MHRA launches public consultation on future of medical device regulation

Launched today by the Medicines and Healthcare products Regulatory Agency (MHRA), the 10-week consultation gives everyone the opportunity to draw on their own experiences and contribute to the improvement of the regulatory framework and therefore patient safety in the future.

From hearing aids and walking sticks, to insulin pumps and thermometers, for many of us, medical devices are an essential part of our everyday lives. We all want to know that the devices we use are safe and effective, so regulation of medical devices really matters, especially where fast-developing technology has changed, and continues to influence, the landscape for medical devices, bringing new, innovative devices to the UK market, including some health apps.

The MHRA is the regulator for medical devices used in the UK. We are seeking views from across the medical devices and healthcare sectors, medical practitioners, patients and the wider public, to inform our future approach. We would like to hear from those who research, manufacture, supply and use medical devices.

Medical devices in the UK are currently regulated under the Medical Devices Regulations 2002. Following the UK's departure from the European Union, the MHRA now has the opportunity to create a world-leading regime that prioritises patient safety while fostering innovation, including streamlining the approval of medical devices.

This consultation is comprehensive – covering a broad range of regulatory issues – from requirements for running clinical investigations, to how devices are assessed before being placed on the market through to importer and distributor obligations and post-market surveillance to transparency and the role of patients. It provides a once in a generation opportunity to ensure the safety and quality of medical devices that many of us rely on, and from which we all benefit.

Dr June Raine, Chief Executive of the MHRA, says:

> The launch of this consultation is an exciting step towards a more robust, world-leading regulatory framework for medical devices in the UK, one that enhances medical device safety and quality, access to devices, and has patients at its heart.

> We know that a problem with a medical device can have a significant impact on people's lives. This consultation offers a once in lifetime chance to help shape the regulations. In order to reach

> this goal, we want to hear from a wide range of people. Delivering for patients is central to our work and we fully recognise the importance of the public and patients' perspectives and encourage them to share their views during this consultation.
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> This is your chance to make a difference to people's experiences with devices by helping shape the regulations around medical devices – from how much scrutiny they face before they reach the market, to how they are tracked and monitored, and what actions are taken if problems with a device arise. It is also an opportunity to impact what products the MHRA regulates – for example, should the MHRA have a role in the regulation of other products which are similar to medical devices such as cosmetic coloured lenses or dermal fillers?

We encourage everyone to share their views on the future of medical devices regulation through this public consultation.

Health and Social Care Secretary Sajid Javid said:

> The UK is home to one of the world's most renowned regulators, ensuring the safety and effectiveness of the medicines and medical devices that we all rely on.
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> This consultation will allow us to revolutionise the regulation of medical devices, making sure our pioneering life sciences sector can continue to lead the world and safeguard the health of our nation.
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> From pacemakers to contact lenses, wheelchairs to pregnancy tests, medical devices play a vital role for the vast majority of us and I encourage everyone who wants to be a part of this mission to put forward their views.

The consultation will close at 11.45pm on 25 November 2021.

We have already hosted two webinars this October, one aimed at industry and one focussing on patients and the wider public. The webinars provided more information about the background to, and scope this consultation and how to respond. Both webinars were recorded and the video recording will be published on Gov.UK in due course.

Notes to editors

1. The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK.

2. The MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The MHRA is an executive agency of the Department of Health and Social Care.

3. This consultation is on a future UK-wide scheme for regulating medical devices. It recognises the Government is seeking a new balance to the Northern Ireland Protocol to place it on a more sustainable footing as expanded on in its Command Paper – Northern Ireland Protocol: The way forward.

4. Under the current approach to the Northern Ireland Protocol, EU rules on medical devices continue to apply in Northern Ireland. The EU Medical Devices Regulation (2017/745) (EU MDR) therefore took effect in Northern Ireland on 26 May 2021 and the in vitro Diagnostic Medical Devices Regulation (2017/746) (EU IVDR) will take effect from 26 May 2022. The EU MDR and EU IVDR will not apply in Great Britain. We welcome views on alignment across all of the UK nations as part of this consultation. The Government is also seeking a new balance to the Protocol and, as set out in its Command Paper, has proposed a dual regulatory regime in Northern Ireland where goods that meet either UK or EU rules could circulate within Northern Ireland.

For any other enquiries about this consultation, please contact futuredevicesregulations@mhra.gov.uk