

Opportunities and risks around future UK regulatory reform of medical devices

Han, Diana; Ibrahim, Hussein; Liu, Xiao; Aiyegbusi, Olalekan Lee; Taylor, Matthew; Denniston, Alastair; Marston, Eliot; Calvert, Melanie

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Opportunities and risks around future UK regulatory reform of medical devices

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The Birmingham Health Partners Centre for Regulatory Science & Innovation was established in 2020 to support the development and delivery of novel therapeutics and medical devices in the UK, through advanced regulatory standards and tools. A truly multidisciplinary initiative, the CRSI aims to bring together experts in medicinal science, health policy and management, clinical trial design, medical law, and patient-reported outcomes research, from across BHP member organisations. The mission of the CRSI is to drive innovation in regulatory science to promote efficient, safe, and cost-effective implementation of new therapies, for the benefit of patients and society. www.birminghamhealthpartners.co.uk

The Regulatory Horizons Council (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.

Executive Summary

The Medicines and Medical Devices Act 2021 provides the UK with a unique opportunity to update the way it regulates medical devices to promote public health, encourage international investment and innovation, improve patient and user safety, and ensure that the UK retains its global standing in the regulation of the life sciences sector. The opportunities afforded by regulatory reform do, however, need to be balanced against the risks associated with regulatory divergence.

The Regulatory Horizons Council commissioned the Birmingham Health Partners Centre for Regulatory Science and Innovation (CRSI) to collate multi-stakeholder views on 'the potential opportunities and risks around future UK regulatory reform of medical devices' and 'how the UK can encourage international investment, innovation, and improve safety in the medical devices area through regulatory and non-regulatory changes'. The CRSI team comprehensively collated views of 30 stakeholders from across the medical device sector using one-on-one, semi-structured interviews. All data were subsequently analysed using a framework approach.

In this report, we outline the potential opportunities and risks around future UK regulatory reform of medical devices and discuss strategies for how the UK can encourage international investment, innovation, and improve safety through regulatory and non-regulatory changes.

Opportunities and risks. The stakeholder engagement process identified a range of opportunities and risks around future UK regulatory reform of medical devices. These fall into four key areas: i) patient and public access to high quality medical devices; ii) international investment and innovation; iii) patient and user safety; and iv) global standing in regulation of the life sciences sector. These findings complement our previous reports on mitigations for the move to the UKCA mark from 01 July 2023, alternative routes to market for medical devices, and lessons learned from COVID-19 in relation to IVD regulations, which discuss other relevant strategies for maximising opportunities and minimising risks.





International Investment Medical device companies – especially small and medium-sized enterprises (SMEs), which constitute the majority of the businesses in the UK medical device sector – are reliant on international investment to fund their research and development (R&D) cycles. Encouraging continued international investment in UK SMEs is, therefore, incredibly important if the UK wants to nurture UK-based innovation and remain at the forefront of the global life sciences sector. In order to encourage international investment, the UK needs to increase investor confidence in the potential returns on their investments. Recommendations from stakeholders regarding regulatory changes that could increase investor confidence include: i) ensuring that new UK regulations are sufficiently aligned with international regulations so that UK medical device companies can easily sell their products in other countries; and ii) encouraging regulators to engage with and support companies developing high-risk, innovative medical devices from an early stage. Recommendations from stakeholders regarding non-regulatory changes that could increase investor confidence include but are not limited to: i) providing clear information regarding new UK regulations; ii) optimising the NHS procurement process for medical devices; and iii) facilitating access to NHS data and infrastructure.

Innovation The UK has a strong track record in the global technology and innovation sector, with a thriving entrepreneurial and start-up culture and a strong network of academic institutions. Today more than ever, innovation has become an important source of economic growth and societal and public benefit in the UK. Recommendations from stakeholders regarding regulatory changes that could promote innovation in the field of medical devices include: i) coordinating the clinical evidence requirements for regulatory approval and health technology assessment (HTA); ii) focusing innovation on clinical need using target product profiles (TPPs) and horizon scanning; and iii) introducing alternative, accelerated regulatory pathways that are similar to Breakthrough Device Designation (BDD) and Humanitarian Device Exemption (HDE) of the U.S. Food and Drug Administration (FDA). Recommendations from stakeholders regarding non-regulatory changes that could promote innovation in the field of medical devices include but are not limited to: i) providing clarity in regulations to minimise implication of uncertainty on innovation; ii) providing financial incentives for medical device R&D; and iii) strengthening collaborative partnership between industry and the NHS.

Safety The regulation of medical devices is primarily concerned with promoting public health by providing patients and users with access to high quality, safe, and effective products; and preventing access to unsafe ones. Any changes to UK medical device regulations should, therefore, ideally improve patient and user safety. Recommendations from stakeholders regarding regulatory changes that could improve safety include: i) increasing the emphasis placed on post-market surveillance (PMS) of medical devices; ii) using medical device databases and registries and unique device identifiers (UDIs); iii) introducing a post-approval ‘transition’ phase during which medical devices that are new to the market are more closely monitored in the ‘real world’ before scaling up their use; and iv) conducting random audits of quality management systems. Recommendations from stakeholders regarding non-regulatory changes that could improve safety include: i) promoting patient and public involvement and use of patient reported outcome measures (which could also be enforced through regulatory changes); ii) encouraging voluntary reporting of suspected medical device incidents; and iii) fostering a culture of learning, rather than a culture of blame, to maximise the lessons learned from any safety incidents that do arise.

Key Findings

What are the potential opportunities and risks around future UK regulatory reform of medical devices?

Key Opportunities

Patient and public access to high quality medical devices

The UK has an opportunity to promote patient and public access to medical devices by designing efficient, streamlined, UK-specific regulatory processes that ensure high quality, safe, and effective devices are made available on the UK market in a timely manner.

International investment and innovation

The UK has several opportunities to stimulate innovation in the medical device sector. One option is for the UK to make NHS data more accessible to innovators to use for R&D of medical devices, especially novel, data-driven devices such as those including artificial intelligence (AI) and machine learning components; and another is for the UK to focus its regulatory resources on complex, cutting-edge medical devices, rather than “run-of-the-mill” ones, as this would offer the UK a competitive advantage on the global medical devices market through faster regulatory approvals for innovative technologies.

Patient and user safety

The UK has multiple opportunities to promote patient and user safety, as highlighted in the Cumberlege report ‘First Do No Harm’. Not only could the UK change legislation to increase the emphasis placed on PMS, but it could also encourage greater collection of patient centred data such as patient-reported outcomes, involvement of patient and public advocates as key stakeholders in medical device R&D, and foster a culture of learning, rather than a culture of blame, from patient safety incidents.

Global standing in regulation of life sciences sector

The UK has traditionally been at the forefront of global regulatory innovation in the life sciences sector. By maximising new and existing international collaborations, and promoting harmonisation with the US, Commonwealth countries, individual EU member states, and elsewhere, the UK has an opportunity to develop a robust, world-leading regulatory regime for medical devices.

Key Risks

If new UK medical device regulations diverge significantly from international regulations, there is a risk that it would increase the regulatory resource burden on both regulators and medical device companies. This would, in turn, potentially lead to: an increase in the cost of medical devices; an increase in the time it takes for medical devices to get to market; and a decrease in the availability and choice of medical devices on the UK market.

If new UK medical device regulations were significantly stricter than international regulations, there is a risk that it would deter medical device companies, causing them to prioritise other markets, such as the EU and US markets, instead. This would, in turn, potentially lead to a decrease in innovation and, by extension, international investment in the UK medical devices area.

If new UK medical device regulations reduce safety requirements relative to current regulations, there is a risk that it would lead to a decrease in the quality of medical devices on the UK market. This could, in turn, have significant repercussions on patient and user safety, and undermine public trust in medical devices and NHS healthcare provision.

If new UK medical device regulations do not sufficiently align with international regulations, there is a risk that medical device companies may decide to leave the UK and relocate elsewhere, such as the EU and US. This would, in turn, potentially lead to a loss of regulatory consultants and other experts that make up the “soft infrastructure” of the UK’s regulatory and life sciences ecosystem.

Key Findings

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

Regulatory Changes

Ensure that new UK regulations are sufficiently aligned with international regulations. Greater access to international medical device markets is likely to increase investor confidence as it increases sales opportunities. Aligning new UK regulations with international regulations, and preferably achieving recognition of equivalence, will maximise the ease by which UK device companies can sell to overseas markets. Similarly, alignment would help to reduce the barriers to importing devices without compromising on device safety and performance.

Encourage early engagement with and support for companies developing high-risk medical devices. High-risk medical devices, such as active implantable medical devices, are much harder to get to market than low-risk ones because they require significantly greater regulatory scrutiny. This makes investing in high-risk medical device companies inherently risky and disincentivises international investors. Ensuring that the MHRA engages with and supports companies that are developing high-risk medical devices from an early stage will increase the likelihood that safe devices will successfully receive market authorisation, thereby increasing investor confidence and international investment.

Non-regulatory Changes

Provide clear guidance on new regulations. Greater clarity around the new medical device regulations is likely to increase market confidence as it enables investors to more accurately estimate the costs associated with a particular investment. Therefore, it is important that the UK provides clear guidance on new medical device regulations; and improves the system by which medical device companies and regulatory authorities communicate.

Utilise investment incentives. Investment incentives are often implemented by governments to encourage international investment. Stakeholders have suggested that optimising financial (grants and loans), fiscal (tax breaks, tax credits, tax relief), and other (subsidised manufacturing infrastructure) incentives could increase investment in the medical devices area. Alongside this, the UK government could actively seek out potential investors and promote the strengths of the UK life sciences sector and UK investment opportunities.

Optimise NHS procurement process. The NHS is the primary purchaser of medical devices in the UK and, as a result, investor confidence is likely to be contingent on securing NHS procurement contracts. The UK could increase investor confidence, and therefore increase investment, by optimising the NHS procurement process for medical devices. Suggestions for optimising the NHS procurement process for medical devices include streamlining the procurement process and coupling it with the HTA.

Facilitate access to NHS data and infrastructure. The UK is considered an attractive place to develop and test medical devices due to the perceived quality of NHS data. The UK could encourage data-driven innovation and, by extension, international investment, by facilitating medical device development and testing in the NHS, and improving the availability and interoperability of NHS data.

Strengthen international R&D collaboration. The UK could encourage international investment by strengthening international collaboration in medical device R&D.

How can the UK encourage innovation in the medical devices area through regulatory and non-regulatory changes?

Regulatory Changes

Coordinate the clinical evidence requirements for regulatory approval and health technology assessment. Regulatory and HTA processes have different but overlapping requirements in terms of the evidence for safety and efficacy that is required, and this can sometimes lead to inefficiency and increased cost. The UK has a specific opportunity to develop an agreed multi-agency approach that harmonises the evidence requirements so that a single process can capture the evidential requirements of both regulatory and HTA processes.

Focus innovation on clinical need using target product profiles and horizon scanning. Using TPPs which outlines the intended use, target populations, and other desired characteristics of a potential product, would help innovators understand continuously evolving patient needs. Additionally, publicly-funded horizon scanning would help innovators identify potential opportunities, gain a clearer idea as to how to address the challenges that are more specific to the UK healthcare system, and provide solutions to complement current clinical practices and technologies.

Introduce alternative routes to market for innovative and breakthrough devices. The US FDA Humanitarian Device Exemption (HDE) programme and Breakthrough Device Designation (BDD) are intended to encourage the development of and facilitate timely access to medical devices for the treatment of rare conditions and life-threatening or irreversibly debilitating diseases respectively. The UK could introduce similar systems to incentivise the development of devices for rare conditions and breakthrough technologies, similar to the MHRA's Innovative Licensing and Access Pathway for medicines.

Non-regulatory Changes

Provide clear guidance regarding regulatory routes to market. A lack of clear guidance on navigating medical device regulations and the consequences of failing to comply with them can deter medical device companies, especially SMEs, from developing new ideas because of the intense resources required in understanding them. This, as a result, is likely to reduce innovation in companies operating in sectors where innovation requires significant investment and longer timescales or where companies are operating in less financially secure markets. Therefore, clearer and more transparent guidance is required regarding regulatory routes to market.

Continue to provide financial incentives for medical device R&D. In recent years, the R&D incentives for both SMEs and large companies have been shown to encourage and reward innovation in the UK. Schemes and funding opportunities such as R&D Tax Credits and Innovate UK create a competitive tax environment for companies to innovate and should continue to be provided to medical device companies. Another suggestion is a revenue and equity sharing system, which can incentivise innovation while decreasing the financial risk of new device development, as companies are only expected to return a share once the funded device is successfully commercialised and generates revenue.

Strengthen collaborative partnership between industry and the NHS. Data is being used to drive innovation in healthcare. As a universal health system, the vast repositories of healthcare data within the NHS offers the UK a unique competitive advantage. Yet, stakeholders identified several hurdles including fragmented and incomplete data; and duplicative permission processes from multiple organisations to access relevant healthcare data. Improved interoperability and accessibility of NHS data present the opportunity for developers to create innovative technologies devices and softwares.

Invest in translational and regulatory sciences. Stakeholders suggested that investing in UK translational and regulatory sciences would help facilitate the transition of innovative medical devices from research to market.

Key Findings

How can the UK encourage safety in the medical devices area through regulatory and non-regulatory changes?

Regulatory Changes

Increase the emphasis placed on post-market surveillance and improve post-market surveillance processes. Many long-term risks associated with medical device use are difficult to identify during pre-market assessments due to the limited number of patients participating in clinical trials, the relatively short time period over which outcomes are measured, and the ethical and practical barriers in performing randomised clinical trials. The UK could promote PMS to enable risks that arise when a medical device is deployed clinically in the 'real world' to be identified in a more timely manner. It is especially important to ensure that regulators have an active rather than passive approach to PMS enabling them to respond early and efficiently.

Use medical device databases and registries and unique device identifiers. One suggestion for how PMS processes could be improved is through the use of publicly-funded and publicly-accessible medical device databases and registries that monitor devices via unique device identifiers (UDIs). The UK could either apply to participate in existing international medical device databases and registries (such as EUDAMED) or invest in developing its own medical device database.

Introduce a post-approval 'transition' phase to the regulatory route to market before routine clinical use. Another suggestion for how PMS processes could be improved is by introducing an additional post-approval 'transition' phase before routine clinical use. The purpose of this new phase would be to more closely monitor medical devices that are new to the market, and ensure that they remain safe when deployed in the 'real world' before scaling up their use. Alternatively, this could be used for types of devices which are deemed to be higher risk or have greater uncertainty in their generalisability, such as AI systems.

Conduct random audits of quality management systems. Quality management systems are the practices and procedures that medical device manufacturers use to ensure quality and safety. Regulators currently rely on self-reporting of quality management systems for low-risk devices, which make up the majority of all devices, by medical device companies. By introducing random audits of quality management systems by regulators, the UK could improve the quality and safety of medical devices.

Non-regulatory Changes

Promote patient and public involvement and use of patient reported outcome measures. Involving patients and the public in the design and development of clinical trials of medical devices and measuring patient experiences directly using patient-reported outcome measures are two solutions suggested by stakeholders that would maximise the chances that all important safety issues are captured during clinical trials of medical devices. Such changes could also be enforced through regulatory changes.

Encourage voluntary reporting of suspected medical device incidents by patients, the public, and healthcare professionals. Voluntary reporting of suspected medical device incidents by patients, the public, and healthcare professionals via the Medicine and Healthcare products Regulatory Agency's Yellow Card scheme should be encouraged as a core component of PMS in the UK. Stakeholders have suggested that education and empowerment is essential to achieve this end at the level of patients and the public; and that education, with a particular emphasis on identifying potential implications with innovative digital medical devices, is essential to achieve this end at the level of healthcare professionals.

Foster a culture of learning rather than a culture of blame. It is impossible to eliminate all safety risks through regulation alone. With this in mind, it is important that regulators, medical device companies, healthcare professionals, patients, and the public maximise learning from the safety incidents that do arise, in the UK and internationally, and foster a culture of learning rather than a culture of blame.



Abbreviations

AI	Artificial intelligence
BDD	Breakthrough Device Designation
BHP	Birmingham Health Partners
COVID 19	Coronavirus disease
CRSI	Centre for Regulatory Science and Innovation
EU	European Union
FDA	Food and Drug Administration
HDE	Humanitarian Device Exemption
HTA	Health Technology Assessment
IVD	In vitro diagnostic
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
PMS	Post-market Surveillance
R&D	Research and development
SME	Small and medium-sized enterprise
UDI	Unique device identifiers
UK	United Kingdom of Great Britain and Northern Ireland
UKCA	United Kingdom Conformity Assessed
US	United States



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Authors

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*joint first authors

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This report reflects the views of a range of stakeholders and should not be attributed to specific individuals or organisations unless explicitly stated.

Drs Han and Ibrahim contributed equally to this report and are recognised as joint first authors.

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Stakeholders

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*Advisory board members

APPENDIX 1: Methods

Qualitative methods were used to collate the views of stakeholders from across the medical device sector.

1. Data Collection

Stakeholder interviews were conducted online via MS Teams between 04 January 2021 and 02 February 2021. A total of 30 one-on-one, semi-structured interviews were conducted with stakeholders from across the medical device sector: medical device companies (n=7), regulatory consultancies (n=6), UK Government agencies (n=5), product testing or certifying bodies (n=4), academics and clinicians (n=4), trade associations (n=2), and patient and public partners (n=2).

2. Data Analysis

Data were managed and analysed thematically using the framework approach (Ritchie et al. 2003, Pope et al. 2000). This method allows a comprehensive review of collected narratives, that is driven by stakeholders' original accounts. Raw data were analysed by two co-investigators (DH and HI). The interviews were reviewed and coded independently using the stakeholder interview questions as an initial thematic framework. Textual codes were grouped into clusters around similar and interrelated concepts and a matrix of themes were created and analysed within Google Sheets.

APPENDIX 2: References

3.1. BHP CSRI Reports

1. Birmingham Health Partners Centre for Regulatory Science and Innovation. Mitigations for the move to the UKCA mark from 01 July 2023. 2021.
2. Birmingham Health Partners Centre for Regulatory Science and Innovation. Alternative routes to market for medical devices. 2021.
3. Birmingham Health Partners Centre for Regulatory Science and Innovation. Lessons learned from COVID-19 in relation to IVD regulations. 2021.

3.2. Others

1. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. *BMJ*. 2000;320(7227):114-116. doi:10.1136/bmj.320.7227.114
2. Ritchie J, Lewis J. *Qualitative research practice: a guide for social science students and researchers*. 2003, London: Sage.

APPENDIX 3: Evidence

What do you think are the potential opportunities and risks around future UK regulatory reform around medical devices?

Themes	Opportunities	Risks
Patient and public access to high quality medical devices	<ul style="list-style-type: none"> Legislation: maximise opportunities for the product to be safe and perform as intended via quick and cost-effective pathways Speedy regulatory approval process that does "not cut corners on safety" Ease of certification within the UK, while maintaining standard & ensuring clinical evidence that is captured in the UK is relevant in other system (e.g. FDA) -> more responsive and quicker process Revisit controversial aspect of EU MDR (e.g. Rule 11: blanket classification of medical software as Class 2A - which requires certification from the NBs - extra cost) and find a way to keep a low-profile entry/opportunity for start-ups that offers a low-risk, innovative softwares. Increase speed: There is an opportunity to create a new UK regulatory system that is more streamlined and faster and more efficient than it has been previously; in the same way that we have been as a country with regards to vaccines. "Opportunity to "reduce the noise". Currently, there is too much noise, as regulation needs to work in 27 different countries and be relevant to 27 different national health strategies. There is an opportunity to have a more "focussed" regulatory system that can prioritise "enabling market access" "The best outcome would be to have an international regulatory system so that companies could produce things and sell them anywhere. But this is not going to happen due to cultural issues. For example, in the US, the up-front cost to the FDA is higher but there are no notified bodies to interpret the FDA guidelines to pay down the line; whereas, in the EU, the up-front cost is lower but due to notified bodies you have more of a drip-feed pay system. Chance to make new bespoke medical devices regulations which are very specific to the UK that produce the best outcomes for the UK's NHS and for the UK's life sciences sector and the UK's internal market. To own our own destiny. We have the power now to own our own legislation Avoid silos: There is an opportunity to create a new UK regulatory system that is more collaborative and works with patients, clinicians, medical device manufacturers, people who perform health technology assessment i.e. NICE, and hospitals. Move towards FDA model where MHRA takes on role of notified bodies. The MHRA could be a more transparent and streamlined organisation that works to a set time frame. This would be a more simple and effective system that makes it easier for medical device manufacturers. The fact that it is more transparent and time-limited makes it more attractive to investors. 	<ul style="list-style-type: none"> Situation in which companies not being able to sell the products because no-one's able to regulate properly If there are insufficient numbers of notified bodies then it will be impossible to get sufficient numbers of medical devices certified. Creating an environment where existing products will need more duplication if UK regulatory seal is not recognised in other territorial space A big risk is that there is sufficient divergence that companies need to go through two separate regulatory processes. The biggest risk is that there is such significant divergence that companies need to produce two different types of the same device (e.g. different packaging) or different evidence sets (e.g. different human factors). More regulations, more resources, paperworks, time, experts required (less focus on innovation), a "tedious" system that do not align with the aim of patient safety Companies may decide against seeking a UKCA mark and selling products on the UK market and choose the EU/US instead. May not "bother" to go through a separate regulatory pathway Manufacturers will be less likely to sell medical devices and IVDs on the UK market if additional bureaucratic barriers and financial costs associated are put in place. If the new regulatory system deviates too far then it will push away 'edge' companies who will not see sufficient incentives to continue selling their products on the UK market. Potential lack of product being available to patients with subsequent impact on patient safety Restriction of choice Being left-behind as a secondary market Limited access to product Raising the regulatory bar would reduce choice and increase cost as companies would be less likely to sell on the UK market and the work required to get products onto the market would be harder and more resource intensive If the UKCA diverges too much from the EU system, then the UK risks becoming a small and isolated country where state-of-the-art medical devices are no longer available. The impact of this will ultimately be borne on patients and the NHS, as they will continue to exist even if the medical devices themselves do not. If new UK medical devices regulation is more resource intensive, then it could increase costs of medical devices, which could ultimately reduce availability of medical patients. Different, separate labelling for the UK may be difficult to handle Bottlenecks in NBs (having the right technical knowledge, resources) -> third party assessment & overall decision/review by NBs (rather than a single unit) Lack of technical experts/coverage in MHRA If new UK medical devices regulations are less efficient it could reduce availability of medical devices. Creating new/additional/unnecessary barriers to trade.

APPENDIX 3: Evidence

Themes	Opportunities	Risks
International investment and innovation	<ul style="list-style-type: none"> • Regulatory innovation, esp. with digital products (which takes relatively short period of time ~6 months) • Data-driven space, digital strategy, scalability of collaboration w. NHSx • More innovative in the way the UK operates (e.g. NIHR Innovation Passport) • Take advantage of unique possibility that NHS brings (e.g. generating data that clinical studies, trials on large number of "right" target population) • Data is "probably the most obvious" asset. Improvement in data quality in evaluation of clinical and cost effectiveness, and safety would be beneficial. • Exportability of data-driven medical device as NICE's global reputation in the quality of evidence • Further research around AI classification (e.g. validation, real understanding of accessibility from health and social professionals on the patient in terms of risk, ethics) • Joined-up approach for innovative tech (connection between different organisations - MHRA, NICE, central NHS, investors) - having the key members understand the tech is important • The UK Government needs to support the industry it wants to create. The UK Life Sciences sector is better placed to create complex cutting-edge medical devices than simple run-of-the-mill ones. This is partly because it already has people with the prerequisite knowledge and skills to create complex cutting-edge medical devices, but also because it is always going to be more affordable to create simple run-of-the-mill ones elsewhere. The UK has to capitalise and make the most of its position and lead the way in the creation of complex cutting-edge medical devices. In order to do this, it needs a specialist regulatory/ethics system to safely support the creation of these complex cutting-edge medical devices. The UK Government could help support this industry by funding a single specialist regulatory/ethics unit (a bit like the Regulatory Horizons Council) that specifically looks at the most complex types of medical devices. • <i>More involvement of patients and public in process of appraising medical devices e.g. in clinical validation trials of medical devices.</i> • Introduction of programs (e.g. breakthrough device designation) to reduce the burden on the NB (only one in UK for Class 3) -> promote innovation, identify significant area of unmet need, provide route to low-volume sales (e.g. Humanitarian Device Exemption, 1000 devices a year) 	<ul style="list-style-type: none"> • Significant regulatory divergence, especially if it is more significant than EU/US rules, will stifle investment and innovation and stop companies bringing products into the UK.
Patient and user safety	<ul style="list-style-type: none"> • Non-blaming culture, where products can be expected to be fallible. • MHRA role to be reactive and investigative when something happens • We should maintain or improve (not decrease) the current levels of focus on safety in our regulation on medical devices. • The opportunity is for the UK to create a new regulatory which promotes innovation whilst protecting safety. The new UK regulatory system should be a 'halfway house' between MD-D and MD-R that 'brings in safety aspects of MD-R' but keeps the 'lighter touch of MD-D'. It is essential that the new UK regulatory system is (a) efficient enough so that investors and innovators are encouraged to use it; (b) safe enough so that patients and users are protected; and (c) aligned enough so that investors and innovators know they can also sell products elsewhere around the world. • Patient involvement in pre- and post-market surveillance (Cumberledge Report) • Robust PMS, that is public-funded (e.g. sustainable national registry in Sweden) 	<ul style="list-style-type: none"> • If we relax the regulation: (1) bad medical devices will be allowed to be sold on the market, (2) individuals will possibly waste money buying things that do not work, (3) individuals will possibly suffer in that the health problem that they bought the medical device to address will not be solved, and (4) the NHS will possibly waste money down stream paying to patch up problems that were not properly sorted out earlier on. • Shortcuts that can open up potential risks to patients.

APPENDIX 3: Evidence



Themes	Opportunities	Risks
Global standing in regulation of life sciences sector	<ul style="list-style-type: none">• Opportunity to become “knowledge leader in regulatory sciences”. This would help “maximise existing collaborations” with US/EU/elsewhere. People will want to meet UK standards which are simplified (through the reduction in noise) and considered state of the art.• UK has already worked on risk management at a high level -> unique opportunities to show the world that our safety protocols and general manufacturing practices are at a high level. (“Endorseability”)• Provide set of robust seamless regulations that third-party nations will also adopt (e.g. MHRA approval allows entry to Commonwealth) & effective collaboration w. Commonwealth partners• US-UK collaboration for future international standardisation• Alignment with the FDA to allow exportability while building competitive advantage"• UK has been leading regulatory sciences in the world/EU (esp. ventilator challenges, where they set the standards for industry requirements and safety requirements)• There is an opportunity to harmonise with wider global standards. So if we are intent on leaving Europe then we should definitely seek to harmonise with other countries – whether that be the IMDRF or MD-SAP or USA or China. - > Reduce duplication and accelerate bench-to-bedside model, production and regulatory sign-offs• Alignment to regulation & leverage lies in MHRA looking at existing resources and make a streamlined process for manufacturers in commonwealth countries to be able to track, trace and secure.	<ul style="list-style-type: none">• Companies relocating abroad• Company dropping-out from UK market due to extra cost• Regulations might create a situation where medical device manufacturers who are based in the UK or decide to set up shop in UK system cannot easily transfer their work elsewhere i.e. they wouldn't be able to easily sell their products in Europe or the USA. This might mean they decide to move elsewhere or set up shop elsewhere.• The UK has a significant “soft infrastructure” for life sciences e.g. lots of expertise and previous site of European Medicines Agency. There is a risk that this “soft infrastructure” will be lost if medical device manufacturers move elsewhere and stop working in the UK.

APPENDIX 3: Evidence

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

Themes	Opportunities
<i>REGULATORY</i>	
Ensure that new UK regulations are sufficiently aligned with international regulations.	<ul style="list-style-type: none">• If the UK regulatory process is transparent, robust, and speedy, and places like the US/EU/China/Japan/elsewhere acknowledge the UK's regulatory process as sufficient, we will have a regulatory space that investors will feel confident investing in. Investors will know that medical devices and IVDs that are developed here are likely to sell elsewhere, as other countries will respect them.• By and large, people will only invest in medical devices in the UK if they are going to see returns on their investment. Therefore, investors are going to look for evidence to suggest that medical devices sell. But evidence that the medical devices company will sell products in England/Wales/Scotland will not suffice. People will want evidence that the medical devices will sell products elsewhere around the world. In order for this to be the case, the regulation needs to ensure that products that are UKCA marked can and will be sold internationally.• Ensuring whatever the regulation is in the UK, it is not in isolation (e.g. MDSAP).• Agreement with other countries to allow an easier entry of devices certified in the UK to foreign markets.• International investors want to know that their medical devices are licensed to use in both the UK and in their home country so it's important for regulatory processes to open up more than one market.• UKCA mark, well-aligned with EU CE mark• It is important to bear in mind that any new UK regulatory system needs to be sufficiently aligned with other international regulatory systems. This is because, no matter how user-friendly the new UK regulatory system is or how user-unfriendly other international regulatory systems are, if investors and innovators cannot easily translate their products to other markets, they will choose the unfriendly international ones over the friendly UK one because it means they can ultimately sell more products and make more money.• Remove the red-tape element of the regulatory process without compromising on priorities of safety/efficacy so that international medical device manufacturers with products that they are currently selling in other countries can easily come to the UK and sell their products here.• MHRA communicate effectively international regulatory bodies, health tech hubs (US) & Department of international trades• Creating an environment where existing products will need more duplication if UK regulatory seal is not recognised in other territorial space• While US is aligning more closely with Europe, divergence will limit to new products. MHRA and other regulators should work to identify alignment in the existing systems and have a two-way dialogue concerning regulatory alignment. (esp. Commonwealth countries - more likely to have a quicker result - and leverage on what we already have in common, like Canada)
Encourage early engagement with and support for companies developing high-risk medical devices.	<ul style="list-style-type: none">• High-risk products are effectively going to be authorised through MHRA clinical investigation -> MHRA Innovation implementing an ecosystem from early-on for a high-risk medical device companies (e.g. implantables) which has a longer runway to products going to market and attracts a larger international investment.

APPENDIX 3: Evidence

Themes	Opportunities
<i>NON-REGULATORY (Continued)</i>	
Provide clear guidance on new regulations.	<ul style="list-style-type: none"> Regulatory processes need to be communicated clearly so that prospective international investors know what they are getting themselves into. This is true for both existing regulatory processes and plans for future regulatory reform. Lack of knowledge and uncertainty are barriers; knowledge and certainty are facilitators. More clarity around regulation and the regulatory pathway helps medical device companies and prospective investors map out what resources and costs are going to be involved. More clarity around and better application of the 'healthcare institution exemption' so that manufacturers know what is required and how to get to the point of 'first test in humans' Improve the system by which innovators communicate with regulators. Early dialogue between innovators and regulators and early advice from regulators to innovators helps innovators know that they're on the right track and provides them with clarity and certainty and confidence. There needs to be systems for acquiring both informal (prior to the process of seeking regulatory approval) and formal (during the process of seeking regulatory approval) advice. This clarity, certainty, and confidence improves the likelihood that investors will agree to invest in a potential product.
Utilise investment incentives.	<ul style="list-style-type: none"> Financial incentive to attract investment in medical devices that address priority problems. Tax breaks and financial incentives for inward investment Research and Development tax relief for the SMEs or Expenditure Credit for larger companies Companies producing low-cost medical devices such as ostomy bags or personal protective equipment no longer manufacture products in the UK because the costs are too high. The manufacturing is now done in places like China and Mexico. If the UK wants to bring some of that manufacturing back, it could subsidise companies to do such things Enhance accessibility to latest technology, tools, and infrastructure (e.g. apparatus to work with - supercomputers)
Optimise NHS procurement process.	<ul style="list-style-type: none"> Improve the NHS procurement process to make it easier to get products into the NHS. People want to come to the NHS because of the quality of the healthcare system but are put off because of the difficulties around procurement. There needs to be a streamlined process for NHS procurement. Rapid and early adoption of new technologies in the UK. Adoption of new tests has historically been slow in the UK because of the way the NHS system works. She tells people from foreign companies to "think of the NHS as a school of fish, not a whale" as they will not be able to necessarily compel the whole NHS to purchase an IVD, but only small areas instead. For example, in the Oxford area, 3 hospitals wanted an Oxford-based company, supported by accelerated access collaborative, to produce 3 different types of economic evidence, which is a challenge for the companies, and off-putting, leading them to prefer to market their products elsewhere. Make it so that all medical devices that are approved by NICE are bought by the NHS as it is pharmaceuticals. Currently, it is still up to the discretion of NHS Trusts to decide whether they want to purchase the medical device or not. This decreases certainty that a product will sell once it has gone through all of the relevant processes. Tackle uncertainty around commissioning which is the "main enemy for companies", especially for digital health and diagnostic devices Open up access to NHS procurement. The UK does not need to necessarily produce all of its own medical devices. We could make it easier for other countries to sell their products to the NHS. The pathology budget from the UK Government is limited and so it's hard for new tests to get paid for. Instead, companies tend to, by experience, have to do the labour-intensive task of going to the clinicians, and getting them to pay for it from their budget, who then, downstream, have to reallocate funding streams within their local organisation, to pay for it.
Facilitate access to NHS data and infrastructure.	<ul style="list-style-type: none"> Open up access to NHS data. The number one reason why companies want to come here is because they perceive NHS data to be of higher quality than health data from other countries. Existing centralised NHS data (e.g. CPRD - GP data) is "something that we (engineers/manufacturers) dream of, in the rest of Europe) Enhancing processes within the NHS to make the NHS easier to work with. Data pool in the NHS as an advantage. Opening up availability for manufacturers to access and generate high quality NHS clinical evidence means investors are reassured and know they'll get evidence they need to sell products in the UK and potentially elsewhere. Improve regulation that allows medical devices to be evaluated in clinical trials in UK medical settings. Medical device companies will be more likely to invest in the UK if they know they can generate high quality clinical evidence in the UK safely and easily. Maintaining "soft infrastructure" for life sciences in the UK. For example, access to large NHS teaching hospitals where medical devices can be clinically validated. Availability of infrastructure around data, faster interoperability, easiness of connecting to healthcare providers and to patient data, and easiness of deploying such software within the NHS Testing ground (for clinical trials) / innovation hub w. NHS as a partner -> promote innovation & investment Better and clearer signposting on which organisations can provide the "right" connection to clinicians (e.g. AHSN + others) Cohesive offering of clinical support from NHS (or NHS Innovation) to companies developing products within the UK Get devices to the consumer quicker in the real-world with the power of our data which allows continuous monitoring, evaluation and dynamic regulation, compared to the static process that all regulators have at the moment
Strengthen international R&D collaboration	<ul style="list-style-type: none"> Promote and increase funding for international academic collaboration (e.g. US, China, India, etc.). Good multinational collaboration between industry and academia

APPENDIX 3: Evidence

How can the UK encourage innovation in the medical devices area through regulatory and non-regulatory changes?

Themes	Opportunities
<i>REGULATORY</i>	
Coordinate the clinical evidence requirements for regulatory approval and health technology assessment.	<ul style="list-style-type: none"> Decrease costs surrounding acquisition of clinical evidence. Medical devices are becoming more like pharmaceuticals when it comes to development costs. This stifles innovation. One example is NHS trusts seeking to make profit from this process. Simply stopping this could make things cheaper. Streamlining clinical investigation and testing processes Getting clinical trials off ground, with right clinicians Create a 'toolbox' for developers/innovators to use from the start to support them in generating the data that is needed to do a clinical evaluation so that all the relevant and required data is being properly collected right from the start. Places like KTN might be best placed to lead on this. Aspect of clinical evidence generation should be shared (for both regulatory approval and HTA decision)
Focus innovation on clinical need using target product profiles and horizon scanning.	<ul style="list-style-type: none"> Target product profile Horizon scanning -> agenda that is not met, should be publicly-funded (esp. for smaller companies) Ensure innovators work with patients in a meaningful manner so that they develop medical devices that meet end-user requirements
Introduce alternative routes to market for innovative and breakthrough devices.	<ul style="list-style-type: none"> Cost for compliance of a product has increased to the point where these products meet niche, unmet needs, are no longer viable -> adoption of Humanitarian Device Exemption FDA Breakthrough device designation
<i>NON-REGULATORY</i>	
Provide clear guidance regarding regulatory routes to market.	<ul style="list-style-type: none"> Regulatory "transparency" is helpful. Companies are more likely to move into new areas if they know the "rules of the game". Provide pre-regulatory support to medical device manufacturers. There needs to be a clear guidance document outlining the route through the regulatory pathway for medical device manufactures to use. Without transparency and clarity, medical device manufacturers are in a position of uncertainty, which stifles innovation. Otherwise, medical device manufacturers would need to deal with uncertainty or pay high costs for regulatory consultant support. There needs to be less confusion around the route to market for innovative digital medical devices including those that incorporate AI. There are too many actors in this arena at present including NHS Digital, NHSx, NICE, etc. Clear, upfront regulatory process for not only big companies but for SMEs Helping manufacturers understand the regulatory process and burden better.
Continue to provide financial incentives for medical device R&D.	<ul style="list-style-type: none"> Tax breaks and financial incentives for inward investment, local skills development as people who train here and more likely to train here, good job opportunities in the UK, good places for innovators to live. Better funding and financial support for innovators Funding streams and financial incentives to support start-ups and manufacturers who want to develop medical devices in the UK. Financial incentives for innovators to design solutions to important problems. For example, make the regulatory approval process free for medical devices that resolve high priority problems. Shared equity (i.e. Wellcome Trust) where the benefits and risks are shared between funders and innovators should be used more widely in the UK/NHS.
Strengthen collaborative partnership between industry and the NHS.	<ul style="list-style-type: none"> NHS is a single, biggest data pool, but it is fragmented without any communication -> utilise effectively those processes. Inter-operability of different system (incl old archaic systems), esp. w new technology around imaging space and AI -> network across a region/area (rather than dealing with individual hospitals) As a developer, data to train with, test and build something that can get to the patient as quickly as possible (the speed, depth and population) Opening up availability for manufacturers to access and generate high quality NHS clinical evidence - reassures innovators that they'll get the evidence they need in the NHS/UK for product to sell Improve culture and scalability of adoption process within NHS Scalability of adoption process within NHS - if something is proved to work and has a significant benefit to certain patient population -> how to achieve the procurement in the whole healthcare system (rather than regional division) -> NHS England/Innovation mandating trust to perform procurement in a transparent way Improve culture of adoption in the NHS. Manufacturers need to know that developing products here will be a good route to seeing products on the UK market.
Invest in translational and regulatory sciences.	<ul style="list-style-type: none"> Advances in regulatory science will attract investors and start-ups. More undergraduate and postgraduate courses in regulation. There are limited numbers of regulatory consultants around which is largely due to a dearth of formal regulatory training opportunities. Most regulatory consultants fell into it through, for example, engineering backgrounds. Supportive ecosystem of regulator, test-houses, and manufacturers & offer guidance on how to meet those needs that is required by UK/EU Strong research / regulatory science / education base Creative environment w. unmet need (Regulators work closely w. clinicians and competence end, where unmet needs can be identified) Maintaining "soft infrastructure" for life sciences in the UK. For example, access to regulatory consultancy. Making it simpler for innovators to get patent protection. Create/sustain a supportive life sciences infrastructure and industry in the UK in general More coordination between medical device manufacturers, clinicians, academics, and regulators. Collaboration, trust in regulation from patients, doctors

APPENDIX 3: Evidence

How can the UK encourage safety in the medical devices area through regulatory and non-regulatory changes?

Themes	Opportunities
<p><i>REGULATORY</i></p> <p>Increase the emphasis placed on post-market surveillance and improve post-market surveillance processes.</p>	<ul style="list-style-type: none"> • The new IVDR EU system has gone a long way towards improving safety and that's one of the reasons why she thinks it's best to remain conformed to it moving forwards. For example, it improves safety through increasing emphasis on post market surveillance. • Continuous post-market surveillance. This is an essential step without which you cannot be sure that something is safe as you will simply not have enough patient numbers from pre-market studies. • There needs to be a greater emphasis on post-market surveillance in medical devices regulation. • Improve post-market surveillance of medical devices. • Improved post-market surveillance might be a good way to improve safe patient outcomes. • Improve post-market surveillance processes and ensure patients are actively involved in the collection of data about adverse events and side effects associated with medical devices • Move away from post-event reactive triggers i.e. more proactive triggers. "If amazon can tell me what I want to buy next week then why can't we use analytics to determine what the next medical device and IVD safety risk is going to be?" • Greater analysis on complaint data early-on (not only adverse incidents) - dichotomy between non-confirmed complaints vs. confirmed complaints, where some complaints are not directly related to safety, but based on negative user experience (which can "usually lead to something more") • Adequate action needs to be taken early (e.g. clear and timely alerts need to be delivered to the specific people using a specific medical device) if there are suspicions about a medical device (e.g. when post-market surveillance data suggesting that something is unsafe).
<p>Use medical device databases and registries and unique device identifiers.</p>	<ul style="list-style-type: none"> • Use of registries that corresponds with other countries' registries • Registries have been helpful as in the context of COVID-19. • Use of registries • Comprehensive post-market device registries that is publicly-funded • A national database of registered medical devices. The EU is building one called EUDAMED, but the UK will not have access it. The UK will need to build its own to promote transparency around the evidence for effectiveness and safety of medical devices. There seems to be limited appetite for this from UK Government. It will be impossible for the MHRA to build one without funding. • Improve robustness of data gathering for registries/databases of medical devices • Continual monitoring evaluation: following on Cumberlege report, NICE and NHS Digital are working on a new database and registry on vaginal mesh implants (and others), ensuring that data is linked to sources, such as hospital episodes statistics. • Improve transparency through databases such as EUDAMED. • Increasing information flows, transparency, open-source data, as the society becomes more aware of benefit vs. safety • Use of universal device identifiers • The rest of the world is moving towards using unique device identifiers (UDIs) which conforms to GS1 framework and it is important that the UK, which currently is not using them, to do so. Every single component of every single device has a unique identifier and this allows us to properly monitor them for safety issues.
<p>Introduce a post-approval 'transition' phase to the regulatory route to market before routine clinical use.</p>	<ul style="list-style-type: none"> • Another phase of innovation which is post-regulation but pre-routine use. • Graduated entry to market – a sort of grace period of transition period from end of clinical validation through to routine NHS use – where products are more closely monitored. • More follow-ups during the first few months after release to understand how the device is actually used in real-life, "extra gate" before manufacturers scale up their production.
<p>Conduct random audits of quality management systems.</p>	<ul style="list-style-type: none"> • The new IVDR EU system has gone a long way towards improving safety and that's one of the reasons why she thinks it's best to remain conformed to it moving forwards. For example, it improves safety by permitting unannounced visits by notified bodies to make sure people are doing their safety checks always rather than simply dotting I's and crossing T's in advance of a planned visit. • Random testing of products (chemical, functional, material assessment) rather than relying on what companies tell us • Independent testing. Attaining medical devices or IVDs and their sub-components and then testing them independently rather than relying on self-certified reporting by manufacturers can help act as a predictive trigger. • Proactive random testing of low-risk medical devices that are not officially regulated to make sure they are fit for purpose. Then we can prohibit the sale of medical devices that do not work. For example, something like 'Which' but for medical devices.

APPENDIX 3: Evidence

Themes	Opportunities
<i>NON-REGULATORY (Continued)</i>	
<p>Promote patient and public involvement and use of patient reported outcome measures.</p>	<ul style="list-style-type: none"> • Use validated patient reported outcomes in clinical trials of medical devices and SPIRIT-PRO/CONSORT-PRO. • Public involvement and engagement in clinical trials of medical devices. • Ensure UK regulatory process enlist patients in a meaningful manner so that medical device manufacturers consider patient concerns – patient reported outcomes relevant here • User engagement. Currently there is a lack of connection between user forums and stakeholders. • Improve patient representation and user input in generation of new medical device regulation. A balance needs to be struck in this regard. You cannot simply pick someone off the street because they will not really understand regulatory affairs. Equally, you cannot simply continue to use patient representatives who are often the same people, and do not always represent patient viewpoints. The Cumberlege Report describes ‘patient ombudsman’ – perhaps it could be something like this.
<p>Encourage voluntary reporting of suspected medical device incidents by patients, the public, and healthcare professionals.</p>	<ul style="list-style-type: none"> • Improve culture of reporting of incidents at the level of practitioners and patients. • Culture of understanding what the role of regulators are • Personal responsibility for users and patients • Education to encourage patients and clinicians to report issues • Better ‘yellow card’ reporting • Foster a culture of reporting, including the failure of a device, critical situation that arise with the context of the device • Improve focus on patient reporting of problems and adverse events associated with medical devices • Foster a culture of knowledge around new medical devices/technology (e.g. digital education in clinicians) • Digital tech: Consensus on technical terminology and nomenclature, AI literacy within organisations, health and social care professionals
<p>Foster a culture of learning rather than a culture of blame.</p>	<ul style="list-style-type: none"> • Change culture so that we have a culture of learning rather than a culture of blame. This has been done successfully in the airline industry and has resulted in safety improvements. • Rather than changing regulations, it is more important to be responsive when events occur • Ensure UK regulatory agency communicates better with international regulatory agencies so that lessons regarding safety are shared for the benefit of humanity • Sharing knowledge and gaining learning from non-NHS medical device users