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## MEDICINES AND MEDICAL DEVICES BILL: PUBLIC SAFETY

*Dear Naren,*

I would firstly like to thank you for your further insightful comments during Committee Stage of the Medicines and Medical Devices (MMD) Bill. Further to my undertaking to write to you in more detail about who makes the decisions on issuing medical device safety warnings concerning a "clear threat to public safety".

### **How a clear threat to public safety is identified, assessed and mitigated**

As you will be aware, no medical procedure is risk free, and the risk posed by any one device used during a procedure can be very different, depending on its intended purpose and benefit.

The Medicines and Regulatory Healthcare products Regulatory Agency (MHRA) assess the potential risks posed by medical procedures and the likelihood of their occurrence by pulling together information from the following sources:

- YellowCard and manufacturer serious incident reports;
- any other safety information available from other sources, such as the National Reporting and Learning System;
- any relevant medical device registries; and
- reports from other regulators (e.g. FDA (USA), TGA (Australia)).

Partly in response to Baroness Cumberlege's "First Do No Harm" report, the MHRA is currently transitioning from investigating individual or one-off medical device incidents to focusing on market surveillance signal detection, validation and prioritisation.

The Lord Patel KT  
House of Lords

This will allow MHRA's specialist resources to be focused on the identification, understanding and managing of the safety issues posing the greatest risk to patients and the public, including those posing a clear threat to public safety. It must be noted that on occasion one single incident can represent a significant risk to patient/ public safety.

MHRA's Devices Division are responsible for all aspects of Medical Device Regulation in the UK (Device Registration/ Attesting Notified Bodies/Clinical Investigations/Market surveillance). The Devices Division recently introduced a new Signals, Risk and Messaging Committee (SRM). This consists of Devices senior management and technical and clinical experts. The SRM meets weekly and provides governance for the delivery of risk management and safety messaging for the highest risk or highest profile issues.

If actions are required there are a range of options open to the Regulator including compliance and regulatory actions against manufacturers. To keep devices in use and benefitting patients, the MHRA also work with the wider health and social care system to mitigate risks associated with the use of medical devices. The options here include:

- a targeted letter to sites affected;
- a safety bulletin and information on our webpages;
- a press release/social media activity; or
- a National Patient Safety Alert, if, through its systems the MHRA determine that the following strict criteria are met:

- ⇒ the issue is more likely than not, to cause one or more death or disability in Healthcare in England in a year.
- ⇒ the actions contained in the alerts must be SMART (specific, measurable, achievable, relevant and time-bound) and aimed at senior individuals within a health organisation, not directly at the healthcare professionals. Those senior people should have the power to effect change within the organisation to meet the alert actions;
- ⇒ where an alert will involve a patient review or notification exercise or generate concern with the public who think they may have been personally affected, the alert issuer has systems in place to work with relevant organisations to ensure local and/or national contact points are in place to provide advice to concerned or affected individuals.

The MMD Bill would greatly aid the MHRA in the future. Clauses 35 (2), (3) and (5) will make a significant difference to the MHRA's ability to engage more openly with patients, relevant health service personnel and with academia with relevant research interests, to better understand risks. This will also greatly facilitate open and clear communication of safety issues, even if the manufacturer is unreasonably opposing any alerting concerning the issue.

### **The Medical Device Information System**

The MHRA are working with NHS Digital on their development of the Medical Device Information System (MDIS) facilitated by Clause 16. Once this system is developed, this will immediately begin to facilitate improved tracking and tracing of patients with implanted

medical devices affected by manufacturers' field safety notices or other safety related interventions, including by MHRA.

New comparative device performance data (from Patient Reported Outcome Measures (PROMs) and surgical interventions collected in the Medical Device Information System and associated registries) will provide MHRA with the means for earlier patient safety intervention and corrective actions concerning under-performing implants. This would also inform future medical device design.

#### **MHRA workstreams**

In the near future, MHRA are also planning to introduce two look-up and auto-populate features to improve adverse incident reporting data quality and ease of use:

- scanning of UDI codes on device packaging for device model and production identifiers; and
- NHS organisation (ODS) look-up of codes from NHSD reference data.

MHRA is also working on a more radical overhaul of its reporting and safety signal detection and management systems via their development of SafetyConnect. This future integrated reporting system for medical device, medicines and blood is planned to be able to receive the reports via hospital local risk management systems, GP systems, NHSI's Patient Safety Incident Management System and the Devolved Administrations' systems.

This initiative, in time, should enable a single locally captured report to be sent to all relevant organisations, thus removing a known major disincentive to reporting to multiple organisations.

SafetyConnect, MDIS and other related initiatives mentioned above will all facilitate improved patient safety information and earlier and more effective safety interventions.

I hope that I have adequately addressed the questions you raised at Committee and I or my officials would be pleased to provide further information as helpful. The Bill team can be contacted at [MMD-Bill@dhsc.gov.uk](mailto:MMD-Bill@dhsc.gov.uk). I will place a copy of this letter in the Library of the House.

*Very best wishes,*



**BARONESS PENN**