ABHI Regulatory Round-up – February 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, 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.

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

UK Trade Strategy **Consultation - ABHI Response**
ABHI Partners With The **Association of Translation Companies**
HIRANI Health Tech **Spring Conference Returns for 2025**
ABHI Spring **Spending Review Submission**
NHS Data Infrastructure Must Support The **Research Needs of The Life Sciences Sector**
2024 Review: **Celebrating ABHI's Impact**
Government Affairs Researcher. **1-year Undergraduate Placement**
Transformation and Growth: **The HealthTech Effect**

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ABHI US accelerator brings UK health tech innovators to Texas

"A delegation of over 10 leading UK HealthTech innovators and Commercial Director from Oxford University Hospitals NHSFT, Jay Mistry, will travel to Texas next week as part of a key trade visit organised by the Association of British HealthTech Industries (ABHI) through its US Accelerator programme.

"Taking place from 3-7 March, the visit will bring together UK HealthTech and NHS leaders for a series of meetings, networking events and introductions across Austin, Dallas and Houston to showcase the excellence of the UK's health technology industry."

Upcoming regulatory group meetings

IVD Regulatory

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

MD Regulatory

- 4th March 10.30-12.30
- 3rd June 10.30-12.30

Upcoming ABHI meetings/events on **Post Market Surveillance**

Date	Time	Event	Location	Join details
27th February	2-4pm	IVD regulatory members group	online	email Steve for an invite
4th March	10.30-12.30	MD regulatory members group	online	email Phil for an invite
14th March	11-12 noon	ABHI member webinar	online	Registration details (MS Teams)
17th March	4-5pm	ABHI international partner webinar	online	Registration details (MS Teams)
1st May	pm	ABHI/Brabners in person event	Manchester	registration details tbc
29th May	2-4pm	IVD regulatory members group	online	email Steve for an invite
3rd June	10.30-12.30	MD regulatory members group	online	email Phil for an invite
5th June	pm	ABHI/IQVIA in person event	London	registration details tbc

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4th March Medical AI Robotics & Technology Conference 2025 I will be speaking on regulations, so be sure to use the **20% discount code for ABHI members**: MEDTECH20 - Register here

31 March. ABHI Member Briefing. This seminar is aimed at introducing potential members, new members, and new employees of member companies, to the work of ABHI. Register here.

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

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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**

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

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 by clicking 'regulation' in the ABHI resource hub.

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MHRA

New

Subject	Relevance
Open consultation Draft guidance on individualised mRNA cancer immunotherapies	This consultation is relevant to medical devices and IVDs used in individualised immunotherapy including **sample collection, genomic tests and bioinformatic software** (inc AI/ML). Please get in touch if you have any thoughts on a **combined ABHI response**. Closes 31st March.
MedRegs blog: New Leadership and a focus on Software	The MHRA's Innovative Devices team has transitioned to the **Innovation and Compliance group** under Interim Executive Director **James Pound**, following Laura Squire's departure. **Marinos Ioannides** has been appointed as the **new Head of Software** and AI Medical Devices, bringing expertise from his previous role as Head of Data Science at the Cabinet Office. The agency is advancing its **AI Airlock pilot** and has released **new guidance on Digital Mental Health Technologies**.

Updates

Subject	Update	Relevance
Digital mental health technology (DHMT)	New guidance document: Digital mental health technology: qualification and classification and associated press release.	The new MHRA guidance is intended to help manufacturers of DMHT to define the characteristics of their devices and determine the appropriate regulatory qualification and classification.
	Toward a New Conceptual Framework for Digital Mental Health Technologies: Scoping Review	Published paper with significant MHRA input. Journal of Medical Internet Research (Mental Health)
MHRA performance data for assessment of clinical trials and established medicines	Includes data (in pdf) for **Clinical Investigations**: February 2024 – January 2025	All targets met
Regulating medical devices in the UK	The web page now includes guidance for the EU **IVDR transition extension** under **Article 110** for the registration of IVD devices with the MHRA.	New guidance on registration of IVDs with certificates and declarations to IVD Directive

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	Additionally, [MHRA] made some minor updates to our current guidance for medical device registration, specifically for devices captured under the **EU MDR transition extension** under **Article 120.**	New guidance on registration of medical devices (reusable/upclassified Class I, or with certificates to MD/AIMD Directives)
Medical devices: UK approved bodies	Amended to update details for **DEKRA Certification UK Ltd (8505)** in the page UK approved bodies for medical devices	If you use DEKRA – **note this change**
Clinical investigations for medical devices	Changed text for optimisation in both 'Serious adverse event (SAE) reporting' sections	If you are running a UK clinical investigation, **be aware** of this update
Consultation on Medical Devices Regulations: Routes to market and in vitro diagnostic devices	Response to **Assimilated EU Law** consultation proposal	The majority of **respondents agreed to remove the revocation date of the four pieces of assimilated law** so that they continue to apply in Great Britain.
AI Airlock pilot cohort	Updated to reflect that Lenus Health have withdrawn from the AI Airlock pilot programme.	To **be aware**

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

World-leading **AI trial to tackle breast cancer** launched

UK **Internal Market Act** 2020: review and consultation closes 3rd April

UK **Health Security Agency Conference**, Manchester Central, 25 and 26 March (** flash sale on remaining few exhibition spaces for SMEs **)

UK-backed **AI companies to transform British cancer care** and spark new drug breakthroughs

Fellowships launched to explore how AI could change the way scientists drive new discoveries

Government ramps up efforts to end **HIV transmissions** in England

NICE announces proposals to transform its **HealthTech programme to drive more technology into the NHS**

Publication of **Engineering Biology** Regulators Network Membership

Health Innovation and Research Alliance NI **(HIRANI), Health Tech Spring conference** Belfast 7/8 April

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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.

Blog: Why **TOPRA is important to me** and should be to you too

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

- CRED Regulatory **Document Writing** and Management 18-19 March London/ online
- Regulatory **Careers** Live 2025 – 28th March Dublin
- Essentials of **European Medical Device Regulatory** Affairs London/online 21 May 2025
- **US Regulation** of Medical Devices London 3-5 June 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
- 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 Workshop: Survivor: The **FDA 510(k)** Program Edition 4 March online
- 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

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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

Urgent call for clarity on clinical strategy discussions

MedTech Europe, AESGP, MedTech &Pharma Platform and COCIR would like to express their concern that the recently updated *MDCG 2019-6: Requirements relating to notified bodies* revision 5, while providing further framework for structured dialogue, has not addressed the **ongoing absence of clinical strategy discussion in the pre-submission space**. As a result, unfortunately, the gap in clinical evidence expectations will persist – with serious consequences for our industry and for devices continuity.

European medical technology industry calls for the EU to join the **Medical Device Single Audit Program** as a Full Member

EU news – European Commission

Commission Implementing Regulation (EU) .../... of XXX amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the **instructions for use may be provided in electronic form**
SGS FIMKO OY (NB 0598) **18th Notified Body designated under MDR** (EU) 2017/745 - Updated Scope
CENTRO NACIONAL DE CERTIFICACION DE PRODUCTOS SANITARIOS (NB 0318), **14th Notified Body designated under IVDR** (EU) 2017/746
New landing page - Medical Devices - **Clinical investigations and performance studies**
Pilot **coordinated assessment for CI/PS**
National requirements for **clinical studies**
FAQ **pilot coordinated assessment** for clinical study sponsors
Participating Member States In the **pilot coordinated assessment**
Guidelines on the **definition of an artificial intelligence system** established by AI Act

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Approval of the content of the draft Communication from the Commission - Commission Guidelines on **prohibited artificial intelligence practices** established by Regulation (EU) 2024/1689 (AI Act)

EU news – European Commission (MDCG)

MDCG 2019-6 rev.5 - Questions and answers: Requirements relating to notified bodies

EU news – European Commission (EMA)

Companion Diagnostics and combination products: Questions & Answers for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the Regulations on medical devices and in vitro diagnostic medical devices (Regulations (EU) 2017/745 and (EU) 2017/746)

EMA establishes regular procedure for **scientific advice on certain high-risk medical devices**

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US news – AdvaMed

AdvaMed Welcomes Introduction of Bipartisan Medtech **Electronic Labeling** Bill

"This bill would expand access to definitive, expert information about how to use each lifesaving, life-enhancing medtech innovation, direct from the manufacturer, without the need for or delay caused by paper instructions."

https://www.congress.gov/bill/119th-congress/house-bill/1539

US news – FDA

Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs
Institutional Review Boards Frequently Asked Questions: Guidance for Institutional Review Boards and Clinical Investigators

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International news – IMDRF

27th IMDRF Management Committee Meeting will be held in Tokyo, Japan from March 10-14, 2025 (**agenda available**)

International news – GHWP

International news – GMDN

Shaping Our Future: Insights and Actions from the GMDN Agency's 2024 Annual Survey
GMDN FOCUS - February 2025

International news – national regulators

Portugal / Infarmed	Information Circular No. 014/CD/100.20.200: Dispensing with information in Portuguese in the **graphical interfaces of medical devices**
Switzerland (Swissmedic)	MU680_21_010: Guidance document: **FSCA economic operators** V3.1
Mexico (COFEPRIS)	NOM-241-SSA1-2025 **Good Manufacturing Practices** for Medical Devices
Canada (Health Canada)	Guidance on terms and conditions for **class II to IV medical devices**
Canada (Health Canada)	Draft Guidance on Managing **Applications for Medical Device Licences**
Italy (Ministry of Health)	National **Breast Implant Registry** – 2024 Report
Ireland (HPRA)	**Certificate of Free Sale** for Medical Devices Process Updates
Netherlands (IGJ)	IGJ calls on healthcare providers: handle the implementation of **generative AI applications** with care

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