ABHI REGULATORY ROUND UP

October/ November 2025

A concise overview of UK, EU, US and global regulatory developments in medical devices, IVDs, and digital health, with practical insights for ABHI members navigating evolving frameworks, standards, and stakeholder engagement.

ABHI Regulatory Round-Up – Oct/ Nov 2025

ABHI

11th December 2025

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Regulatory Updates are provided in collaboration with MedBoard, the data intelligence platform monitoring regulatory news from 225+ Countries in 15+ Regulatory Areas, in real time. Visit www.MedBoard.com to learn more about the cloud platform and its regulatory, clinical, and market solutions to stay on top and manage information and data within the MedTech industry.

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Executive highlights

Coming up soon

- Draft of new GB regulation (UKCA) and reliance on US/Australia/Canada approvals to be notified to the WTO after the break.
- MHRA consultation expected after the break on continued indefinite recognition of CE MDR/IVDR in Great Britain.
- European Commission expected to publish a proposal **16th December**: to revise MDR and IVDR as part of a broader health package. This may introduce changes to timelines, requirements, innovation pathways and digitalisation.
- EU consultation on Notified Body practices (Annex VII) expected soon.
- Draft EU implementing act on well-established technologies anticipated in December

UK Regulatory Developments

- MHRA and FDA deepening collaboration on innovation and reliance routes, including AI governance via the National AI Commission (details)
- MHRA performance data shows 100% of clinical investigation applications processed within timelines; initial assessments averaging 56 days (details)
- Major shift planned for rare disease treatments, aiming for regulatory flexibility and streamlined pathways

EU Regulatory Updates

- EUDAMED's first four modules will be mandatory from 28 May 2026
- New guidance and standards published, including for spectacle frames, clinical assessments, and harmonised standards for surgical clothing and sterilizers

International Regulatory News

- IMDRF published guidance on predetermined change control plans for SaMD
- Australia, Canada, Brazil, Egypt, India, Japan, Malaysia, South Africa, South Korea, Spain, Switzerland, and others have released new or updated regulatory guidance and standards (see full round up for links)

ABHI Member Actions

- Upcoming regulatory group meetings for IVD and MD members—dates and formats listed in the round up

- Member offers include free consultations and discounts on regulatory services

Standards and Guidance

- Multiple new British Standards published for medical devices, IVDs, implants, health software, and more
- Drafts for public comment include standards for electronic IFU for IVDs, medical robots, and chemical disinfectants

Spotlight Sessions

- **Regulation as a Catalyst – The UK's Strategic Advantage for HealthTech Innovation -** *Key Takeaway:* The UK is signalling a clear ambition to be a global leader in healthtech innovation. For ABHI members, this is a moment to engage with a regulatory system that is evolving a more attractive environment for bringing safe, effective technologies to patients.
- **Health Institution Exemption – Stakeholder Survey -** *Key Takeaway:* The exemption for GB health institutions is vital for meeting unmet clinical needs, but MHRA found guidance unclear and definitions ambiguous, especially for software and AI. Strong support exists to keep the exemption, with calls for clearer, practical guidance and better post-market surveillance.
- **GMDN – Current and Upcoming Applications -** *Key Takeaway***:** Accurate use of GMDN is critical for regulatory compliance, supply chain efficiency, and global interoperability. It underpins UK MHRA registration, supports NHS procurement, and aligns with international UDI systems, making it essential for market access and post-market surveillance.

Spotlight Session - Sharing Regulatory Insights Across the ABHI Community

Key Takeaway: 📌 Share your regulatory insights to support peers across the HealthTech sector. Spotlight Sessions are your opportunity to help others navigate change by contributing timely, practical perspectives.

Spotlight sessions are short, focused articles to highlight a specific regulatory topic relevant to ABHI members. These sessions are intended to provide practical insights and interpretation of regulatory changes and feature expert perspectives from across ABHI membership.

Whether you are new to ABHI, new to the industry or you've seen all these changes come and go before, if you have an idea for a Spotlight Session, please drop me a line.

Submission guidance:

Length: 300–500 words
Tone: Concise, neutral, non-promotional
Audience: Professional readers familiar with regulatory frameworks (especially ABHI members in regulatory, quality and market access)
Scope: UK, EU and/or global HealthTech regulation. Medical devices, IVDs and/or digital health.
Style: May include expert opinion or member perspectives

Include author name and affiliation
Ensure factual accuracy and cite sources where appropriate
ABHI will provide the title and key takeaway, but contributors may suggest their own
Submit by the middle of the previous month (mid-September for the October Round-Up) with earlier suggestions welcome.

I am keen to include spotlight sessions on international subjects

- ***EU regulations***
- ***US, Australia, Canadian regulations***
- ***International updates***

Please let me know if you would like to submit a draft for the 2026 editions of Regulatory Round Up

UK Updates

ABHI

Key regulatory updates from ABHI (please make sure you are registered and logged in to 'My ABHI')

Women's Health: Time to **Listen. Time to Act.**

Women have been calling to be heard. **It is time we truly listen.** To their experiences, their needs, and their bodies.

In this report, ABHI sets out a focused plan to address the systemic inequities that have long shaped women's health, outlining practical steps across clinical practice, research, innovation, and investment to drive meaningful and lasting change.

ABHI Response: EU Call for **Evidence on MDR & IVDR Revision**

The ABHI response to the European Commission's call for evidence on the targeted revision of the Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Device Regulation (IVDR) can be found here.

We prepared this combined submission reflecting **member inputs and priorities**, and as ever, we thank our Members for their contribution to this work.

ABHI Quarterly Communications **Report - Q3 2025**

"This quarter brought one of the most significant developments for our sector in recent years. The MHRA's announcement to consult on the indefinite recognition of CE-marked devices represents a major milestone, and is one that ABHI has tirelessly advocated for on your behalf. It is the result of enormous effort from the ABHI team, but crucially, it has only been possible because of the experiences and evidence you, our members, have consistently shared. Thank you. We now await the consultation, but it is an encouraging signal of a more open and responsive MHRA. I am delighted that their CEO, Lawrence Tallon, will be joining us at our Annual Conference in November to discuss this further."

MHRA at ABHI HealthTech Conference: A Unified Vision for Innovation and Safety

At the ABHI UK HealthTech Conference on 12 November 2025, Lawrence Tallon, MHRA Chief Executive, delivered a keynote that set a clear direction for UK medical device regulation. Tallon emphasised that regulation should enable innovation, not hinder it, and outlined MHRA's priorities: indefinite CE marking recognition (with consultation planned to remove 2028/2030 deadlines), a renewed UKCA pathway focused on first-in-market and AI-driven technologies, and new international reliance routes for products approved in Australia, Canada, and the US, subject to GB-specific requirements. Tallon stressed the importance of partnership between MHRA and industry to ensure reforms deliver real-world benefits for patients and the health system.

The session also covered MHRA's commitment to international harmonisation, its leadership in AI standards, and practical reforms such as strengthened post-market surveillance, mandatory Unique Device Identification, and conditional access for innovative devices. Tallon's appearance signalled MHRA's intent to balance innovation and safety, deepen global collaboration, and provide long-term certainty for manufacturers. Engagement with MHRA consultations and ABHI groups will be essential for companies to shape and prepare for these changes.

Electronic Submissions are the Future of Medical Device Regulation – Why the Wait?

A white paper from Veeva (co-authored with ABHI, Akra Team, Axon and Scarlet) advocates for standardised electronic submissions to improve efficiency, reduce costs and support regulatory alignment. It highlights benefits for Notified Bodies and SaMD developers and calls for EU action to define a common format. Watch out for more on digitalisation coming soon!

Advanced Programme on Regulatory Systems **Oxford Law**

This is a 2.5-day professional development course (23–25 February 2026, Worcester College) designed for regulators, policymakers, and industry leaders. It provides an overview of regulatory principles, goals, and evolving models, moving beyond traditional enforcement to approaches informed by behavioural science and socio-legal research.

TOPRA Symposium – Call for Abstracts (2026)

TOPRA invites regulatory professionals to submit abstracts for its flagship annual symposium, taking place 19–21 October 2026 in Utrecht, Netherlands. The event is Europe's leading forum for healthcare regulatory affairs, covering human medicines, medical devices, IVDs, combination products, veterinary medicines, and SMEs.

Deadline: 30 January 2026;

Upcoming regulatory group member meetings *(meeting packs and minutes from past meetings are available to members)*

IVD Regulatory

- 26th March pm (Virtual)
- 25th June pm (F2F with MD Regulatory Group)
- 24th September pm (Virtual)
- 3rd December pm - tbc

MD Regulatory

- 10th March (Virtual)
- 25th June (F2F with IVD Regulatory Group)
- 15th September (Virtual)
- 1st December (F2F) - tbc

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ABHI Regulatory Group Leadership

IVD Regulatory

Co Chairs: Sue Spencer (Compliance Connextions) & Megha Iyer (ThermoFisher Scientific)

Vice Chair: Erin Wigglesworth, (Cepheid)

Secretariat: Steve

Medical Device Regulatory

Chair: Cait Gatt, (Boston Scientific)

Vice Chairs: Clare Huntington, (Pennine Healthcare), Roland Back, (Abbott), & Darren Thain, (Smith & Nephew)

Secretariat: Phil

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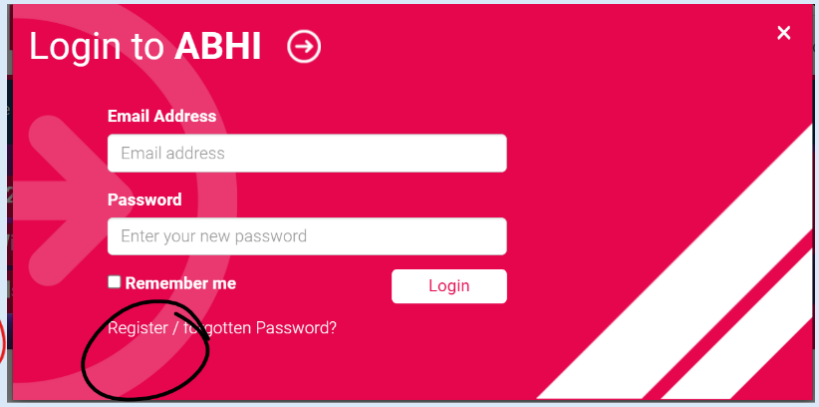
Spotlight session - Maximising Your ABHI Membership

Key Takeaway: 📌 Call for Action! Register and tailor your communication preferences to access targeted regulatory updates, join specialist groups, and benefit from events like the Member Briefing. Active engagement ensures timely insights and full use of ABHI's support and resources.

We're thrilled to have you on board as part of the ABHI community. To make sure you're staying up to date, we encourage you and your colleagues to register on the ABHI website. By registering your details with us, you'll be added to our mailing list for key member communications like *Primed* and much more.



You can update your preferences to select which mailings to receive. If you wish to unsubscribe from ABHI communications, you can do so at any time here. You can view our Privacy Policy here.

If you're looking for deeper insights and opportunities, you can join our member groups tailored to specific areas of interest. If you are already part of one of our regulatory mailing lists (IVD, MD or digital), you'll get your own copy of this 'Regulatory Round Up' as well as ad hoc updates and regular meeting invites.

We want you to get the most out of your membership, so if you have any questions or need help with anything - whether it's accessing resources or navigating member benefits - let us know. We're here to support you.

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Member Offers

8foldgovernance - Free Post Market Surveillance Review

MedBoard: Unified Data Platform –5-20% **discount**

OMC Medical Regulatory Consulting – free 30 minute **consultation**

Psephos Biomedica Regulatory Consulting – free 30 minute **consultation**

RegMetrics – 15% **discount**

TOPRA Training Courses - 10% **discount**

If you would like to extend an offer to our wider membership, get in touch with communications@abhi.org.uk

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Updates from MHRA

Title	Summary	Update History	Relevance
MedRegs Blog: **Innovative approaches to Med Tech regulatory reform**		24 November 2025	
Clinical investigations for medical devices	Clarified EU MDR can be met for GB only studies Updated when application to MHRA is required and added links on where to find MHRA flow charts Updated to include link to combined medicine and device trials guidance. New section 'Pilot of a medical device clinical investigation fee waiver programme for micro and small sized enterprises'. Updates to Flow Chart for GB Clinical Investigations to greater align with UK MDR Updates/expansion of GB Flow Chart Accompanying Guidance, with examples Added link to Northern Ireland performance studies submission guidance Re-linking of CI biological safety guidance Update to 'Assessment of CI applications' wording	Multiple updates - Latest revision on 5 Dec 2025	Clarification that EU MDR requirements can still be met for GB-only studies provides reassurance for sponsors aiming to maintain broader compliance. Introduction of a pilot fee waiver programme for micro and small enterprises offers an opportunity to reduce cost barriers for clinical investigations. Updates to the GB flow chart and accompanying guidance, including practical examples, improve alignment with UK MDR and make the submission process clearer and easier to navigate.
Clinical trials that include an in vitro diagnostic device	Guidance on submitting an application for approval of a	New page reiterating and	MHRA approval is needed for trials combining an IVD with a medicine, clarifies sponsor

	clinical trial that includes an in vitro diagnostic device	clarifying previous guidance	responsibilities for device safety and performance, and links to submission processes and supporting documents.
Digital mental health technology (collection)	• Consolidates DMHT guidance and research; latest update adds harms reporting research. • Points to qualification/classification guidance and PMS expectations.	Nov additions listed in update history	Helpful for developers aligning DMHT SaMD product claims and PMS to GB rules.
Digital mental health – user and public perspectives	• Explores attitudes to identifying/reporting harms and awareness of Yellow Card. • Informs future regulatory/evaluation frameworks.	Publication entry only	Supports PMS design and user-centred safety reporting.
Health Institution Exemption – Stakeholder survey (Outcome)	MHRA gathered input from health institutions on the "health institution exemption" (which allows in-house manufacture of devices) and published the analysis of responses	Published 12 Aug 2025; Updated 21 Nov 2025 – outcome report published	REFER TO – spotlight session later in document
Register medical devices to place on the market	• Updated fees implementation and management guidance, to correct minor typos only, no change to content. Updated link to survey on fees implementation and management guidance • Published guidance: Preparing for the implementation and	Updated 5 Nov 2025	Reference for market access planning and UKRP arrangements.

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	management of the new device registration fee		
RegulatoryConnect (service guidance)	• Confirms programme wind-down after review; portal retains tracking and live authorisation views. • MHRA developing new strategy-aligned tech solution.	Update on RegulatoryConnect – Nov 2025	Signals continuity for current tracking; watch for replacement solutions.
AI Airlock – regulatory sandbox for AIaMD	• Collection hub for AI Airlock with sandbox reports and simulation workshops. • Phase 2 cohort publication and next-phase selection news.	Includes Phase 2 cohort and Nov updates	Key for AIaMD developers to understand expectations and sandbox opportunities.
UK–US regulators collaboration on med tech and AI	• MHRA outlines deeper collaboration with FDA on innovation and reliance routes. • Includes AI governance via National AI Commission.	Publication entry only	Supports recognition/reliance advocacy and transatlantic alignment.
MHRA Performance Data (transparency)	• October KPIs: 100% of clinical investigation applications within timelines. • CI initial assessments averaging 56 days.	Latest update 20 Nov 2025	Assists ABHI members in timeline planning and stakeholder engagement.
Rare therapies and UK regulatory considerations	• Policy paper positions UK to lead rare therapies; consult in early 2026. • Press release flags overhauling rulebook and forming consortium.	Publication entries only	Framework intent influences diagnostics/companion devices and system pathways.
MHRA appoints first Chief Medical and Scientific Officer	• Announces Prof Jacob George as first CMSO to lead science strategy. • Role likely to shape device/AI agendas and engagement.	Publication entry only	Leadership change likely to shape device/AI/recognition agendas.

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Major change for rare disease treatments on way, signals MHRA	New paper sets out UK regulator's intentions to overhaul rulebook for rare disease therapies in UK	News	MHRA plans a major shift to accelerate access to rare disease treatments, aiming for earlier patient benefit through regulatory flexibility and streamlined pathways. For IVD and diagnostic test manufacturers, this signals increased demand for companion and stratification diagnostics to support these therapies, with potential opportunities for faster approvals and closer integration in clinical development.
Government cuts red tape with cutting-edge tech	• Cross-government announcement of tech/AI aims. • Sets context for regulatory digitalisation and adoption.	Publication entry only	Context for enabling environment for digital health.

Spotlight Session – Regulation as a Catalyst – The UK's Strategic Advantage for HealthTech Innovation

Key Takeaway: 📌 The UK is signalling a clear ambition to be a global leader in healthtech innovation. For ABHI members, this is a moment to engage with a regulatory system that is evolving a more attractive environment for bringing safe, effective technologies to patients.

MHRA has outlined their plans for a 5-year future strategy in a collection of blogs from key authors*.

Across the MHRA's strategy blog series and reflected in the theme to the ABHI 2025 HealthTech conference, a consistent message is emerging: regulation is not simply a gatekeeper, it is a driver of innovation. For global healthtech developers and manufacturers, this signals a clear opportunity. The UK is beginning to position itself as a launchpad for innovation, where smart, proportionate regulation can enable faster access to market and, ultimately, to patients.

This shift is articulated by a range of expert voices. Lawrence Tallon, MHRA Chief Executive, sets the tone by calling for a regulatory system that is agile, risk-proportionate and co-created with those it serves. Professor James Levine describes how "rules themselves can heal", highlighting how frameworks like the the Innovative Licencing Access Pathway (ILAP) – sister programme to Innovative Devices Access Pathway (IDAP) - can accelerate access to transformative technologies. Professor Henrietta Hughes, England's Patient Safety Commissioner, reminds us that innovation must be grounded in trust and patient partnership. Professor Sir David Spiegelhalter introduces the concept of the "preference zone", where informed patient choice is enabled by regulation that balances safety with individual values. And Professor Alastair Denniston, Chair of the National Commission on the Regulation of AI in Healthcare, outlines the principles of a future-ready framework for AI and digital health: safe, fast and trusted.

For medical devices, IVDs and digital health, this evolution is particularly relevant. The IDAP pilot offered early scientific advice and coordinated regulatory support for novel devices. IDAP reflects a broader cultural shift: regulation is becoming a collaborative process, not a barrier. This is especially important for small and mid-sized innovators, for whom regulatory clarity and timeliness can determine commercial viability with opportunity to scale internationally.

The MHRA's strategy should acknowledge that regulation must offer more than compliance. It must offer something of value. For developers, this means a system that supports earlier engagement, clearer expectations and predictable timelines. And for patients, it means earlier access to innovation that meets their needs.

Market authorisation of healthtech is not the end goal. It is one step on the journey to clinical adoption and patient benefit. Real-world evidence, post-market surveillance and patient-centred design are all part of the regulatory lifecycle. Professor Hughes emphasises the importance of listening to lived experience to detect safety signals that may not emerge in trials. Professor Denniston highlights the need for transparency

and accountability in AI regulation, particularly as AI systems evolve post-deployment. These perspectives reinforce the idea that regulation must be dynamic, responsive and grounded in trust.

The concept of the "preference zone", as described by Professor Spiegelhalter, is particularly relevant to digital health. He acknowledges that some interventions may not be universally recommended but may still be appropriate for individual patients who understand and accept the risks. Regulation, in this context, becomes an enabler of informed choice supporting clinicians and patients to navigate complex decisions with greater confidence.

For ABHI members, the UK is signalling it is actively enabling healthtech innovation. Those who engage early, embrace proportionate regulation, and build with patients in mind will be well-positioned to lead in this evolving landscape. The MHRA's strategy invites industry to be part of the conversation, and part of the solution.

As the UK continues to shape its regulatory future, there is a window of opportunity for healthtech developers to help define what "good" looks like whether in AI, diagnostics, or next-generation devices. The direction of travel is clear: regulation is no longer just about permission. It is about partnership, progress and delivering better outcomes for patients.

*MHRA Strategy blog series (collection)

- Lawrence Tallon introduces … Looking to our future: reflections on the strategic choices ahead for the MHRA
- Sir David Spiegelhalter: Regulation in an age of personalised medicine
- Professor James Levine: When policy becomes medicine
- Professor Henrietta Hughes: Putting Patient Safety at the Heart of Regulatory Innovation
- Professor Alastair Denniston: The future regulation of AI in healthcare

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List of MHRA webinars relevant to medical devices and IVDs

Subscribe to MHRAgovuk on youtube for past events and MHRA conferences page for future events.

MHRA Board meetings held in public	(from 2020)
EU Exit and post-transition guidance, Regulation of Medical Devices Webinar	October 2020
Medical devices consultation webinar – Industry	October 2021
Medical Devices Regulations Webinar	January 2023
Regulatory Management System webinar	March 2023
MHRA MedTech Regulatory Reform Webinar	March 2024
AI Airlock Webinar	July 2024
MHRA Digital Mental Health Technologies	July 2024
MHRA Chair Anthony Harnden starts role	January 2025
Post-market Surveillance and Vigilance of Medical Devices	May 2025
RegulatoryConnect Programme update	May 2025

There is also a suite of video tutorials on registering your devices with MHRA

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Other UK news

UKHSA conference: Manchester 22/23 September 2026.

Government Announces New **HIV Action Plan**

The Government has today announced a major new HIV Action Plan, backed by £170 million, to help end new transmissions in England by 2030. The plan expands access to testing, tackles stigma, and introduces the first-ever national programme to reconnect people with life-saving HIV care.

MHRA Recruitment for IVD Expert Advisory Group (IVD EAG)

The MHRA is seeking senior professionals for part-time, fixed-term roles within its Interim Devices Working Group (IDWG):

The MHRA is recruiting a Chair, Expert Members and a Lay Member for its In Vitro Diagnostics Expert Advisory Group through the Interim Devices Working Group. These part-time, fixed-term roles require senior professionals with experience in patient safety, regulatory science and diverse expertise. Responsibilities include advising on IVD standards, safety and risk assessment, reviewing complex evidence and ensuring inclusive discussions. Applications, including CV and required forms, should be submitted via GOV.UK or NHS Jobs to CSTrecruitment@mhra.gov.uk. Deadlines are 30 January 2026 for the Chair and 6 February 2026 for Expert Members.

Chief Medical Officer's annual report 2025: infections

Professor Chris Whitty's annual report focuses on infections and warns against complacency. The report stresses the need for strong surveillance and rapid response to emerging and imported infections, highlights antimicrobial resistance as a growing global threat, and calls for sustained investment in workforce and infrastructure to maintain preparedness for epidemics and pandemics. It urges government and healthcare systems to prioritise infection control and improve vaccine coverage to protect public health.

Spotlight Session - Health Institution Exemption – Stakeholder survey

Key Takeaway: 📌 The exemption for GB health institutions is vital for meeting unmet clinical needs, but MHRA found guidance unclear and definitions ambiguous, especially for software and AI. Strong support exists to keep the exemption, with calls for clearer, practical guidance and better post-market surveillance.

From Sue Spencer (Compliance Connextions)

MHRA have responded to the Health Institution Exemption (HIE) survey. This was a stakeholder survey published in August 2025, it is not a consultation as a precursor to revising the legislation it is purely to understand the current state of play.

Stakeholders were asked to consider,

- Motivations: why, and to what perceived impacts, are health institutions using the HIE?
- Conditions of use: under what conditions are health institutions using the HIE currently, including QMS approaches, to help us understand the level of assurance of these devices being undertaken in the market already.
- Extent of use: what is the nature and level of devices the HIE is being used for.

MHRA received feedback that:

- The HIE is widely used and those that responded were using it to meet unmet need. 22% of those that responded were not aware that the HIE existed and that 1/3 of respondents found the MHRA guidance is unclear particularly about some key definitions relating to the scope of what is and is not included. There was a request for more detailed, practical, and device-specific guidance.
- The survey results found that SaMD including AI and general medical devices were the most common devices manufactured under the HIE, the majority stated they were not applied on an "industrial scale".
- The majority of devices are using within the HIE or its vicinity; however, some are used in the patient's homes. Bearing in mind the increased use of software and Apps this is likely to grow.
- It is good to hear that 90% of HIE had adopted a QMS either ISO 15189, ISO 13485 or ISO 9001 and have prepared technical documentation, approvals for use, incident reports and change management; however, the majority do little post market surveillance.
- 90% of hospitals used the HIE to address unmet need and in particular use it to address complex cases with unique needs and there is strong support to keep it.

So, in summary the key concerns were a lack of clarity in the guidance it was vague, and definitions ambiguous leading to difficulty applying the HIE consistently. Improved guidance is something ABHI would support. The survey concluded that HIE devices had "a generally positive safety and performance profile" 87% used some form or reporting but only 19% used MORE and 24% the Yellow Card system.

In short, the feedback strongly suggests the need for the HIE and that guidance needs to be improved to make the expectations clearer and future proof in particular for the use of Apps and AI.

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Update on British Standards Projects October/November 2025

Status	Closing Date	Description	Committee
Published Standard	30/09/2025	BS ISO 19223-3:2025 Lung ventilators and related equipment. Vocabulary and semantics. Respiratory care	CH/121 - Anaesthetic and respiratory equipment
Published Standard	30/09/2025	BS ISO 5092:2025 Additive manufacturing for medical. General principles. Additive manufacturing of non-active implants	CH/150 - Implants for surgery
Published Standard	30/09/2025	BS EN ISO 5832-2:2025 Implants for surgery. Metallic materials. Unalloyed titanium	CH/150/1 - Materials for surgical implants
Published Standard	30/09/2025	BS EN IEC 63322:2025 Security of ME equipment containing high-activity sealed radioactive sources	CH/62/3 - Equipment for radiotherapy, nuclear medicine and radiation dosimetry
Published Standard	30/09/2025	BS ISO 7376-2:2025 Anaesthetic and respiratory equipment. Video laryngoscopes	CH/121/5 - Airways and related equipment
Published Standard	31/10/2025	BS EN 16128:2025 Ophthalmic optics. Reference method for the testing of spectacle frames and sunglasses for nickel release	CH/172/3 - Spectacles
Published Standard	31/10/2025	BS EN ISO/IEEE 11073-10103:2025 Health informatics. Device interoperability. Nomenclature, implantable device, cardiac	IST/35 - Health informatics
Published Standard	31/10/2025	PD IEC TS 81001-2-2:2025 Health software and health IT systems safety, effectiveness and security. Coordination. Guidance for the implementation, disclosure and communication of security needs, risks and controls	CH/62/1 - Common aspects of medical equipment, software, and systems

Published	30/11/2025	BS EN ISO 18777-2:2025 Transportable liquid oxygen systems for medical use. Particular requirements for portable units	CH/121/6 - Medical gas supply systems
Published	30/11/2025	BS ISO 18192-3:2025 Implants for surgery — Wear of total intervertebral spinal disc prostheses. Impingement-wear testing and corresponding environmental conditions for test of lumbar and cervical prostheses	CH/150/5 - Surgical Implants - Osteosynthesis and spinal devices
Published	30/11/2025	BS ISO 7206-12:2025 Implants for surgery — Partial and total hip joint prostheses. Deformation test method for press-fit acetabular component	CH/150/4 - Surgical Implants - Bone and Joint Replacements
Published	30/11/2025	BS ISO 6631:2025 Tissue-engineered medical products — Quantification of bovine type I collagen marker peptide with liquid chromatography — Tandem mass spectrometry	BTI/1 - Biotechnologies
Published	30/11/2025	PAS 2600:2025 Continuous glucose monitoring systems. Design verification and validation of performance. Specification	ZZ/1 - Generic committee reference
Published	30/11/2025	PD ISO/TS 4452:2025 Specification and demonstration of system reliability of single-use drug delivery systems	CH/84 - Catheters and syringes
Published	30/11/2025	BS EN ISO 15223-1:2021+A1:2025 Medical devices. Symbols to be used with information to be supplied by the manufacturer. Part 1: General requirements. Amendment 1: Addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific	CH/210/3 - General information for medical devices
Published	01/12/2025	BS EN IEC 62570:2025 Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	CH/62/2 - Medical imaging equipment, software, and systems
Draft for public comment	06/12/2025	BS ISO 24884 Electronic Instructions for Use for In Vitro Diagnostic Medical Devices. Minimum required information and means of delivery	CH/212 IVDs
Draft for public comment	09/12/2025	BS EN ISO 8536-5 Infusion equipment for medical use — Part 5: Burette infusion sets for single use, gravity feed	CH/212 IVDs

Draft for public comment	16/12/2025	BS ISO 10974 Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	CH/150/2 - Cardiovascular implants
Draft for public comment	17/12/2025	BS EN ISO 13408-2:2018/A1 Aseptic processing of health care products. Part 2: Sterilizing filtration. Amendment 1	CH/198 - Sterilization and Associated Equipment and Processes
Draft for public comment	31/12/2025	BS EN IEC 60601-2-28 Amd.1 Ed.3.0 Amendment 1 - Medical electrical equipment. Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	CH/62/2 - Medical imaging equipment, software, and systems
Draft for public comment	31/12/2025	BS EN 80601-2-78 Ed.2.0 Medical electrical equipment. Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation	CH/62/4 - Particular medical equipment, software, and systems
Draft for public comment	31/12/2025	BS EN 80601-2-77 Ed.2.0 Medical electrical equipment. Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment	CH/62/4 - Particular medical equipment, software, and systems
Draft for public comment	13/01/2026	BS EN 14885 Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics	CH/216 - Chemical disinfectants and antiseptics
Draft for public comment	17/01/2026	BS EN ISO 9626 Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods	CH/84 - Catheters and syringes
Draft for public comment	18/01/2026	BS EN ISO 7864 Sterile hypodermic needles for single use — Requirements and test methods	CH/84 - Catheters and syringes
Draft for public comment	22/01/2026	BS EN IEC 60601-2-44 ED4 Medical electrical equipment. Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	CH/62/2 - Medical imaging equipment, software, and systems

Draft for public comment	02/02/2026	BS EN ISO 8537 Sterile single-use syringes, with or without needle, for insulin	CH/84 - Catheters and syringes
Draft for public comment	02/02/2026	BS EN ISO 7886-1 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use	CH/84 - Catheters and syringes

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EU news

MDCG

MDCG 2025-8 Guidance on the implementation of the Master UDI-DI solution for s**pectacle frames, spectacle lenses and ready-to-wear reading spectacles**

European Commission

SGS FIMKO OY 19th N**otified Body designated under IVDR** (EU) 2017/746

Commission implementing regulation (EU) 2025/2086 of 17 October 2025 laying down, pursuant to Regulation (EU) 2021/2282 on **health technology assessment,** procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of **joint clinical assessments** of medical devices and in vitro diagnostic medical devices at Union level, as well as templates for those joint clinical assessments

Commission implementing decision (EU) 2025/2078 of 17 October 2025 amending Implementing Decision (EU) 2021/1182 as regards **harmonised standards for surgical clothing and drapes, medical face masks and sterilizers for medical purposes**

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Q&A on practical aspects related to the implementation of the **gradual roll-out of Eudamed p**ursuant to the MDR and IVDR, as amended by Regulation (EU) 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of **interruption or discontinuation of supply**, and **transitional provisions for certain in vitro diagnostic medical device**.

Risks to safety and quality in **donor screening** and SoHo preparations due to poor implementation of the MDR and IVDR and the resulting shortage of essential CE-Marked devices

NOTICE d.o.o 3121st **Notified Body designated under MDR** (EU) 2017/745

Commission Decision (EU) 2025/2371 of 26 November 2025 on the notice regarding the functionality and the fulfilment of the functional specifications of certain electronic systems included in the **European Database on Medical Devices** referred to in Article 34(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council

The **EUDAMED** four first modules will be mandatory to use as from 28 May 2026

Pilot coordinated assessment for **clinical investigations/ performance studies**

Team NB

ICIM Spa 425th **Notified Body designated under MDR** (EU) 2017/745
NBS MDRIVDR **Call For Evidence Targetted Revision** EUrules-20250106

Changes to **companion diagnostic devices under the IVDR,** Annex IX, section 5.2 that require prior approval by a notified body.

TEAM NB Position Paper on MDR Application and appropriate surveillance **Transfer agreement**

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US news

FDA

Menstrual Products – Performance Testing and Labeling Recommendations: Draft Guidance for Industry and Food and Drug Administration Staff

Quality Management System Information for Certain Premarket Submission Reviews: Draft Guidance for Industry and Food and Drug Administration Staff

Immunology and Microbiology Devices; Reclassification of Nucleic Acid-Based Test Systems for Use with a Corresponding Approved Oncology Therapeutic Product; Proposed Amendment; Proposed Order; Request for Comments

How to Prepare a **Pre-Request for Designation** (Pre-RFD): Guidance for Industry

International news

IMDRF

Essential Principles and Content of Predetermined Change Control Plans

MedTech Canada

NEW Canada **MDSAP Survey**: Advancing Medical Device Quality and Engagement

Any questions regarding the survey, please contact MDSAP@medtechcanada.org who can address any queries you may have.

International regulators

Argentina (ANMAT)	Provision 8799/2025 The activities of marketing and storage in national jurisdiction or for interprovincial trade, of drugs, chemical products, reagents, pharmaceutical forms, medicines, diagnostic elements and any other product of use and application in human medicine and the persons of visible or ideal existence who intervene in such activities
Australia (TGA)	Therapeutic Goods (Medical Devices) Regulations 2002 Compilation No. 69
	Therapeutic Goods Regulations 1990 - Compilation No. 127
	Consultation: Adoption of International Scientific Guidelines in Australia R01-2025
	Complying with the Essential Principles on the safety and performance of medical devices
Brazil (ANVISA)	Manual for the Regularization of Medical Equipment and Software as a Medical Device
Canada (HC)	Guidance on managing applications for medical device licences
	Consultation on modernizing the medical device establishment licensing (MDEL) framework- Phase II
Egypt (EDA)	The Egyptian Guideline for Medical Device Vigilance System 2025
India (CDSCO)	Draft Guidance Document on conduct of Medical Device Software under MDR, 2017
Japan (PMDA)	FAQs regarding reporting adverse drug reactions and medical device malfunctions in clinical trials and periodic clinical trial reports
Malaysia (MDA)	Malaysia-United States agreement on reciprocal trade: A landmark achievement for the medical device sector
	NPRA GLP Compliance Programme – Frequently Asked Questions (FAQ)
Malta (Medicines Authority)	Guidance for Application to be submitted when applying for Designation as a Notified Body / Extension for Scope under the Regulations (EU) 2017/745 or 2017/746
Nicaragua (MOH)	Administrative Resolution No.0020 2025 Online Medical device import procedures

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Philippines (FDA)	Draft for Comments || Guidelines on the Inspection of Medical Device Establishments
Singapore (HSA)	GN-02-R7 Guidance on Licensing of Manufacturers Importers and Wholesalers of MD
	GN-17 R4: Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT
	GN-18 R4: Guidance on Preparation of a Product Registration Submission for In Vitro Diagnostic Medical Devices using the ASEAN CSDT
South Africa (SAHPRA)	Medical Devices Reliance Guideline
South Korea (MFDS)	Legislative notice of the Prime Minister's Decree on partial revision of two laws and regulations, including the Enforcement Regulations of the Medical Device Act to reflect the reorganization of the government organization
	Partial Revision of the Regulations on Reporting of Medical Device Production, Export, Import, and Repair Performance
	Partial Revision of the Regulations on in Vitro Diagnostic Medical Device Items and Grades for Each Item
	Partial Revision Notice (Draft) of the "Regulations on Medical Device Items and Grades by Item"
Spain (AEMPS)	The Council of Ministers approves the new Royal Decree on medical devices for in vitro diagnostics
	Circular 3/2001: Regulation of clinical research with medical devices
Switzerland	Swissdamed UDI Devices module
	BW630_40_795: Handbook swissdamed User Guide - Playground
	BW630_40_871: Guidance document swissdamed Service Agreement
	BW690_00_001: Guidance document: Service Agreement Export Certificates MEP
WHO (WHO)	Development of medical device policies, 2nd ed

Spotlight Session – GMDN – current and upcoming applications

Key Takeaway: 📌 Accurate use of GMDN is critical for regulatory compliance, supply chain efficiency and global interoperability. It underpins UK MHRA registration, supports NHS procurement and aligns with international UDI systems, making it essential for market access and post-market surveillance.

From Dr. Vasileios Zampetoulas (PhD) GMDN Agency

Introduction

The Global Medical Device Nomenclature (GMDN) consists of Term names and definitions used across various sectors of healthcare to standardise the naming, identification, grouping, and management of medical devices worldwide. GMDN is maintained by the GMDN Agency, a registered UK charity and non-profit organisation, in collaboration with stakeholders, such as regulators, manufacturers, and healthcare providers.

Registration:

GMDN is used in regulatory systems for device registration, as part of the pre-market approval. In the UK, for example, GMDN helps ensure that products are genuine and registered with the Medicines and Healthcare products Regulatory Agency (MHRA). In addition, the MHRA will introduce a new annual medical devices registration fee to support post-market surveillance, effective from 1 April 2026, based on GMDN Level 2 Categories (or Level 1, where no Level 2 exists).

Supply Chain:

GMDN is also used in the supply chain to streamline procurement processes, identify alternative products in case of supply disruptions, and group products for tendering. In the UK, it is an approved NHS standard for device identification. Additionally, the recent partnership between the GMDN Agency and the UK's Department of Health and Social Care (DHSC) will lead to further incorporation of GMDN into device databases and platforms, including the Product Information Management system (PIM), facilitating device traceability and interoperability across systems.

Unique Device Identification Systems:

GMDN has been an integral part of the Unique Device Identification (UDI) system used by the Food and Drug Administration (FDA) in the US since 2013. UDI allows the identification of each device's make and model variation, while GMDN assists with the non-proprietary naming and

grouping of these devices based on their clinically significant attributes, facilitating post-market surveillance amongst other uses. Other countries, such as Australia and Brazil, are also expected to implement UDI systems incorporating GMDN.

Worldwide Medical Device Access:

GMDN is embedded in medical device information platforms managed by the World Health Organization (WHO), such as the MeDevIS (Priority Medical Devices Information System), to facilitate access to priority medical devices worldwide.

Innovation:

GMDN Agency aims to facilitate the analysis of innovation across the medical device industry. GMDN can help define the scope of innovation, distinguish between innovative and non-innovative devices, and identify gaps where innovation is possible.

Importance of Accurate GMDN Term Assignments:

For the successful application of GMDN, users need to assign the GMDN Terms accurately to the medical devices. GMDN Agency provides support to its members through an Enquiry service, workshops, user guides, and video tutorials that guide and train users on accurate Term assignments.

Sources:

Register medical devices to place on the market - GOV.UK

DAPB4004: Global Medical Device Nomenclature (GMDN) - NHS England Digital

MEDEVIS

Appendix - Resource Library

ABHI Regulatory Round Up – past issues

- June 2025
- May 2025
- April 2025
- March 2025
- February 2025
- December 2024
- September 2024
- Summer 2024

ABHI briefing papers

- HealthTech Regulations - Driving Economic **Growth and Patient Safety In The UK**
- Regulation of Medical Devices and In **Vitro Diagnostic Medical Devices in Northern Ireland**
- Electronic Labelling for **Medical Devices and IVDs**
- How to Best Implement the **EU IVDR – Dos and Don'ts**
- Overview of Main Changes **Brought About by the IVDR**
- Update on the UKCA **Mark: A Rapidly Evolving Landscape**
- International Regulatory Recognition **in the UK**

UK legislation

- **Medicines and Medical Devices Act** 2021
- The **Medical Device Regulations 2002**. UK Statutory Instrument no 618 (UK MDR 2002)
- **The National Archives** *"… capture, preserve and make accessible UK central government information published on the web. The Web Archive includes videos, tweets, images and websites dating from 1996 to the present day."*

MHRA

- MHRA gov.uk website
- MedRegs Blog
- Public Access Registration Database (PARD)
- MHRA careers hub