Chief Medical Officer for Scotland

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The Scottish Government
Riaghaltas na h-Alba

Dear Colleague

MEDICAL DEVICE REGULATION (MDR) PREPAREDNESS AND MEDICAL DEVICES POLICY FRAMEWORK AND ACTION PLAN 2024-2026

Purpose

1. To provide NHS Boards with the Medical Device Policy Framework and Action Plan which has been developed to support Boards to achieve compliance with proposed changes to UK Medical Device Regulation (MDR).

Context

2. The planned revision of the UK medical devices regulations (UK MDR), by the UK Medicines and Healthcare products Regulatory Agency (MHRA), designed to improve patient safety will introduce new and additional legislative requirements for NHS Boards, particularly for in house manufactured devices, software as a medical device and high risk implantable devices.

3. The Medical Devices Policy Framework and Action Plan (Annex A) is focussed on MDR preparedness and improving the foundations needed to support medical devices policy, and has been developed through engagement with NHS Boards and Local Authority Incident Safety Officers.

4. The Framework's Action Plan sets out the key Actions to be progressed in the period 2024-2026, mainly for the SG Medical Devices Unit (MDLU) in partnership with the NHS Scotland Scan for Safety Programme being led by NSS, the national Incident Reporting and Investigation Centre (IRIC) also NSS and with support from Health Improvement Scotland (HIS).

5. The 9 Actions for Health Boards are based on existing requirements in CEL 35 (2010) and CEL 43 (2009) with a focus on improving local assurance processes for MDR compliance and the safe management of medical devices, utilising the outcome of the national actions.

Summary

6. The Framework **aim is to improve patient safety and outcomes in medical devices** through four key themes.

From the Chief Medical Officer for Scotland
Professor Sir Gregor Smith

8 February 2024

SGHD/CMO(2024)1

Addresses

For action
Chief Executives, NHS Boards
Executive Directors responsible for Medical Device Policies, NHS Boards

For information
Chairs, Board Medical Device Committees
Incident and alerts Safety Officers (ISON), NHS Boards and Local Authorities
IRIC
Clinical Engineering Leads
Nurse Directors
AHP Directors
Healthcare Science Leads
eHealth Leads, NHS Boards
COSLA
SOLACE
Diagnostics Steering Group
PHS SNAP Programme
Medical Devices Committee (MDC)
SHTG

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- **Assurance of implementation of UK MDR** relating to primarily NHS Boards and the application of national guidance on "Management of Medical Devices in health and social care" (SHTN 00-04) in Scotland:
- **improving and utilising medical device data at national level** and maximising its use to improve patient safety;
- **improving the information available to patients** about medical devices used in their care; and
- **improving infrastructure for medical devices at national level** with a first key step the establishment of a national Medical Devices Committee.

7. A national Medical Devices Committee has been established, co-chaired by the Chief Medical Officer and on behalf of NHS Board Chief Executives, Gordon James, to provide leadership and offer direction to NHS Scotland in its preparation for the medical devices regulatory regime, due to be in effect from summer 2025. Draft Terms of Reference provided in Annex B.

8. The Actions in this Framework are intended to be the start of the key foundations for developing medical devices policy in NHS Scotland. Implementation of this first Framework, covering the period 2024-2026 will enable an evidence based medical device policy to evolve.

NHS Scotland Scan for Safety Programme

9. The NHS Scotland Scan for Safety Programme will implement point of care scanning to link patients to implantable devices used in their care and is due to be completed by March 2026. The Scan for Safety Programme, led by NSS, is working in partnership with Health Boards to deliver electronic traceability of high risk medical devices and ensure that Health Boards comply with the future Medical Device Regulation requirements.

10. A further CMO letter will follow specifically on this.

Monitoring and Evaluation

11. A monitoring and evaluation framework and self-assessment tool for Boards is being developed as part of this Framework. The SG MDLU will be undertaking regular reviews of progress reporting to the newly established Medical Devices Committee (MDC).

Action for Boards

12. NHS Board Executive Directors responsible for medical device policies are asked to take forward the Board Actions relevant to them through their local Board Medical Device Committee.

Yours sincerely

Gregor Smith

Professor Sir Gregor Smith
Chief Medical Officer for Scotland

Annex A

Medical Devices Policy Framework and Action Plan

Introduction

The Medical Devices Policy Framework and Action Plan, developed through engagement with NHS Boards and Local Authority Incident Safety Officers, encompasses several existing programmes of work, including improving preparedness for Medical Device Regulations (MDR) planned to come into force in July 2025.

The Framework **aim is to improve patient safety and outcomes in medical devices** delivered though four key themes:

- **Assurance of implementation of UK MDR** relating to primarily NHS Boards and the application of national guidance on "Management of Medical Devices in health and social care" (SHTN 00-04) in Scotland:
- **improving and utilising medical device data at national level** and maximising its use to improve patient safety;
- **improving the information available to patients** about medical devices used in their care; and
- **improving infrastructure for medical devices at national level** with a first key step to establish a national Medical Devices Committee.

Preparing for the future – laying the foundations for future Action Plans

These actions are intended to be the start of the key foundations for developing medical devices policy in NHS Scotland. Implementation of this first Framework and Action plan, covering the next 2 years will enable an evidence based medical device policy to evolve.

Key Themes and Action Plan 2024-2026

Theme 1: Assurance of implementation of UK Medical Device Regulations (MDR) for NHS Boards and application of national guidance on "Management of Medical Devices in health and social care" (SHTN 00-04)

Why this matters

The process to develop the future UK Medical Device Regulations by the Medicines and Healthcare products Regulatory Agency (MHRA) is underway with future regulations due to come into effect in a three phased approach; Transitional Arrangements (Laid 2023), Post Market Surveillance (Implementation Summer 24), Future core MDR (July 2025).

The UK Government published response to the public consultation on the future regulation of medical devices provides the direction and intention of the future regulatory framework. High impact areas for Health Boards and Local Authorities include significant changes to Health Institute Exemption relevant to in-house manufacturing, Software as a Medical Device, requirements regarding storage Unique Device Identifiers linked to patients for high risk implantable devices.

Actions 2024-26

Scottish Government:
Baseline current NHS Board positions on medical device policy development, their scope and governance.

Provide guidance to support Boards to develop local medical devices policies that provide assurance of management of medical devices compliance with regulatory requirements and integrates with other Board safety and governance structures.
Establish a SLWG with the Clinical Engineering and eHealth communities to develop guidance and a Once for Scotland approach where possible on the management of Software as a Medical Device (SaMD).
National Services Scotland should:
Update the national "Guidance on the Management of Medical Devices in Health and Social Care" to reflect the changes in MDR and developments in the medical devices landscape in Scotland.
Undertake, through the Incident and Safety Officers Network (ISON), an MDR preparedness gap analysis on In House Manufacture by Health Institutions including the extent to which ISO 13485 or equivalent QMS is being implemented.
Establish a SLWG to develop a Monitoring and Improvement Framework to measure Boards/LAs compliance against "Guidance on the Management of Medical Devices in Health and Social Care" (which includes appropriate MDR requirements).
Health Improvement Scotland should:
Ensure the pipeline from evidence to adoption of new medical device health technology assessments is enhanced through engagement with Boards and key stakeholders.
NHS Boards should:
Review local NHS Board medical device policies and governance structures in line with "Guidance on the Management of Medical Devices in Health and Social Care" and MHRA regulatory requirements to identify gaps and produce a local Action Plan.
As part of Board's local governance structures consider how MDR compliance risks will be monitored and escalated at Board level.
Ensure their medical device polices are linked to governance processes that support the implementation of the relevant Scottish Health Techologies Group (SHTG) health technology assessments.

Theme 2: Improving and utilising medical device data at national level and maximising its use to improve patient safety

The Covid 19 pandemic exposed the challenges in identifying supply and use of key medical devices and equipment and has resulted in significant investment to improve particularly supply chain knowledge of devices and equipment. Baroness Cumberlege's Independent Review of Medicines and Medical Devices (Cumberlege Review) documented the significant limitations for traceability and record keeping for transvaginal mesh and made key recommendations to establish a national database linking medical devices and patients.

What we are doing

The NHS Scotland Scan for Safety Programme led by NSS, in partnership with NHS Boards, will deliver a national approach to traceability for high risk implantable devices used in acute care and provide a source of data to improve safety, knowledge and outcomes for medical devices.

Actions 2024-26

Scottish Government should:
In partnership with the Scottish Government National Audit Programme Board (SGNAPB) and Scottish National Audit Programme (SNAP), promote the linkage of device data into clinical outcome data collections.
Work closely with the Scan for Safety Programme in considering how we can support national medical device data to deliver value and impact.
National Services Scotland should:
Work in partnership with NHS Boards to implement the NHS Scotland Scan for Safety Programme, with a focus on high risk implantables until 2026.
Develop a National Reporting Framework to confirm how the medical device data which will be made available through Genesis and Medical Devices Data Hub will be used and shared.
Develop a National Reporting Framework to confirm how the data which will be made available through the National Medical Equipment Management System (NMEMS) will be used and shared.
NHS Boards should:
Work in partnership with NSS to implement the NHS Scotland Scan for Safety Programme including the National Medical Equipment Management System.
Following the pilot and evaluation of the Pelvic Floor Registry (PFR), implement across all Boards; and improve ascertainment in the Breast and Cosmetic Implant Registry (BCIR) to inform improved outcomes for patients and services.

Theme 3: Improving the information available to patients about medical devices used in their care

Why this matters

Patient and citizen insight in the design, planning and delivery of medical device improvements are essential in ensuring we deliver what is important to patients in a person-centred health and care system.

What are we doing

Initial discovery work including a literature review by Health Improvement Scotland on patient experiences and opinions about medical devices have provided valuable insights that will be used to guide medical devices policy as well as shape future patient involvement. The MDLU and the SFS programme in partnership with the HIS Gathering Views programme are undertaking patient insights work on medical devices to ensure patient views is built into the foundation of the work of MDLU and the SFS programme.

Actions 2024-26

Scottish Government should:
Develop a guide for NHS Boards and local authorities on best practice in providing information to patients about medical devices.
Health Improvement Scotland should:

Working in partnership with the MDLU and Scan for Safety Programme undertake citizen engagement to build a better understanding of patient attitudes to, for example, receiving information about devices used in their care, and to reporting adverse events with devices used in their care through their Gathering Views process.
National Services Scotland should:
Provide information to those sites where Scan for Safety is being implemented covering: the changes patients may notice due to implementation of the programme, the information which will be captured as part of the scanning process and how this will be stored and used.
NHS Boards should:
Consider how Boards can apply the national guidance on patient information on medical device to locally produced information.
Consider how local initiatives can support patients to report issues and adverse events related to medical devices.

Theme 4: Improving infrastructure for medical devices at national level

Why this matters

The infrastructure to support the safety, management and improvement for medical devices requires review. Local Board policies and structures are varied and in some Boards this will form a significant challenge to achieving assurance of compliance with a new and more complex regulatory regime. At national level, there are limited national forums for escalation or opportunities for leadership, sharing knowledge and delivering a national approach to challenges.

Governance and Accountability

As a first step, a national Medical Device Committee (MDC)) has been established to provide leadership and offer direction to NHS Scotland. A Medical Devices Regulation Community on Teams has also been established to facilitate knowledge and best practice sharing.

Monitoring and Improvement

The journey for improvement in medical device safety, Board structures and roles and assurance of compliance with regulation and national policy will take a number of years. Working in partnership with Boards, we will develop a monitoring and improvement framework to support the compliance with regulation and existing national policy guidance

What we are doing in 2024

Scottish Government:
Establish a national Medical Device Committee to provide leadership and guidance on MDR Preparedness and the national Actions in this Framework
Input to the monitoring and improvement framework for compliance with UK MDR and national policies and guidance.
With NHS Education for Scotland (NES), create national medical device regulation education and training resources for health and social care staff, hosted on TURAS
Establish an Medical Device Regulation Community to share opportunities for sharing knowledge and best practice across the system

NHS Boards should:
Implement the national Monitoring and Improvement Framework when available
Use the national workforce planning process to signal any changes in workforce requirements required for MDR compliance

Annex B

SG Medical Devices Committee – Draft Terms of Reference (Abbreviated Version)

1. Purpose of Medical Devices Committee (MDC)

To provide leadership and offer direction to NHS Scotland in its preparation for the medical devices regulatory regime due to be in place by 2025.

2. Responsibilities

The Committee will:

- Seek to add to preparedness, including by commissioning SLWGs through the SG Medical Devices and Legislation Unit (MDLU) with the relevant Subject Matter Expertise (SME) to develop Once for Scotland approaches and/or national guidance, where possible and considered useful.

- Oversee the development of mechanisms to provide assurance of compliance with regulatory and supporting national guidance for NHS Boards, particularly through local Board medical device policies and ensuring the development of a Monitoring and Improvement Framework, that NHS Boards can use to measure their compliance against national guidance.

- Advise the SG Medical Devices Unit about the delivery of a Scottish Government Medical Device Policy Framework which is being considered (which will have the aims of supporting NHS Boards with their regulatory compliance and improving patient safety and outcomes in medical devices).

- Where existing national structures are in place, the role of the Committee will be to direct those to the most appropriate structures. For example, particular service issues which would be for their respective governance routes such as Diagnostics Steering Group, Digital Portfolio Board or National Infrastructure Board.

Chair and Membership

Co-chaired by CMO and Gordon James on behalf of NHS Board Chief Executives with membership at Board Executive Director level and Subject Matter Experts.

Meeting Dates for 2024

- 15 March 2024
- 29 May 2024
- 28 August 2024
- 21 November 2024

January 2024