ABHI Regulatory Round-up – March 2025

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Introduction

In this regulatory round-up, you will find updates from UK, EU, US and internationally as well as some upcoming dates for your diary.

We have included a list new and updated MHRA notices, some training events from TOPRA and RAPS, Standards updates, plus international updates from industry and regulators across the world. There are also a few member opportunities. If you have any updates that you want us to consider for a future edition, please get in touch.

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.

MedBoard

ABHI

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

Upcoming ABHI events on **Post Market Surveillance**

1st May We have partnered with ABHI member - **Brabners** - to deliver an in-person event in **Manchester**. Register to hear more from MHRA, ABHI and specialist medical device lawyers on post market surveillance in the UK.

5th June This session will be held at **IQVIA's London** headquarters and is designed to provide you with critical insights into post-market surveillance (PMS) and the practical implementation of the new MHRA requirements. Register to gain insights on MHRA's new guidelines, post-market surveillance, and compliance strategies from industry and regulatory experts.

MHRA post-market surveillance guidance. Since the draft MHRA guidance was published in January, I have spoken with about a thousand people (members, non-members and other stakeholders) and submitted about 50 pages of feedback from ABHI to MHRA on your behalf. We can expect the

guidance to be revised around the June deadline and it will be interesting to see what changes have been made in response to this comprehensive feedback by ABHI. **Thank you to everyone who worked so hard to submit feedback and comments!!!**

Life Sciences 2035: Developing **the Skills for Future Growth**

This report highlights the urgency of **equipping the workforce with the advanced skills required to tackle emerging healthcare challenges**, to foster continuous innovation, and to maintain the UK's leadership in the global HealthTech arena.

*"This is a valuable report. By fostering strong partnerships across the UK, we can train and **attract top talent to meet the life sciences workforce needs** for the future. It is important that we seize this opportunity to make a lasting impact, to grow the UK's £108 billion life sciences sector."* Science Minister, Lord Vallance

ABHI's Gender Equality Survey

We encourage individuals of all genders and at all levels within your organisation to participate. The survey is **available here** and will remain open until **11 April 2025**.

Women in HealthTech seminar

Gender Equality survey findings will be presented at our ever-popular annual *Women in HealthTech* seminar and networking event on **20th May 2025, 16:30 - 19:30**, where industry leaders will explore how we can better support and empower women in the workplace. You can **register for the event here**.

ABHI submitted an industry response to the consultation from the European Commission on **eIFU legislation.**

ABHI submitted an industry response to the consultation from the European Commission on **EU MDR/IVDR targeted evaluation** alongside a detailed response to the questionnaire. Both responses are closely aligned with the MedTech Europe response, which we collaborated on.

ABHI submitted an industry response to the MHRA consultation on immunotherapy. Please get in touch if you need a copy of the response.

ABHI's Quarterly Communications **Report: Q1 2025**

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The ABHI report "Transformation and Growth: **The HealthTech Effect**" highlights the UK's HealthTech industry's potential to drive NHS innovation and economic growth, emphasizing the need for targeted support to fully realize its benefits. Key recommendations include appointing a HealthTech Champion, establishing a world-class regulatory system, enhancing translational research support, improving NHS capital funding, and strengthening data infrastructure.

🌞Please could you take part in a short research questionnaire to find out how the regulations have impacted clinical research in NI?
The European Union **Medical Device Regulations in Northern Ireland** Survey🌞

👉Advance notice: **ABHI HealthTech Conference** 11 - **12 November 2025** (Day 1: UK Market, **Day 2: Regulation**)

Upcoming regulatory group member meetings
IVD Regulatory

- 29th May 2-4pm
- 4th September 2-4pm
- 27th November 2-4pm

MD Regulatory

- 3rd June 10.30-12.30

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**

ABHI Professional Associate Members with an expertise in Post-Market Surveillance work, who have expressed an interest in assisting ABHI manufacturers include:

2Harris Consulting; Kathleen Harris, Managing Director, Kathleen@2Harris.com
8Fold Governance; Daniel Mannion, Director of Professional Services, daniel@8foldgovernance.com
AKRA Team; Dr. Andrew Gibson, Managing Consultant, andrew.gibson@akrateam.com
Brabners; Claire Burrows, Partner, claire.burrows@brabners.com
IMed Consultancy; Jonathan Ripley, Managing Director, jonathan@imedconsultancy.com
LFH Regulatory; Helen George, Business Manager, info@lfhregulatory.co.uk

ABHI Member Travelers paper: The Growth & Future of the MedTech Industry

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

Sign up for our other ABHI newsletters *Primed* and *Monthly Bytes*

You can find past ABHI regulatory resources in the ABHI resource hub.

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MHRA

New

Subject	Relevance
New chief executive appointed at MHRA	Lawrence Tallon is appointed as the **new Chief Executive Officer of MHRA**.
Lawrence Tallon begins role as new MHRA CEO	Lawrence Tallon today (1 April 2025) begins his role as Chief Executive Officer of the Medicines and Healthcare products Regulatory Agency (MHRA). *We are hoping to meet Lawrence and team very soon.*
UK scientists develop DNA sequencing system to fight superbugs	"In a UK first, **MHRA and Barts Health NHS trust have designed a DNA sequencing programme** to diagnose bacterial infections much faster and more accurately."
New study shows MHRA collaboration with hospital DNA sequencing service cuts time to diagnose infections	
MHRA Safety Roundup: March 2025	Summary of the **latest safety advice** for medicines and medical device users
MHRA showcases next phase of regulatory science to bring innovative treatments to patients sooner	**Seven new CERSIs** came together to showcase how partnerships will modernise regulation in AI, clinical trials, and advanced therapies, bringing innovations to patients sooner. *My favourite quote of the day from outgoing CEO Dame June Raine "Regulations follow science – but mustn't lag behind"*
February performance data	The only **device related KPI** covered by MHRA performance data is the assessment of clinical trial applications (100% in time)

Updates

Subject	Update	Relevance
Government response MHRA consultation on statutory **fees**: proposals on ongoing cost recovery	The MHRA has confirmed increased fees for medical devices and IVDs starting early Q1 2025/26, using the Treasury's cost-recovery model. The **controversial annual fee linked to GMDN codes is paused**, but the one-off registration fee will rise from £240 to £261.	ABHI welcomes the pause on the annual GMDN code fees but we are concerned that overall fee increases may deter manufacturers from the UK market. The sharp rise in clinical investigation fees may redirect studies elsewhere, particularly

	An overall **8.85% fee increase** will be reviewed biennially. Clinical investigation fees, increase significantly. New **SME payment easement** allows instalments. A new **£987/hour regulatory advice service** will be introduced. **Approved Body fees** will also increase.	affecting SMEs so we will advocate for additional protective measures for SMEs. ABHI is also concerned about consistency and timeliness of the new regulatory advice service. We will continue to advocate for fair, transparent regulations to support innovation and maintain UK competitiveness. **Member feedback remains vital.**
MHRA fees	Updated fees payable to the MHRA from 2025.	
Digital Mental Health Technologies	March newsletter	Reception for published MHRA guidance Further market research on how users identify and report adverse events. Upcoming MHRA speaking events Feedback from an AI in mental health workshop Registration for a 'DMHT Guidance Deep Dive' webinar will be open in the next few weeks.
Guidance: Export medical devices	Clarification that Certificate of Free Sales cannot be ordered for **IVDs for performance evaluation.**	If you have IVDs for performance evaluation, note this update.
AI Airlock	Exploring AI in Healthcare: Insights from the AI Airlock Pilot	A blog post on the MHRA AI Airlock provides an **overview of the pilot cohort projects**
The Innovative Devices Access Pathway (IDAP)	Updated to reflect that Lenus Health have exited the IDAP pilot programme.	Unfortunately Lenus went bankrupt while on the pilot programme (they also had to withdraw from the AI sandbox pilot)
Medical devices: information for patients	Updated guidance to include a new section **'Mobility scooters for personal use** '	MHRA advice on buying a mobility scooter

Exceptional Use Authorisation	New/updated advice on how to apply for an exceptional use authorisation to place medical devices on the UK market.	This page clarifies MHRA position on assessing and granting authorisations for exceptional use of a non-conforming device.
Guidance: **Register medical devices to place on the market**	Clarification that if registered device characteristics change this may require re-registration, in which case the statutory fee will be payable.	**Changing device characteristics** (non-sterile to sterile or vice versa, trade/brand name, UDIs or any field that cannot be updated in DORS) means the device will need to be re-registered
	Inclusion of links to guidance for the **EU IVDR transition extension** under Article 110 for the registration of IVD devices with the MHRA.	Reference to updated EU IVDD certificate validity.
	Clarification concerning maximum validity for **Letter of Designation**.	**I can't find the update in the published page. If you spot it or if you can't spot it either but need to know, please get in touch.**
	Correction to countries that **Northern Ireland Authorised Representatives** can represent manufacturers from.	

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
MHRA RegulatoryConnect portal launch webinar	March 2024
AI Airlock Webinar	July 2024
MHRA Digital Mental Health Technologies	July 2024
MHRA Chair Anthony Harnden starts role	January 2025

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

Other UK Government updates

The regulation of **artificial intelligence as a medical device**: government response to the Regulatory Horizons Council – this is the government's response to recommendations in the RHC report.

Policy paper **New approach to ensure regulators and regulation support growth**

Other UK updates

IBMS Response: **At-Home PSA Tests: Inaccurate results** highlight the need for stronger regulation and greater public awareness

NIHR HRC IVD **Redefining the value of diagnostics technologies in healthcare**

NIHR IVD **Biomarker Accelerator** Conference 2025 Imperial College 2 May 2025 09:00 - 18:00

CADDA Launch events (Centre for Advanced Diagnostic Development and Application)

- Canterbury Launch Event – 8th April
- London Launch Event – 6th May
- Manchester Launch Event – 8th May

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BSI updates

Applications are now open for Subcommittee Chair CH/210/3 "General information for Medical Devices"

(Preparation, revision and amendment of British Standards in the field of general terminology and symbols for medical devices.)

Please submit your application with a CV to lindsey.ferrari@bsigroup.com by **15th May 2025.**

The REP symbol standard – new country codes

ISO 15223-1:2021/Amd 1:2025 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

On 5 March 2025, ISO 15223-1:2021/Amd 1:2025 was published with a significant change to the Authorized Representative symbol. The amendment changes the [EC] part of the symbol graphic to [XX] and specifies that the [XX] text can now be replaced with country codes or other text recognized by a country's jurisdiction, making the symbol usable by any jurisdiction and no longer limiting its use to the European Union. In addition to modifying the graphical symbol, the amendment included a definition of Authorized Representative, simplified the symbol title to Authorized Representative, and revised the description to indicate the authorized representative in the identified country or jurisdiction.

Status	Closing Date	Description	Committee
Published standard		BS ISO 8536-6:2025 Infusion equipment for medical use. Freeze drying closures for infusion bottles	CH/212 - IVDs

Published standard		BS EN ISO 8871-5:2025 Elastomeric parts for parenterals and for devices for pharmaceutical use. Functional requirements and testing	CH/212 - IVDs
Published standard		BS EN ISO 13402:2025 Surgical and dental hand instruments. Determination of resistance against autoclaving, corrosion and thermal exposure	W/- - Miscellaneous Standards
Published standard		BS EN IEC 61846:2025 Ultrasonics. Therapeutic focused short pressure pulse sources. Characteristics of fields	EPL/87 - Ultrasonics
Published standard		BS ISO 8600-1:2025 Endoscopes. Medical endoscopes and endotherapy devices. General requirements	CPW/172 - Optics and Photonics
Draft for public comment	22/04/2025	BS EN 18165 Electronic cigarettes and e-liquids - Child safety requirements and test methods	CH/437 - Electronic Cigarettes & E-liquids
Draft for public comment	18/07/2025	BS EN 18167 Quality along the patient pathway in medical imaging in Radiology services	CH/304/-/2 - Patient Pathways
Draft for public comment	03/05/2025	BS EN ISO 10477 Dentistry. Polymer-based crown and veneering materials	CH/106/2 - Prosthodontic materials
Draft for public comment	19/05/2025	BS EN ISO 1942:2020/Amd 1 Dentistry. Vocabulary. Amendment 1: Definitions for types of tests used in standards development	CH/106/5 - Terminology
Draft for public comment	02/06/2025	BS EN ISO 9680 Dentistry. Operating lights	CH/106 - Dentistry
Draft for public comment	23/04/2025	BS EN ISO 7551:2023/Amd 1 Dentistry. Endodontic absorbent points. Amendment 1	CH/106/1 - Dental restorative and orthodontic materials

Draft for public comment	06/05/2025	BS EN ISO 10873 Dentistry — Denture adhesives	CH/106/7 - Oral hygiene products
Draft for public comment	21/05/2025	BS EN ISO 23402-1 Dentistry. Portable dental equipment for use in non-permanent healthcare environment. Part 1: General requirements	CH/106 - Dentistry
Draft for public comment	12/04/2025	BS EN ISO 10650 Dentistry — Powered polymerization activators	CH/106 - Dentistry
Draft for public comment	20/05/2025	BS EN ISO 10322 Ophthalmic optics. Semi-finished blanks	CH/172/3 - Spectacles
Draft for public comment	21/05/2025	BS EN ISO 10993-11 Biological evaluation of medical devices. Part 11: Tests for systemic toxicity	CH/194 - Biological evaluation of medical devices
Draft for public comment	03/05/2025	BS EN ISO 10524-3 Pressure regulators for use with medical gases. Part 3: Pressure regulators integrated with cylinder valves (VIPRs)	CH/121/6 - Medical gas supply systems
Draft for public comment	03/06/2025	BS EN ISO 22367 Medical laboratories. Application of risk management to medical laboratories	CH/212 - IVDs
Draft for public comment	22/05/2025	BS EN IEC 80601-2-60/AMD1 ED.2 Medical electrical equipment. Part 2-60: Particular requirements for the basic safety	CH/62/4 - Particular medical equipment, software, and systems

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Upcoming events from TOPRA & RAPS

The TOPRA **Employer Partner** programme is designed for organisations that want to formally demonstrate their outstanding commitment to the professional development and wellbeing of regulatory affairs professionals.

TOPRA events **Remember to use the 10% off TOPRA courses for ABHI members*

- **Innovative Medical Devices**: How to Navigate the Regulated MedTech Landscape to Place These on the Market Online 6th May
- Essentials of **European Medical Device Regulatory** Affairs London/online 21 May 2025
- Regulatory **Careers** Live 2025 – 13 June Brussels
- The **Medical Device Introductory Course** 16 - 18 June, London
- Essentials of **In-Vitro Diagnostics Regulatory** Affairs 11 July, London/online
- **US Regulation** of Medical Devices London/online 23-25 July 2025
- Regulatory **Careers** Live 2025 – 9 September, London
- Design Development and Certification of Medical Devices 8-10 September London/Online
- Medical Devices/IVDs **Symposium** 2025 Berlin 30 September - 1 October 2025
- Regulation of **In-Vitro Diagnostics Medical Devices** London/online 20-22 October
- **Leadership and Strategic Management** in Regulatory Affairs London/Online 10-12 November
- Essentials of **European Medical Device Regulatory Affairs** London/online 26 November
- Regulation of **Electrical, Electronic and Software Devices** London/online 2-4 December

RAPS events

- RAPS Webcast: Get Your **FRA** Now 15 April online
- Workshop: **Cybersecurity** Unauthorized Online 25th March
- RAPS Workshop: **Conflict Resolution and Negotiation**: Effective Tools and Techniques 24 April online
- RAPS Workshop: **Strategies in Meetings**: Achieving Your Objectives 8 May online
- RAPS **Euro Convergence 2025** Brussels 13-16 May
- RAPS Workshop: **Dangerous Documents**: Avoiding Land Mines in your Records and Emails 22 May online
- RAPS Workshop: The **Role of the PRRC** Under the MDR and IVDR 29 May online
- RAPS Workshop: Unlocking the Power of Generative **AI in Regulatory Intelligence** 04 June online
- RAPS Workshop: **Global Expedited Pathways** (US/Global) – Medical Devices 09 September online

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EU news - MedTech Europe

The **MedTech Forum** 2025, Lisbon 13-15 May

MedTech Europe developed a decision guide flowchart for applying **Article 10a MDR/IVDR on supply discontinuity**. In addition to the flowchart, BVMed commissioned a legal opinion into Article 10a compliance.

MTE Advocacy - Exemption of **Routine Blood Draws** from Article 58.1(a) of the IVDR

Position paper: Submission of **vigilance reports to Notified Bodies** under EU MDR & IVDR

EU news – European Commission

SCHEER - Minutes of the Working Group meeting on **brain stimulators** of 19 March 2025
MDCG 2020-16 rev.4 Guidance on **Classification Rules for in vitro Diagnostic Medical Devices** under Regulation (EU) 2017/746
Commission Implementing Regulation (EU) 2025/454 of 7 March 2025 laying down the rules for the application of Regulation (EU) 2024/1689 of the European Parliament and of the Council as regards the establishment of a **scientific panel of independent experts in the field of artificial intelligence**
European Union reference laboratories (EURLs) in the field of in vitro diagnostic medical devices Information pack for candidate laboratories V5
Frequently Asked Questions on the **European Health Data Space** V1
Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the **European Health Data Space** and amending Directive 2011/24/EU and Regulation (EU) 2024/2847
AI in Healthcare: EU Priorities and Ecosystem Synergies

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EU news – European Commission (MDCG)

Ongoing/planned **guidance development** and deliverables of MDCG Subgroups – January 2025*

MDCG 2020-16 rev.4 Guidance on **Classification Rules for in vitro Diagnostic Medical Devices** under Regulation (EU) 2017/746

EU news – European Commission (EMA)

Pilot on the **Advice from the Expert Panels** to Manufacturers of High-Risk Medical Devices

Team NB

MDR **Technical Documentation Training f**or Manufacturers - Survey Report

New Training for Manufacturers: **Clinical Evaluation Review** Training

Press Release **Certificates with Conditions** - Team NB Statement

EU News – BioMed Alliance

MUST READ BioMed Alliance publishes new comprehensive review of regulatory framework for medical devices and IVDs MUST READ

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US news – AdvaMed

2024 **annual report**

Advamed's **MedTech Conference**. 5-8th October, San Diego

US news – FDA

Federal Court Strikes Down LDT Final Rule On March 31, 2025, the US District Court for the Eastern District of Texas struck down the US Food and Drug Administration's (FDA) final rule under which FDA would have started regulating most **laboratory-developed tests (LDTs)** as medical devices on May 6, 2025.

Evaluation of **Sex-Specific Data in Medical Device Clinical Studies** - Guidance for Industry and Food and Drug Administration Staff

eSTAR In Vitro Diagnostic Version 5.5/ Non-In Vitro Diagnostic Version 5.5

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International news – IMDRF

Technical Document: Terminologies for Categorized **Adverse Event Reporting** (AER): terms, terminology and codes

Consultation document (closes 30th May): Playbook for Medical Device **Regulatory Reliance** Programs

Outcome statement: **27th MC Meeting Tokyo**, Japan March 2025

International news – GHWP

Website Updates Announcement

29th GHWP Annual Meeting will be held in Bangkok 1-4 Dec 2025

International news – GMDN

Global Medical Device Nomenclature (GMDN): A valuable tool for the development of **National Essential Diagnostics Lists (NEDLs)**

GMDN FOCUS – March 2025

International news – Other Global Trade Associations

MTAA **Annual Report**

Canada's MedTech **Conference 8 May**

Canada's Regulatory & Quality Medtech **Conference 10-12 June**

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International news – national regulators

TGA	**Consultation: Proposed changes to the IVD medical device classifications and definitions** (closes 8th May 2025)
South Korea (MFDS)	Good **Machine Learning** Standards for Medical Device Development - Guiding Principles
Saudi Arabia (SFDA)	MDS-G024 - Guidance for ISO 13485 Requirements and Corresponding SFDA-MDS Requirements
Australia (TGA)	Therapeutic Goods Legislation Amendment (**Australian Unique Device Identification** Database and Other Measures) Regulations 2025
Saudi Arabia (SFDA)	MDS G26 - Guidance on **Companion Diagnostic IVDs**
Singapore (HSA)	Best Practices Guide for Medical Device **Cybersecurity**
Belgium	Guideline **Submission Processes of Clinical Investigations** according to MDR in Belgium V11