Department of Health & Social Care

From Minister Andrew Gwynne MP
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for Public Health and Prevention
39 Victoria Street
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Dr Caroline Johnson MP
House of Commons
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4 December 2024

Dear Caroline,

Re: The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024

I would like to thank you for responding on behalf of the opposition to the debate on The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 last week.

These regulations introduce clearer and more robust requirements for post-market surveillance (PMS) of medical devices to improve patient safety and signal a crucial shift in the way we regulate medical devices in Great Britain.

In developing these draft regulations, we have taken a pragmatic approach to international alignment, which prioritises patient safety while supporting global harmonisation across the medical device sector. You raised several questions relating to the impact on the NHS and patient data confidentiality, and I undertook to provide written responses.

Cost of new measures to the NHS

The measures introduced through these draft regulations are not expected to directly impose costs on the NHS. The majority of devices registered with the MHRA have EU regulatory approval and already comply, or are moving towards compliance with, EU PMS requirements. The enhanced PMS requirements in GB will bring parity between the requirements for manufacturers to report adverse events to the MHRA for both CE and UKCA marked devices and ensure a consistent approach to PMS across the whole of the UK.

As is the case for all regulatory changes, some manufacturers may have to update their processes which may increase their costs, and these costs could be passed on to the NHS or see manufacturers choose not to supply the UK market. However, the government believes that the long-term health and economic benefits that the draft regulations will deliver through improved patient safety, outweigh these risks.

High profile medical device safety issues, such as those associated with vaginal mesh, have resulted in significant health impacts for patients and their families, as well as high economic

costs for patients and for the NHS. These draft regulations will help to prevent such safety issues, by improving the ability of both the manufacturer and the MHRA to identify and manage safety issues with medical devices placed onto the Great Britain market before they escalate.

Information on patients' experience

These draft regulations introduce requirements for the manufacturer to maintain a post-market surveillance system that is proportionate to the risk posed by the device and is appropriate to the type of device. This must be based on a post-market surveillance plan that includes processes for the collection and assessment of information about user experience in relation to safety and performance, including through patient and public engagement, where appropriate.

To fulfil these requirements, it will be the manufacturer's responsibility to identify opportunities for patient and public engagement on the safety and performance of their medical device. The suitability of this engagement will depend on the specific device. The MHRA will provide detailed guidance to help manufacturers fulfil these important responsibilities.

Patient confidentiality

These draft regulations will require manufacturers to prepare reports that summarise their post-market surveillance data. These reports aim to provide an overview of device safety and performance, helping manufacturers to identify trends in their data. The reports are not for public release, do not identify individual patients and so do not pose a risk to patient confidentiality, as these will focus on overall device performance and safety rather than be attributed to individual patients.

We anticipate this regulation will encourage greater use of existing registries, which provide a reliable source of data that manufacturers can use to fulfil regulatory reporting requirements. The NHS England Outcomes and Registries Programme was established in 2022 to develop a single, unified registry solution – the Outcome Registries Platform. The Outcome and Registries Programme was established in 2023 and is delivering a number of core workstreams to fulfil the recommendations of "First do no harm: the report of the Independent Medicines and Medical Devices Safety Review", chaired by Baroness Julia Cumberlege, and the Paterson Inquiry report. Our intention is to unify the fragmented governance, access, financial and technical landscape of registries and audits.
The Outcomes and Registries Programme will collect data and use it for the primary purpose of improving patient safety.

This draft statutory instrument represents the first legislative step towards broader medical devices regulatory reform. It will create a strong foundation for further regulatory amendments that enhance the safety of medical devices, improve their availability and support innovation. We intend to bring further improvements to patient safety by introducing additional measures that must be taken before a product can be put on the market through future legislation. This will include measures for unique device identifiers and implant cards that will further support transparency and traceability within the healthcare system, while respecting patient confidentiality. We will also use the assurances that these draft

regulations provide to underpin the introduction of new efficient International Reliance routes to market in GB, ensuring the safe supply of medical devices to UK patients.

I hope this response provides the reassurance sought and am copying it to members of the Third Delegated Legislation Committee present at the debate.

I have also deposited a copy of this letter in the libraries of both Houses.

Yours sincerely,

ANDREW GWYNNE