 7, Section 31.

[85] MHRA (2022) Consultation on the future regulation of medical devices in the United Kingdom. Chapter 7, Section 31.

[86] MHRA (2022) Consultation on the future regulation of medical devices in the United Kingdom. Chapter 7, Section 31.

Council understands that the MHRA is moving forward with these proposals, given concerns over the risk of 'product creep', whereby new devices on the market can, in practice, end up being very different from the devices to which they claimed equivalence.[87] Indeed, some of the stakeholders interviewed argued that, prior to the implementation of the EU MDR, manufacturers who did claim equivalence did so usually to the first-in-market device, subsequently making design changes that resulted in an entirely different product years down the line with unclear risks (as initial risks were based on assumptions of the equivalent device) and little data to support their safety (as they always leveraged the data of the first-in-market device).

In the context of neurotechnology, concerns over equivalence and the risk of product creep were also shared by BSI and some of the academics interviewed. Those criticising reliance on equivalence claims argued that it can be particularly concerning in the case of invasive neurotechnologies, given their direct contact with the human brain. In its 2013 report, the Nuffield Council on Bioethics cautioned against relying on other clinical investigations to demonstrate conformity, given the special nature of the brain, and recommended minimising the use of equivalence data. [88] The Nuffield Council argued that the condition of equivalence must be satisfied in relation to its effect, not only its purpose, performance and safety. Furthermore, clear justification for approving neurodevices on the basis of equivalence data alone should always be provided and open to scrutiny.

Nonetheless, further restrictions on the applicability of equivalence claims could have adverse effects on beneficial innovation. Innovation does not occur in isolation and commonly builds on the work of others. Regulators should therefore be able to ensure that innovators can easily reference already approved components, which have proven to be safe, whilst ensuring adequate protections are in place to avoid 'product creep'. The Council recognises this is a very complex debate that must be treated with care.

> **<u>Recommendation 5:</u> The MHRA should consider options for facilitating generation and presentation of clinical evidence and avoiding unnecessary repetition of clinical trials to avoid negatively impacting innovation** by (1) evaluating whether equivalence requirements are appropriately balanced against the class and risk of the device, in order to mitigate adverse impacts on innovation and (2) encouraging and supporting ABs to set up a programme similar to the FDA Masterfile System that allows applicants to reference another company's technical information without compromising their proprietary information.
>
> Annex 1 of MEDDEV 2.7/1, revision 4, outlines the clinical, technical, and biological characteristics that should be taken into consideration for the demonstration of

[87] MHRA (2022) Government response to consultation on the future regulation of medical devices in the United Kingdom. Chapter 7, Section 31.

[88] Nuffield Council on Bioethics (2013). Novel neurotechnologies: intervening in the brain. https://www.nuffieldbioethics.org/publications/neurotechnology

equivalence.[89] However, these characteristics are currently applied equally to all equivalence claims, regardless of the class of the device. The Council agrees that stakeholder concerns over 'product creep' are well founded, especially in the case of implantable neurotechnologies, class III devices and certain wearables, and justify more stringent equivalence controls. However, in the case of **lower risk** neurotechnologies, the potential for 'product creep' may be offset by the risk of unnecessarily inhibiting innovation in the sector. In some of these cases (and always excluding implantable devices and class III devices), less stringent equivalence requirements, or allowing partial equivalence claims, may be a more proportionate response to the risks that might arise as a result of 'product creep', especially when combined with post-market studies to monitor adverse events. Ensuring that the practice of claiming equivalence is robust *and* reasonable is a topic that deserves further consideration. The Council recommends that the MHRA evaluates whether equivalence requirements are proportionate to the class and risk of the device by conducting a study that explicitly considers the negative impacts that additional requirements may have on innovation.

The Master File System set up by the FDA in the US allows a company to share their technical documentation with the regulator and give permission to another manufacturer to reference it in their application, without giving them access to their proprietary information.[90] According to the stakeholders interviewed, the commercial sector would be very supportive of this kind of initiative, since it could avoid duplication of submissions and facilitate data sharing between manufacturers whilst protecting IP and trade secrets. It would also ensure that ABs have access to all the technical files necessary to assess the device as part of the conformity assessment process.

Even though Master Files are used in the US to avoid the repeated submission of data for the use of raw materials in medical devices, the initiative could also be helpful in the context of equivalence claims. The MHRA outlined in its consultation on the future regulation of medical devices in the UK a proposal to require manufacturers to have a contract in place when the device to which they are claiming equivalence is marketed by another manufacturer.[91] In doing so, the MHRA is seeking to ensure that manufacturers have access to all the necessary technical documentation but, in practice, this may be challenging to implement and severely limit the ability of manufacturers to make equivalence claims when they do not own the device. Whilst manufacturers may be open to ABs reviewing their technical documentation, they are unlikely to be willing to directly share their confidential information with another manufacturer to support their equivalence claims, since this could compromise their trade secrets. A Master File system could therefore ensure ABs have access to all the necessary technical documentation whilst overcoming concerns over sharing confidential information with another manufacturer by means of a contract.

[89] MEDDEV 2.7/1 REVISION 4. June 2016.

[90] For further information see: https://www.fda.gov/medical-devices/premarket-approval-pma/master-files

[91] MHRA (2021) Consultation on the future regulation of medical devices in the United Kingdom. Chapter 7, Section 31.

<u>Recommendation 6:</u> The MHRA, Approved Bodies and the NHS should work together to establish a sandbox programme for neurotechnology devices in the UK. Drawing on experiences from the Information Commissioner's Office (ICO) Sandbox Programme[92], the NHS Testbeds Programme[93], and the DiGA[94] (Digitale Gesundheitsanwendungen, 'Digital Health Applications') fast-track scheme in Germany, the suggested sandbox programme would provide an environment in which regulators and manufacturers can collaborate in a pre-competitive space to facilitate safe harbour discussions concerning neurotechnologies that do not have a well-trodden regulatory pathway and where the ability of MHRA to directly provide advice may be more limited.

Promising innovative devices that meet the essential safety requirements could be made available to patients on a small scale and during a one-to-two-year period, whilst data are generated to determine medical benefit. During this period, manufacturers could be reimbursed for the use of their devices and be issued a 'comfort from enforcement' notice, indicating that there will not be immediate regulatory action over any breaches of the existing medical devices regulations, as long as there is continuous engagement and communication between the manufacturer and the regulators, and any breaches are notified immediately. Similar to the FDA Breakthrough Device Designation,[95] eligible manufacturers would also benefit from

[92] In 2019, ICO launched its sandbox programme. Participants of the sandbox programme can expect not to be immediately prosecuted for any breaches in the data protection framework as long as a collaborative and cooperative dialogue is maintained with the ICO Sandbox Team. Participants also benefit from receiving tailored support and advice from ICO experts to embed 'data protection by design.' The programme is open to all organisations that intend to develop innovative services that use personal data, but ICO publishes the areas of focus they would be interested in working on to guide applications. For more information see https://ico.org.uk/for-organisations/regulatory-sandbox/the-guide-to-the-sandbox/

[93] NHS Test Beds are partnerships between businesses and NHS organisations (which can also include academia, local government and the third sector) that are established to test combinations of innovations (digital products and services) in a real clinical setting, improving patient care at the same or less cost. For further information see https://www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/test-beds/nhs-test-beds-programme/

[94] In Germany, patients are reimbursed when they purchase a Digital Health Application listed on the DiGA directorate. To be in the directorate, candidate applications need to prove they meet the necessary security, functionality, quality, data protection, data security and interoperability requirements as well as having a CE mark. They also need to prove they have a medical benefit but, even if they cannot, they can still enter the directorate for a period of 1 year (max 2) until the benefit is established through a comparative study. For further information see: DiGA and The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V (German FIDMD Guidance)

[95] In the US, some medical devices are eligible for the FDA's BDD, i.e. when a device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions and meets one of the following criteria: 1) it represents breakthrough technology; 2) no approved or cleared alternatives exist; 3) it offers significant advantages over existing approved or cleared alternatives; or 4) its availability is in the best interest of the patient. Beneficiaries of this exemption can enjoy expedited engagement with the FDA (including sprint discussions and engagement with senior management), receive help drafting a data development plan that may allow for more post-market over pre-market data collection, guidance on more efficient and flexible design of clinical studies, and priority review of submissions. For further information see: Breakthrough Devices Program and Breakthrough Devices Program FDA Guidance 2018.

expedited engagement with the MHRA and Approved Bodies to help them generate data and, if appropriate, meet all the requirements necessary to eventually obtain UKCA marking and gain full market approval. The sandbox programme would therefore not reduce the requirements with which manufacturers must comply, but would break down compliance into different stages and offer an environment to facilitate data collection and investment whilst ensuring safety. It would also allow the regulator to test its own regulatory processes in the face of a new technological application.

Establishing a sandbox approach and drawing on the successes of the FDA Breakthrough Device Designation was supported by academics, businesses and investors. Manufacturers argued that the initiative would allow them to innovate and get their products to market earlier, generating revenue and granting them more time to solve questions on wider approval and adoption. BSI also saw value in establishing sandboxes as a way of increasing dialogue between regulators and manufacturers and helping to identify how the device can deliver value and improve outcomes in the NHS.

This option could be considered alongside MHRA's proposal to create a Pathway for Innovative MedTech as part of its consultation on alternative routes to market. The alternative pathway would be available to devices according to the size of the patient population, the scale of innovation and the size of the manufacturer and would allow manufacturers to place their device in the market before obtaining the UKCA marking, under specific conditions. Manufacturers would still be required to obtain the UKCA mark after the pre-market approval phase.[96]

The Council has evaluated the likely impact of regulatory divergence when evaluating each of the recommendations on medical neurotechnologies suggested above. As many stakeholders pointed out, regulatory divergence could reduce the number of neurotechnologies being commercialised and developed in the UK, with resulting trade implications. Some stakeholders argued that the UK should be aiming to harmonise its regulatory framework with the United States, since emerging evidence shows that manufacturers may prioritise FDA authorisation over the CE mark following implementation of the EU Medical Devices Regulation (EU MDR).[97] However, other stakeholders argued that harmonisation with the EU should be prioritised. Indeed, some trade bodies and entrepreneurs are concerned that the transition from CE to UKCA marking might result in additional red tape that could hamper innovation and the commercialisation of beneficial products in the UK.[98] Divergence from the EU MDR could be particularly concerning given Northern Ireland's relationship with the rest of the UK.

[96] MHRA (2021) Consultation on the future regulation of medical devices in the United Kingdom. Chapter 14, section 73.

[97] Nick Paul Taylor (2022). US replaces EU as priority market for medtech industry: survey. MEDTECHDIVE. https://www.medtechdive.com/news/us-replaces-eu-priority-market-medtechs/620450/

[98] James Tapper (2022). Brexit red tape puts brakes on UK innovation and EU sales. The Guardian. https://amp.theguardian.com/business/2022/oct/29/brexit-red-tape-puts-brakes-on-uk-innovation-and-eu-sales

However, the Council has not identified any significant negative trade implications of the report's recommendations.

Finally, the Council notes that some of the above recommendations relate to broader, systemic issues in respect of MHRA regulation of medical devices. However, in this report, they reflect the points made by stakeholders *specifically* concerning the regulation of neurotechnologies in the UK. As noted above in the context of MHRA capacity, implementing these recommendations would make an important contribution to increasing innovation in this very important sector by removing unnecessary regulatory impediments.

4.2 Regulating non-medical uses of neurotechnologies

The commercialisation of neurotechnologies for non-medical purposes is still in its early stages and is limited by a paucity of evidence of effectiveness and accuracy, and the impact of design and trust issues. Many stakeholders argued that it will be difficult to justify use of invasive devices for non-medical purposes given the associated risks to brain tissue, and that most non-medical innovation will likely occur in the non-invasive space. Several stakeholders thought direct-to-consumer devices with narrow-use cases were likely to become available within the next 5 years.

There are already many examples of non-invasive neurotechnology applications being used or trialled in recreational, educational, work, wellness, and sport settings. More light-hearted case studies have also been described recently in the press. For instance, *L'Oréal* has partnered with the neurotechnology company, *Emotiv*, to help consumers find the fragrance that best suits their emotions using an EEG headset.[99] Similarly, BMW partnered with *Brainboost* at CES 2022 to showcase a car that can change its colour according to the user's brain activity.[100]

Non-medical case studies and use cases [BOX 2]

Gaming – A wide range of companies have been working to develop devices that aim to redefine how users interact with videogames. Applications being developed range from headsets that provide insights to improve the gaming experience, to BCIs that allow users to control aspects of the game directly with their brain.[101]

Education – In 2019, the US company *BrainCo* trialled an EEG headband in Chinese primary schools. The device records patterns of brain activity in real-time, with the intention of quantifying student engagement, aimed at allowing teachers to monitor student attention and personalise learning**.** The trial had to be discontinued due to opposition from parents.[102]

[99] L'Oreal (2022). L'Oréal, in partnership with global neurotech leader, Emotiv, launches new device to help consumers personalize their fragrance choices. https://www.loreal.com/en/press-release/group/press-release-scent--sation/

[100] BMW Group (2022). Colour change with the power of thought: The BMW iX Flow meets neuro-technology. https://www.press.bmwgroup.com/global/video/detail/PF0008914/colour-change-with-the-power-of-thought:-the-bmw-ix-flow-meets-neuro-technology

[101] See https://brainattach.com/ and https://www.next-mind.com/technology/. Also, Anthony Cuthbertson (2021). Valve is building brain-computer interface for fully-immersive video games, president reveals. Independent.https://www.independent.co.uk/tech/valve-brain-computer-interface-video-game-b1792225.html

[102] Michael Standaert (2019). Chinese primary school halts trial of device that monitors pupils' brainwaves. The Guardian. https://www.theguardian.com/world/2019/nov/01/chinese-primary-school-halts-trial-of-device-that-monitors-pupils-brainwaves

Workplace – Preliminary findings from researchers at Texas A&M University provide some evidence that transcranial Direct Current Stimulation (tDCS) can act as a countermeasure against fatigue in safety-critical workers, such as firefighters, nurses, and accident and emergency (A&E) doctors.[103]

Wellness – Applications are already being commercialised that claim to improve a person's focus, meditation practice or sleep patterns. Examples range from headbands to headphones, often paired with apps or training programmes that use neurofeedback to improve performance.[104]

Sport – Neurotechnology devices have been used to improve performance in professional sport. For example, Liverpool Football Club has been working with the neurotechnology company *Neuro11* to optimise player performance and train penalty-taking and set-piece delivery. The club's manager, Jürgen Klopp, dedicated Liverpool's 2022 FA Cup win to the neurotechnology company after winning the trophy on penalties.[105]

Under existing medical device regulations, whether a device is classed as a medical device depends on whether it is intended to be used for the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury. Stakeholders commented that the distinction between medical and non-medical use cases is not always clear cut. It is for the manufacturer to define the intended purpose of a device, and even though this should be construed objectively, and from the standpoint of the reasonably informed consumer, most stakeholders agreed that manufacturers have some leeway to design their product claims to avoid qualification as a medical device and thereby sit outside of medical devices regulations.[106] In interviews, stakeholders provided several examples of manufacturers

[103] Alleynah Veatch Cofas (2022). Energizing The Brain: Combating Worker Fatigue Using Wearable Neurotechnology. Texas A&M TODAY. https://today.tamu.edu/2022/01/20/energizing-the-brain-combating-worker-fatigue-using-wearable-neurotechnology/

[104] https://choosemuse.com/, https://neurable.com/headphones, https://brainboost.de/en/

[105] Zak Garner-Purkis (2022). Liverpool FC's Brain Games Are Just The Start Of A Neuroscience Revolution. Forbes. https://www.forbes.com/sites/zakgarnerpurkis/2022/03/26/liverpool-fcs-brain-games-are-just-the-start-of-a-neuroscience-revolution/?sh=3d12b0e4655f & James Olley (2022). Jurgen Klopp dedicates Liverpool's FA Cup final shootout win to neuroscience company. ESPN. https://www.espn.co.uk/football/story/4665493/jurgen-klopp-dedicates-liverpools-fa-cup-final-shootout-win-to-neuroscience-company

[106][106] This is an area MHRA is examining. MHRA maintains that manufacturers that claim that their device's intended purpose is non-medical, when it is *medical*, sit outside conformity and will be held to account. As part of the Government response to MHRA's consultation on the future regulation of medical devices in the United Kingdom, MHRA has outlined its intention to "bring into scope of the UK medical devices regulations, products for which a manufacturer claims only an aesthetic or another non-medical purpose, but which are similar to medical devices in terms of their functioning and risk profile." See section 1: https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom/outcome/chapter-1-scope-of-the-regulations

who had tried to frame the intended purpose of their device to avoid being classified as a medical device.

For example, *Flow Neuroscience*'s brain stimulation devices were required to go through the medical device approval process to be commercialised in the EU, as their intended purpose was to treat depression. By contrast, *Halo Neuroscience*'s device was initially commercialised without needing regulatory approval, because the company did not claim that it could be used to treat a particular medical condition; rather, they claimed that it could be used to improve general cognitive performance. Despite using very similar technology, the two products were subject to completely different regulatory requirements before the implementation of the EU MDR. When *Flow Neuroscience* acquired *Halo Neuroscience* in 2021, it is reported that they decided not to commercialise *Halo*'s products as wellness devices, given their associated risks. [107]

Whilst safety concerns clearly arise in medical uses of neurotechnologies, especially implantables, the neuro-taxonomy proposed in Figure 1 above makes it clear that concerns may also arise in the non-medical application space, due to risks of organic harm to users, caused by direct modulation of brain activity or by inappropriate data access and use. Moreover, the traditional harm-benefit analysis applied when evaluating the appropriateness of medical applications is more complex, and sometimes inapplicable, when it comes to non-medical uses. Findings from the public dialogue commissioned by the Royal Society in 2019 also show that, broadly, the public is more wary of non-medical use cases, since they struggle to understand the potential benefits and the problems these neurotechnology applications are trying to solve.[108] The question then arises: should non-medical neurotechnologies be regulated and how should we evaluate this very broad range of purposes (and devices) in respect of the risks presented? What alternatives to regulation exist for non-medical uses of neurotechnology that raise fewer concerns?

If uses of non-medical neurotechnologies are not required to comply with medical device regulations, they would still have to meet the requirements in place for other kinds of

[107] See: Laura Lovett (2021). Flow Neuroscience buys fellow brain stimulation company Halo. Mobihealthnews.https://www.mobihealthnews.com/news/flow-neuroscience-buys-fellow-brain-stimulation-company-halo, Flow Neuroscience (2021). Flow acquires Halo - a great step for the future of neuromodulation. https://flowneuroscience.com/content/wp-content/uploads/2021/02/Flow-Neuroscience-acquires-assets-of-leading-neuromodulation-company-Halo-Neuroscience-1-2.pdf, Colin Behrens (2021). Flow acquires brain stimulation technology developer Halo. MEDICALDEVICENETWORK.https://www.medicaldevice-network.com/news/flow-stimulation-technology-halo/#:~:text=Flow%20Neuroscience%20has%20acquired%20the,in%20an%20at%2Dhome%20setting, Alice Ferng (2018). Halo Neuroscience's Headset Zaps Your Brain To Train It. Medgadget. https://www.medgadget.com/2018/02/halo-neuroscience-neuropriming-headset.html, Rebecca Sohn (2020). Just because you can stimulate your brain with these headphones doesn't mean you should. Scienceline. https://scienceline.org/2020/03/just-because-you-can-stimulate-your-brain-with-these-headphones-doesnt-mean-you-should/

[108] Anita van Mil et al. (2019) From our brain to the world: views on the future of neural interfaces. Hopkins Van Mil. https://royalsociety.org/-/media/policy/projects/ihuman/public-engagement-full-report.pdf?la=en-GB&hash=5B6417E1881961853318F4CD570CA07A

consumer devices. However, the existing regulatory framework under this scenario is highly fragmented, with responsibilities split across different government Departments and regulators. Stakeholders were therefore particularly worried that *under-regulation* may occur in the following areas as a result:

4.2.1 Cybersecurity

Stakeholders expressed divergent views regarding the nature and extent of cybersecurity risks in the context of neurotechnology. Businesses thought that hacking, including inappropriate access to neurodata, is not currently a serious concern. Too much energy, they claimed, is invested in cybersecurity without there being much evidence of hacking of medical devices in the past.

However, a recent report from Internet of Things (IoT) cybersecurity company *Cynerio* has found that 53% of healthcare IoT devices used within hospitals have at least one critical vulnerability that could compromise patient safety, data confidentiality or service availability.[109] In the UK, the *WannaCry* cyber-attack in 2017 disrupted the work of at least 34% of NHS trusts in England. NHS England still does not know the full extent of the disruption and a National Audit Office investigation found that the attack could have been easily prevented by following basic IT security best practice.[110] Indeed, stakeholders interviewed pointed out that many neurotechnologies already have an operating system – and some can even be remotely programmed through the internet.

BSI also warned about the risks of downplaying cybersecurity challenges. Neurotechnologies are increasingly designed to allow remote access, with significant functional advantages, but with attendant concerns around cybersecurity. Even if the likelihood of a successful attack is low, the potential consequences of unconsented recording from, or interfering with, an individual's nervous system may be severe. Given the nascent stage of development of the sector, addressing cybersecurity concerns now, making data-collecting neuro-devices ‘secure by design’, offers an opportunity to avoid some of the challenges that have been posed by other digital technologies in the past and thereby build trust.

In their discussions with the Council, most stakeholders relied on medical examples to discuss the cybersecurity risks of neurotechnologies, since medical applications are generally more mature than non-medical. However, cybersecurity could be a particularly concerning issue for non-medical use cases because these kinds of applications are faced with less stringent regulations. Connectable, non-medical neurotechnology applications fall under the scope of the new Product Security and Telecommunications Infrastructure (PTSI) Bill, introduced in the Houses of Parliament by the Secretary of State for Digital,

[109] Cynerio (2022). Research Report: The State of Healthcare IoT Device Security 2022 https://www.cynerio.com/landing-pages/the-state-of-healthcare-iot-device-security-2022

[110] National Audit Office (2017). Investigation: WannaCry cyber attack and the NHS. https://www.nao.org.uk/report/investigation-wannacry-cyber-attack-and-the-nhs/

Culture, Media and Sport in 2021.[111] The bill was drafted in response to the security challenges raised by the increasing number of IoT technologies and provides new powers to specify and amend minimum security requirements, imposing new duties on manufacturers, importers and distributors to ensure the security of their products and making them liable for any breaches. Upcoming regulations will mandate minimum security requirements considered in the Code of Practice for Consumer IoT Security,[112] including (1) banning default passwords, (2) the requirement to have a vulnerability disclosure policy and (3) the requirement to ensure transparency about the length of time for which the product will receive security updates.[113]

However, some products, such as medical devices, will be exempt from having to comply with the PSTI Bill's requirements above as they are understood to require higher levels of protection, whilst the bill focuses on addressing the baseline security requirements of connectable products. If the 7th recommendation of this report were adopted, neuromodulating devices with no intended medical purpose would be classed as medical devices and therefore fall outside the bill, together with other medical neurotechnologies. However, this would still leave an increasing number of neurorecording wearables, used for a wide range of different purposes, under the scope of the bill. While the risks posed by these devices are arguably lower than those posed by other neurotechnologies, they are still vulnerable to security breaches that could result in illegitimate access to an individual's neural information. It therefore remains unclear whether the baseline protections considered in the bill will sufficiently address the security concerns raised by these non-medical neurotechnology applications. The provisions in the bill have been drafted with less risky devices in mind (such as smartphones, connected fitness trackers, appliances, and cameras), while the impact of security breaches in the case of neurotechnology applications can be higher, given their access to the brain's activities. Product-specific regulation that mandates additional security requirements on top of those considered in the PSTI Bill and that is tailored to the specific concerns raised by non-medical neurotechnologies may therefore be required in the future. This is a matter that deserves further research and consideration, and that should be kept under review by DCMS.

Even though medical neurotechnologies have to comply with vertical security requirements as part of the medical device regulations, there could also be security gaps in medical use cases. In the NHS, digital technologies need to comply with the ten data security standards created by the National Data Guardian, as well as with the Security of Network

[111] Product Security and Telecommunications Infrastructure Bill https://bills.parliament.uk/bills/3069

[112] Department for Culture, Media and Sport (2018). Code of Practice for Consumer IoT Security. https://www.gov.uk/government/publications/code-of-practice-for-consumer-iot-security

[113] Department for Culture, Media and Sport (2021). Product Security and Telecommunications Infrastructure (PSTI) Bill: Factsheets. https://www.gov.uk/government/collections/the-product-security-and-telecommunications-infrastructure-psti-bill-factsheets

and Information Systems regulations.[114] Moreover, NHS Digital has published guidance in this space for healthcare professionals procuring and deploying connected medical devices. [115] However, NHS Digital states on its website that existing guidance is more applicable to larger devices than to smaller ones, such as implantables, suggesting a gap in the guidance currently available. Indeed, some stakeholders argued that existing guidance does not address the bigger picture security risks associated with an increasing number of connectable and small medical devices.

4.2.2 Safety

Safety could be a concern not only for implantable devices but also for wearables, especially those that modulate neural activity, since their long-term effects on brain tissue and function remain unclear. UK product safety legislation requires manufacturers to ensure that products are safe before they are placed on the market, complying with all relevant legislation. A range of safety regulations are in place designed to deal with specific hazards, for example, risks of electrocution or fire, or to protect products from electromagnetic interference, which may affect performance or interfere with other electrical or radio equipment. Examples of regulations relevant to non-medical neurotechnologies are the Electrical Equipment Safety Regulations (2016)[116] and the Radio Equipment Regulations (2017).[117] Where products are not subject to product-specific regulations, they must in any case comply with the General Product Safety Regulations (2005), which require that all products be safe under normal or foreseeable use.[118] Product safety regulations are enforced by Local Authority Trading Standards and supported by the Office for Product Safety and Standards (OPSS) as the national regulator. As part of its functions, OPSS can oversee obligations on manufacturers, importers and distributors under relevant safety legislation, as well as recall products from the market if necessary.

However, product safety legislation does not specifically address the safety of the user in the case of neurotechnology applications, since it has not been drafted with these kinds of applications in mind. For example, whilst the Electrical Equipment Safety Regulations 2016 set out principal elements of the safety objectives for electrical equipment designed for use within certain voltage limits, they do not specifically consider, for example, the impact neurotechnologies may have on brain plasticity. In addition, designated

[114] The Network and Information Systems Regulations 2018 https://www.legislation.gov.uk/uksi/2018/506/made

[115] NHS Digital (2021). Cyber security guidance for healthcare professionals procuring and deploying connected medical devices. https://digital.nhs.uk/cyber-and-data-security/guidance-and-assurance/guidance-for-procuring-and-deploying-connected-medical-devices#suggested-guidance-for-cyber-security-of-connected-medical-devices

[116] The Electrical Equipment (Safety) Regulations 2016https://www.legislation.gov.uk/uksi/2016/1101/contents

[117] The Radio Equipment Regulations 2017. https://www.legislation.gov.uk/uksi/2017/1206/contents/made

[118] The General Product Safety Regulations 2005. https://www.legislation.gov.uk/uksi/2005/1803/contents/made

standards[119] play an important role in supporting manufacturers to meet their legal requirements by helping them to demonstrate that their products, services or processes comply with GB law. It should also be noted that unlike medical devices regulation, the applicable product safety legislation does not mandate any conformity assessment procedures for a third party to assess the safety of new devices before they reach the market. As a result, some stakeholders argued that additional protections may be needed in this space.

The Council believes that additional protections are indeed needed in the case of neurotechnologies that modulate neural activity through the *direct* provision of energy, hence the 7th recommendation suggesting that these devices be classified as medical devices. In the opinion of the Council, existing product safety legislation is proportionate to the risks posed by recording wearables at present. However, this is not to say that recording wearables pose no risks. Indeed, recording wearables can also be used to modulate neural activity without directly providing energy through 'neurofeedback', or rely on the provision of energy to the brain to record neural information. In future, the risks posed to brain plasticity by some recording neurotechnologies may be deemed comparable to those posed by modulating neurotechnologies. This is a matter that deserves further consideration and that should be kept under review as part of the Council's future governance proposal (Recommendation 13).

4.2.3 Misleading claims

In addition to concerns about safety, the effectiveness of many non-medical neurotechnology devices has not been established. Indeed, claims such as 'improved mental well-being,' 'increased focus and attention' or 'better mind/body/spirit integration' made by neurotechnology companies operating in the DTC space can be particularly challenging to verify.[120] Accuracy in the claims made about a device is important, both in terms of safety and consumer rights. For instance, consumers may be using these devices to treat mental health conditions, without success, instead of seeking appropriate medical advice and treatment. Ideally, there should, therefore, be no difference between what the product reports doing and what it actually does. This is particularly important considering the degree of 'hype' in the sector reported by many of the neuroethicists, neuroscientists and government stakeholders interviewed.

In the UK, the Consumer Rights Act 2015 (CRA) provides a broad framework that specifies consumers' rights and outlines the responsibilities of businesses in this space[121] and the Consumer Protection from Unfair Trading Regulations 2008 (CPRs) outline further

[119] https://www.gov.uk/guidance/designated-standards

[120] Statements taken from the website of DTC neurotech companies.

[121] Consumer Rights Act (2015). https://www.legislation.gov.uk/ukpga/2015/15/contents/enacted

rules to prevent consumers from being misled.[122] Generally, misleading practices that distort or are likely to distort the economic behaviour of the average consumer with regard to the product or service are banned by the CPRs. This includes prohibiting false or deceptive messages (concerning a product or its effects) as well as the omission of important information in order to mislead a consumer.

However, in contrast to medical devices, the accuracy of the claims made about non-medical neurotechnologies are not verified before they are placed on the market. Instead, enforcement relies on reports made by consumers or other manufacturers to local Trading Standards through Citizens Advice.[123,124] Trading Standards can also proactively monitor the market to identify non-compliant businesses, but funding has decreased significantly in recent years, and, in practice, reactive work (such as responding to complaints made) often predominates over proactive enforcement.

Alternatively, misleading claims may also be reported to the Advertising Standards Authority (ASA) in respect of the Advertising Codes.[125] As a self-regulatory agency funded by industry, ASA can act on non-compliance claims by naming non-compliant advertisers on their website and liaising with social media companies and search engines to remove their content.[126] Usually, most marketers quickly amend or withdraw non-compliant content following ASA's 'name and shame' strategies, but offenders can also be referred to Trading Standards when legal enforcement is required. Moreover, ASA can also set up intelligence-scanning functions for priority areas to proactively identify non-compliant marketers without relying on individual complaints, but neurotechnology was not one of these areas at the time of writing.

Any delay in enforcement entails a significant gap, between the launch of the product to market and any harm being identified, a period during which consumers can be negatively impacted. In the case of neurotechnology, it is the Council's view that the risk of harm arising from recording wearables does not merit imposing pre-market checks, hence the recommendation to class these devices as non-medical devices. Nonetheless, it is important to keep this decision under review and to ensure that Trading Standards have

[122] Beyond misleading claims, the CPRs also ban aggressive sales techniques as well as other conducts that fall below the level that may be expected towards consumers. For further information see https://www.businesscompanion.info/en/quick-guides/good-practice/consumer-protection-from-unfair-trading

[123] See https://www.gov.uk/consumer-protection-rights, https://www.which.co.uk/consumer-rights/regulations, https://www.citizensadvice.org.uk/consumer/scams/reporting-a-scam/

[124] The Competition and Markets Authority (CMA) is also responsible for ensuring businesses operate within the law and protecting consumers from, for example, unfair trading practices. However, its remit focuses on addressing market-wide issues rather than scrutinising individual complaints.

[125] See: Committee of Advertising Practice (2010). Non-broadcast Code. https://www.asa.org.uk/codes-and-rulings/advertising-codes/non-broadcast-code.html & Committee of Advertising Practice (2010). Broadcast Code. https://www.asa.org.uk/codes-and-rulings/advertising-codes/broadcast-code.html

[126] See: About the ASA and CAP https://www.asa.org.uk/about-asa-and-cap/about-regulation/about-the-asa-and-cap.html

appropriate enforcement powers and sufficient resources to proactively monitor the market and intervene to avoid harm to consumers. Publishing guidance, such as that issued by the ASA on efficacy claims made on homeopathic treatments[127], may also be helpful in clarifying what could be considered a misleading claim in the context of uses of neurotechnology.

Overall, stakeholders argued that non-medical devices may be under-regulated and that a levelling of regulatory requirements may be necessary, since the risk profile of a device used for non-medical purposes is likely to be very similar, if not identical, to that presented by its use for medical applications. In other words, whether a device is used either for medical or non-medical purposes is not an important determinant of its associated risks. However, some argued that it is important to identify the specific gaps in existing regulation and avoid hyperbolic claims that could result in excessive, damaging regulation. Unnecessary regulation of the non-medical space may increase the cost of useful and effective devices and harm smaller companies that produce them.

Recommendation 7: All brain modulation devices (invasive and non-invasive) should be regulated under the medical devices framework, irrespective of the purpose for which they are marketed, as proposed by the MHRA.[128]

This option aligns with the approach the European Union has taken towards regulating non-medical neurotechnologies in Annex XVI of the MDR.[129] Indeed, the European Commission has recently closed a consultation on its proposal to class all brain stimulation devices as Class III devices, since their use may modify neuronal activity in the brain in forms that have long-lasting impacts and unintended effects that may be difficult to reverse, including 'atypical brain development, abnormal patterns of brain activity, increased metabolic consumption, fatigue, anxiety, irritability, headaches, muscle twitches, tics, seizures, vertigo and skin irritation at the electrode site.'[130]

In addition, the Council thinks that the **MHRA should designate *all* neuromodulation devices as medical devices (and not only *brain* modulation devices, as currently**

[127] Advertisement Standards Authority (2020). Health: Homeopathy. https://www.asa.org.uk/advice-online/health-homeopathy.html

[128] MHRA (2021) Consultation on the future regulation of medical devices in the United Kingdom. Chapters 1, Section 2.1.

[129] REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Annex XVI.

[130] Draft Implementing Regulation laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12972-Medical-devices-reclassification-of-products-without-an-intended-medical-purpose_en

suggested), including devices that modulate the peripheral nervous system, since these can also pose comparable risks that are similar to their medical counterparts.

The Council believes that when designating all neuromodulation devices as medical devices, the MHRA should consider:

1. Keeping under review any requirements of the existing medical device regulations that are either not applicable or not proportionate when assessing low-risk 'wellness/well-being' devices;
2. Issuing guidance on how existing medical device regulations should be applied to non-medical use cases and prioritising engagement with manufacturers that did not previously have to comply with medical device regulations to help them better understand the regulatory pathways to market;
3. Working with existing and future Approved Bodies to increase capacity in processing the assessment/approval of the increasing number of DTC neurotechnologies that will likely be developed in the coming years, given existing capacity issues;
4. Amending the Health Institution Exemption to exempt researchers working in industry or academia on the proof of concept or early feasibility study of lower-risk, non-invasive, non-medical neurotechnologies from having to comply with all medical device regulations, even if they are not partnered with a health institution. This is to avoid limiting research on non-medical neurotechnologies as a result of such increased regulatory oversight;
5. Working with NHS Digital to draft additional guidance on the cybersecurity of small connectable devices. Existing guidance on the cybersecurity of medical devices will likely be unable to cope with an increasing number of neurotechnology wearables deployed within a wide range of use settings given its current focus on larger devices used in a clinical setting;
6. Clarifying the conditions under which equivalence claims between non-medical neurotechnologies and analogous medical neurotechnologies may be justified. The MHRA could follow the approach outlined in the EU MDR, whereby equivalence requirements are applied in the same way to medical and non-medical devices recognising that 'clinical benefit' should be reinterpreted as a requirement to demonstrate the effective performance of the device when it has a non-medical purpose.[131]

Recommendation 8: Non-invasive devices that *only record* neural information (i.e., neurorecording wearables) for non-medical purposes should not be regulated by the MHRA but should be compliant with general consumer protection, security, product safety, privacy and sectoral regulations, according to their use cases. This conclusion reflects the neurotechnology taxonomy described in Figure 1: the risk of negative impacts on neural function posed by devices that *only* record neural activity are not comparable to those of modulating devices.

[131] MDCG 2020-5. Clinical Evaluation – Equivalence, a guide for manufacturers and notified bodies.

The most pressing risks posed by non-medical, record-only wearables relate primarily to data privacy and are addressed by Recommendations 9 and 10 on mental privacy. As discussed in this section, the risks posed by these devices in relation to safety, cybersecurity and misleading claims are lower and do not merit a pre-market approval process and the sorts of competencies and experience provided by the MHRA and ABs. It is the Council's view that existing regulations (such as Product Safety legislation, the PSTI Bill in relation to cybersecurity and CRA and CPRs in relation to misleading claims) are a proportionate response to the challenges so far posed by non-medical recording wearables.

Some issues may still require further consideration, for example (1) ensuring Trading Standards have appropriate enforcement powers and resources to proactively monitor the market, (2) studying the impact neurorecording wearables may have on brain plasticity through neurofeedback and the provision of energy, and (3) determining whether product-specific regulation that mandates additional cybersecurity requirements on top of those considered in the PSTI bill is needed for non-medical neurotechnologies. These issues should be monitored and studied as the market develops and non-medical use cases and their associated risks are better understood.

It is also important to ensure that neurorecording wearables are being used for genuine non-medical purposes and that manufacturers are not using this option as a loophole to avoid medical regulatory oversight. For example, it is important to ensure that data collected by recording wearables marketed as non-medical devices are not then used for medical purposes. If they are, then this should be reflected in the intended purpose of the device, which should then be classed as a medical device. The MHRA, ASA and Trading Standards should work together to monitor whether manufacturers are misconstruing, intentionally or otherwise, the intended purpose of their device.

The suggested approach would have the following implications for the Council's neurotechnology taxonomy – all areas shaded in green would be regulated as medical devices:

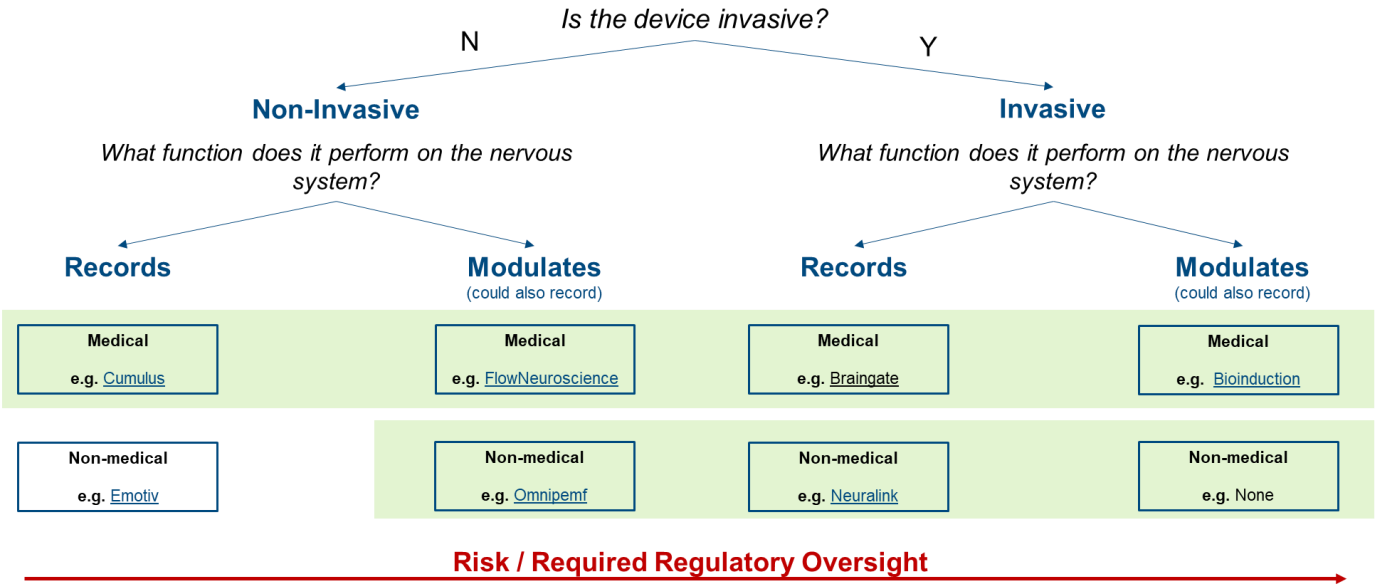

Figure 2. In green: all areas of the RHC's suggested neurotechnology taxonomy that should be classified as devices with medical purposes.

Classifying some non-medical neurotechnologies as medical devices could set a precedent that leads to the MHRA having oversight of other wellness devices that, in a similar fashion to neurotechnology, require additional protections to those covered by general consumer protection regulations. A wide range of new neurotechnology use cases will appear within the next few years and the Council could see no good reason to support MHRA oversight of devices as different as mind-controlled drones and meditation devices. However, as most of these use cases will be enabled by neurorecording wearables, the proposal entails these non-medical applications remaining beyond the remit of MHRA regulation. In the proposal, each non-medical use case enabled by a recording wearable would be overseen by the regulator relevant to the particular context in which the application is deployed (for example, the Civil Aviation Authority for mind-controlled drones and the Department for Education for neurotechnologies used in an educational setting), whilst devices must still comply with general consumer protection, product safety, privacy and cybersecurity legislation. Cross-cutting issues are addressed as part of the Council's proposal for a cross-government network outlined in recommendation 13. This position should be kept under review as more evidence is gathered on the impact of modulating devices on brain plasticity and as the possible future use cases of neurotechnology are better understood.

In formulating this recommendation, the RHC also considered other options for regulating non-medical neurotechnologies, including the creation of a new regulator or expanding the functions of another existing regulator. Under this option, the new regulator would have been tasked with developing guidance on non-medical neurotechnologies and establishing

a new pre-market certification system that ensures the safety and security of these devices without emulating medical device regulations. In addition to non-medical neurotechnologies, the new regulator could also have been tasked with covering the increasing number of wellness devices that can blur the distinction between medical and non-medical applications.

This option was rejected in favour of seeking to leverage existing regulatory structures and associated expertise, aiming to avoid the potential confusion and upheaval caused by introducing a new regulator into the neurotechnology ecosystem, or handing new responsibilities to an existing regulator. Though these played a secondary role in the Council's reasoning, there are also financial benefits with this approach, given the difficulties, costs and delays associated with upskilling a new (or existing) regulator with no previous experience of assessing the impact of technologies on human physiology. Many of the stakeholders and regulators interviewed also emphasised the importance of assessing existing capabilities before assigning new functions to a regulator. This is especially the case when considering neurotechnology applications, such as modulating wearables, since their impact on brain plasticity is still poorly understood but is likely to be considerable, warranting a degree of caution.

The Council's proposal would avoid the associated uncertainty and potential negative impacts on commercialisation of neurotechnology that could arise as a result of a lack of a clear regulator for non-medical neurotechnologies and the resulting fragmentation in the regulatory framework if a 'wait and see' option is chosen. This could also negatively impact consumer trust (as a result of potential safety and security breaches) and make it challenging to monitor uses of non-medical neurotechnology applications in order to develop an evidence base for future regulation.

5. Developing an anticipatory and agile governance framework that fosters responsible development and commercialisation of neurotechnologies in the UK

This report focuses on the near-term and medium-term future (next 5 –10 years) in respect of the intended impacts of its recommendations. Any predictions of future events are beset by uncertainty and this is especially so when considering the nature and impact of rapidly evolving technologies, including neurotechnologies. Some of the concerns noted below rely on predictions of the future power of neurotechnologies that sometimes appear to border on science fiction: the capacity of neurodevices to invade mental privacy by 'reading minds', or control someone's intentions and actions, thereby eroding or eliminating their agency and associated mental integrity and identity. The RHC has adopted a pragmatic approach, focussing on reducing unnecessary barriers to commercialisation of neurotechnology with a view to securing benefits for patients, while adopting a careful approach to the regulation of some non-medical applications. It is not the Council's intention to ignore or belittle concerns about the future power of neurotechnology. This technology raises genuine concerns about the future relationship between the human mind and its environment (including other minds), even challenging what we traditionally consider to be the characteristics of minds and their capabilities. Recommendations outlined below acknowledge these issues by suggesting that there should be *ongoing* oversight of the development of neurotechnologies, in national and international forums, supported by governance frameworks that permit rapid innovation in the public interest whilst promoting safety and protecting human rights.

5.1 Challenges arising from the collection and use of neurodata: mental privacy, integrity and neurodiscrimination

Determining what lies within the scope of the definition of 'neurodata' can be challenging, since observable behavioural data can be linked back to information about the nervous system; for example, it is claimed that early signs of Parkinson's disease can be detected from computer keyboard interactions.[132] The Council has restricted its definition of

[132] James Dalton (2016). Computer keyboards can be used to detect Parkinson's disease symptoms at home. Independent. https://www.independent.co.uk/tech/computer-keyboards-typing-parkinson-s-disease-symptoms-science-health-a7348406.html

neurotechnology to devices that *directly* record and/or modulate the activity of the nervous system, and so has excluded from its considerations the aforementioned type of neuro*behavioural* data. Most commonly, neurodata in the context of this report are considered to be generated directly by the nervous system; these data are collected, measured and processed by implantable or wearable devices. Such data can then be further analysed using sophisticated computation (using machine learning/AI tools) in order to reliably link such neural activity with neurological/ neurobehavioural/ psychological states. Nonetheless, the Council's recommendations acknowledge that further research is needed to test the boundaries of its proposed definition of 'neurodata' for regulatory purposes, and to understand better the concerns raised by use of neurobehavioral data in different settings, in order to determine whether a broader definition of 'neurodata' is required. For example, companies such as *Thymia* use machine learning to make mental health assessments faster, based on neurobehavioral data such as facial micro-expressions and speech patterns.[133]

Neurodata and genomic data are similar in many ways: both are difficult to anonymise, sensitive, probabilistic rather than deterministic, predictive, etc. However, some of the challenges posed by neurodata are unique:

1. **Neurodata exist in a 'write-read' format**. Neurotechnology devices can not only detect neural signals and 'decode' the information contained within them, but also *alter* such signals through neuromodulation, since the nervous system can both send and receive electrical signals.[134] Elegant studies have shown that it is possible to generate visual 'hallucinations' in the brain of a mouse, such that the mouse behaves as if it is seeing an object, when in fact what it 'perceives' is the product of direct intervention in the visual cortex.[135]
2. **Neurodata relate to unspoken information, including hidden intentions, memories, attitudes, beliefs and unconscious neural information.** As highlighted in the Council of Europe's 2021 report on 'Common Human Rights Challenges Raised by Neurotechnologies in the Biomedical Field', the brain is considered to be the last resort of privacy since it harbours unspoken information that, in principle, cannot be accessed even if an individual's observable behaviour was continuously monitored.[136] Neurotechnologies could in principle provide access to such information. For example, studies have shown that neurotechnology could be used to gain access to an individual's unconscious neural preparation for free

[133] https://thymia.ai/

[134] Council of Europe (2021). Common Human Rights Challenges Raised by Neurotechnologies in the Biomedical Field.

[135] Carrillo-Reid, L., Han, S., Yang, W., Akrouh, A., & Yuste, R. (2019). Controlling visually guided behavior by holographic recalling of cortical ensembles. Cell, 178(2), 447-457. https://www.sciencedirect.com/science/article/pii/S0092867419306166

[136] Council of Europe (2021). Common Human Rights Challenges Raised by Neurotechnologies in the Biomedical Field.

decision-making, allowing the data controller to accurately predict what the individual intends to do before they even know themself.[137]

3. **Neurodata are easily accessible**. Neurotechnologies can process and present neurodata in a format that everybody can understand, opening new frontiers in how they can be used.
4. **The scale of neurodata collection and processing will be considerable**, as adoption of direct-to-consumer neurotechnologies rapidly increases. Neurodata could be used to make very granular inferences concerning people's mental states when combined with other forms of contextual data.

For similar reasons, other stakeholders also argued that neurodata have a significance that goes beyond other kinds of health data.

Neurodata can pose the following forward-look challenges:

5.1.1 Mental privacy

Advances in neurotechnology in recent years – allied to ML/AI approaches to data analysis - have allowed the quantitative and qualitative analyses of neurodata, supporting ever more sophisticated analyses that can link brain states with mental states.

For example, recent work using high-density electrocorticography (ECoG) recordings of speech-related brain activity has allowed identification of brain activity patterns related to inner speech. This real-time decoding of speech in an interactive, conversational setting, has important implications for patients who are unable to communicate (Moses et al 2019).[138] Similar approaches have used neuroimaging/ neurorecording to correlate brain states with particular experiences or memories. Even general preferences have been analysed in this way. An exploration of risk-taking behaviour in US Democrats and Republicans using fMRI brain imaging showed that brain activity differed in the two groups: Democrats showed significantly greater activity in the left insula, while Republicans showed significantly greater activity in the right amygdala, allowing the authors to suggest that liberals and conservatives engage different cognitive processes when they think about risk.[139] We have already heard how visual percepts and even intentions can be similarly decoded (Section 5.1). Such approaches have resulted in the development of neuromarketing, through which certain companies attempt to use neurotechnology to measure consumers' preferences and impressions of their advertisements or products.

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[137] Bode, S., He, A. H., Soon, C. S., Trampel, R., Turner, R., & Haynes, J.-D. (2011). Tracking the unconscious generation of free decisions using uitra-high field fMRI. *Plos one, 6*(6), e21612. & Soon, C. S., He, A. H., Bode, S., & Haynes, J.-D. (2013). Predicting free choices for abstract intentions. *Proceedings of the National Academy of Sciences, 110*(15), 6217-6222.

Moses, D. A., Leonard, M. K., Makin, J. G., & Chang, E. F. (2019). Real-time decoding of question-and answer speech dialogue using human cortical activity. *Nature communications*, *10*(1), 1-14. https://www.nature.com/articles/s41467-019-10994-4?teal_wdm=016fb5f30430001d94c398e2e27f000c03a0be00490

[139] Darren Schreiber et al. (2013). Red Brain, Blue Brain: Evaluative Processes Differ in Democrats and Republicans. https://doi.org/10.1371/journal.pone.0052970

Examples such as these have created a sense that neurotechnology can decode any brain data, allowing so-called 'brain reading', making public an essentially private, mental domain, which is normally only disclosed if an individual chooses to share their mental contents through testimony. However, this is unrealistic and potentially misleading. Firstly, such studies in laboratory conditions always have limitations in their general applicability and accuracy; they are probabilistic, decoding brain activity through the use of sophisticated, statistical algorithms that are not always accurate. They are also limited in terms of the detail of mental contents they aim to disclose. Current neurotechnologies cannot analyse functional brain states to reveal (decode) cognitive, perceptual or other types of mental content in a way that is as full, rich and granular as the experiences themselves. For example, decoding the semantic content of everyday thoughts using brain data alone – thoughts such as 'Reading this report is one of the most interesting things I have done this year and I will recommend it to my new neighbour' – in real-time, is simply beyond the scope of neurotechnology today, and for the foreseeable future. No such mind-reading can be performed. Nonetheless, previously undiagnosed pathological brain states may be identified inadvertently when recording for another purpose, and a degree of caution is warranted.[140]

Invasive applications generally provide more detailed and reliable information concerning someone's mental states than wearables. Use of technologies such as 'closed-loop' Deep Brain Stimulation (DBS), which involves directly recording brain activity 24/7, raises particular concerns given their high spatial and temporal resolution and continuous use. Instead, wearables usually have a lower resolution, as they must address the challenges associated with recording neurosignals through a physical barrier of hair, skin, flesh and bone.[141] Data recorded through wearables are also vulnerable to noise, since wearables can be easily misplaced and moved as a result of commonly being used outside a clinical setting without medical supervision. Nonetheless, non-invasive applications can also pose considerable privacy challenges as, unlike invasive applications, they will be deployed and used in a wide range of non-medical contexts.

The implications of neurotechnology and use of neurodata for mental privacy are not yet understood. It is still unclear how neurodata will interact with other kinds of contextual data. Indeed, it is already possible to obtain very sensitive health-related information without using neurotechnologies. Some stakeholders have argued that neurotechnology is just part of the broader debate on health data privacy and that, at this moment in time, it is not the most concerning part.

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[140] Stampacchia, S., et al. (2022). Fingerprinting of brain disease: Connectome identifiability in cognitive decline and neurodegeneration. *bioRxiv*. https://www.biorxiv.org/content/10.1101/2022.02.04.479112v1.abstract & Finn, E. S., et al. (2015). Functional connectome fingerprinting: identifying individuals using patterns of brain connectivity. *Nature neuroscience*, *18*(11), 1664-1671. https://www.nature.com/articles/nn.4135!

[141] IBM (2021). Privacy And The Connected Mind. https://fpf.org/blog/how-neurotechnology-can-benefit-society-while-leading-with-privacy-and-ethics/

In this report, the right to mental privacy is understood as an entitlement: *not* to have one's neurodata (brain data, neural data, etc) collected, analysed or used in an unauthorised or illegitimate fashion. Some stakeholders, such as patient associations, emphasised informed consent and ownership of neurodata as being crucial to building trust. However, some of the privacy experts interviewed argued that questions around consent and ownership are not appropriate or useful in this context. For example, debates around *ownership* of data, understood as a legal concept, do not clarify answers to questions concerning who can use and access data and are unlikely to guarantee self-determination, increase market efficiency, provide users a foothold in the data economy, clarify legal uses of information, or encourage data-driven innovation.[142] Consent alone is not the solution, since it requires being informed about how the data will be used and it may not be possible to fully know this in advance. Individuals may regret their choice once they know more about the specific activities for which their data are being used. Regulation should therefore focus on ensuring the measurement, collection, processing and analysis of data is trustworthy and transparent, allowing the data subject to access information and have a say in the process, consistent with individual rights such as data portability and the right to be forgotten.

Neurodata are *data*; so general data protection requirements are relevant to regulation of their collection and use. Unlike some jurisdictions, the UK already has an overarching and exhaustive data protection framework, including the UK GDPR. The government launched a consultation "Data: a new direction" on reforming the UK's data protection framework, following our departure from the EU.[143] In the consultation response published in June 2022, the government outlined its plans to make it easier for organisations to use and reuse data for research purposes, establish more flexible and risk-based approaches to compliance, boost trade by reducing barriers to data flows and expand the functions of ICO.[144] Government also has plans to reform how data are used within the NHS.[145]

High-level, non-specific data that cannot identify or be linked to an individual is not considered as personal data under the existing data protection framework and would

[142] Liddell, K., Simon, D. A., & Lucassen, A. (2021). Patient data ownership: who owns your health? Journal of Law and the Biosciences, 8(2), lsab023. https://doi.org/10.1093/jlb/lsab023

[143] DCMS (2021). Data: a new direction. https://www.gov.uk/government/consultations/data-a-new-direction

[144] DCMS (2022), Data: a new direction - government response to consultation https://www.gov.uk/government/consultations/data-a-new-direction/outcome/data-a-new-direction-government-response-to-consultation, TechUK (2022). Plans to reform the UK's data protection regime represent an important evolution for the UK GDPR. https://www.techuk.org/resource/plans-to-reform-the-uk-s-data-protection-regime-represent-an-important-evolution-for-the-uk-gdpr.html

[145] DHSC (2022). Data saves lives: reshaping health and social care with data. https://www.gov.uk/government/publications/data-saves-lives-reshaping-health-and-social-care-with-data/data-saves-lives-reshaping-health-and-social-care-with-data#annex-a-legislative-changes

therefore fall outside the scope of the GDPR.[146][147] The key question, therefore, that needs to be answered is ‘when are neurodata *personal* data?’ This is a question that deserves further research and consideration. Raw neurodata may not be considered to be so, but it is likely that most collected and processed neurodata will be classed as personal data under the UK GDPR.[148] As highlighted by IBM in its report, *Privacy and the Connected Mind,* "although identification of individuals based solely on their collected personal neurodata is likely to be a difficult challenge, it has been shown to be possible with relatively little data (less than 30 seconds-worth) within a laboratory setting, and some experts believe that such identification is feasible, if not today, then in the near-term.”[149]

The GDPR defines special categories of data that can only be processed if one of the ten specific conditions captured under Article 9 of the GDPR is met.[150] Health data are considered as special category data under the GDPR, but it remains unclear how neurodata would be classified when they are not being processed in a medical context, as defined in Article 4 of the UK GDPR[151] and in Schedule 1 of the Data Protection Act.[152] Since the definition of ’health data’ hinges on the intended purpose, it is likely that the data collected by the increasing number of consumer neurotechnologies, deployed in a wide range of contexts from gaming to the workplace, will not be classed as health data. Even if they are not classified as health data, neurodata could still fall under one of the other special data categories (racial or ethnic origin, political opinions, biometric data, sexual orientation, etc.). Nonetheless, there is a risk that many forms of sensitive neurodata (such as data used for targeted advertisement) would not fall under any of the definitions included in the GDPR and, therefore, not be considered special category data under the GDPR. This could lead controllers and processors to assume that uses of sensitive neurodata that are not currently classed as special category data under the UK GDPR are

[146] There are exceptions in the instance of anonymised data and considerations around pseudonymised data. In these cases, whether data are classed as personal depends on the likelihood of reidentification. For further information see ICO (2022). Draft Anonymisation, Pseudonymisation and Privacy Enhancing Technologies guidance. Chapter 3: Pseudonymisation. https://ico.org.uk/about-the-ico/ico-and-stakeholder-consultations/ico-call-for-views-anonymisation-pseudonymisation-and-privacy-enhancing-technologies-guidance/

[147] ICO. Guide to the UK General Data Protection Regulation (UK GDPR). https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/key-definitions/what-is-personal-data/

[148] Rainey, S., McGillivray, K., Akintoye, S., Fothergill, T., Bublitz, C., & Stahl, B. (2020). Is the European Data Protection Regulation sufficient to deal with emerging data concerns relating to neurotechnology? Journal of Law and the Biosciences, 7(1), lsaa051. https://doi.org/10.1093/jlb/lsaa051.

[149] IBM (2021). Privacy and the Connected Mind.

[150] This is on top of the lawful basis for processing captured in Article 6. Moreover, five of the conditions captured in Article 9 of the GDPR also require meeting additional conditions set out in the Data Protection Act (2018).

[151] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (United Kingdom General Data Protection Regulation). https://www.legislation.gov.uk/eur/2016/679

[152] Data Protection Act 2018. Schedule 1. https://www.legislation.gov.uk/ukpga/2018/12/schedule/1/enacted

not particularly risky, when in reality, their misuse or loss can prove highly detrimental to individuals.

Even if neurodata are not classed as special category data, stakeholders have reported that it may be more challenging to exercise general individual rights considered in the GDPR, such as the right to erasure, data portability, etc. in the context of neurodata, given the closer contact of neurotechnology with human brains/minds (as stated earlier, neurodata exist in a write-read format and can therefore also *influence* the data subject). Some also argued that the operationalisation of GDPR principles, such as transparency obligations, may therefore have to be redefined to properly ensure the autonomy of data subjects in exercising their rights in this new context. This does not necessarily entail drafting new regulations, but clarifying first how the data protection framework should be applied in this new context given the lack of case studies.

In this context, the proposals made by the Council of Europe and Dr Ienca on establishing a Mental Data Protection Impact Assessment (MDPIA) could be valuable.[153] The Council recognises that government is proposing removing the requirement for organisations to undertake a Data Protection Impact Assessment (DPIA) as part of its consultation on "Data: a new direction."[154] However, the Council thinks the MDPIA proposal could be adapted to the UK regulatory context and that ICO could clarify compliance requirements for organisations working with neurodata as part of government's plans to introduce new 'privacy management programmes.'

Recommendation 9: The Information Commissioner's Office (ICO) should clarify how the data protection framework would be applied to neurodata. The Council would like ICO's work on neurodata regulation to lead in the future to the publication of guidance, drafted in collaboration with the neurotechnology community. In particular, information and advice on the following would be welcomed:

a. A definition of 'neurodata', clarifying the extent to which *neurobehavioral* data should be classed as neurodata for regulatory purposes;
b. Guidance to help manufacturers identify which neurodata would be classed as personal data and thereby covered by the GDPR, and also which neurodata would be classed as health data;
c. An outline of ICO's expectations for how existing GDPR principles would be applied by data controllers and processors operating in this space.

Recommendation 10: In reforming the UK Data Protection Framework, **the Department for Culture, Media and Sport (DCMS) should (1) consider creating a new special category for neurodata** to ensure their processing is limited under Article

[153] Council of Europe (2021). Common Human Rights Challenges Raised by Neurotechnologies in the Biomedical Field. Marcello Ienca & Gianclaudio Malgieri (2021). Mental Data Protection and the GDPR. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3840403

[154] Department for Digital, Culture, Media & Sport (2022). Data: a new direction. https://www.gov.uk/government/consultations/data-a-new-direction

9 of the GDPR and **(2) assess whether existing protections are proportionate** to the risks posed by different kinds of neurodata.

5.1.2. Mental integrity

As discussed previously, neurodata exist in a 'write and read' format. Challenges to mental integrity can therefore arise from the ability of neurotechnologies to influence someone's mental states by altering their neural signals without authorisation. There is still no broad consensus on how to define mental integrity. In the literature, some refer to this concept as 'freedom of thought' and 'cognitive liberty'.[155] For the purposes of this report, a right to mental integrity is understood as the right to exercise autonomous control over one's own mind and decisions.[156] Mental integrity can therefore be understood as the psychological counterpart of physical or bodily integrity.[157]

The extent to which neurotechnologies will be able to significantly alter mental states in a controlled fashion remains unclear. Manipulating mental states is already possible in animals, as experiments discussed above have shown that it is possible to induce visual 'hallucinations' in mice.[158] It is still unclear whether external agents will be able to manipulate a healthy person's mental states without their consent, but studies have shown that it is possible to deliver sensory information (percepts) to blind patients by direct stimulation of the visual cortex[159] or to restore tactile feedback to people with a spinal cord injury.[160] There is also evidence of people being able to manipulate their own brain activity through neurofeedback.[161]

Some stakeholders commented that direct-to-consumer neurotechnologies with the power to manipulate human mental states in a controlled fashion could appear within the next 10 to 20 years and that future applications may undermine our capacity to reason as autonomous agents, unlike any other treatment or device. Such an eventuality would raise

[155] Council of Europe (2021). Common Human Rights Challenges Raised by Neurotechnologies in the Biomedical Field.

[156] Discussion of mental autonomy and integrity is distinct from debates around free will, a concept about which many neuroscientists are sceptical. Mental integrity is best understood as supporting agency i.e. the ability to act on the basis of one's own thoughts and reasoning.

[157] Council of Europe (2021). Common Human Rights Challenges Raised by Neurotechnologies in the Biomedical Field.

[158] Carrillo-Reid, L., Han, S., Yang, W., Akrouh, A., & Yuste, R. (2019). Controlling visually guided behavior by holographic recalling of cortical ensembles. Cell, 178(2), 447-457. https://doi.org/10.1016/j.cell.2019.05.045

[159] Fernández, E., et al. (2021). Visual percepts evoked with an intracortical 96-channel microelectrode array inserted in human occipital cortex. *The Journal of clinical investigation*, *131*(23). https://www.jci.org/articles/view/151331

[160] Shelchkova, N. D., et al. (2022). Microstimulation of human somatosensory cortex evokes task-dependent, spatially patterned responses in motor cortex. *bioRxiv*. https://www.biorxiv.org/content/10.1101/2022.08.10.503543v1#:~:text=Intracortical%20microstimulation%20(ICMS)%20of%20somatosensory,via%20brain%20controlled%20bionic%20hands.

[161] Sitaram, R., Ros, T., Stoeckel, L. et al. (2017). Closed-loop brain training: the science of neurofeedback. Nat Rev Neurosci 18, 86–100. https://doi.org/10.1038/nrn.2016.164

challenging questions for conventional interpretations of human agency and accountability. For example, judges have already decided to overturn an armed robber's jail sentence after his aggressive behaviour was attributed to a brain tumour.[162]

Other stakeholders predicted that neurotechnology will not alter human behaviour in ways that are drastically different from existing treatments, given that there are many ways of influencing behaviour and altering brain plasticity, including drugs, targeted advertising, meditation - even reading a book or having a conversation.

Most stakeholders agreed that threats to mental privacy constitute a more pressing regulatory challenge than threats to mental integrity. Nonetheless, mental integrity is a topic that requires further research and consideration and should be closely monitored, as proposed in recommendation 13 on future-facing governance, even though no further regulatory measures are recommended at this stage.

5.1.3 Neurodiscrimination

Neurodiscrimination occurs when individuals or population groups are unfairly disadvantaged by inferences made from neurodata and/or biases in their collection and processing. Neurodata could potentially be used to predict mental health status, as well as human capabilities, thus enabling new forms of discrimination - for example, making it easier to detect whether someone has a mental health problem through the biomarkers and electrical signatures detected by the device, with consequences for employment or insurance. Other potentially unjust or prejudicial uses of neurotechnology, which have ethical and legal dimensions, have also been discussed, including the use of neuroimaging (fMRI or EEG) as a form of lie detection or as a means to reveal aspects of 'character' that could be used to screen job applicants. The latter may be of heightened significance given the apparent increase in employment tribunals due to neurodiversity discrimination claims.[163]

The extent to which the existing data protection framework offers adequate safeguards against unjust inferences from neurodata remains unclear.[164] The UK GDPR includes considerations concerning fairness, but most of the issues raised as a result of unfair inferences fall under the scope of the Equality Act 2010.[165] Further research is therefore required to understand whether the provisions in both Acts are sufficient to address the

[162] Matthew Moore (2013). Robber's aggression was 'due to brain tumour.' Independent. https://www.independent.co.uk/news/uk/crime/robber-s-aggression-was-due-to-brain-tumour-8500309.html

[163] Alan Price (2022). Discrimination Claims Relating To Neurodiversity Up By A Third. TheHRDIRECTOR. https://www.thehrdirector.com/business-news/tribunals/discrimination-claims-relating-neurodiversity-third/

[164] Sandra Wachter & Brent Mittelstadt (2018). A Right to Reasonable Inferences: Re-thinking Data Protection Law in the Age of Big Data and AI. https://www.law.ox.ac.uk/business-law-blog/blog/2018/10/right-reasonable-inferences-re-thinking-data-protection-law-age-big

[165] Government Equalities Office and Equality and Human Rights Commission (2013). Equality Act 2010: guidance. https://www.gov.uk/guidance/equality-act-2010-guidance#:~:text=Print%20this%20page-,Overview,strengthening%20protection%20in%20some%20situations.

particular challenges neurotechnology could pose in sensitive settings such as the workplace or education. This issue is addressed further as part of recommendation 13 on future-facing governance considerations.

Another potential source of neurodiscrimination may be biases in the algorithms used to process/analyse neurodata. The discriminatory potential of using AI in healthcare is already well documented[166] and the data protection framework already offers some such protections. Article 22 of the GDPR protects data subjects from solely automated decisions that have a legal or similarly significant effect.[167] Article 22(4) further limits automated decision-making when this relies on special category data.[168] In these situations, data processors need to implement safeguards to protect the data subject's rights and freedoms and can only process data if explicit consent has been granted or if there is substantial public interest. Therefore, if the RHC's recommendation to create a new special data category for neurodata was implemented, their use for automatic inferences would be severely limited, reducing the risk of neurodiscrimination in these kinds of circumstances.

5.2 Accessibility and long-term use

The use of neurotechnologies can also raise accessibility concerns, in both medical and non-medical settings. As noted in the public dialogue on neural interfaces commissioned by the Royal Society in 2019 and discussed in the public engagement roundtable hosted by the RHC, accessibility is an issue the public seems to be particularly concerned about and addressing it seems key to increasing the acceptability of neurotechnology.

In a medical setting, ensuring accessibility entails a future where neurotechnologies are available to all who have a medical need: (1) a baseline level of neurotechnologies widely available according to incidence of conditions; (2) access to trials to a wide range of people and (3) affordable devices.[169] In the UK, the NHS is committed to equity of access for medical devices that are shown to be effective and safe, and is well-placed to deliver

[166] Norori, N., Hu, Q., Aellen, F. M., Faraci, F. D., & Tzovara, A. (2021). Addressing bias in big data and AI for health care: A call for open science. Patterns, 2(10), 100347. https://doi.org/10.1016/j.patter.2021.100347

[167] Nonetheless, automated decision-making may be allowed when the decision is necessary for a contract, it is authorised by law or it is based on the individual's explicit consent. For further information, see: ICO. Automated decision-making and profiling. https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/automated-decision-making-and-profiling/

[168] ICO. Guide to the UK General Data Protection Regulation (UK GDPR). Rights related to automated decision-making including profiling. https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/rights-related-to-automated-decision-making-including-profiling/

[169] Anita van Mil et al. (2019) From our brain to the world: views on the future of neural interfaces. Hopkins Van Mil. https://royalsociety.org/-/media/policy/projects/ihuman/public-engagement-full-report.pdf?la=en-GB&hash=5B6417E1881961853318F4CD570CA07A

on this. However, not all neurotechnologies work in all brain, skin, and hair types. There could therefore be a risk that neurotechnologies are not designed with inclusivity in mind, and do not work across the diverse population of the UK. Inclusivity requires various factors to be taken into account in the development and evaluation of these devices. To mitigate this, regulators need to strike a balance between ensuring diversity in the design and implementation of clinical trials and not allowing trials to fail as a result of having to recruit too many patients for whom the device is not suitable.

Non-medical applications can also give rise to accessibility concerns, as direct-to-consumer devices are likely to be out of reach for many individuals in the UK. Members of the public seemed concerned that neurotechnologies could lead to the establishment of two-tiered communities, divided between those who can afford the devices and those who cannot.[170] This might be a particular concern in fields such as professional sport, education and the workplace, where the enhancement of performance could significantly exacerbate existing disparities. This possibility was highlighted by participants in the RHC public engagement roundtable. However, some of these concerns go beyond what can easily be addressed by regulatory reform, because they relate to broader and deep-rooted social problems.

> **Recommendation 11: The DHSC should consider adopting policies to ensure that neurotechnologies are available to a wide patient base regardless of their personal characteristics**. The MHRA could assist by (1) collating data on access to neurotechnologies across different groups and by (2) leveraging the suggested sandbox programme to encourage the development of neurotechnologies for underserved patient groups. For example, neurotechnologies that target patients for whom there is no alternative neurotechnology available could be prioritised for the sandbox programme over applications for which there is already an alternative. Uses of neurotechnologies that target minority patient groups will arguably be more likely to succeed in a sandbox environment, where researchers can count on tailored support and continual engagement with regulators and ABs, in contrast to the standard conformity assessment process.

There are also some unresolved issues around the management and support for long-term implants. This was a particularly important area of concern identified in the public engagement roundtable hosted by the RHC. Some manufacturers reported that it is unclear who should be responsible for supporting and upgrading the device once they have been implanted, especially if a company folds. For instance, many of the hundreds of patients that received an *Argus II* retinal implant have felt abandoned after the

[170] Anita van Mil et al. (2019) From our brain to the world: views on the future of neural interfaces. Hopkins Van Mil. https://royalsociety.org/-/media/policy/projects/ihuman/public-engagement-full-report.pdf?la=en-GB&hash=5B6417E1881961853318F4CD570CA07A

manufacturer decided to discontinue work on the device.[171] If this were to happen in the case of brain implants, the consequences could be even more severe.

> **Recommendation 12:** As part of its plans to amend the UK Medical Devices Regulations to clarify and strengthen the requirement for manufacturers to implement a post-market surveillance and vigilance system,[172] the **MHRA should consider requiring manufacturers to present a plan describing how they intend to manage long-term implants installed in patients, as part of their submission to Approved Bodies.** The plan should capture (1) the commitment of the manufacturer to repair, upgrade or remove the device (including software) as required, (2) specific instructions on how to maintain and remove the device that can be followed by a third-party in case the company folds and (3) detailed description of arrangements for long-term monitoring of adverse events in a post-market phase. The MHRA should also ensure that it has adequate resources to ensure post-market vigilance and to intervene and mediate when a company folds and a handover of responsibilities must be organised.

5.3 Future-facing governance considerations

Stakeholders were divided about whether the challenges and opportunities posed by neurotechnologies call for major changes to the existing regulatory framework or just fine-tuning. In preparing this report, we have opted for a pragmatic approach, focussing on near- to medium-term challenges and making recommendations that leverage existing regulatory structures, whilst encouraging their evolution in a direction characterised by anticipation, agility and proportionality. We also recognise the need to put in place structures that meet the future needs of this dynamic, fast-moving area of technology development that has the potential to be controversial. The RHC wishes to promote an ongoing debate about neurotechnologies and their evolving contribution to our society, one that is evidence-based, future-facing, innovative and inclusive.

Countries such as Chile have opted for introducing neurotechnology-specific legislation that introduces changes in their constitutional framework by defining neurorights and limiting the use of non-medical neurotechnologies and neurodata.[173] However, those that oppose a new overarching regulatory framework for neurotechnology argue that this approach can be problematic, because it lumps very different applications together without tailoring the regulatory approach to the particular context. In the case of neurotechnology,

[171] Eliza Strickland & Mark Harris (2022). Their Bionic Eyes Are Now Obsolete and Unsupported. IEEE Spectrum. https://spectrum.ieee.org/bionic-eye-obsolete

[172] MHRA (2021) Consultation on the future regulation of medical devices in the United Kingdom. Chapter 8, Section 48.

[173] UNESCO (2022). Chile: Pioneering the protection of neurorights. https://www.unesco.org/en/articles/chile-pioneering-protection-neurorights & Senado Republica de Chile (2021). Protección de los neuroderechos: inédita legislación va a la Sala. https://www.senado.cl/proteccion-de-los-neuroderechos-a-un-paso-de-pasar-a-segundo-tramite

there are already many overarching pieces of legislation that could apply, including general consumer protection regulation, the Equality Act 2010 and the UK GDPR. Opponents of introducing new frameworks therefore argue that we should first clarify how existing regulation applies to neurotechnology, filling the gaps where necessary.

Overall, stakeholders agreed that regulation should be flexible enough to cope with longer term issues. Many argued that alternatives to regulation should be considered over hard measures to address longer-term issues. For instance, article 24 of Spain's Digital Rights Charter sets out a series of aims that future regulation on neurotechnology should fulfil.[174] The Charter is therefore not regulatory in nature, but rather aims to provide a reference framework to guarantee citizens' rights in the digital age. However, critics of this kind of approach point out that there are already many ethical guidelines and principles available concerning neurotechnology. Soft approaches risk not being implemented if there are no incentives for the private sector to take them seriously.

Internationally, another approach to addressing the forward-look implications of neurotechnologies that has recently gained traction across the international community is a 'neurorights' framework (see Box 3: 'Neuroethics & Neurorights').

[174] Some of these aims include preserving individual identity, guaranteeing individual self-determination, safeguarding the confidentiality and security of neurodata, guaranteeing the dignity of the person, equality and non-discrimination. For further information see: La Moncloa (2021). The Government adopts the Digital Rights Charter to articulate a reference framework to guarantee citizens' rights in the new digital age. https://www.lamoncloa.gob.es/lang/en/gobierno/news/Paginas/2021/20210713_rights-charter.aspx

Neuroethics & Neurorights [Box 3]

Whilst some of the achievements of neurotechnology seem almost miraculous, in other respects they appear rudimentary, at least in comparison to what the human brain can achieve unaided on a daily basis, e.g. effortless communication of highly complex ideas between two speakers who have never met. But it is important to remember that as a society, in respect of neurotechnology, we are on an innovation trajectory whose future is impossible to confidently predict. That future is likely to involve much more widespread use of much more powerful neurotechnologies in numerous walks of life, and this prospect raises ethical and social issues of great significance. These neurotechnologies will include implantables, but many more examples of wearables[175]. A flourishing community of academics, scientists and commentators has in recent years addressed a number of concerns generated by research in neuroscience and related developments in neurotechnology, some of which are discussed in this report: impacts on mental privacy, mental integrity and agency, the possibility of human augmentation/enhancement, accessibility and equity, and consequences for our understanding of human capability, identity and dignity – in brief, of 'what it means to be human'. Addressing such questions is one main aim of the discipline of 'neuroethics', and as with all discussions of ethics, authors adopt particular ethical models, perspectives or principles to frame questions and provide answers. The objective of such answers is ultimately to recommend how we *should* act individually and collectively in respect of neurotechnology applications. In addition to the role played by conventional medical ethics considerations, the need for public dialogue and the importance of public trust in innovators, manufacturers and regulators are also relevant in this context.

[175] Yuste, R., Goering, S., Bi, G., et al. (2017). Four ethical priorities for neurotechnologies and AI. Nature, 551(7679), 159-163. https://doi.org/10.1038/551159a

One popular way of framing the issues here is to focus on rights: rights to mental privacy, mental integrity, etc, otherwise known as neurorights. A neurorights framing has been central to a number of reports and publications in recent years, including those from the Neurorights Foundation[176] and the Committee on Bioethics of the Council of Europe.[177] Talk of rights has the advantage of being intrinsically amenable to legal interpretations: human rights worth protecting are worth enshrining in law. The question then arises as to whether existing human rights legal provisions, especially international instruments such as the UN Universal Declaration of Human Rights, already contain the necessary provisions for the protection of neurorights, or whether a new 'neurorights declaration', complementing existing legal instruments, is required. The International Bioethics Committee (IBC) of UNESCO[178] and other organisations[179] have recommended the latter approach. Others, including stakeholders we heard from, have recommended caution in respect of declaring new neurorights, with the perception that 'rights inflation' could potentially undermine their intended positive impact by spreading general scepticism about the importance of rights in guiding behaviour. The OECD has also stressed the importance of acknowledging diverse ethical and cultural values, rather than *universal* principles, in developing governance frameworks. The OECD and others also emphasise the importance of public deliberation/dialogue[180] and the role of the private sector itself in setting standards for responsible innovation.[181] A number of commentators have stressed that special consideration should also be given to vulnerable groups, including children. Clearly, these considerations underline the complexities of incorporating ethical arguments into public policy.

[176] https://neurorightsfoundation.org/home-1

[177] Council of Europe (2021). Common Human Rights Challenges Raised by Neurotechnologies in the Biomedical Field.

[178] International Bioethics Committee (2021). Report of the International Bioethics Committee of UNESCO (IBC) on the ethical issues of neurotechnology https://unesdoc.unesco.org/ark:/48223/pf0000378724

[179] Ienca, M., & Andorno, R. (2017). Towards new human rights in the age of neuroscience and neurotechnology. Life sciences, society and policy, 13(1), 1-27. https://doi.org/10.1186/s40504-017-0050-1 & Goering, S., Klein, E., Specker Sullivan, L. et al (2021). Recommendations for Responsible Development and Application of Neurotechnologies. Neuroethics 14, 365–386. https://doi.org/10.1007/s12152-021-09468-6

[180] Royal Society (2019) iHuman: Blurring lines between mind and machine. https://royalsociety.org/topics-policy/projects/ihuman-perspective/

[181] Pfotenhauer, S. M., Frahm, N., Winickoff, D., Benrimoh, D., Illes, J., & Marchant, G. (2021). Mobilizing the private sector for responsible innovation in neurotechnology. Nature biotechnology, 39(6), 661-664 https://doi.org/10.1038/s41587-021-00947-y

Many neurorights are what are traditionally called 'negative rights', describing an entitlement to be free to act, speak (or think) without impediment or fear of the consequences. Negative rights, such as freedom of speech, are rights *not to* be subjected to threats, abuse, coercion or violation by others, and rights to mental privacy and integrity are also negative rights in this sense. However, positive rights are entitlements *to* the actions of others, in the form of supporting interventions such as health care, education or even internet access. Regrettably, positive rights have received much less attention in the literature on neurorights, but it is noteworthy that UNESCO highlights the right to enjoy the benefits of scientific progress and its technological applications,[182] as does the UN[183], which here means an entitlement to have access to *safe and effective* neurotechnologies. The RHC would like to see a balance between promotion of rights that protect patients and other neurotechnology users from potential degradation of their health, mental privacy and mental integrity, and the promotion of entitlements to the benefits of neuroscience research and neurotechnology innovation. As with the use of other emerging technologies, how to achieve such a balance is likely to be a topic of discussion for many years to come, and the RHC would like to see the creation of outward-facing expert forums and related public spaces to promote and support the necessary dialogues.

As part of its engagement with multiple government departments and organisations, the Council has found that understanding of the regulatory implications of present and future neurotechnology applications is limited. This is partly due to the nascent stage of the technology, but it is also a result of the lack of central leadership and coordination between policy makers and regulators working in this sector. Indeed, there are many government organisations that have an interest in neurotechnology, or more broadly, in human augmentation technologies, including government departments such as DHSC, DCMS, MOD, Cabinet Office, and regulators such as ICO and MHRA. However, each one looks at different aspects of neurotechnology regulation (often using different terminology and working in silos) and, at the moment, there is no single policy team within government that is addressing and coordinating the government response to the cross-cutting challenges posed by rapid developments in neurotechnology.

The absence of a cross-government approach towards neurotechnology governance is particularly concerning given the transformative potential of the technology. By leveraging the nervous system and its data in new and unprecedented ways, neurotechnology has the potential to redefine how humans interact with one another and with their environment. In some ways, neurotechnology could redefine 'what it means to be human'. By acting now and influencing the trajectory of the sector, government has an opportunity to proactively enhance the trustworthiness of those developing, using and overseeing neurotechnology,

[182] See https://en.unesco.org/human-rights/science

[183] See Article 4 (f, g) of United Nations Convention on the Rights of Persons with Disabilities and Optional Protocol

and thereby *public* trust, and avoid future polarised debates that have limited the development of other emerging technologies in the past. There is also a risk that important and necessary conversations around cross-cutting ethical questions on neurotechnology fall through the cracks of the responsibilities of the different government departments and regulators under the existing governance structure.

Many international organisations have already started holding discussions on different aspects of neurotechnology regulation, with the aim of developing an international governance framework. This includes the OECD recommendation on Responsible Innovation in Neurotechnology (to which the UK is a signatory and which it is expected to implement)[184], the work of the UN Human Rights Council, the development of standards for non-medical use cases at the International Organisation for Standardisation (ISO), as well as UNESCO's Bioethics Committee work on the ethical issues of neurotechnology (including their proposal to convene a multidisciplinary group of experts to develop an international governance model that identifies gaps in the existing human rights framework and develops normative instruments).[185] The UK has traditionally been very active in promoting technology governance internationally as part of the OECD and through its membership of the G7. However, the existing fragmentation in responsibilities across departments and the lack of central leadership have meant that it has been challenging in the past to ensure there is a strong, united UK voice in international initiatives on neurotechnology. Other countries are already shaping the agenda on neurotechnology governance and the UK government could miss an opportunity to promote UK values in this space if it does not act swiftly.

As with other emerging technologies, the lack of cross-government coordination could also lead to a fragmented regulatory framework, in which manufacturers struggle to clearly identify and comply with different and overlapping requirements. Regulatory fragmentation would increase the costs of innovation, discourage newcomers and inhibit the development of a sector that could treat tens of thousands of patients suffering from neurological conditions in the UK and make a significant economic contribution. The RHC has been the first UK government body to consider the regulation of neurotechnology holistically but, given the nature of the Council's remit, its work on neurotechnology regulation and governance can only be temporary. Another government body will need to take forward this work and the approaches to regulation outlined in this report should be kept under review and amended or supplemented as understanding of the use cases, risks and benefits of neurotechnologies in a wide range of societal contexts increases.

Recommendation 13: HMG should ensure that senior accountability is set out to drive forward and coordinate thinking on neurotechnology regulation across

[184] OECD/LEGAL/0457 Recommendation of the Council on Responsible Innovation in Neurotechnology (2019). https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0457

[185] International Bioethics Committee (2021). Report of the International Bioethics Committee of UNESCO (IBC) on the ethical issues of neurotechnology https://unesdoc.unesco.org/ark:/48223/pf0000378724

government to enable its transformative potential by addressing existing leadership gaps and avoiding the risks of regulation that is disproportionate or fragmented.

The Council believes that Cabinet Office and its Office for Science and Technology Strategy, the Technology Strategy team at BEIS and the Government Office for Science should work together to identify the most appropriate lead. Their current lack of ownership of any specific areas of neurotechnology regulation places them in a good position to hold government to account and unify its approach to neurotechnology regulation without becoming its policy owner.

The agreed body could consider establishing a cross-governmental network of regulators and government departments, including (but not limited to) the MHRA, ICO, OPSS, DHSC, DCMS, BEIS and MOD, allied to wide-ranging expertise from industry, academia, patient/user perspectives and medicine. The main purpose of the network would be to review and adapt regulations according to the latest evidence available by ensuring there are clear policy owners and supporting their work by sharing expertise and resources. A network model such as this could address regulatory fragmentation and lack of coordination whilst leveraging the expertise of each regulator (and critical sectoral advisers) and avoid the creation of organisations that could duplicate the work of existing regulators. Government has successfully trialled this model in the past. A good example is the Digital Regulation Cooperation Forum (DRCF), which brings together CMA, ICO and Ofcom to increase cooperation and coordination, and deliver coherent, informed and responsive regulation for the UK digital economy.[186]

Based on the findings of the Council's report, the network could consider prioritising:

1. Agreeing a common terminology that can be used across government and across all applications of neurotechnologies, building on the taxonomy suggested by the Council;
2. Monitoring the use of neurotechnologies in sensitive sectors such as military, employment, insurance, education, surveillance, security and judicial to build the evidence base to inform future regulation;
3. Clarifying whether existing regulations (such as the Equality Act 2010) provide sufficient safeguards against the challenges posed by impacts on mental integrity, neurodiscrimination, transparency, agency, personal choice and accessibility in a non-medical setting, and developing practical guidance where necessary;
4. Examining policy and regulatory responses to difficult topics that deserve further research and consideration. This includes but is not limited to (1) the impact of DTC neurotechnologies being used in conjunction with apps on vulnerable individuals, (2) the repurposing of medical neurotechnologies for non-medical purposes and vice versa, (3) the enhancement or augmentation of human

[186] https://www.gov.uk/government/collections/the-digital-regulation-cooperation-forum

performance in different contexts and (4) the impact of neurorecording wearables on brain plasticity;

5. Developing proposals to engage the public in the development of regulation in this space and understand public attitudes towards neurotechnology uses through, for instance, the BEIS Public Attitudes Tracker and public dialogue initiatives.

In the future, this model could be replicated for other emerging technologies which, as with neurotechnology, (1) have transformative/disruptive potential, (2) can give rise to particularly difficult regulatory challenges and (3) lack a clear and coordinated government response.

Recommendation 14: HMG should play an active role in international initiatives on neurotechnology and proactively collaborate with other countries to develop an international governance framework that takes account of UK values in the future development of neurotechnology. This includes, but is not limited to, the implementation of the OECD Council Recommendation on Responsible Innovation in Neurotechnology, the development of standards at the ISO and the work of the Council of Europe and United Nations Human Rights Council on 'neurorights'. The UK contribution to such initiatives could be coordinated through the suggested cross-government network (recommendation 13) to ensure all relevant departments have an opportunity to comment on cross-cutting issues and that the UK government engages internationally with a united voice.

6. Conclusion

The RHC hopes that this report will pave the way to wide-ranging discussions on the current regulation of neurotechnology, on the part of innovators, regulators, policymakers, patient/user representatives and other stakeholders, with a view to ensuring a more proportionate and agile regulatory framework. The Council considers such inclusive discussions to be a requirement of securing the benefits of safe and effective applications for all users. This report marks the beginning of an ongoing dialogue that we, as a society with an international reputation for bioscience research and responsible innovation, must have in order to navigate a course for the development of this exciting yet challenging area of technology.

Annex I: Outcomes of the RHC/RS roundtable on prior public engagement exercises

On April 25th 2022, the RHC hosted a three-hour roundtable together with the Royal Society (RS) to discuss the findings of their public dialogue on neural interfaces commissioned in 2019. The virtual roundtable was facilitated by the Innovation Space team within BEIS and brought together 30 participants from academic and regulatory backgrounds, including government officials, public engagement experts, clinicians, neuroscientists and ethicists, in order to identify:

I. The key findings of the public dialogue exercise conducted on behalf of the Royal Society in 2019 that have clear implications for regulation and;
II. Where the RHC can add value given its remit to encourage innovation through regulatory reform.

Why public engagement is important

Multiple international organisations (including the OECD and the UNESCO) have recently recognised the importance of enabling social deliberation on neurotechnology to ensure that the views from those that could be affected by the technology are considered early in the decision-making process. Given neurotechnology is still in the early stages of its development, engaging the public now is also an excellent opportunity to build trust.

The importance of engaging the public on neurotechnology regulation was also recognised during the roundtable discussions. Participants argued that engaging with the public is important for understanding what is acceptable and to ensure regulation is proportionate. Public opinion can help regulators and policy makers identify the likely social acceptability of different neurotechnology use cases, highlighting the areas that require greater regulatory engagement as future policy is considered and where greater regulatory control needs to be seen to be present.

The Council's approach towards public engagement and challenges faced

Considering public attitudes towards neurotechnology regulation, whilst important, is challenging given its nascent stage of development. In the case of some emerging technologies, such as artificial intelligence and genetic technologies, public debate has been widespread, driven partly by a mature ecosystem of representatives and advocacy groups. By contrast, the neurotechnology ecosystem is less well advanced, which influenced how the Council approached Engagement with wider stakeholders.

A short literature review revealed that public attitudes towards neurotechnology regulation are still poorly understood. In the UK, the most prominent public engagement exercise is the public dialogue on neural interfaces commissioned by the Royal Scoeity in 2019.[187] In Europe, a few engagement exercises have been conducted on human enhancement technologies as part of the Sienna project[188], neuroscience as part of the Human Brain project[189] and BCIs as part of the Nano2all project[190]. However, none of these exercises explicitly considered public attitudes towards regulation itself.

To address these gaps, the Council considered different options, including a deliberative online survey and the commission of a public dialogue exercise on neurotechnology regulation. However, these options were eventually discarded given their costs and time requirements. This reflects the difficulties of aligning the need for public engagement with the timelines of the policy cycle. The Council therefore opted for hosting an expert roundtable to discuss the regulatory implications of a previous public engagement exercise to guide the recommendations in its report and pave the way for future public engagement in this area. The discussion was guided by 12 pre-defined questions that had received the feedback of the Expert Advisory Group that had helped inform the RS Public Dialogue. These questions touched on areas such as medical and non-medical neurotechnologies, overarching regulatory principles to ensure the acceptability of neurotechnologies and future areas for public engagement.

Findings on medical applications

Participants were asked to consider questions surrounding the commercialisation of medical devices, since findings from the Royal Society public dialogue indicate that the public is overall very enthusiastic and supportive of neurotechnologies used for medical use cases. Participants were particularly hopeful that neurotechnologies can, in the future, restore freedom and independence to elderly people and those suffering with disabilities, increase therapy personalisation, reduce the cost of NHS treatments, increase life expectancy, and much more. Topics such as ensuring faster commercialisation, ensuring

[187] Anita van Mil et al. (2019) From our brain to the world: views on the future of neural interfaces. Hopkins Van Mil. https://royalsociety.org/-/media/policy/projects/ihuman/public-engagement-full-report.pdf?la=en-GB&hash=5B6417E1881961853318F4CD570CA07A

[188] Kantar (2019). SIENNA D3.6: Qualitative research exploring public attitudes to human enhancement technologies. https://zenodo.org/record/4081193#.Y334_nanw2w & Marie Prudhomme (2019) SIENNA D3.5: Public views of human enhancement technologies in 11 EU and non-EU countries https://zenodo.org/record/4068194#.Y335KHanw2w

[189] Human Brian Project (2017). Citizens' View on Neuroscience and Dual Use Online Consultation & Human Brain Project (2017). European Citizens' View on Neuroscience and Dual Use.

[190] Nano2all (2017). BCI Dialogue with French Citizens) & Nano2all (2017). BCI Dialogue with Spanish Citizens)

device safety and balancing the interests of those who stand to benefit from medical neurotechnology (especially patients) with those of the wider public were therefore discussed during the roundtable and have been noted that these topics should continue to form a part of the neurotechnology conversation going forward.

When discussing the topic of commercialising medical devices, participants discussed two key suggestions: the first, that changes to clinical trials could be introduced to facilitate commercialisation; and the second, that increased engagement and support to navigate the regulatory framework could help innovators commercialise their applications.

When considering in more depth how faster commercialisation could be balanced with ensuring safety, most participants agreed that regulation needs to ensure patients are supported across the entire product life cycle, especially for long-term implants. Participants also mentioned the importance of post-market monitoring. It was highlighted that whilst there is an expectation for companies to set out how they will monitor their product in a post-market phase as part of the conformity assessment process, there is no *obligation* for companies to do so. It was strongly felt that this current system needs change.

Although it was recognised that stronger regulatory powers are needed in some areas of emerging technology, such as neurotechnology, some participants also noted that increasing regulatory oversight can hinder innovation. Participants also suggested using assessments from external providers for devices as a way of guaranteeing independence. However, it was noted that the split in responsibilities between regulators and Approved Bodies can make it difficult for innovators to navigate the regulatory process.

Findings on non-medical applications

Alongside medical devices, participants were also asked to consider questions around the application of non-medical devices including any hopes, concerns and regulatory responses they may have. Findings from the RS Public Dialogue show that, broadly, the public seems more hesitant about potential non-medical use cases because their potential benefits, and the associated problems they are trying to address, are much more poorly understood than for their medical counterparts. During the roundtable, topics such as concerns surrounding non-medical technologies, whether special protections are needed and what these would be and also whether any regulatory measures where needed as a basis for public reassurance for non-medical devices were discussed.

Despite agreeing that the development of consumer applications will be driven by non-invasive wearables over invasive devices, participants still thought that non-medical use cases could give rise to multiple concerns, such as the use of neurodata for targeted advertisement or the lack of understanding over the impact that non-invasive wearables can have on brain plasticity. Further findings from this topic include participants being

divided on who should regulate non-medical neurotechnologies and on whether a new regulator is required.

Findings on overarching acceptability considerations

Finally, the public dialogue commissioned by the RS identified (1) accessibility, (2) safety, (3) transparency and personal choice, and (4) governance as key areas that can influence the general acceptability of neurotechnologies. Participants were asked to consider these areas and discuss whether any regulatory measures are needed at this stage in this regard.

In response to these questions, it was found that participants believe technology-specific regulation may not be able to cope with the challenges posed by neurotechnology because these are common to other technologies and also relate to wider societal issues. It was also believed that currently there is a deep lack of understanding of the scope, long-term development and opportunities/risks presented by neurotechnologies. It was thought that, as a result, personal choice is currently not sufficiently well informed and that additional considerations to guarantee it may be needed, depending on the context.

Neurotechnology public engagement moving forward

When discussing the questions above, participants also reflected on public engagement more broadly and considered:

1. How to approach regulation based on what is known about public attitudes towards neurotechnology;
2. The role of public engagement going forward; and
3. How to *better* engage the public.

It was thought that understanding of neurotechnologies and their potential is still limited across the general public and that currently there are mixed attitudes to neurotechnology, whether that is apprehension or enthusiasm. It was also pointed out that attitudes towards these areas are being influenced by science fiction stories, which can ultimately skew public perception drastically. As a result of this, there was a strong consensus amongst participants that this needs to change, given the rapid pace of the current non-medical healthcare commercialisation. It is therefore important that moving forward (1) public engagement is sought at an early stage (whilst ensuring the public understands the issues at hand for the engagement to be meaningful), (2) engagement considers multiple publics to ensure data are useful and reliable and (3) the type of engagement is tailored to the use case and kind of application.

It was also suggested that when carrying out public engagement there needs to be an understanding and acceptability of risk, as the sole purpose of public engagement is to encourage honest and transparent communication. Ideally, any responses to such

engagements should contribute to establishing a proportionate regulatory response. Lastly, to help build public trust and support, it was suggested that public involvement in governance and regulation should be approached as a dynamic and ongoing process, with an emphasis on the need to make more explicit connections between public engagement and anticipating societal risks.

Annex II: Glossary

- **Neurotechnologies:** Devices that can be placed inside, on or in close proximity to the human body and used for different purposes, medical and non-medical, to directly record and/or modulate the activity of the nervous system.
- **Medical neurotechnology:** A device whose purpose whose purpose is to diagnose, prevent, monitor, treat or alleviate neurological disease or injury.
- **Invasive devices**: A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.
- **Non-invasive devices:** Includes wearables and also external devices, such as scanners.
- **Neurorecording:** The *direct* collection, measurement, processing and/or analysis of neurodata to deliver insights into the nervous system and/or interact with another device.
- **Neuromodulation:** The alteration of neural activity through the *direct* provision of energy (electric, magnetic, etc.) to a target area.
- **Optimisation/Enhancement:** Neurotechnologies that allow individuals to reach or exceed their biological potential. This does not include applications that restore an individual's performance to its baseline level when it has been degraded by a medical condition or injury.
- **History of safe use:** When the safety of the device has already been confirmed with clinical data and from experience of continued use of an equivalent device.
- **Irreversible:** Neurotechnologies that have a permanent impact on nervous system function.
- **Duration:**
    - Transient - normally intended for continuous use for less than 60 minutes.
    - Short-term - normally intended for continuous use for no more than 30 days.
    - Long-term - normally intended for continuous use for more than 30 days.
- **Use case of concern**: Neurotechnologies that require special consideration given the sensitive nature of the context in which they are used. Examples may include,

but are not limited to, applications used for military, employment, insurance, education, surveillance, security and judicial purposes.

- **Spatial and temporal resolution:** The smallest interval (in space and/or time) at which separate neural activities can be detected or modulated.

Annex III: Acknowledgements

This report has been authored by Dr Andy Greenfield, Professor Joyce Tait and Professor Alastair Denniston.[191] Key contributors from the Better Regulation Executive were Diego Rodriguez Mejias, Elizabeth Salmon, Henry Phillips and Zoe Wright.

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- Stephanie Croker, Government Office for Science (GOS)
- Dan Perkins, Office for Science and Technology Strategy (OSTS)
- Isabel Webb, BEIS

[191] Further information on the Regulatory Horizons Council, its members and a register of interests are available at https://www.gov.uk/government/groups/regulatory-horizons-council-rhc

Industry

- Ivor Gillbe, *Bioinduction*
- Emil Hewage, *BIOS Health*
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- Sergio M. de del Castillo, Office of Neurological and Physical Medicine Devices (FDA)
- Reema Patel, IPSOS
- Nick Hudson, Advertising Standards Authority (ASA)
- Cherie Leung, ASA