Department for Science, Innovation & Technology

Department of Health & Social Care

From Rt Hon Andrew Griffith MP,
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Regulatory Horizons Council
By email: RegulatoryHorizonsCouncil@beis.gov.uk

Dear committee members of the Regulatory Horizons Council,

Regulatory Horizons Council Report on the regulation of neurotechnology: Government response

Thank you for producing this report on the regulation of neurotechnology and for your recommendations to the Government. This Regulatory Horizon Council (RHC) report outlines the huge potential of neurotechnology to influence how we live and interact with one-another across work, education and other areas of our lives – and how well positioned the UK is to deliver on this potential.

It was a timely production, as it is clear that neurotechnology, particularly in the context of medical devices, has advanced significantly in recent time and the Government must take a leading role in shaping this area of innovation.

The report shows that regulation can be a key enabler for innovation in neurotechnology, which echoes the government's position, set out in our Science & Technology Framework, that regulation done correctly can stimulate demand for science and technology, attract investment, while representing UK values and safeguarding citizens.

Department for Science, Innovation and Technology (DSIT)

We set up the DSIT to position the UK at the forefront of global scientific and technological advancement, which includes delivering regulation to support our economy, security and public services.

We are therefore pleased to say that DSIT will be taking on responsibility for coordinating action on neurotechnology across government, ensuring that we support a growing UK sector, and champion a pro-innovation approach that will help to develop and launch technologies that could change people's lives in the UK.

We have responded to the RHC's recommendations below where they concern the remit of DSIT and the Information Commissioner's Office (ICO) (an executive non-departmental public body, sponsored by DSIT).

Department of Health and Social Care (DHSC)

The report is a reminder of the potential of neurotechnology in the treatment of patients and the importance of continuing to safeguard public health.

The report has a focus on medical device regulation, which is an area of ongoing reform. The majority of the recommendations made are broadly in line with the ongoing work of the DHSC and the Medicines and Healthcare products Regulatory Agency (MHRA).

The Government intends to introduce regulations in future that will implement a substantial reform of the current regulatory framework for medical devices in the UK. The approach to this reform was outlined in the 2022 Government response to the consultation on the future regulation of medical devices in the UK. The response can be found here: Consultation on the future regulation of medical devices in the United Kingdom - GOV.UK (www.gov.uk)

The reform includes making the UK a focus for innovation and the best place to develop and introduce innovative medical devices. The medical technology strategy, published in February 2023, outlines how we will ensure the health and social care system can reliably access safe, effective and innovative medical technologies that support the continued delivery of high-quality care, outstanding patient safety and excellent patient outcomes in a way that makes the best use of taxpayer money. The medical technology strategy can be found here: Medical technology strategy - GOV.UK (www.gov.uk)

To support this, we have launched the Innovative Devices Access Pathway (IDAP) pilot[1]. This is a new regulatory and access pathway that facilitates the development of innovative technologies that meet an unmet need. IDAP provides innovators and manufacturers with a multi-partner support service including targeted scientific advice and reimbursement into the NHS to bring new products to patients sooner. The pilot is run by the MHRA, the National Institute for Health and Care Excellence (NICE), NHS England, Scottish Health Technologies Group (SHTG) and Health Technology Wales (HTW), and the lessons learned will inform the development of the future IDAP pathway.

We will take steps to develop best-in-class regulations and uphold safety standards for medical devices. We will encourage innovative, and sustainable, product development to better meet patient needs, diagnosis and outcomes. We will monitor the evolution of

[1] The Innovative Devices Access Pathway (IDAP) - pilot phase - GOV.UK (www.gov.uk)

neurotechnologies closely to ensure that actions can be taken to support appropriate regulation.

We have responded to the RHC's recommendations where addressed to DHSC or MHRA.

RHC Recommendation 1

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

Response to Recommendation 1 – Accept

The MHRA strives to provide as much assistance to manufacturers as appropriate. Early engagement is preferred for all parties within the context of legal restrictions and resource capacity. To support early engagement, the Innovation Office has been set up to provide a 'front door' to obtaining assistance from the MHRA. The Innovation Office hosts Innovation Surgeries to provide an informal opportunity to discuss innovators' enquiries in more detail. The discussions and comments made by the MHRA during those meetings are to provide innovators with initial guidance on developing their product and how they might bring their product to market.

RHC 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.

Response to Recommendation 2 – Accept in principle

Guidance on medical devices and its regulations are publicly available and we encourage its use. We recognise the wide product scope of neurotechnology, and several medical device components may be integrated into the neurotechnology product, meaning guidance is spread across several resources and therefore more challenging to navigate. We commit to reviewing existing guidance and will consider generating novel guidance orientated towards neurotechnology as an end-to-end product.

RHC Recommendation 3

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

Response to Recommendation 3 – Accept in principle

We accept that bringing together expertise on neurotechnology would be beneficial in managing it as an emerging technology in the future, especially in terms of convergence with other emerging areas and rapid changes in the global medical technology landscape. The MHRA has in-house capability in this area, and frequently convenes external subject matter experts where there is a gap or need for bespoke expertise. This system is available for any neurotechnology issues that arise.

We do not currently consider a dedicated sub-group is necessary given the small number of products within scope. However, the Government commits to keeping the need for a dedicated MHRA sub-group focused on neurotechnology under review.

RHC 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.

Response to Recommendation 4 – Accept in principle

The Government continues to support the appropriate funding required for the operation of the MHRA, considering all its functions and keeping these under review. The MHRA's regulatory functions for medical devices are primarily funded by DHSC, with the remaining revenue from fees charged for services.

We are aware of the global pressures on conformity assessment bodies and are considering how best to mitigate constraints as part of the medical device regulatory reform. In January 2024, the MHRA designated two new UK Approved Bodies, bringing the total number to nine. The MHRA continues to support organisations seeking designation as an Approved Body. We anticipate Approved Body capacity will increase as approval need rises. Approved Bodies are private companies and the Government cannot dictate which type of products they assess.

RHC 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.

Response to Recommendation 5 – Accept in principle

The Government is supportive of innovation and the MHRA continues to work to understand how evidence can be generated in a proportionate way. The MHRA has recently launched

the IDAP to accelerate the development of cost-effective medical devices and their integration into the UK market, by providing an integrated and enhanced regulatory and access pathway to developers.

In addition, on 30 October 2023 the MHRA has announced it is taking forward its new 'regulatory sandbox', the AI-Airlock[2]. This will provide a regulator-monitored virtual area for developers of artificial intelligence (AI) as a medical device to generate robust evidence.

The Government does not consider that the current options for generating and presenting clinical evidence are unnecessary. As the statutory regulator for product safety in healthcare, the MHRA has a duty to patient and public safety. As set out in the Government response to the consultation on the future regulations of medical devices[3], the Government intends to introduce requirements on entire equivalence on a biological, technical and clinical basis. This approach will help mitigate the risks of 'product creep' where new devices on the market in practice become very different from their 'equivalent' devices, which can result in serious patient safety risks[4].

There is also currently a limited pool of neurotechnology products available for which new devices can claim equivalence.

RHC Recommendation 6

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

Response to Recommendation 6 – Accept in principle

The MHRA recognises the benefits of regulatory sandbox programmes and other innovative approaches in the appropriate circumstances. We are currently focussing on the regulation of AI as a medical device given the challenges with evidence generation.

The MHRA recently announced the AI-Airlock to support innovators of AI as a medical device to understand and deliver what is required to ensure the real-world viability of these devices. In the context of software or AI as a medical device, our "Airlock" process is akin to a regulatory sandbox. The AI-Airlock will be ready to launch in April 2024.

It is our view that the sandboxing programme for neurotechnology proposed by the RHC would not currently be risk-proportionate for the testing of these high-risk and complex products. The risk profile of testing software as a medical device within a monitored setting

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[2] MHRA to launch the AI-Airlock, a new regulatory sandbox for AI developers - GOV.UK (www.gov.uk)
[3] Consultation on the future regulation of medical devices in the United Kingdom - GOV.UK (www.gov.uk)
[4] Gefen, A., Santamaria, N., Creehan, S. and Black, J., 2019. Patient safety may be compromised if study conclusions are generalized to products that make similar claims but have no equivalent research evidence. *Journal of Patient Safety and Risk Management*, *24*(1), pp.37-45.

differs greatly between the majority of neurotechnologies, such as neuromodulation and implantable neurotechnology.

As a risk-proportionate alternative to the proposal for a sandbox programme for neurotechnology, the MHRA has a pre-existing route to generate clinical evidence for medical devices prior to seeking conformity assessment approval through clinical investigations. Manufacturers must inform the MHRA about a clinical investigation for a medical device at least 60 days before starting the investigation and obtain approval for their proposal. This process allows manufacturers to generate the data required to support reaching conformity requirements whilst protecting patient participants. Guidance on notifying the MHRA about a clinical investigation is available on GOV.UK[5].

RHC 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.

RHC 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.

Response to Recommendations 7 and 8 – Accept

The Government accepts these two recommendations. The MHRA intends to introduce similar requirements to the EU Medical Device Regulations (MDR): Annex XVI where there is benefit to the UK. This would bring devices without an intended medical purpose, which have similar functionality and patient risk profiles to products that have a stated medical purpose, into scope of existing regulations.

Products without an intended medical purpose which do not meet these parameters are not intended to come into scope of the medical devices regulations. These would continue to fall under the scope of the existing regulations governing this type of product.

[5] Notify the MHRA about a clinical investigation for a medical device - GOV.UK (www.gov.uk)

RHC 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.

Response to Recommendation 9 – Accept

By 2025, the ICO will develop specific neurodata guidance as part of its ongoing work in this area. This will consider the interpretation of core definitions and approaches, set out our views on emergent risks and provide use-based and sector-specific case studies to highlight good practice.

RHC 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.

Response to Recommendation 10 – Accept in Principle

We agree on the importance of protecting neurodata. The UK's data regime already provides enhanced protection for personal neurodata when it takes the form of biometric data for the purpose of uniquely identifying someone, health data, or genetic data. Article 9(1) sets out a prohibition on these specific types of processing. Such processing may only occur if it meets a condition in Article 9(2), as supplemented by Schedule 1 in the Data Protection Act 2018.

The UK GDPR also provides general protection for personal data such as requirements that it be processed fairly and lawfully, and rights for data subjects. These include the right to access personal data and the right to have it erased.

The government is keeping protections under review and will not hesitate to take action in future as needed.

RHC 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.

Response to Recommendation 11 – Accept in principle

We are working with system partners at pace to implement solutions to streamline and join-up the innovation adoption pathway: from providing clear signals to industry on the innovation we need, to reforming regulation, comparative assessment and clearer procurement pathways.

To underpin the innovation pathway, we are working in collaboration with industry and the health system to improve existing datasets by enhancing the data quality, coverage, structure and access. Having higher quality, joined-up, comprehensive data for MedTech will make it easier to compare products, reducing search time and making it easier to make informed choices to select the right product, at the right price, in the right place.

We are committed to ensuring equitable medical device practices, spanning from design through to use. Government recently published its response to the Equity in Medical Devices: Independent Review, endorsing the findings and outlining the steps being taken to address the recommendations. The MHRA have also recently updated their guidance on software as a medical device[6], which highlights the current state of the art with respect to avoiding bias and ensuring adequate representation of populations within the intended purpose.

There is a need to ensure maximal benefits and safety can be achieved from the use of medical devices across the whole population. Where there is clinical need, alternative routes to market, such as IDAP or exceptional use authorisations, are available.

RHC 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.

Response to Recommendation 12 – Accept

The Government is proceeding with the proposal to amend the UK medical devices regulations to clarify and strengthen the requirement for manufacturers to implement a post-market surveillance system. The legislation is expected to be laid in parliament in the first half of 2024 and will come into force at least six months later.

[6] Crafting an intended purpose in the context of software as a medical device (SaMD) - GOV.UK (www.gov.uk)

RHC 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.

Response to Recommendation 13 – Accept

DSIT will take on responsibility for cross-government coordination on neurotechnology, including convening relevant departments on regulatory issues. All partners listed in the recommendation will be involved and we will monitor other interested parties from across government, including ALBs.

Government will continue to consult with experts in academia and industry on establishing a proportionate regulatory framework that encourages the safe and effective development of neurotechnology in the UK.

RHC 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.

Response to Recommendation 14 – Accept

Government will be active in international neurotechnology initiatives, such as at the OECD and UNESCO, ensuring that international agreements are compatible with the UK's approach to the proportionate regulation of neurotechnology, as well as UK values more broadly.

The Government recently attended and engaged in the International Conference on the Ethics of Neurotechnology and will continue to take opportunities to engage internationally in line with our international approach to promote open, responsible, secure and resilient principles for the development, adoption and use of technology.

Department for Science, Innovation & Technology

Department of Health & Social Care

We look forward to continuing to work with the RHC and the wider community of neurotech experts and innovators in the UK to deliver on the proposals set out above, and in turn realise the significant opportunity of neurotechnology by supporting its commercialisation and use.

Yours sincerely,

Rt Hon Andrew Griffith MP
Rt Hon Andrew Stephenson CBE MP