REGULATORY HORIZONS COUNCIL

Regulatory Horizons Council

Report on Medical Devices

19 August 2021

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Foreword

Regulatory reform in medical devices is urgently needed. The complexity of new medical devices is mind boggling and is driven by the speed of advances in technology and material science and their potential application to solve debilitating or life-threatening human conditions. In turn this brings enormous personal benefits and greater individual risks.

The existing medical device regulatory framework will require additional support to encompass emerging products such as artificial intelligence, exoskeletons or neural implants.

Here is an opportunity for the UK, as we leave the EU, to be a global leader in the development and evaluation of medical devices. We have our own thriving medical devices industry, but we also have a unique and enviable trinity of a respected independent Medicines and Healthcare products Regulatory Agency (MHRA) and a globally respected independent agency for assessing efficacy and value for money through the National Institute for Health and Care Excellence (NICE) and the best international GP, hospital and clinical audit data. So, in my view, we are better equipped than any other country to meet the challenge and harness the opportunities offered by this explosion in technology.

This report from the Regulatory Horizons Council is a timely call for action.

It offers a route to more effective safety assurance through mechanisms that consider the whole product lifecycle, how we detect adverse events which occur rarely or a long time after use of the device and how we trace and recall patients when needed.

Importantly this report is firmly patient-centred: accelerating innovation, assuring safety, and increasing engagement of patients with the process of development and regulation.

This report also considers a number of ways we can be smarter in our use of data and technology to join up *digital systems*. Examples include more effective use of unique device identifiers on medical devices, and collection of lifelong data in a systematic way will improve detection of adverse events and our ability to intervene earlier. There is also a role for ensuring better joining up of the *human systems* – ensuring that disparate health providers and regulators communicate effectively with each other and with patients.

The opportunities are enticing. Effective implementation of the recommendations will bring tangible economic benefits and enable our patients to benefit from the very best of UK and global innovations more rapidly than at present.

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Chair, Birmingham Women's and Children's NHS Foundation Trust

Formerly, Medical Director of the NHS in England (2007-18).

Acknowledgements

This report would not have been possible without the help of our stakeholders, colleagues, and the wider medical devices community.

Many thanks go to our stakeholders, who offered their expertise to participate in workshops, interviews and bilateral meetings, both for the purposes of Regulatory Horizons Council (RHC)-led events and for the work of Birmingham Health Partners Centre for Regulatory Science and Innovation (CRSI).

Also, to Birmingham Health Partners, whose effective engagement with stakeholders and ensuing high quality reports supported the evidence gathering by the RHC that has led to this report.

1.Executive Summary

Medical devices are an essential tool for the delivery of healthcare, ranging from the relatively simple and external (such as sterile gloves) to the complex and invasive (implantable defibrillators, deep brain stimulators, etc). This is an area of intense innovation, and one in which there are ever-increasing opportunities to improve people's lives through devices that address health needs, including in diagnosis, treatment, or disease prevention.

The COVID-19 pandemic has highlighted how being able to invent, develop and scale reliable *in vitro diagnostic* tests saves lives. Advances in *imaging technologies* mean that health care professionals can now detect diseases earlier and monitor treatments more reliably. Advances in *implantable and wearable devices* mean that our health status can be monitored in real time, and treatment delivered rapidly, even within seconds.

The range, complexity, and rapid evolution of new types of medical devices does however bring challenges in the field of regulation, namely, how to support innovation in medical devices to accelerate benefit to patients and the growth of this sector, whilst also enhancing safety. Concern regarding the safety of some medical devices has been raised in the context of high-profile cases such as the use of metal-on-metal hip replacements, PIP silicone breast implants, and pelvic mesh, and indeed the last of these was specifically considered as part of the Independent Medicines and Medical Devices Safety Review (IMMDS Review) published in 2020. As part of her report, Baroness Cumberlege noted 'There is potential to do so much good, but we must ensure the risks of increasingly complex healthcare are understood and where the system is not sure of the risk it must say so.'[1]

In this report the RHC reviews the overarching question, "*How can the UK encourage international investment, innovation and improve safety in the medical devices area through regulatory and non-regulatory changes?"* This question is particularly timely in the context of three major contemporary events: the UK's exit of the European Union (EU), Europe's transition of its regulatory framework, and the global urgency of the COVID-19 pandemic.

Within this broader question, the report focused on these specific questions:

[1] https://www.immdsreview.org.uk/Report.html

What are the mitigations that could be implemented to facilitate the move to the UK Conformity Assessed (UKCA) mark being mandatory for medical devices from 01 July 2023?

What are the potential alternative routes to market for medical devices that are currently being used internationally that could be transposed to the UK market and regulatory system?

What are the key challenges that have arisen around the application of in vitro diagnostic (IVD) regulations during the COVID-19 pandemic?

The RHC findings and recommendations arising are:

A) There is a need to build a regulatory system for medical devices that works for patients

- **Recommendation 1:** The regulation of medical devices should be centered on the needs of patients, informed by patients, record outcomes that matter to patients, and provide evaluations that are understandable to patients

B) There is a need to increase capacity to address present needs and emerging opportunities

- **Recommendation 2:** Strengthen and increase funding to the MHRA[2] to significantly expand their capacity in medical devices including in emerging technologies
- **Recommendation 3:** Address bottlenecks in the approval of medical devices, notably the shortage of UK approved bodies (ABs) for conformity assessment
- **Recommendation 4:** Prepare mitigations that supplement AB capacity to ensure supply of devices after transition to UKCA

C) There is an opportunity for the UK in international leadership and partnership in medical devices

- **Recommendation 5:** Support the MHRA to increase UK visibility, international engagement and leadership
- **Recommendation 6:** Invest in the UK as a global centre for regulatory science and the training of regulatory professionals with expertise in medical devices, including in emerging technologies

[2] The MHRA is an executive agency of the Department for Health and Social Care: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

- **Recommendation 7:** Build international partnership through mutual recognition agreements and domestic assurance or reliance routes where this may lead to overall efficiencies whilst preserving safety

D) There is an opportunity to use medical devices as a template to help enable regulatory innovation that improves patient safety, system efficiency and UK growth

- **Recommendation 8:** Identify and resource areas where regulatory innovation within the medical device sector may attract inward investment and growth
- **Recommendation 9:** Develop a UK patient safety data base that collects key details of all medical devices and monitors patient safety and wellbeing moving forward

E) There is a need to build resilience and prepare for future threats

- **Recommendation 10:** Pandemic preparedness should include fast-track evaluation of new in vitro diagnostics
- **Recommendation 11:** Reporting of diagnostic tests should be transparent and standardized

Table 1. Recommendations and routes to achieving them

	Recommendation	This should be achieved by
1	**The regulation of medical devices should be centred on the needs of patients, informed by patients, record outcomes that matter to patients, and provide evaluations that are understandable to patients**	• Increasing patient involvement within the MHRA, through increasing patient representation on expert groups and within decision-making processes, in addition to continuing to expand existing patient consultation initiatives. • Increasing the use of patient-reported outcomes throughout the regulatory pathway, including both conformity assessment and post-market surveillance. • Include the routine collection of patient reported outcomes within the MHRA's strategic objective 'to embed state-of-the-art surveillance across medicines and medical devices'[3]

[3] MHRA_Delivery_Plan_21-23_Final_210618.pdf (publishing.service.gov.uk)

2	**Strengthen and increase funding to the MHRA to significantly expand their capacity in medical devices including in emerging technologies**	• For government to work closely with MHRA to ensure that it has the additional targeted investment within medical devices that allows it to not only meet increased demands required by its remit but also support innovation in areas of opportunity such as software as a medical device, and emerging technologies.
3	**Address bottlenecks in the approval of medical devices, notably the shortage of UK approved bodies (ABs) for conformity assessment**	• Open reporting by the MHRA of the number of ABs approved and in application • MHRA to regularly review both actual and projected AB capacity in line with actual and projected demand from manufacturers to support efficient timelines in conformity assessment • Risk mitigation measures for addressing any anticipated shortfall in AB capacity should be in place and may include engagement and incentivization strategies • Providing adequate support and guidance to ABs that assess high risk devices
4	**Prepare mitigations that supplement AB capacity to ensure supply of devices after transition to UKCA**	• Maintaining the 1st of July 2023 deadline for some devices but consider extending for others • Considering assurance or reliance routes, or mutual recognition of devices
5	**Support the MHRA to increase UK visibility, international engagement and leadership**	• Clearly defining the full remit of MHRA and ensuring that they have the tools/resources to deliver • Considering the needs of the medical devices sector while exploring agreements relating to reliance or assurance routes and mutual recognition with international markets

		• Supporting the MHRA as needed in the process of gaining full membership to MDSAP and IMDRF
6	**Invest in the UK as a global centre for regulatory science and the training of regulatory professionals with expertise in medical devices, including in emerging technologies**	• Creating one or more centres of excellence in regulatory science and innovation in healthcare, which should have research, innovation, education, and training roles. • Explore mechanisms to incentivise training in regulation, including through investing in training opportunities and apprenticeships in relevant institutions, such as the MHRA and Approved Bodies, and other relevant institutions. • Utilise the excellence of the UK's academic sector to support the MHRA in its international role, being able to lead in efficient and innovative regulatory approaches, including in emerging technologies.
7	**Build international partnership through mutual recognition and reliance or assurance where this may lead to overall efficiencies whilst preserving safety.**	• Considering reliance or assurance, or mutual recognition of devices as a long-term solution
8	**Identify and resource areas where regulatory innovation within the medical device sector may attract inward investment and growth.**	• Working collaboratively with the sector to build an innovation friendly regulatory framework for medical devices • Supporting the development of a clear pathway for emerging technology through additional resources online and additional advisors within this area as per recommendation 6 • Maintaining an understanding of emerging areas of innovation and therefore where the government might want to increase investment or incentives
9	**Develop a UK patient safety data base that collects key details of all**	• Supporting the MHRA, NHS-Digital and others to build on and bring

	medical devices and monitors patient safety and wellbeing moving forward. **A: Strengthen existing safety reporting through digital tools and the use of comprehensive data collection from health systems, patients and carers to a central MHRA-held UK Patient Safety Database** **B. When medical devices are used, their unique device identifier (UDI) should be recorded as standard within a patient's health record, and this should be returned to a central MHRA led UK Patient Safety Database**	together current data programmes to create a combined reporting system for adverse incidents, medicines, medical devices, blood and counterfeit products under the established yellow card brand to ensure patient safety,[4] leading to an MHRA-held database that can support medical devices (and other healthcare products) • Ensuring the MHRA has adequate resource for this work • Supporting and providing needed resource to the MHRA in the development of a Patient Safety Database • Introduce legislation that would require devices to have a UDI
10	**Pandemic preparedness should include fast-track evaluation of new in vitro diagnostics**	• Consolidation of the learning from the successes and challenges of developing and regulating IVDs for SARS-CoV2 during the COVID-19 pandemic, including the successful use of Target Product Profiles (TPPs) to ensure future accelerated development and regulatory pathways

[4] https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about#our-priorities

2. Introduction

The RHC is an independent expert committee that identifies the implications of technological innovation, and provides government with impartial, expert advice on the regulatory reform required to support its rapid and safe introduction. It conducted horizon scanning and prioritisation exercises[5] to first get to a shortlist of priority areas[6], and then selected four initial areas to focus on: medical devices, fusion energy, genetic technologies and unmanned aircraft.

This report represents views from across the RHC and was led by Alastair Denniston with particular support from Andy Greenfield, and also from Matt Ridley, Joyce Tait, Parag Vyas and RHC Chair Cathryn Ross.[7]

2.1 Why medical devices and why now?

What do we mean by medical devices?

In broad terms a medical device is 'an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose'.[8]

Priority areas for the RHC are technological innovations and/or business models with high potential economic, social and environmental benefit, and where regulatory reform is needed to facilitate the rapid and safe introduction of these products, services and business models.[9] Medical devices was identified by the RHC as a priority area that has high potential benefits for the UK, where regulatory reform may be required to maximise the scope for innovation to bring about those benefits.

[5] https://www.gov.uk/government/publications/the-prioritisation-of-future-innovations

[6] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949318/potential-priority-areas-for-the-council.pdf

[7] https://www.gov.uk/government/groups/regulatory-horizons-council-rhc#membership

[8] https://www.who.int/medical_devices/definitions/en/

[9] https://www.gov.uk/government/publications/the-prioritisation-of-future-innovations

Health benefits - improving health, avoiding harm

With the UK leaving the EU, there is great opportunity to independently set out a regulatory framework for medical devices in Great Britain that is best aligned to the people of the UK. The Medicines and Medical Devices Act 2021[10] allows the UK to amend the UK Medical Devices Regulations 2002[11], so that it can make changes to its own secondary medical devices legislation. The Act aims to ensure that the NHS and patients have faster access to the best innovative medicines and medical devices, so the UK can use this opportunity to promote better patient outcomes and population health and prioritise patient safety.

The opportunity provided by the UK's exit from the European Union is accompanied by the challenge to regulators, manufacturers, and other stakeholders of managing the very substantial changes that will be required to make the best of this opportunity. Change has been compounded by the transition to new regulations around medical devices in the EU (that also apply in Northern Ireland). The EU Medical Device Regulations (2017/745) (MDR) apply from 21 May 2020 and the in vitro Diagnostic Medical Device Regulations (2017/746) (IVDR) will apply from 21 May 2021. It is clear that now more than ever the UK needs to signal a clear way forward and embody leadership to inspire international confidence and confidence within the sector.

Another major driver for considering medical devices at this time, is the increasing opportunity offered by new devices such as artificial intelligence as a medical device, but for which the existing frameworks may not be ideal. Finally, the Covid-19 pandemic has heightened collective awareness of the importance of medical devices (ranging from personal protective equipment to in vitro diagnostic tests for the SARS-Cov2 virus). There is an opportunity to investigate what lessons can be learned about the existing frameworks, communications and resources that could be used in the event of a future pandemic, as well as lessons learned from the vaccine rollout.

Economic benefits

The UK life sciences sector plays an important part in the UK economy, it employs 256,100 people and generates an annual turnover of £80.7 billion.[12] Additionally, the UK medical technology industry is the 2nd largest employer in Europe (100,000 people) after Germany (200,000 people)[13] and is comprised of over 2,000 companies, more than 80% of which are Small and Medium Sized Enterprises (SMEs).[14] Additionally, the UK medical

[10] https://www.legislation.gov.uk/ukpga/2021/3/enacted

[11] https://www.legislation.gov.uk/uksi/2002/618/contents/made

[6]https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/910590/Bioscience_and_Health_Technology_Statistics_2019.pdf

[13] https://www.medtecheurope.org/wp-content/uploads/2019/04/The-European-Medical-Technology-Industry-in-figures-2019-2.pdf

[14] https://www.abhi.org.uk/multimedia/docs/industry-recommendations/abhi-industry-recommendations.pdf

devices industry itself employs around 50,000 people, additionally supporting a further 250,000 indirectly.[15] The industry has the potential to thrive and contribute to the UK economy, providing the UK recognises the significant opportunity to take advantage of the current medical devices landscape, and position itself to become a 'science superpower', fulfil the Government's manifesto commitments to create a global hub for life sciences in the UK and remain at the forefront of the global life sciences sector.

Unlocking innovation

In the current climate, in which the Medicines and Medical Devices Act 2021 has been passed into law, which requires the Secretary of State when amending or supplementing secondary legislation, to consider the likelihood of the United Kingdom being seen as a favourable place in which to carry out research and development of medical devices, the UK has a unique opportunity to assess, update and improve the medical devices regulatory space. Additionally, supporting the growth of the UK life sciences sector and ensuring the UK remains at the forefront of the global life sciences sector now that the transition period has ended.

International leadership

In light of the UK leaving the EU, there is an opportunity for the UK to be a recognised leader in its own right, developing international partnerships through exploring agreements relating to reliance or assurance routes, or mutual recognition, as well as international programs and forums, such as Medical Device Single Audit Program (MDSAP) and the International Medical Device Regulators Forum (IMDRF). These new opportunities provide a platform for expanding the UK's international reputation, and allowing the UK to have the opportunity to develop the international medical devices landscape, as well as giving the UK the freedom to explore exciting domestic initiatives that could inspire collaborative working internationally and shared learning.

2.2 Scope

2.2.1 Key questions:

How can the UK encourage international investment, innovation and improve safety in the medical devices area through regulatory and non-regulatory changes?

[15] https://www.abhi.org.uk/multimedia/docs/industry-recommendations/abhi-industry-recommendations.pdf

What are the mitigations that could be implemented to facilitate the move to the UKCA mark being mandatory for medical devices from 01 July 2023?

What are the potential alternative routes to market for medical devices that are currently being used internationally that could be transposed to the UK market and regulatory system?

What are the key challenges that have arisen around the application of IVD regulations during the COVID-19 pandemic?

2.2.2 Key questions methodology

The key questions were developed iteratively based on internal conversations within the Council and between the Council and a stakeholder network comprising of the Medicines and Healthcare products Regulatory Agency (MHRA), Department of Health and Social Care (DHSC), National Health Service X (NHSX) and Office for Life Sciences (OLS), in which the stakeholders identified high priority questions based on the criteria of value and feasibility.

A. Value – an area of importance in which there was clear value obtained from the RHC leading and driving this work forwards considering their independence, objectivity, stakeholder engagement expertise, networks and agile working practices.

B. Feasibility – an area in which the RHC could rapidly and usefully contribute, considering the timeframe and scope of the RHC.

2.3 Research conducted on the RHC's behalf

Birmingham Health Partners (BHP) Centre for Regulatory Science and Innovation (CRSI) was commissioned by the RHC to produce four reports:

- Report: Opportunity and risks around future UK regulatory reform of medical devices (Appendix A)
- Report: Lessons learned from COVID-19 in relation to IVD regulations (Appendix B)
- Report: Alternative routes to market for medical devices (Appendix C)
- Report: Mitigations for the move to the UKCA mark from 01 July 2023 (Appendix D)

These reports were based on a combination of literature reviews, one-on-one semi-structured interviews, a multidisciplinary stakeholder workshop and a postworkshop survey; the full methodology is included in the reports (Appendices A-D). The RHC independently evaluated all evidence provided to it through the literature reviews and stakeholder engagement exercises. Themes and stakeholder recommendations that emerge from this evidence have been appraised and considered against key criteria (section 3).

3.Key Criteria

This section looks at the key criteria the RHC arrived at for the medical devices recommendations and sets out how these criteria were arrived at.

The documents below were used as sources on innovation-friendly regulation to help develop the criteria.

3.1 Key sources relevant to innovation-friendly regulation and medical devices regulation in the UK

Innovation-friendly regulation

2019 BEIS White Paper on Regulation for the fourth industrial revolution[16] – Identified six challenges that need to be addressed, e.g., "*ensure that our regulatory system is sufficiently flexible and outcomes-focused to enable innovation to thrive".*

2020 BEIS Research on Regulatory approaches to facilitate, support and enable innovation[17] – Reviewed broad types of innovation-friendly approaches, e.g., "*supporting experimentation and testing of innovations using 'sandboxes' and 'testbeds'".*

2020 World Economic Forum Toolkit for Regulators on Agile Regulation for the Fourth Industrial Revolution[18] – Identified key tools for good regulatory practice, e.g., foundations such as "openness, proportionality and fairness".

Medical device regulation

2020 The Independent Medicines and Medical Devices Safety Review[19] - Reported on the English healthcare system's response to reports of harmful side effects and what could be improved upon.

Medicines and Medical devices Act 2021[20] - Seeks to fill the gap at the end of the transition period by introducing regulation-making powers in relation to human medicines

[16] https://www.gov.uk/government/publications/regulation-for-the-fourth-industrial-revolution

[17] https://www.gov.uk/government/publications/regulator-approaches-to-facilitate-support-and-enable-innovation

[18] https://www.weforum.org/about/agile-regulation-for-the-fourth-industrial-revolution-a-toolkit-for-regulators/

[19] https://www.immdsreview.org.uk/Report.html

[20] https://www.legislation.gov.uk/ukpga/2021/3/enacted

and their clinical trials, veterinary medicines, and medical devices to allow existing regulation to be updated.

3.2 Key considerations

3.2.1 Criteria that are urgent and specific to medical devices

Whilst drafting our recommendations, we developed some key considerations specific to medical devices that guided the development of our recommendations and supported our prioritisation in this area.

A. Ensure continuity of availability of medical devices to the citizens of the UK
B. Improve safety of medical devices with regard to the recommendations of the IMMDS Review
C. Create a landscape that is fit-for-purpose for new forms of devices, such as Artificial Intelligence as a Medical Device

A. Ensure continuity of availability of medical devices to the citizens of the UK

After 30th June 2023, all medical devices will require a UKCA mark to remain on the market, which has the potential to affect medical device availability for patients. Therefore, it is a priority for the RHC to ensure our recommendations support continued availability.

B. Improve safety of medical devices with regard to the recommendations of the IMMDS Review

In the IMMDS Review, Baroness Cumberlege highlighted concerns around safety and areas for improvement including increased responsiveness to patient reports, and transparent and compassionate collaboration to resolve problems as they arise to ensure patient safety.

C. Create a landscape that is fit-for-purpose for new forms of devices, such as Artificial Intelligence as a Medical Device

Any recommendations the RHC makes should consider ensuring that future forms of medical devices are considered in regulation and processes, to facilitate innovation and provide an attractive place for both national and international investment.

3.2.2 Other criteria related to regulation for innovation

Recognising that the RHC is pro-innovation in the development of regulation, we also considered wider principles of regulation that support innovation while also prioritising safety.

D. Proportionality and agility
E. Perception and trust
F. Lessons learnt and understanding
G. Experimentation and forward-looking
H. Support and collaboration

D. Proportionality and agility

When reviewing changes to medical devices regulation, we considered whether our recommendations were adaptive, flexible and streamlined, ensuring innovation potential was not hampered by the recommendations.

E. Perception and trust

In the IMMDS Review, Baroness Cumberlege concluded that public perception and trust should be prioritised to ensure confidence in moving forward into a new regulatory landscape. The public and patients should feel confident that their safety and patient experience will be enhanced or, at the very least, remain the same quality; the industry would need to be confident of adequate resource; the regulators should have suitable clarity to allow for adequate planning and execution; and all could benefit from innovative advances that could improve the sector overall.

F. Lessons learnt and understanding

The importance of reflection, responsiveness and situational awareness was highlighted by the experience of the sector during the COVID-19 pandemic, especially in the balance between the market driving innovation for IVDs and central coordination directing/overseeing the nature and utility of those innovations.

G. Experimentation and forward-looking

Our recommendations consider the importance of understanding the context and trends of the sector, linking lessons learned and applying previous experience to new innovative projects, to promote safe and proportionate experimentation and regulatory flexibility while maintaining appropriate anticipation of risks and trends, without compromising safety.

H. Support and collaboration

Recommendations should support the development of collaborative working, aiding the work of businesses, manufacturers, regulators and stakeholder groups to work effectively together to allow for innovation and sector growth in the UK, while reducing bureaucracy where it is safe to do so. We must also ensure recommendations incorporate global considerations, promoting international collaboration and partnerships, where beneficial, while maintaining UK independence and minimising reliance on international relationships.

4. Key Themes

In responding to the overarching and contributory questions, the literature reviews and stakeholder engagement exercises highlighted a number of common themes which are highlighted below. Themes were also identified while developing our recommendations and through the commissioned BHP reports (Appendices A-D).

4.1 Overarching Themes

Theme 1: Opportunity for regulatory independence

The UK now has an opportunity to create regulatory frameworks that improve safety, and ensure that the UK regulations are fit for the newer types of devices that have come to market since the current EU Directives underpinning UK medical device regulations, given effect in UK law by the UK Medical Device Regulations 2002 were drafted. Indeed, the regulations should also anticipate technologies that are currently or imminently seeking entry. Examples include the expansion of software as a medical device (SaMD), including artificial intelligence as a medical device (AIaMD), and the anticipated arrival of adaptive algorithms that can potentially update continuously in response to new data, changing its performance metrics relative to the time point at which regulatory approval was given. With its new scope for independent regulatory activity, the UK can respond and ensure that its regulatory frameworks are able to anticipate and respond more quickly to new challenges and opportunities.

Theme 2: The threat of regulatory divergence

There is a very high level of concern from stakeholders regarding the risks of regulatory divergence and the impact that this would have by erecting new barriers to regulatory approval for devices for import and export.

- Regarding imported devices: patient representatives, device manufacturers, notified bodies and regulatory experts advise that there is a high risk of patients losing access to certain devices after the ‘hard-stop’ of 30 June 2023 discussed further below.
- Regarding UK manufactured devices for export: device manufacturers express concern regarding the additional costs that will be incurred to achieve the CE conformity assessment in addition to the UKCA mark in order to trade on the GB and EU markets, and that this will make them less competitive.
- Regarding Northern Ireland: stakeholders have reported that they are considering relocating their businesses to Northern Ireland, in response to their perception of

uncertainty around the future of the UK's regulatory position. This also enables them to take advantage of the opportunity of parallel regulatory pathways available to them.

Theme 3: The need for certainty, clarity and guidance through the changing regulatory landscape

Investment and other strategic decisions for device manufacturers will depend on the additional requirements that a new regulatory framework will necessitate. An already complex regulatory landscape in medical devices is made potentially more challenging due to ongoing changes within European legislation and Northern Ireland (but not Great Britain), which have moved to EU MDR and will move to EU IVDR in future. There is a consistent view from stakeholders of the need for greater clarity in the regulatory pathways for different types of devices, and support in navigating these pathways.

4.2 Transition from CE to UKCA marking in 2023

Theme 4: Risk to patient safety and reduced access to devices arising from lack of capacity in approved bodies within the UK

There is currently a severe lack of capacity in UK Approved Bodies (ABs) to undertake conformity assessment for compliance of medical devices, with applicable regulatory requirements before placement of the new UKCA mark on such a device. This is seen by our stakeholders as a very significant risk to individual patients and the wider health system that may lose access to essential devices if the current timetable is maintained (with UKCA marking being mandatory for medical devices placed on the GB market from 1st July 2023).

Theme 5: Risk of reduced competitiveness of UK device manufacturers

Reduced competitiveness may arise from (1) delays in awaiting conformity assessment due to the lack of capacity of UK approved bodies, and (2) increased costs arising from the need to seek separate regulatory approval in the EU if the manufacturer wishes to continue to export to that market.

The shortage of ABs is evident, but what is also of concern is that the existing notified bodies (NBs) are themselves stretched by the introduction of MDR, and the imminent introduction of IVDR in 2022 within the EU. This significantly reduces their capacity and potential interest in undertaking the additional requirements to become UK ABs. Even if they achieved this designation, their capacity to undertake the additional work would be more limited than at other times due to the additional burden of MDR/IVDR-related work.

4.3 Alternative routes to market

Theme 6: Need to maximise relevance through new international engagement and leadership

The UK's regulatory expertise and the excellence of the MHRA is widely recognised. Leaving the EU inevitably results in lost influence within the EU market but brings new opportunities to participate with international regulatory initiatives, most notably the MDSAP and the IMDRF, for both of which the MHRA currently holds official observer status and is en route to full membership.

This is an exciting opportunity for the UK - and particularly the MHRA - to be recognised in its own right as an international leader in the regulation of medical devices, and to be working directly with the most forward-thinking states shaping the future of international regulation. Additionally, participating in international programs such as MDSAP may bring efficiencies and potentially save costs for device manufacturers who wish to reach multiple international markets.

Theme 7: Opportunity for efficiency through acceptance of domestic assurance or reliance and mutual recognition, including exploration of Mutual Recognition Agreements (MRA)

International regulatory co-operation may be facilitated by various mechanisms, including mutual recognition agreements (MRA), which may facilitate market access through removing duplicative processes or allowing them to take place in the country of manufacture. MRAs can be valuable in reducing technical barriers to trade and should be considered as part of a spectrum of tools to enhance co-operation.

In the context of the rapid timeline to the UK's move to independent conformity assessment (UKCA) and the need to safeguard the supply of medical devices to UK patients, a unilateral domestic assurance or reliance route to market may be a useful initial step. In such an assurance or reliance route, it is at the discretion of the competent authority (the MHRA in the UK) whether to recognise the suitability of the approval or conformity assessment of the recognised regulatory authority. The level of additional assurance needed would depend on the risk class of the device in question.

4.4 Learning from the COVID-19 pandemic in relation to in vitro diagnostics (IVD)

Theme 8: Regulation of diagnostic tests should consider the risk of harm when used at scale and not simply at the individual level

The use of safe, effective diagnostic tests for SARS-Cov-2 was a key part of the response to the Covid-19 pandemic, but it also highlighted a number of examples of poor-quality tests that were brought to market under self-certification. The appearance of such tests may have caused harm both through the generation of False Negatives (i.e., false reassurance that the individual did not have the condition) or False Positives (false concern that they had the condition when they did not). This may cause harm at the individual level, but with an infectious disease it may have far-reaching consequences at a population level as it undermines the ability to contain the infection. Additionally, the credibility of high-quality, accurate tests may be undermined by association, negatively impacting their use and hindering policymakers.

Theme 9: Pandemic-preparedness should include facilities that support the efficient development, evaluation, and regulation of in vitro diagnostics

One of the most critical responses to the pandemic was to be able to develop and scale reliable diagnostic tests. Specific challenges noted during the Covid-19 pandemic with regard to in vitro diagnostics included the importance of securing reference materials (for evaluating the tests), the need to increase the level of assurance with regard to in vitro diagnostic devices that self-certify, and the need to increase capacity within the IVD regulatory pathway to accelerate time to approval of safe and effective devices. Additionally, there is a need to improve clarity regarding the intended use of an IVD (including the population or pathway it is intended for), and for transparency of reporting of performance data.

5. Recommendations

The evidence gathered was evaluated in the context of the below considerations, when drafting recommendations, the RHC examined how each one responded to the criteria. Our recommendations should support one or more of the below:

A) Ensure continuity of availability of medical devices to the citizens of the UK
B) Improve safety of medical devices with regard to the recommendations of the IMMDS Review
C) Create a landscape that is fit-for-purpose for new forms of devices, such as Artificial Intelligence as a Medical Device

5.1 Building a regulatory system for medical devices that works for patients

Recommendation 1: The regulation of medical devices should be centred on the needs of patients, informed by patients, record outcomes that matter to patients, and provide evaluations that are understandable to patients

This can be achieved through the following:

- Increasing patient involvement within the MHRA, through increasing patient representation on expert groups and within decision-making processes, in addition to continuing to expand existing patient consultation initiatives.
- Increasing the use of patient-reported outcomes throughout the regulatory pathway, including both conformity assessment and post-market surveillance.
- Include the routine collection of patient-reported outcomes within the MHRA's strategic objective 'to embed state-of-the-art surveillance across medicines and medical devices'[21]

The intended use of all medical devices should be to directly or indirectly benefit patients. Patients and relevant health professionals should be engaged in all possible stages of the design pathway of a medical device, and there should be an expectation that evidence of the level of engagement is included in regulatory submissions. Patients should also be increasingly involved with the regulatory process itself. The IMMDS Review chaired by Baroness Cumberlege, notes that *'When making regulatory decisions on benefit and risk*

[21] MHRA_Delivery_Plan_21-23_Final_210618.pdf (publishing.service.gov.uk)

of medicines and medical devices, the MHRA should demonstrate how patient views have been taken into account.'[22]

Furthermore, regulatory decisions should ensure that they have considered the outcomes that matter most to patients, which often requires a more holistic approach, such as through *patient-reported outcomes.* Such outcomes provide self-assessments of patients' symptoms and measures of quality of life and should form part of the required evidence for conformity assessment *and* be a required outcome for post-market clinical follow-up (where this is indicated as part of post-market surveillance). This broader approach should help reduce the chance of approving products that may pass one set of requirements but cause net harm to individuals through worsening of symptoms or quality of life that would not have been detected by traditional measures. Finally, reporting of regulatory evaluations and decisions needs to be transparent and communicated in ways that are clear to patients as well as other stakeholder groups.

5.2 Increasing capacity to address present needs and emerging opportunities

Recommendation 2: Strengthen and increase funding to the MHRA to significantly expand their capacity in medical devices including in emerging technologies

This can be achieved by:

- Government working closely with MHRA to ensure that it has the additional, targeted investment within medical devices that allows it to not only meet increased demands required by its remit but also support innovation in areas of opportunity such as software as a medical device, and emerging technologies.

Medical devices are an important contributor to the health of UK citizens, and a growing industry that significantly contributes to employment and economic growth in the UK. Investing in the MHRA and wider regulatory framework of the UK's medical device sector should be seen as a key part of the investment strategy for growth and innovation, as well as supporting the UK Government's manifesto commitments to create a global hub for life sciences and aligning with aspirations to position the UK as a global leader, with the initiative to seize emerging opportunities.

Our recommendations do not seek to advise on a specific funding model, which could be provided, by central government or a funding mechanism from the private sector, or perhaps a combination of both. However, when considering the benefits of potential funding models, it is worth recognising the IMMDS Review, which identified 'a major

[22] https://www.immdsreview.org.uk/Report.html

concern raised by patient groups is the role of industry funding in organisations responsible for advice and regulation'[23].

The MHRA has internationally regarded expertise in this area but requires increased, longer-term investment to meet new challenges including divergence from the EU framework and increasing diversity and complexity of devices.

The field of medical devices is rapidly expanding, and the safety requirements are becoming more demanding, notably in such areas as software including AI as a medical device (SaMD, AIaMD). The capacity of the MHRA and the wider regulatory system to ensure the safety of UK citizens, and to support device manufacturers through efficient regulatory processes urgently requires increased resourcing and a commitment to long-term investment in this area.

Recommendation 3: Address bottlenecks in the approval of medical devices, notably the shortage of UK approved bodies (ABs) for conformity assessment

This can be achieved through the following:

- Open reporting by the MHRA of the number of ABs approved and in application
- MHRA to regularly review both actual and projected AB capacity in line with actual and projected demand from manufacturers to support efficient timelines in conformity assessment
- Risk mitigation measures for addressing any anticipated shortfall in AB capacity should be in place and may include engagement and incentivisation strategies
- Government providing adequate support and guidance to ABs that assess high risk devices

One of the most immediate challenges to the pathway for a medical device to market - and one which could significantly harm both patients and the device industry - is the drastic reduction in capacity in those organisations that can undertake conformity assessment, i.e., in UK ABs due to the requirement that all medical devices need a UKCA mark to access the market, which has been reported by our stakeholders in interviews and workshops conducted by CRSI (Appendix D). The number and capacity of ABs for conformity assessment needs to be significantly increased. This needs to be addressed urgently if meeting the UKCA market requirements is going to be the sole route to the GB market from 1st July 2023.

To not act now on the emerging issue of the reduced capacity of ABs risks missing a number of opportunities for international collaboration and experience sharing as the UK develops its own independent regulatory voice, opportunities for investment in new ABs

[23] https://www.immdsreview.org.uk/Report.html

and general expansion of the sector, as well as not taking advantage of an increase in job opportunities. The MHRA should continue to openly report the number of ABs approved and begin to report on those currently under consideration to provide assurance as to current and projected capacity.

In addition, the MHRA should regularly review both actual and projected AB capacity with actual and projected demand from manufacturers to support more efficient timelines. AB capacity should be considered both for medical devices generally, and for particular device types for which the capacity may be more limited. Risk-mitigation measures for addressing any anticipated shortfall in AB capacity should be in place and may include engagement and incentivisation strategies. Consideration should also be given as to whether the MHRA should be resourced to provide pre-market support on specialist routes to market.

Recommendation 4: Prepare mitigations that supplement AB capacity to ensure supply of devices after transition to UKCA

This can be achieved through the following:

- Maintaining the 1st of July 2023 deadline for some devices but considering extending for others
- Considering assurance or reliance routes, or mutual recognition of devices

Whilst such interventions and incentivisation *may* achieve adequate AB capacity for all medical devices for the UK in the longer term, there is a high level of concern over whether AB capacity can be expanded to the required level within the proposed time frame (i.e., before 1st July 2023).

To avoid risking a shortage in the supply of medical devices to UK patients and to support the UK medical device industry, it will be necessary to also put in place other mitigations that address the immediate and short-term challenges. This should be part of a coherent strategy with contingency plans that include one or more of the following options:

- Stepped approach to the current UKCA timeline:
    - A stepped approach that may retain the 1st of July 2023 for some types of device but provide later cut-off dates for other types of device. This approach is about spreading the number of conformity assessments required over a greater length of time; the alternative mitigation of a postponement of the UKCA date for *all* devices is possible but would likely lead to a severe peak in demand in the months preceding the new deadline, exceeding capacity and causing avoidable delays.
    - This stepped approach seeks to flatten the curve of demand, and could be based on class of device, intended use of device, type of application (new vs renewal) or some other categorisation that should be as clear as possible to all stakeholders.
- Alternative routes to market that supplement the UKCA

- Capacity should also be increased by exploring all opportunities for reliance on or domestic assurance of the decisions taken by other recognised regulatory authorities.

5.3 International leadership and partnership in medical devices

Recommendation 5: Support the MHRA to increase UK visibility, international engagement and leadership

This can be achieved through the following:

- Clearly defining the full remit of MHRA and ensuring that they have the tools/resources to deliver
- Considering the needs of the medical devices sector while exploring agreements relating to reliance or assurance routes and mutual recognition with international markets
- Supporting the MHRA as needed in the process of gaining full membership to MDSAP and IMDRF

The MHRA is recognised globally for their expertise but has hitherto been operating within the EU framework and limitations of representing the consolidated EU position on device regulations. There is now an opportunity for the MHRA to provide a clear, independent voice, and bring their expertise and experience more visibly to the global stage, supporting international efforts to increase regulatory cooperation, and reduce potential barriers to trade.

Opportunities include taking an increasing role in the development of international standards (notably in sectors of importance to the UK such as AIaMD), exploring membership of international programmes such as MDSAP (MHRA is already in the process of a staged approach to achieving full membership, for MDSAP and IMDRF) and through government engagement in regulatory cooperation mechanisms such as MRA.

Changes in regulation should ensure that the UK regulatory framework including post-marketing surveillance is fit-for-purpose for both current devices and emerging technologies (such as AIaMD) and that this framework is efficient and easily navigated by innovators and medical device manufacturers.

Recommendation 6: Invest in the UK as a global centre for regulatory science and the training of regulatory professionals with expertise in medical devices, including in emerging technologies

This can be achieved through the following:

- Creating one or more centres of excellence in regulatory science and innovation in healthcare, which should have research, innovation, education, and training roles.
- Exploring mechanisms to incentivise training in regulation, including through investing in training opportunities and apprenticeships in relevant institutions, such as the MHRA and approved bodies, and other relevant institutions.
- Utilising the excellence of the UK's academic sector to support the MHRA in its international role, to allow it to lead in efficient and innovative regulatory approaches, including in emerging technologies.

The medical device sector is rapidly expanding, with increases in the number of devices requiring regulatory approval and the complexity thereof. This requires specialist regulatory knowledge both of the device sector, and sometimes highly subspecialist knowledge within that sector. There is an opportunity here for the UK to build on its excellence in regulation, to train regulatory experts for the UK and for the world.

Benefits include:

(1) increasing the pool of UK experts needed by ABs, UK regulators and the wider sector to support access to the UK market;

(2) increasing the number of regulatory experts available to support the UK device industry in more efficiently accessing both UK and global markets; and

(3) increasing the UK's influence globally as a leader in the regulation of medical devices. Not acting now could risk reduced patient access to medical devices and patient safety, due to a lack of professionals in this space after leaving the EU.

In parallel, there is an opportunity to not only increase training in regulatory *practice*, but also support the UK's capacity to be an innovator in regulation through investing in regulatory *science.*[24] Regulatory science brings scientific approaches that enhances the way in which regulation ensures quality, safety and efficacy of medical products, including devices. The innovation in regulation that this supports can benefit the UK both at the national level - enhancing patient safety and accelerating routes to market - and at the global level - influencing international practice and potentially promoting inward investment.

Investment in training and in regulatory science could be efficiently achieved by a small number of centres of excellence, similar to the FDA's Centres of Excellence in Regulatory Science and Innovation (CERSI), which should have research, innovation, education and training roles. These centres should work as a network and may distribute particular areas of expertise or responsibility between them, so as to most effectively deliver on the regulatory and innovation needs of the UK health sector. A strategic advisory committee should be appointed to ensure that the network delivers to the UK's regulatory needs and

[24] https://www.birminghamhealthpartners.co.uk/Advancing%20Regulatory%20Science%20and%20Innovation%20in%20Healthcare.pdf?_t=1594305225

should include representation from the MHRA and other key stakeholders. In terms of education and training, this network would be responsible for working with health regulators, UK approved bodies and other relevant organisations to support the development of the UK's regulatory workforce. In terms of research and innovation, this network would make the excellence of the UK's academic sector more accessible to health regulators, providing efficient access to additional scientific support and the ability to scope and evaluate innovative models of regulation. Whilst the focus of this report is medical devices, these centres of excellence would also be able to support other aspects of regulation notably drugs and other healthcare products (aligning to the MHRA), and potentially of the healthcare services themselves (aligning to the Care Quality Commission).

Recommendation 7: Build international partnership through mutual recognition and reliance or assurance where this may lead to overall efficiencies whilst preserving safety.

This can be achieved through the following:

- Considering reliance or assurance, or mutual recognition of devices as a long-term solution

The use of reliance or domestic assurance routes is important both to address the short-term capacity need (to supplement AB's capacity - see Recommendation 4) but also has a longer-term value to the whole regulatory framework in reducing redundant effort, supporting device manufacturers through reducing barriers to markets, and increasing efficiency and reducing cost for patients and the wider health system in order to benefit from medical devices. MRAs can support long term resilience within the UK's regulatory framework and support international trade and growth in the medical devices sector.

5.4 Using medical devices as a template to help enable regulatory innovation that improves patient safety, system efficiency and UK growth.

Recommendation 8: Identify and resource areas where regulatory innovation within the medical device sector may attract inward investment and growth.

This can be achieved through the following:

- Working collaboratively with the sector to build an innovation friendly regulatory framework for medical devices

- Supporting the development of a clear pathway for emerging technology through additional resources online and additional advisors within this area, as per recommendation 6
- Improving understanding of emerging areas of innovation and therefore highlighting how the government may want to target increased investment or incentivisation

The UK's future framework for the regulation of medical devices should be rapidly responsive and where possible anticipatory to new types of device that seek access to market. It should aim to make the UK the globally preferred place for medical device innovation, with a clear pathway for emerging technologies that is efficient, enables patients to benefit early but safely, and encourages the rapid building of the clinical evidence that may be required for full market authorisation in the UK or in international markets.

Benefits to the UK device industry and connected industries will be particularly great where this regulatory reform intersects with areas of opportunity for wider innovation and growth (such as software, artificial intelligence, etc). Additionally, such areas of regulatory innovation could be used as template projects to support the UK in building some of the most efficient and effective regulatory systems for medical devices and medicines in the world, focused on the patient and enabled by digital tools.

Recommendation 9: Develop a UK patient safety data base that collects key details of all medical devices and monitors patient safety and wellbeing moving forward.

Recommendation 9A: Strengthen existing safety reporting through digital tools and the use of comprehensive data collection from health systems, patients and carers to a central MHRA-held UK Patient Safety Database

This can be achieved through the following:

- Supporting the MHRA, NHS-Digital and others to build on and bring together current data programmes to create a combined reporting system for adverse incidents, medicines, medical devices, blood and counterfeit products under the established yellow card brand to ensure patient safety,[25] leading to an MHRA-held database that can support medical devices (and other healthcare products)
- Ensuring the MHRA has adequate resource for this work

[25] https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about#our-priorities

As highlighted In the IMMDS Review, Baroness Cumberlege noted that there is a need for '*substantial revision particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes.'* (IMMDS Recommendation 6). This need was highlighted by the risks around implantable devices (such as pelvic mesh), but there is an opportunity for this principle to be extended to other forms of devices and medicines, moving to the point where safety monitoring for all medicines and devices would be supported through the routine collection of data from health service contacts (digitally) and directly from patients and carers (digital where possible such as through smartphone apps, but with alternative methods available). It is recognised that this will be a major programme of work which may build upon the work of the Medical Device Information System, led by NHS Digital, which has not yet been established, but current signalling suggests will aim to collect and retain information relating to implantable devices across the UK, and MHRA's 'Yellow Card' scheme that allows for the collection and monitoring of safety concerns, to engage the key agencies across the UK, and builds on existing digital infrastructure to drive greater medical device data collection and dissemination.

The objective of this programme is to create an MHRA-led database focused on safety which can provide near real-time feedback, and automatically alert regulators where potential harms are detected, for example where a particular adverse event is occurring more frequently than expected. Data should be safely returned to the MHRA at participant level. The value of doing so at participant level is entirely around safety: first, this can be linked to unique device identifiers for medical devices (Recommendation 10), enabling detection of any adverse events not just for a device type, but within a version number, or particular batch of that device; second, adverse events that only arise when risk factors coincide (including demographics, co-existing health conditions, combinations of treatments) can be detected; thirdly, the scale of a UK-wide approach enables earlier and more confident detection of rare events, whilst also being more cost-efficient than separate approaches across the four nations. The MHRA has experience in the handling of large-scale routinely collected data through the Clinical Practice Research Datalink (CPRD) which collects de-identified data from GP practices from across all four nations of the UK.

Recommendation 9B: When medical devices are used, their unique device identifier (UDI) should be recorded as standard within a patient's health record, and this should be returned to a central MHRA led UK Patient Safety Database

This can be achieved through the following:

- Supporting and providing needed resource to the MHRA in the development of a Patient Safety Database
- Introduce legislation that would require devices to have a UDI

All devices destined for the UK should be required to have a UDI, and this should be held within a safe and confidential UK Device Identifier Database using standard nomenclature as recognised in IMDRF UDI Guidance document N7. To address the risks associated with implanted devices, the IMMDS Review notes *"A central patient-identifiable database should be created by collecting key details of the implantation of all devices at the time of the operation. This can then be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures."* (IMMDS Recommendation 7).

Implantable devices are a clear example of why such a database is necessary, but non-implantable devices may also cause harm to the individual and may carry equal need to rapidly trace and recall individuals who may have been affected, with capability to efficiently identify whether there is a safety issue in a whole batch or version number, or indeed all copies of that device. It is recommended therefore that Unique Device Identifiers (UDIs) should be recorded, with due attention given to the importance of handling sensitive data, as standard within electronic health records as part of routine care, and form part of the return to the proposed MHRA-held Patient Safety Database.

5.5 Building resilience and preparing for future threats

Recommendation 10: Pandemic preparedness should include fast-track evaluation of new in vitro diagnostics

This can be achieved through the following:

- Consolidation of the learning from the successes and challenges of developing and regulating IVDs for SARS-CoV2 during the COVID-19 pandemic, including the successful use of Target Product Profiles (TPPs) to ensure future accelerated development and regulatory pathways

The development and approval of IVDs to respond to a future pandemic should be supported by a range of measures aimed at accelerating the pathway. The development of such tests can be driven by Target Product Profiles (TPPs), in which the desirable characteristics and minimally acceptable specifications of a product that is needed to address a well-defined clinical problem is pre-specified. In the event of a future infectious disease outbreak, TPPs should be used to drive the development of IVDs.

Recommendation 11: Reporting of diagnostic tests should be transparent and standardised

This can be achieved through the following:

- Mandating that the performance of diagnostic tests are reported transparently and utilising the international *Standards for Reporting of Diagnostic Accuracy Studies* framework[26]

Reporting of diagnostic tests should be aligned to international standards and include both adequate descriptions of the methods to enable replication and verification, and adequate description of the results to enable comparison with other tests. Methods should include sufficient description of both the test under evaluation and of the reference test to enable replication; details of the participants and samples, including how they were recruited, or the samples obtained, and how any missing data or inconclusive samples were handled. Results should include contingency tables containing the actual experimental results; point estimates and confidence intervals for each of sensitivity, specificity, positive predictive value, and negative predictive value.

[26] Bossuyt PM, Reitsma JB, Bruns DE et al. . STARD 2015: an updated list of essential items for reporting diagnostic accuracy studies. *BMJ* 2015;351:h5527.

Appendixes

Appendix A. Report: Opportunity and risks around future UK regulatory reform of medical devices

Appendix B. Report: Lessons learned from COVID-19 in relation to IVD regulations

Appendix C. Report: Alternative routes to market for medical devices

Appendix D. Report: Mitigations for the move to the UKCA mark from 01 July 2023

Appendix E. RHC Approach to the Medical Devices Report

How did the RHC arrive at medical devices as a Deep Dive Area?
The RHC conducted a rigorous horizon scanning exercise over a 6-week period and generated a list of 544 distinct innovations. Innovations were then mapped into broader groupings before being prioritised through three primary criteria: economic impact, societal benefits and scope for regulatory change. From this information and refined list, council members then applied their judgement and expertise to select their first tranche of priority areas to conduct deep dive reports into: fusion energy; genetic technologies; unmanned aircraft and medical devices.

How did the RHC identify and refine its scope and key question for the report?
This is set out in section 2.2.2 of the report.

How did the RHC engage stakeholders?

Birmingham Health Partners (BHP) Centre for Regulatory Science and Innovation (CRSI) was commissioned by the RHC, on a pro-bono basis, to conduct substantial stakeholder engagement to produce four reports. These reports were based on a combination of literature reviews, one-on-one semi-structured interviews, a multidisciplinary stakeholder workshop and a postworkshop survey; the full methodology is included in the reports (Appendices A-D). The RHC independently evaluated all evidence provided to it through the literature reviews and stakeholder engagement exercises.

The RHC also worked closely with the Department for Health and Social Care (DHSC), Medicines and Healthcare products Regulatory Agency (MHRA), Office for Life Sciences and NHSX.

Given that the RHC's medical devices deep dive was conducted during the COVID-19 pandemic, all the RHC's engagement was via email, Microsoft Teams, Zoom, or phone call. Whilst this virtual engagement provided certain challenges, it allowed the RHC to reach a wide range of stakeholders more quickly than via traditional in-person engagement.

What could the RHC have done differently in retrospect?

As can be expected, more time and more resources would have allowed for increased stakeholder engagement and more in-depth analysis. However, this approach was balanced against the importance of moving quickly in order to support early decision making about this emerging technology. The RHC's view is that this still allowed for a robust report that identified and provided advice on the crux of the matter in scope.

Working with another organisation, in this case BHP, did mean that there was less direct stakeholder engagement with the RHC which made it slightly more complicated to interpret some of the data. It was also necessary to agree governance between the two organisations for this project, which required resource. However, these points were outweighed by the increased capacity and expertise that working with BHP provided.

What Worked Well in the Approach

The selection of medical devices as a topic was very timely during the Covid-19 pandemic, and this helped increase engagement from stakeholders, including government officials.

As mentioned above, working with BHP helped with capacity. In addition, BHP also used a variety of stakeholder engagement tools effectively to collect evidence that may have been harder for the Council to obtain itself. In addition, the relationship between the Council and BHP worked very well, including clearly defining remits to ensure the different reports avoided duplication and complemented each other's work.

Appendix F: Abbreviations

AI Artificial Intelligence

AIaMD artificial intelligence as a medical device

BHP Birmingham Health Partners

CERSI Centres of Excellence in Regulatory Science and Innovation

COVID-19 Coronavirus disease 2019

CPRD Clinical Practice Research Datalink

CQC Care Quality Commission

DHSC Department of Health and Social Care

EU European Union

FDA Food and Drug Administration

IMDRF International Medical Device Regulators Forum

IMMDS Independent Medicines and Medical Devices Safety Review

IVD In Vitro Diagnostic

IVDR EU EU Regulations for in vitro diagnostic medical devices

MDR EU EU Regulations for Medical Devices

MDSAP Medical Device Single Audit Program

MHRA Medicines and Healthcare products Regulatory Agency

MRA Mutual Recognition Agreement

NBs Notified Bodies

NHS National Health Service

NMPA National Medical Products Administration

OLS Office for Life Sciences

RHC Regulatory Horizons Council

SaMD Software as a Medical Device

TPP Target Product Profiles

UDI Unique Device Identifier

UKCA UK Conformity Assessed