Chief Medical Officer for Scotland

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The Scottish Government
Riaghaltas na h-Alba

Dear Colleague

MEDICAL DEVICE REGULATION (MDR) PREPAREDNESS: PATIENT IMPLANT CARDS, IMPLANT PATIENT INFORMATION LEAFLETS AND MHRA YELLOW CARD SCHEME

Purpose

1. To highlight to NHS Boards:

a) Under planned new GB Medical Device Regulatory requirements healthcare professionals will be required to provide their patients receiving an implant with a Patient Implant Card and Implant Patient Information Leaflet.
b) The importance of providing patients with accurate device information, particularly for implanted devices, during consent procedures.
c) The importance of health professionals advising patients that in addition to always reporting any issues to their healthcare professional or team managing their care, that patients can also report any adverse events with their implant to the Medicines and Healthcare products Regulatory (MHRA) Yellow Card scheme.

Background

2. The draft GB Pre-Market regulations have now been published on the World Trade Organisation website and are due to be in force during 2027. These contain new Medical Device Regulatory (MDR) requirements for healthcare organisations and healthcare professionals about the traceability of implantable devices, patient implant cards and patient implant information. These measures will deliver more rapid traceability in the event of a device recall and provide patients with accurate device information.

3. To help Boards meet the regulatory requirements for improved implanted device traceability, the NHS Scotland Scan for Safety Programme, is working with NHS Boards to put in place a digital Point of Care (PoC) scanning system across all Health Boards in Scotland until March 2027. All NHS Boards will also be required to ensure that they have a systematic approach for ensuring that all patients receive a manufacturer supplied Patient Implant Card and Patient Implant Information leaflet specifically about the implants they will receive.

From the Chief Medical Officer for Scotland
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The Chief Nursing Officer for Scotland
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Addresses

For action
NHS Board Chief Executives
NHS Board Medical Directors
NHS Board Nurse Directors

For information
NHS Board AHP Directors
NHS Board Directors of Finance
NHS Board Heads of Procurement
NHS Board Scan for Safety Leads
NHS Board Employee Directors
NHS Board Deputy Finance Directors
NHS Board Digital Leads
NHS Board Medical Device Committee Chairs
PHS SNAP Programme
Incidents Reporting and Investigation Centre (IRIC)

Scottish Academy of Royal Colleges

Further Enquiries to:

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Scan for Safety Programme:
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Patient Implant Cards and Patient Information Leaflet Regulatory Requirements

Manufacturer Regulatory Requirements

4. The new GB MDR requires manufacturers to provide a Patient Implant Card in a standardised format. This format includes device identification, manufacturer name and website and space to record the patient name, date of implantation and name and address of the implanting healthcare entity.

5. The manufacturer must also provide an implant Patient Information Leaflet which, in addition to device and manufacturer identification contains:

a) the expected lifetime of the device and requirements relating to the safety or performance of the device
b) warnings, precautions or measures to be taken by the patient or a healthcare professional regarding reciprocal interference with reasonably foreseeable external influences
c) information on the materials and substances in the implantable device to which the patient could be exposed,
d) any other warnings or information necessary for the safe use of the device by the patient

6. Some low -risk implanted medical devices are excluded from this requirement: for example sutures, screws, plates, dental crowns. A full list is available in the draft regulations.

Healthcare Providers GB Pre Market Regulatory Requirements

7. Healthcare providers are responsible for ensuring that every patient discharged with a new implant has been provided with an implant card with the patient and hospital details completed and that both the implant card and implant information leaflet are given to the patient. It is important that this process ensures sufficient explanation and discussion that the patient understand the importance of retaining these cards long term. Healthcare providers may wish to include this information as part of a safe surgery checklist where this is appropriate.

8. When procuring implantable medical devices, NHS Boards should ensure that manufacturers and suppliers provide them with the required Implant Cards and Patient Information Leaflets.

MHRA Yellow Card Scheme for Patient reporting

9. The provision of Implant Cards and Patient Information Leaflets to patients provides an important opportunity to improve patient safety for medical devices by enabling patients to complete patient experience and incident reports with accurate device identification.

10. Medical device safety incidents are under-reported both by healthcare professionals and patients and public awareness of the MHRA Yellow Card scheme is low in Scotland. Patients should always report medical device issues to their healthcare professional in the first instance, however we encourage health care professionals to highlight the Yellow Card reporting route available to patients during discussions with them. The MHRA Yellow Card scheme provides a range of resources for patients, including a web based reporting tool for medical devices and medicines.

11. Steps are being taken to improve the visibility of the MHRA Yellow Card reports made by patients in Scotland through the regular publication of the Incident Reporting and Investigation Centre (IRIC) Flashcards and providing patient information on NHS Inform and other patient facing resources, to sign post to the MHRA Yellow Card Scheme information. The MHRA are also taking steps to publish medical device safety information on a UK basis, as is already available for Medicines.

Safety Signals Monitoring

12. Health and care professionals should continue to report any medical device safety issues on the local reporting and learning system and to IRIC, if their Board does not operate a Once for Scotland reporting system. All safety reports made to IRIC are routinely shared with the MHRA and monitored for medical device safety signals.

Actions for NHS Boards and Healthcare Professionals

13. When procuring implantable medical devices, NHS Boards should ensure that manufacturers and suppliers provide them with the required Implant Cards and Implant Patient Information Leaflets.

14. NHS Boards are responsible for having a systematic approach to ensuring that the patient and hospital details are completed and both the Implant card and implant Patient Information leaflet are given to the patient. It is important that this process ensures sufficient explanation and discussion that the patient understands the importance of retaining these cards long term.

15. Healthcare professionals should also highlight to patients, where appropriate, the MHRA Yellow Card reporting scheme available to patients to help improve patient safety for medical devices.

16. NHS Boards, in discussion with their Board MDC, should ensure that they have arrangements in place to audit the implementation of their regulatory requirement, when in force, for providing implant cards and implant leaflets to all patients with a new implant.

Yours sincerely

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Chief Nursing Officer for Scotland

Professor Christine McLaughlin
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