New proposals to strengthen medical devices regulation and bolster UK life sciences sector

- New proposals published to strengthen the regulation of medical devices in the UK and support our life sciences sector to tackle future health challenges
- highlights opportunity for the UK to take advantage of its departure from the EU and create UK-specific regulation that puts patients first
- follows the government's new Life Sciences Vision, which outlined ambitions for the sector over the next decade, putting it at the heart of plans to build back better from the pandemic

A new report published today by the Regulatory Horizons Council (Thursday 19 August) sets out how the UK could strengthen the regulation of medical devices, learning lessons from the response to the coronavirus (COVID-19) pandemic while boosting the UK's world-class life sciences sector.

The Regulatory Horizons Council (RHC) is an independent expert committee which identifies the regulation needed to foster technological innovation and provides government with impartial, expert advice on the regulatory reform required to support its rapid and safe introduction. Their new proposals set out how medical devices such as pacemakers or implantable defibrillators should be regulated to ensure we can tackle healthcare challenges effectively, now and in the future.

The report identifies the UK's departure from the European Union as an opportunity to build a UK-specific regulatory system that puts patients at the heart of decision-making processes – for example by increasing patient representation on expert groups for advice on medical research and devices, and by providing evaluations of medical devices that are easily understandable. It highlights the opportunities now available to the UK, not only to respond more quickly to new advances in technology, but to work with like-minded countries in shaping international regulation.

Life Sciences Minister Nadhim Zahawi said:

> Our life sciences industry is at forefront of global, modern regulation, as demonstrated by the speed and flexibility of the UK's development and rollout of COVID vaccines.
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> Today's report supports our ambition to capitalise on the UK's departure from the European Union and put in place streamlined regulation that will ensure we can bring to market safe and effective medical devices quickly, benefitting patients across the country.

It calls for lessons to be learnt from the UK's COVID-19 response, including addressing delays in medical device approval so that equipment can be authorised effectively and at speed. It also recommends that pandemic preparedness should include fast-track evaluation of new in vitro diagnostics and that reporting of diagnostic tests be transparent and standardised.

The report also highlights opportunities for the UK to take a leading role in the development of international standards, notably in sectors of importance such as AI, while exploring membership of international programmes such as the Medical Device Single Audit Program (MDSAP).

Innovation Minister Lord Bethell said:

> The UK's brilliant life sciences sector has excelled during the pandemic, pioneering important research and developing vaccines and treatments for COVID-19 which have saved countless lives across the globe.
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> Our regulator, the MHRA, was the first in the world to approve a COVID-19 vaccine and will soon be outlining proposals for a new regulatory framework for medical devices which will prioritise safety and help UK patients benefit from cutting-edge medical technology. This report is a welcome addition to help shape this area.

It suggests using medical devices as a template to help enable broader UK regulatory reform that improves patient safety and system efficiency by identifying areas where regulatory reform may attract inward investment and growth.

Today's publication follows the launch of the government's new Life Sciences Vision, published last month, which outlined ambitions for the sector over the next decade, including the Medicines and Healthcare products Regulatory Agency's (MHRA) forthcoming consultation on a new regulatory framework for medical devices.

Earlier this year the Medicines and Medical Devices Act 2021, which provides a framework for updating the UK life sciences regime, received Royal Assent. This Act is a milestone in ensuring that after leaving the EU, the UK remains a world-leading regulator by supporting the delivery of the Life Sciences Vision, but also by and ensuring the UK can continue to embrace new health innovations.

The Act allows us to maintain a regulatory system that does what is best for the UK supporting innovation and protecting patient safety. The UK government remains committed to working collaboratively with industry to deliver key ambitions for a future medical devices regime.

Today's report highlights the opportunity for the UK to show international leadership and become a global centre for medical device regulation.

The Business Secretary Kwasi Kwarteng has written to the Regulatory Horizons Council welcoming the report, and the Department of Health and Social Care will respond in detail to its recommendations following the response to the forthcoming MHRA consultation.

About the Regulatory Horizons Council (RHC)

The Regulatory Horizons Council (RHC) is an independent committee, sponsored by the Department of Business, Energy and Industrial Strategy (BEIS), that identifies the implications of technological innovation. It provides government with impartial, expert advice on the regulatory reform required to support its rapid and safe introduction of new technologies.

Establishing the RHC was one of the key recommendations from the government's white paper on Regulating for the Fourth Industrial Revolution. The RHC is currently undertaking deep dives with recommendations for government on regulatory reform on:

The Council has decided on its next programme of work for later this year including; principles for pro-innovation regulation, hydrogen, neurotechnology, and artificial intelligence in healthcare.

Learn more about the RHC.