Global Counsel

Navigating the Future:

Medical devices and diagnostics regulation in the UK

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SUPPORTED BY Abbott

Foreword

From cardiovascular disease and obesity to diabetes and cancer, medical devices and diagnostics give us the power to prevent and treat many of the biggest health threats facing today's society. The economic and social costs associated with these diseases grow more significant every year. Overweight and obesity, for example, costs the UK economy £98 billion a year, including £19.2 billion for the NHS[1].

The medical devices and diagnostics sector is already driving a new era of preventative healthcare. At the same time, as the UK's largest employer in the life sciences sector, turning over £34 billion a year[2], our sector is a powerful engine for economic growth. Abbott alone supports 12,000 jobs in the UK and contributes £1 billion in Gross Value Added (GVA) to the UK economy[3].

Robust, effective and balanced regulation is paramount to unlocking our sector's potential. Introducing a new regulatory framework in the UK presents an exciting opportunity for the new Government, the MHRA, Approved Bodies and of course, the sector at large. For government and industry to seize this opportunity together will require clarity over timelines for regulatory reform - predictability and reliability are critical for our sector, to inform future business planning, product development and market launch to ensure safe, effective products reach those who need them.

As a global company, we recognise the potential for a new domestic framework to boost the attractiveness of the UK to global regulators and companies. The UK should aim to strike a balance between international harmonisation in many areas – to streamline decisions and reduce administrative costs and burden – whilst also establishing a national route to market that is globally competitive and incentivises companies to choose the UK first over other larger markets. The MHRA can be an effective sovereign regulator that is smartly positioned across a global regulatory landscape.

Abbott is pleased to support this timely White Paper developed by Global Counsel on the UK's regulatory framework for medical devices and diagnostics. The new government has assumed office with priorities to refocus healthcare more towards prevention and closer to home through the use of the latest innovative technologies, and with a focus on regulatory innovation. We hope this report provides a constructive contribution to ongoing policy and legislative developments.

Yuan Fang
Divisional Vice President for Global Strategic Regulatory
Abbott

1. https://institute.global/insights/public-services/unhealthy-numbers-the-rising-cost-of-obesity-in-the-uk
2. https://www.abhi.org.uk/
3. Abbott's Economic Contribution to the UK, Oxera, 2024.

Executive Summary

This paper was written by Charlie Norell and Valerie Jentzsch in Global Counsel's Health & Life Sciences practice, with input from Abbott who commissioned the research. It draws on in-depth interviews with a selection of leading expert stakeholders representing industry, UK Approved Bodies, regulators, clinicians, central government and key opinion leaders. To encourage open conversations, quotes from interviewees have been included on a non-attributable basis and assigned according to job title or organisation type to maintain anonymity. We would like to thank this group for their insightful contributions and support throughout the development of this paper.

As the UK establishes its own post-Brexit regulatory framework for medical devices and diagnostics – and a new set of policymakers grapple with complex questions regarding its future - this paper aims to inform their thinking and policy development. Given the potential breadth of this topic, the scope of this paper mainly focuses on regulatory processes and practices relating to medical devices and diagnostics for sale and use in the UK. It does not cover the adoption and spread of innovative technologies following regulatory approval. GC have written about this topic separately with the Association of British HealthTech Industries (ABHI) in the report: "Unleashing Innovation in the NHS: Barriers and opportunities for the adoption and spread of healthcare technologies"[4].

This paper also takes a global perspective. The findings and recommendations reflect a number of lessons that the UK can learn from other geographies, particularly the European Union and United States. It identifies ways in which the UK can benefit from international harmonisation whilst also promoting an attractive regulatory environment to global companies. A core theme throughout all of the recommendations is a heightened need for the UK's regulatory framework to have predictability, reliability and certainty – necessary traits to remain globally competitive. All stakeholders highlighted the importance of predictability in order for industry to plan the development and launch of new innovative products. Below we set out the full list of shortened recommendations, with further detail provided later in the report.

Summary of Recommendations

01 The MHRA should publish an updated detailed Future Roadmap with clear timelines for implementing key pieces of legislation, to give industry and relevant bodies clarity and predictability on next steps.

02 The MHRA, potentially in partnership with industry, should develop a set of materials and training programmes designed to educate clinicians on the UK's regulatory landscape for medical devices.

03 As new regulations are brought into force, the UK Government, MHRA and its relevant ecosystem partners should ensure that the appropriate infrastructure, databases and guidance documents are in place at the time of implementation of the new framework to support industry and UK Approved Bodies in implementing them smoothly and effectively.

4. https://www.global-counsel.com/insights/report/unleashing-innovation-nhs-barriers-and-opportunities-adoption-and-uptake-healthcare

Summary of Recommendations

04 In developing additional statutory legislation governing UK Conformity Assessment (UKCA) marking, the Department of Health and Social Care (DHSC) should consider flexibilities that maximally align the UK with the regulatory requirements of other key regulators in larger markets.

05 The DHSC and the Medicines and Healthcare products Regulatory Agency (MHRA) could explore taking a greater role in the regulation of medical devices, with an initial focus on combination products as a test case. Options should assess whether the MHRA has sufficient expertise, resource and capacity to regulate certain medical devices to a greater extent. This would require extensive coordination across multiple organisations including the MHRA, UK Approved Bodies, manufacturers, healthcare professionals, and end users.

06 The MHRA should continue to explore ways of providing early scientific advice to companies, with clear routes to market, such as by expanding the remit of the Innovative Devices and Access Pathway (IDAP) following a successful pilot phase and implementing the outcomes of its recent consultation, subject to industry support.

07 In exploring the potential remit and scope of a new Regulatory Innovation Office (RIO), the government could consider basing this Office in a more cross-government position (e.g., with the support of the Cabinet Office), enabling it to pull on more levers and influence, and ensuring any focus on the life sciences sector covers all of medicines, medical devices and diagnostics.

08 The DHSC and the MHRA should collaborate with UK Approved Bodies to develop policy options for expanding their role, in a legally-compliant way, to be stronger sources of expertise and early scientific advice and - for those which are also EU Notified Bodies - whilst still complying with EU regulations.

09 UK Approved Bodies, in partnership with the MHRA, should consider straight-forward solutions to drive efficiencies in conformity assessment processes.

10 DHSC, working with the MHRA, National Institute for Health and Care Excellence (NICE) and the National Health Service (NHS), should outline how they intend to implement the recommendations of the independent review of Equity in Medical Devices to ensure ethical and social evidence are considered more strongly in medical device assessments for both quality and safety, as well as assessments for reimbursement.

An opportunity for change

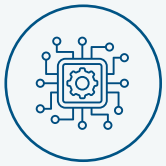
The UK medical devices sector is a dynamic and vital part of the economy, characterised by significant turnover, robust export activity, and a large and diverse workforce. The size of the UK medical technology market is estimated at over £27 billion[5], compared to €160 billion[6] in the EU and $180 billion[7] in the US. The UK is a major player in the global medical technology market, with an export value of over £5.6 billion[10] per year. While smaller than both the €11 billion[9] in the EU and over $44 billion[10] in the US, the UK's export power in comparison to the size of the market is significant. In the UK, the medical technology sector employs around 154,000 people[11], compared with over 880,000 in the EU[12] and 519,000 in the US[13]. These figures demonstrate the severity of the challenge facing the UK in competing with larger global markets. As this report will show, there are several ways by which the UK can remain an attractive destination to seek first regulatory approval and launch medical devices despite its smaller market size.

The UK's medical devices and diagnostics sector is also experiencing three broad contextual shifts, each involving risks and opportunities to anticipate. Navigating these shifts enables manufacturers to have a unique view of the UK's future regulatory landscape. They include:

Regulatory. After exiting from the European Union, the UK is seemingly in the process of transitioning to a sovereign regulatory framework, including through the introduction of UK Approved Bodies and the UKCA marking. For medical devices – whilst manufacturers are now able to use the UKCA marking, and have been since January 2021 - the UK government has extended recognition of the EU Conformity Assessment until 30 June 2028 or 30 June 2030 depending on the nature and risk of the medical device or diagnostic[14]. Whilst CE marked medical devices are still accepted on the Great Britain market, it is unclear whether the government are similarly considering its indefinite extension, or whether the UKCA mark will be prioritised. It is also unclear why a UK or EU manufacturer would choose a UK-only conformity assessment instead of one that is recognised across the EU and UK. As such, this paper considers the potential opportunities for the UKCA marking scheme. In particular, it explores how this regulatory shift could work to the UK's advantage if the MHRA and approved bodies are able to implement streamlined, pro-innovation measures, such as early access pathways, that incentivise manufacturers to choose a UK-based conformity assessment.

5. https://www.gov.uk/government/publications/medical-technology-strategy/medical-technology-strategy
6. Thttps://www.medtecheurope.org/datahub/market/
7. https://www.fortunebusinessinsights.com/u-s-medical-devices-market-107009
8. https://www.gov.uk/government/publications/medical-technology-strategy/medical-technology-strategy
9. https://www.medtecheurope.org/datahub/trade/
10. https://www.advamed.org/member-center/resource-library/the-economic-impact-of-the-medical-technology-industry/
11. https://www.gov.uk/government/publications/medical-technology-strategy/medical-technology-strategy
12. https://www.medtecheurope.org/datahub/employment-companies/
13. https://www.advamed.org/member-center/resource-library/the-economic-impact-of-the-medical-technology-industry/
14. https://www.gov.uk/government/news/uk-government-announces-extension-of-ce-mark-recognition-for-businesses and https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1166483/Infographic_-_Devices_transition_timeline.pdf

Political. A new government following the July 2024 general election marks a significant political shift with implications for the medical devices and diagnostics sector. At the time of writing, the new government is building a platform for a series of healthcare reforms, namely through three "shifts": from treatment to prevention, hospital to community-based care, and analogue to digital by harnessing new technologies. The investigation into the state of the NHS by Lord Ara Darzi[15], and commitments to publish both a 10-year health plan[16] and NHS Innovation and Adoption Strategy[17] represent strong signals of intent. Underlying these reforms is a more fundamental reframing of DHSC's remit to be an economic growth department[18]. As new technologies promise productivity gains, cost savings and better patient outcomes, regulation will be a critical feature of their pathway into the UK market.



Technological. Greater adoption, uptake and general public awareness of healthcare technologies is accelerating these shifts. Examples include: wearable technologies, such as smart watches, able to gather data points in real-time and provide an even more accurate picture of a patient's condition; in vitro diagnostic medical devices, and At-Home Rapid Antigen tests, quickening the shift from hospital to community care whilst granting patients more autonomy over their health; and AI as a medical device (AIaMD), including for cancer imaging, with the potential to provide more accurate diagnoses and free up radiologist workloads. Some of these products have been around for decades, with innovation occurring through gradual, iterative processes. Others have experienced more transformative leaps in shorter spaces of time. In all cases, today's public health challenges underscore an urgent societal need for healthcare technologies that offer viable, cost-effective solutions.

This context presents a fertile ground for new policy thinking and untapped opportunities in the medical devices sector. In the following sections, this paper outlines the findings from in-depth interviews with stakeholders and proposes a series of recommendations in each area for policymaker consideration.

15. https://www.gov.uk/government/publications/independent-investigation-of-the-nhs-in-england
16. https://www.gov.uk/government/news/pm-major-surgery-not-sticking-plaster-solutions-needed-to-rebuild-nhs
17. https://labour.org.uk/change/build-an-nhs-fit-for-the-future/
18. https://www.gov.uk/government/news/secretary-of-state-makes-economic-growth-a-priority

Key findings and recommendations

COMMUNICATING CLARITY AND PREDICTABILITY

Updating the roadmap towards a future regulatory framework with clear timelines

Clear, consistent communication from the MHRA on what changes will take place and when these can be expected will give industry and bodies necessary clarity"

DIRECTOR OF UK AND EU REGULATORY AFFAIRS

Earlier this year, the MHRA published their roadmap for delivering a future regulatory framework for medical devices[19]. Since then, a new government has assumed power and the milestones indicated in the original roadmap have been missed as a result of developments outside the regulator's control, as also recognised by the MHRA itself.[19-1] This is understandable as officials and regulators wait for greater certainty over the priorities of new ministers. Nonetheless, several stakeholders suggested that the MHRA should publish an updated Roadmap with clear timelines for delivery – taking into consideration the need for departmental and ministerial approvals and legislative processes. There was a recognition of the "holding state" that the industry is currently in, as they remain unsure of what their strategy to market entry in the UK should be whilst a lack of clarity and predictability remains. Publishing an updated Roadmap would give all ecosystem partners, particularly manufacturers and UK Approved Bodies, far greater clarity around upcoming changes and enable them to prepare accordingly.

From a political standpoint, the anticipated stability of a new government was considered to represent a key opportunity to foster collaboration between relevant stakeholders involved in the regulation of medical devices and diagnostics – including the MHRA, NICE, NHSE and DHSC, amongst others. By driving collaboration, experts expressed hope for a pro-active and harmonised approach to regulatory and policy change for this crucial sector of UK industry.

Recommendation: The MHRA should publish an updated detailed Future Roadmap with clear timelines for implementing key pieces of legislation, to give industry and relevant bodies clarity and predictability on next steps. This would recognise any delays in the implementation of the UKCA marking following the UK general election in July 2024.

19. https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices
19-1. https://medregs.blog.gov.uk/2024/09/25/an-update-on-our-plans-for-med-tech-regulatory-change/

Building a bridge between regulatory processes and clinical entrepreneurs

Clinicians developing innovative devices need to juggle their day jobs on the side. Navigating a complex regulatory landscape makes launching products even more challenging"

CLINICAL ENTREPRENEUR

As both clinical innovation and regulatory landscapes evolve, interviewees reflected on the growing gap in understanding between the two fields. The complexity of the UK's regulatory framework may not be well understood by clinicians developing new technologies, and particularly as evidence requirements become increasingly more stringent and clinicians often lack the time to obtain regulatory support. The burden and cost of moving through regulatory processes was also considered to be disproportionate on SMEs and clinical entrepreneurs, which respondents believed could hinder future innovation. Establishing a scheme to exchange expertise between clinicians, the MHRA and approved bodies, developing specific training programmes, and creating clinician-facing regulatory guidance documents were highlighted as possible solutions to upskill the clinical community in medical device regulation. Relating to the above recommendation, this proposal calls on both government and industry to communicate and educate those who are building new technologies and seeking to comply with the regulatory framework. Some of these aspects could be addressed in the evolving format of Innovate UK Regulatory Science and Innovation Networks (RSINs)[20], where proposals include the development of education and training materials. RSINs could be encouraged to play a facilitative role in helping to bridge the knowledge gap and communicate emerging thinking.

Recommendation: The MHRA, potentially in partnership with UK Approved Bodies and industry, should develop a set of materials and training programmes designed to educate clinicians on the UK's regulatory landscape for medical devices, as a first step to helping them navigate the various processes as they develop and potentially support the launch of an innovative product in the UK.

TAKING AN INTERNATIONALLY-MINDED APPROACH

Learning lessons from implementation in Europe

EU MDR and EU IVDR lacked the right delivery mechanisms and infrastructure to be implemented in a timely manner, impacted by political events – Brexit, COVID-19 - which exacerbated delays."

EXPERT INDUSTRY ADVISOR ON MEDICAL DEVICE REGULATION

The UK can learn important lessons from the European Union's experience implementing the EU Medical Device Regulation (MDR)[21] and In Vitro Diagnostics Regulation (IVDR)[22]. Stakeholders considered the regulations themselves appropriate in terms of their aims and requirements on manufacturers. However, they highlighted several factors impacting their implementation, such as significant reliance of the EU framework on several Implementing Acts, the delay in publishing Medical Devices Coordination Group (MDCG)[23] guidance - for which the publication timetable was not aligned with MDR transition dates – and delay in establishing the list of harmonised standards. Further delays were seen in the notification of certification bodies, where overloaded Notified Bodies (NB) could not manage a coming wave of certifications before

20. https://iuk.ktn-uk.org/opportunities/uk-regulatory-science-and-innovation-networks-discovery-phase/
21. hhttps://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32017R0745
22. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0746
23. https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/medical-device-coordination-group-working-groups_en

2024. Adding to these was the delay in implementing the EUDAMED[24] database and the departure of the MHRA due to Brexit, as an expert partner to inform the implementation process.

As the UK plans to transition away from the EU framework, respondents viewed it as critical to ensure that the underlying infrastructure is in place at the time of implementation of the new regulations and ready to adapt to a new framework. In particular, the MHRA as a sovereign regulator should have the capacity to deliver areas within its competence, such as post-market surveillance, whilst also working closely with – and providing high-quality guidance for – UK Approved Bodies. If the UK is able to take forward the learnings from the EU and harness the advantages brought about by having one centralised competent authority, this would represent a crucial opportunity to prevent future bottlenecks and maintain the UK's regulatory attractiveness. A first step could be for the MHRA to undertake a comparative gap analysis of the EU and UK contexts to comprehensively review all guides, standards, data collection capabilities and notification processes that will be required to ensure smooth implementation.

Recommendation: As new regulations are brought into force, the UK Government, the MHRA and its relevant partners should ensure that the appropriate infrastructure, databases and guidance documents are in place at the time of implementation of the new regulatory framework to support industry and UK Approved Bodies in implementing them smoothly and effectively. A first step could be for the MHRA to undertake a comparative gap analysis of the EU and UK contexts to comprehensively review all guides, standards, data collection capabilities and notification processes that will be required to ensure smooth implementation.

Unlocking the benefits of international harmonisation

Capacity, predictability, flexibility and openness in its regulatory framework all make the US an even more attractive place to launch a medical device."

DIRECTOR OF GLOBAL REGULATORY AFFAIRS

The overwhelming sense from stakeholders was that the UK's position in the regulatory world post-Brexit has shifted. The MHRA leaving the EU's regulatory consortium meant losing a long-standing source of expertise with which to work, share and delegate resources. Stakeholders also noted that the MHRA itself suffered an exodus of expertise from the organisation – and across many areas of the business, including but not limited to, medical devices. As a result, the UK must now adapt to being a sovereign regulator as part of a larger international regulatory landscape. To do this, respondents emphasised the need for the UK's regulatory framework to take a dual approach: on the one hand, through sophisticated international harmonisation and deference; and on the other, making strategic decisions to specialise in - and allocate resource to – specific technology areas where the UK has the opportunity to be a first mover. Such an approach could reduce administrative costs, speed up assessment processes, and ensure the resources of the MHRA and UK Approved Bodies are effectively utilised.

Experts considered that the UK's domestic pathway, namely the UKCA marking, as a potential tool for international attractiveness. Concerns were raised about the attractiveness of a UK domestic route, when manufacturers could seek an EU Conformity Assessment to grant them access to both the EU and UK or an Food and Drug Administration (FDA) approval enabling US sales plus 'fast track' in various accepting countries including Australia and Latin American countries. For example, proposals for an updated UKCA marking scheme with minimal additional requirements compared to other geographies, and potentially involving incentives to better compete with EU Conformity Assessment or FDA approval. There should also be a concerted effort to ensure the UKCA mark is internationally recognised, with reciprocal agreements in place. A starting point for international recognition could be mutual access to Commonwealth countries with a similar healthcare system to the UK such as Canada, Australia and New Zealand. Given intrinsic links to the EU - such as in supply chains, co-located companies, and clinical research partnerships - the UK should avoid creating additional requirements

24. https://webgate.ec.europa.eu/eudamed/landing-page#/

that would burden manufacturers that straddle UK and EU markets.

Respondents also pointed to the MHRA's leading international role in informing global standards through its participation in the International Medical Devices Regulatory Forum (IMDRF)[25]. As greater international harmonisation reduces burdens for both industry, national regulators, and conformity assessment bodies, the UK could stand to benefit from "having a seat at the multilateral table". The UK's participation in international standard-setting forums was viewed as a strength that should be more widely communicated to, and recognised by, industry stakeholders.

Recommendation: In developing additional statutory legislation governing UKCA marking, the DHSC should consider flexibilities that maximally align the UK with the regulatory requirements of other key regulators in larger markets. Reducing bureaucracy, costs and assessment times through greater harmonisation could make the UK's national route more attractive to global companies looking to launch products in the UK. The Government and MHRA should also clarify the make-up of the new regime in terms of the benefits of achieving a UKCA marking and pursuing the international recognition route of approval. The benefits, timelines and incentives of each route should be communicated to enable industry and relevant bodies adequate time to prepare market access strategies to support innovation and adoption.

ENABLING INNOVATION THROUGH REGULATION

Promoting a proportionate and agile regulatory framework

The UK needs a proportionate, agile framework for medical devices. It needs to balance innovation through early access, and robust post-market surveillance."

FORMER SENIOR REGULATOR

Across all interviews, a key theme was defining a proportionate regulatory framework that balances innovation and varying risk levels with robust safety measures. Interviewees considered that most medical devices in the market today bear a lower risk, and therefore should move quickly through the assessment process to reach patients and clinicians. Alongside this, the UK's framework should instil a pragmatic approach that can grant new, innovative products earlier access to the market - including through the use of risk-categorised clinical studies and acceptance of more types of evidence, such as in-silico data. Another relevant example noted by respondents was products without an intended medical purpose where regulators can bridge the gap between general product safety regimes and a medical devices regime by generating scaled UK guidance for considerations of risk-benefit. In such cases, respondents emphasised that a governance framework should be based on a proportionate, adaptive approach supported by relevant guidance that avoids additional legislative changes.

To counterbalance pro-innovation and early access measures, the framework should ensure robust post-market surveillance, involving close collaboration between the regulator, UK Approved Bodies, and manufacturers. There was a consensus that the framework generally, and post-market surveillance specifically, should be geared towards those devices and diagnostics that pose the highest risk (e.g., implantables and high-risk Artificial Intelligence (AI) enabled functions).

This approach could also be reflected in the MHRA's own structure by allocating greater strategic resources and expertise to innovative medical device regulation. This would reflect the vital role of medical devices and diagnostics in the future of healthcare, particularly in light of the new government's focus on prevention and shifting care to community settings. Experts acknowledged the MHRA's much greater resource allocation to, and expertise in, medicines regulation. Whilst acknowledging the complexity of regulating combination products, industry respondents further considered whether the regulation of

25. https://www.imdrf.org/

combination products could be an area to pilot a new approach across the MHRA, particularly given the MHRA's expertise across medicines as well as medical devices. Some respondents believed that the specificities of combination products also contributed to the hampered implementation of MDR and IVDR in the EU.

Recommendation: DHSC and the MHRA should explore options for whether the MHRA could take a greater role in the regulation of medical devices, with a potential focus on combination products as a test case. Options should assess whether the MHRA has sufficient expertise, resource and capacity to regulate certain medical devices to a greater extent. This would require extensive coordination across multiple organisations including the MHRA, UK Approved Bodies, manufacturers, healthcare professionals, and end users.

Facilitating earlier scientific advice and faster adoption

"IDAP has the potential to be a game-changer, but it needs to recognise that devices differ from medicines. Innovation in Medtech is a much more iterative process."

SENIOR CIVIL SERVANT

Interviewees welcomed the pilot phase of the MHRA's Innovative Devices and Access Pathway[26] (IDAP) "in principle", but considered it too early to determine its success. Industry respondents suggested ways of improving the first version of IDAP, such as: assessing patient safety and economic benefit in parallel; expanding its allocated funding following a successful pilot phase; and learning any lessons from the first iteration of the Innovation Medicines and Licensing Pathway[27] (ILAP) where there was a lack of clarify over the roles and responsibilities of organisations involved, namely between the MHRA, NICE and NHS England. Experts also reflected on the contentious definition of "innovation" which, for medical devices, may include novel indications for use, additional patient populations, manufacturing to increase capacity to supply product, material changes to make the product more sustainable or improve ease of use, in addition to more transformative leaps. This definition of innovation should be reflected in the post-pilot phase of IDAP to inform a wider set of criteria, allowing more devices to be potentially eligible. An expansion of eligible technologies for NICE's Early Value Assessment[28] (EVA) scheme – with ringfenced funding attached – could also be considered to drive access for new technologies and adoption through to the NHS.

To complement the roll-out of IDAP, experts indicated that the MHRA could take a more formal role in offering scientific advice to devices manufacturers. For example, to support their understanding of the risk classification process and assessment pathway, including quality management and evidential requirements. This is particularly pertinent in light of the limited role (by law) of EU Notified Bodies and UK Approved Bodies in being able to provide consultancy support to manufacturers. In August 2024, the MHRA published a consultation on proposals to update its statutory fees and to create a new service to provide regulatory advice meetings for medical devices[29]. If the MHRA is unable to establish such a function, interviewees pointed out that DHSC and DSIT could also explore deferring this to the new Regulatory Science and Innovation Networks (RSINs) to exploit the UK's strong body of medical devices expertise whilst avoiding any suggestion of regulatory capture.

Recommendation: The MHRA should continue to explore ways of providing early scientific advice to companies, with clear routes to market, such as by expanding the remit of IDAP following a successful pilot phase and implementing the outcomes of its recent consultation, subject to industry support. In this context the role of UK Approved Bodies should be clarified.

26. https://www.gov.uk/government/publications/the-innovative-devices-access-pathway-idap
27. https://www.gov.uk/guidance/innovative-licensing-and-access-pathway
28. https://www.nice.org.uk/about/what-we-do/eva-for-medtech
29. https://www.gov.uk/government/consultations/mhra-consultation-on-statutory-fees-proposals-on-ongoing-cost-recovery/mhra-consultation-on-statutory-fees-proposals-on-ongoing-cost-recovery

Driving regulatory innovation

Industry, government and regulators need to work together to maintain the UK's strong track record in regulatory innovation"

SENIOR CIVIL SERVANT

Consensus amongst respondents was that the UK continues to make good strides in regulatory innovation. However, greater collaboration between industry, government and regulators is needed to ensure the UK can take advantage of the latest technologies and products, which in some cases could be transformative. Particularly relevant areas for this discussion included software and AI as a medical device, and devices without an intended medical purpose. Experts felt that these areas need further consultation with industry and dedicated guidance and standards that take a technology-specific approach. Creating opportunities for industry and regulators to discuss new regulatory approaches to these types of devices will be critical in the long-term.

In driving innovation, interviewees pointed to the role of AI in driving productivity if accompanied by investments in workforce upskilling. For example, by supporting clinical staff in diagnostic decision-making and scheduling surgeries. The MHRA has published its own strategic approach to AI[30], considering the role the technology may play in expediting regulatory processes, including for UK Approved Bodies. A key initiative is the MHRA's new AI Airlock pilot[31], bringing together ecosystem partners to address novel regulatory challenges poses by AIaMD.

The new government's plans for a Regulatory Innovation Office (RIO), if and when it is established, could provide the necessary means to instil these approaches across government. However, interviewees pointed out the need for a new RIO to have adequate 'teeth' to deliver its aim of driving regulatory efficiency. They also cautioned against a RIO that initially focuses on medicines rather than medical devices - given the latter are more ubiquitous, less expensive for the NHS to buy in many cases, and will likely play an even bigger role in community-based care and prevention. Diagnostics in particular can be used earlier in key disease pathways and sometimes avoid the need for more costly pharmaceutical interventions.

Recommendation: In exploring the potential remit and scope of a new RIO, the government could consider basing the Office in a more cross-government position (e.g., with the support of the Cabinet Office), enabling it to pull on more levers and influence, and ensuring any focus on the life sciences sector covers all of medicines, medical devices and diagnostics.

MODERNISING THE ASSESSMENT JOURNEY

Adapting the roles of UK Approved Bodies

There are clear opportunities for the UK, but harnessing them requires bold thinking beyond existing conformity assessment structures."

EU NOTIFIED BODY

As the UK moves away from the EU and the corresponding regulatory framework post-Brexit, experts identified opportunities for the roles of UK Approved Bodies to be adapted within this new context. There was a general appreciation of the asks raised by UK Approved Bodies on international recognition and for clarity of their role within this. As UK Approved Bodies are commercial entities, there is a natural reluctance to

30. https://www.gov.uk/government/publications/impact-of-ai-on-the-regulation-of-medical-products
31. https://www.gov.uk/government/collections/ai-airlock-the-regulatory-sandbox-for-aiamd

adopt assessments conducted elsewhere and thereby take on the associated liability.

Interviewees also considered that UK Approved Bodies are untapped sources of early advice and expertise – while recognising that, under the current framework, UK Approved Bodies may not be able to provide consultancy services to manufacturers in the UK as this does not comply with the responsibilities of their work as EU Notified Bodies under the EU framework. However, these organisations that are both a Notified Body (EU) and Approved Body (UK) often have sites located in each geography, with governance and quality system processes in place to ensure their competences in different jurisdictions are not conflicted. Agreement with the EU on what is and is not permitted within a 'structured dialogue' would be helpful towards this end.

Recommendation: DHSC and the MHRA should collaborate with UK Approved Bodies to develop policy options for expanding their role, in a legally-compliant way, to be stronger sources of expertise and early scientific advice and - for those which are also EU Notified Bodies - whilst still complying with EU regulations.

Driving efficiencies in assessment

Overall, the regulatory system for medical devices and diagnostics is fit for purpose, but there is scope within various areas of the system to drive change and efficiency."

UK APPROVED BODY

Whilst experts considered the assessments conducted by UK Approved Bodies to be suitable, they identified opportunities throughout the assessment process to improve efficiencies. For example, based on experiences during COVID-19, a move towards more hybrid and remote auditing of Quality Management Systems (QMS) – and ultimately real-time monitoring – would unlock efficiencies for both Approved Bodies and manufacturers. On evidence, in the long-term, expanding the role of in-silico trials and computational methods could reduce the number of over-burdensome human trials while ensuring patient safety and driving efficiencies.

On post-market surveillance, respondents emphasised the need to reduce duplication of data collection across jurisdictions and to ensure that auxiliary insights, e.g., for horizon-scanning, are generated from available data. Experts pointed out that the recommendations of the Cumberlege Review[32] on medicines and medical devices safety, published in 2020, proposed the creation of a medical device information system (MDIS) which has not been implemented to date. One interviewee put forward the need to code devices and link surveillance databases with patient records in order to track the use and outcomes of devices throughout the patient journey. This approach could also support the mining of data in a systematic way to identify, if an issue arises, whether this was due to the device itself or the user or other factor. For this to materialise, all stakeholders involved in post-market surveillance should be brought together to discuss harmonisation of data and databases.

Several interviewees highlighted the critical role of the MHRA in detecting harmful trends based on incidents reported to them, pointing to the case of metal-on-metal hip replacements identified through the National Joint Registry[33] established in 2002. Experts acknowledged that such databases are expensive and would need central government funding, as well as clear guardrails on usage of and access to included data. One respondent noted the creation of a surveillance database[34] in Germany, funded by the Ministry of Health, as well as in France and Austria, which are also taking national approaches.

Recommendation: UK Approved Bodies, in partnership with the MHRA, should consider straight-forward solutions to drive efficiencies in conformity assessment processes, such as shifting to hybrid and/or remote model of QMS audits, and the acceptance of the Medical Devices Single Audit Program (MDSAP) as a means of demonstrating compliance with QMS requirement. To improve post-market surveillance, the MHRA should explore more comprehensive data gathering systems that both ensure patient safety and manufacturer compliance.

32. https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-report
33. https://www.njrcentre.org.uk
34. https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/DMIDS/Oeffentliche-Datenbanken/Datenbankinfo-MPA/_node.html

Equity in medical devices and diagnostics

From a health system point-of-view in particular, ensuring that we balance equitable innovation with access is a crucial consideration."

KEY OPINION LEADER

Respondents often cited an independent review on equity in medical devices[35] published in 2024, which found equity to be a key part of product development, but lacking from formal assessments. Ensuring that existing biases are removed and/or mitigated in the development and use of medical devices – for example, biases seen in AI software devices - was a key consideration raised by experts. Alongside the creation of clinical and economic evidence, there was a reflection that evidence on ethics, equity and social value around medical devices and diagnostics should also be taken more into account during the assessment process. Whilst acknowledging that this point extends beyond safety and quality assessments under the remit of the MHRA and Conformity assessment bodies, experts supported greater consideration of equity across the full development, approval and adoption process of medical devices.

Recommendation: The new government, working with the MHRA, NICE and the NHS, should outline how they intend to implement the recommendations for the independent review of Equity in Medical Devices to ensure ethical and social evidence are considered more strongly in medical device assessments.

35. https://www.gov.uk/government/publications/equity-in-medical-devices-independent-review-final-report

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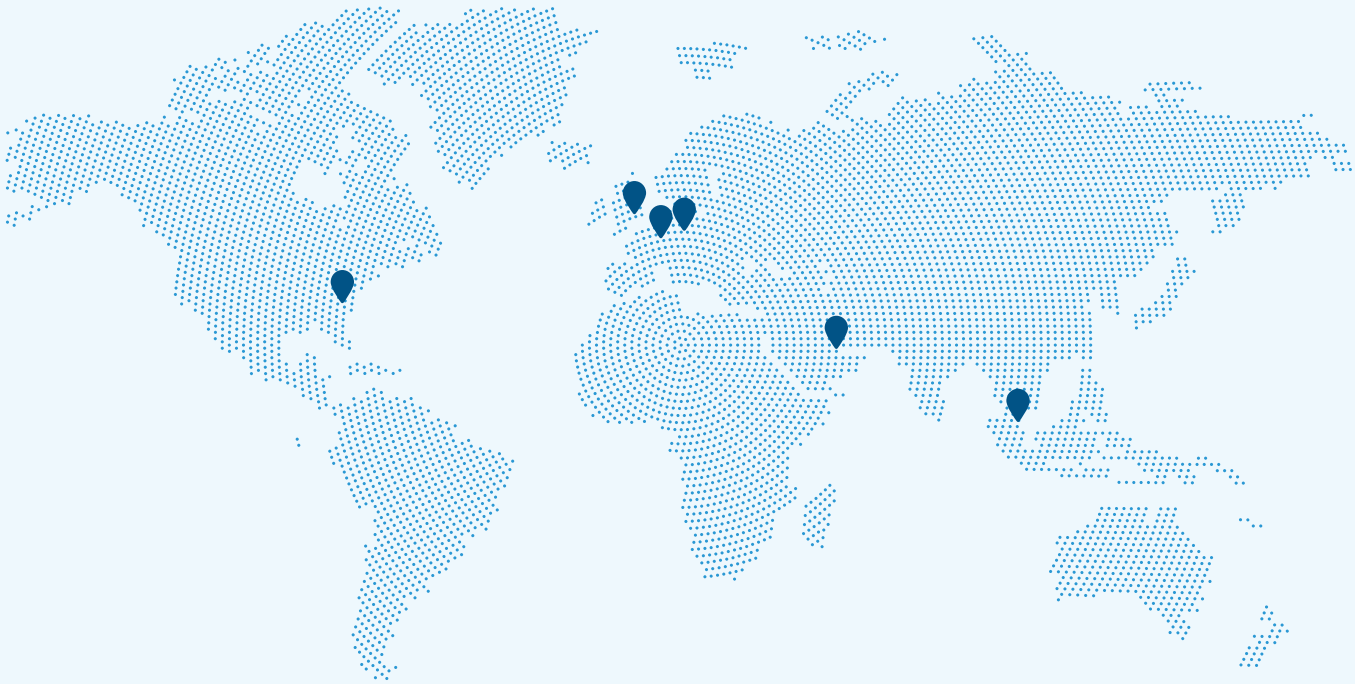

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