ABHI Regulatory Round-up – May 2025

Contents

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3rd June 2025

ABHI Regulatory Round-up – May 2025

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')

🌼**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.** 🌼

Friday, 3 October **ABHI Member Briefing** This seminar is aimed at introducing potential members, new members, and new employees of member companies, to the work of ABHI. It is also a great opportunity to understand the broader work we do outside of your immediate sphere of interest/expertise. The event will provide attendees with detailed information on the current critical issues relevant to the health technology industry, as well as ABHI's workstreams.

ABHI Regulatory Round-up – May 2025

☞Advance notice: ABHI HealthTech Conference 2025

"An unmissable opportunity to connect with peers, gain practical knowledge, and identify the growth opportunities shaping the future of HealthTech."

11 - 12 November 2025 (Day 1: UK Market, Day 2: Regulation) Early Bird discount now available

2G & 3G Switch-Off: Industry Update Mobile Network Operators will switch off 2G and 3G networks by 2033, with some changes occurring sooner. Many impacted devices use 2G for machine-to-machine (M2M) and IoT services in sectors like healthcare.

The European Union Medical Device Regulations in Northern Ireland Survey *aims to find out more about the experiences of professionals involved in any aspect of research, investigations, or evaluations that has involved any medical device or IVD in Northern Ireland since 2021.*

You do not need to be based in Northern Ireland to participate in this questionnaire.

Regulators' Pioneer Fund round 4 Regulators and local authorities can apply to the Regulators' Pioneer Fund with initiatives that will help create a UK regulatory environment for business innovation and investment. The competition window for Round 4 will close on **Thursday 31 July 2025 at 11:59pm** BST.

Manchester University NHS Foundation Trust - Innovative Technology Adoption Programme. Selected technologies will benefit from receiving fast track product support and full testbed process, with associated governance and operational support to facilitate successful implementation. Please complete this form to submit your technology or innovation proposal for consideration by MFT.

A third Statutory Instrument (SI) in the **UK's Persistent Organic Pollutants (POPs) legislation** came into effect which now omits HealthTech from the UV-328 and Dechlorane Plus entries. This means that, for the time being, the restriction on these two substances has been lifted for our sector. The SI's accompanying Impact Assessment provides detailed background on the decision.

ABHI Regulatory Round-up – May 2025

Upcoming regulatory group member meetings *(webpage now includes the slides/minutes from past meetings)*

IVD Regulatory

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

MD Regulatory

- September tbc

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

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

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

ABHI Regulatory Round-up – May 2025

MHRA

New

Subject	Relevance
Meet the women helping ensure that **digital mental health technologies** are safe, effective and developed considering the needs of the people who use them	News story covering the role of MHRA in regulating mental health apps. MHRA and NICE are developing user-focused guidance for digital mental health technologies, aiming to clarify regulation, ensure safety, and support integration into UK healthcare. (and see also the webinar recording on DMHT regulations from 15th May)
Webinar: **AI Airlock Webinar** - Pilot insights and phase 2. 19th June 2025	*"This webinar will provide an update on the AI Airlock pilot programme that ran from April 2024 through to March 2025, including a summary of the pilot projects, early insights into recommendations and lessons learnt. You will also hear about the second phase of the programme including the key focus areas as well as information on how to apply."*
MedRegs Blog: Are you prepared for **Post-Market Surveillance?**	Blog outlining some changes to PMS regs in GB – digested read: "*From 16 June 2025, new UK Post-Market Surveillance requirements apply. Manufacturers must implement proactive systems for monitoring, risk management, and timely reporting. Clearer information for users and healthcare professionals is expected. MHRA guidance and updates to MORE will be in place.*"

Updates

Subject	Update	Relevance
GB **post market surveillance.** Information for manufacturers and Guidance on the updates to reporting forms following implementation of the PMS regs	A new GB-specific report from will be introduced in June and be made mandatory in October.	Look out for the new report form and plan to make changes to your GB PMS vigilance reporting process
Guidance: **Assistive technology**: definitions, examples and safe use	Section 3.1, changed from from "wheelchairs (including powered wheelchairs)" to "wheelchairs (manual self and attendant-propelled, powered self and attendant-controlled)".	This is a minor change to the examples of assistive technologies as medical devices. If you make or supply wheelchairs in the UK, assess this change for relevance to your organisation.
Medical devices: list of **UK approved bodies**	Added Active Implantable Medical Devices to DEKRA certification	If you use DEKRA as a UKAB and you produce AIMD and you are considering UKCA, assess this change for relevance to your organisation.

Medical devices given **exceptional use authorisations**	Exceptional use authorisations (EUA) are now decoupled from COVID	If you need might need to make an application for EUA, make sure you understand the current guidance.
MHRA Performance Data	100% of **clinical investigations** are assessed within the statutory timeline	If you are looking to apply to begin a clinical investigation in the UK, note the current timescales for assessment.

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

ABHI Regulatory Round-up – May 2025

BSI updates

BSI blog: Greening MedTech: **The Impact of Procurement-Based Demand on Sustainability**

In June 2025, BSI will be running **Healthcare Week** consisting of five webinars:

- 09 June 2025 12:00 - 13:00 **Digital & AI in Healthcare**
- 10 June 2025 12:00 - 13:00 **PFAS phase out and its impact on medical devices**
- 11 June 2025 12:00 - 13:00 **Regulatory update - what's happening in the world of medical devices in the EU and UK**
- 12 June 2025 12:00 - 13:00 **Circularity in Healthcare**
- 13 June 2025 12:00 - 13:00 **The Power of In Silico Trials: AI, Innovation, and Its Impact on Healthcare**

Update on Projects June 2025

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 ISO 19223-2:2025 Lung ventilators and related equipment. Vocabulary and semantics. High frequency and jet ventilation	CH/121 - Anaesthetic and respiratory equipment
Published Standard		BS EN IEC 60601-2-68:2025 Medical electrical equipment. Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment	CH/62/3 - Equipment for radiotherapy, nuclear medicine
Published Standard		BS ISO 5868:2025 Ophthalmic optics and instruments. Anomaloscopes for the diagnosis of red-green colour vision deficiencies	CH/172/6 - Ophthalmic instruments

Published Standard		BS EN ISO 22675:2025 Prosthetics. Testing of ankle-foot devices and foot units. Requirements and test methods	CH/168 - Prosthetics and orthotics
Draft for public comment	01/06/2025	BS ISO 25557 Care quality for older persons at home and in care facilities	CH/314 - Ageing Societies
Draft for public comment	04/06/2025	BS EN IEC 62570 Ed.2.0 Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	CH/62/2 - Medical imaging equipment
Draft for public comment	11/06/2025	BS EN ISO 19211 Anaesthetic and respiratory equipment. Fire-activated oxygen shut-off devices for use during oxygen therapy	CH/121 - Anaesthetic and respiratory equipment
Draft for public comment	11/06/2025	BS EN ISO 3630-8 Dentistry. Endodontic instruments. Part 8: Accuracy of electronic apex locator	CH/106 - Dentistry
Draft for public comment	11/06/2025	BS EN ISO 8325:2023/AMD 1 Dentistry. Test methods for rotary instruments. Amendment 1	CH/106 - Dentistry
Draft for public comment	11/06/2025	EN ISO 8980-3:2022 AMD 1 Ophthalmic optics. Uncut finished spectacle lenses. Part 3: Transmittance specifications and test methods. Amendment 1	CH/172/3 - Spectacles
Draft for public comment	11/06/2025	BS ISO 20364 Healthcare organization management. Guidance for healthcare organizations' response to the surging diagnostic demands in a pandemic	CH/304 - Healthcare Organization Management
Draft for public comment	11/06/2025	BS EN ISO 8980-4 Ophthalmic optics — Uncut finished spectacle lenses —. Part 4: Specifications and test methods for the properties of anti-reflective coatings and hydrophobic coatings	CH/172/3 - Spectacles
Draft for public comment	14/06/2025	BS EN ISO 3964-1 Dentistry. Coupling dimensions for handpiece connectors. Part 1: Mechanical properties	CH/106 - Dentistry
Draft for public comment	17/06/2025	BS EN 1422 Sterilizers for medical purposes. Ethylene oxide sterilizers. Requirements and test methods	CH/198 - Sterilization and Associated Equipment and Processes
Draft for public comment	18/06/2025	BS EN ISO 7396-1 Medical gas pipeline systems. Part 1: Pipeline systems for compressed medical gases and vacuum	CH/121/6 - Medical gas supply systems

Draft for public comment	24/06/2025	BS EN ISO 11986 Ophthalmic optics. Contact lenses and contact lens care products. Determination of preservative uptake and release	CH/172/9 - Contact lenses and contact lens care products
Draft for public comment	24/06/2025	BS EN ISO 11987 Ophthalmic optics. Contact lenses. Determination of shelf-life	CH/172/9 - Contact lenses and contact lens care products
Draft for public comment	25/06/2025	BS EN ISO 20342-4 Assistive products for tissue integrity when lying down. Part 4: Test methods for durability	CH/173 - Assistive products for persons with disability
Draft for public comment	25/06/2025	BS EN IEC 63521 ED1 Machine Learning-enabled Medical Device – Performance Evaluation Process	CH/62 - Medical equipment, software, and systems
Draft for public comment	02/07/2025	BS EN 63612 Ed.1.0 Ultrasonics – Intraluminal short pressure pulse therapy sources – Characteristics of fields	EPL/87 - Ultrasonics
Draft for public comment	08/07/2025	BS ISO 11193-2 Single-use medical examination gloves —. Part 2: Specification for gloves made from poly(vinyl chloride)	CH/205/3 - Medical gloves
Draft for public comment	08/07/2025	BS ISO 11193-1 Single-use medical examination gloves —. Part 1: Specification for gloves made from rubber latex or rubber solution	CH/205/3 - Medical gloves
Draft for public comment	08/07/2025	BS EN ISO 18369-1 Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications	CH/172/9 - Contact lenses and contact lens care products
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	19/07/2025	EN ISO 16571:2024/A1 Systems for evacuation of plume generated by medical devices. Amendment 1	CH/121/6 - Medical gas supply systems
Draft for public comment	24/07/2025	BS EN IEC 60601-2-93 ED1 Medical electrical equipment. Part 2-93: Particular requirements for the basic safety and essential performance of neutron capture therapy equipment	CH/62/3 - Equipment for radiotherapy, nuclear medicine and radiation dosimetry

ABHI Regulatory Round-up – May 2025

Upcoming events from TOPRA & RAPS

TOPRA's **Regulatory Rapporteur** provides expert insights and updates on global regulatory affairs in the healthcare and life sciences sectors. They would like your feedback to help inform and shape future plans.

Please spend a few minutes on the ***Regulatory Rapporteur readership survey***

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

- 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 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

ABHI Regulatory Round-up – May 2025

EU news - MedTech Europe

MedTech Europe calls for medical technology sector to be an integral part of the **future Life Sciences Strategy**

Leaflet: Towards a **revised EU regulatory framework** for medical devices

MedTech Europe priorities for the **Danish Presidency** of the Council of the European Union

MedTech Europe: practical guide for the use of European Medical Device **Nomenclature**

EU news – European Commission

SCHEER - Minutes of the Working Group meeting on Brain stimulators of 11 April 2025
Manufacturer Incident Report (MIR) template version 7.3.1
DNV Product Assurance AS, Notified Body designated under IVDR 2017/746

EU news – European Commission (EMA)

EMA/285848/2020: Product Management Service (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe v.2.3

ABHI Regulatory Round-up – May 2025

US news – AdvaMed

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

AdvaMed's **AI Policy Roadmap** promotes safe, effective integration of AI in medical devices. It supports FDA's risk-based oversight, streamlined updates through the PCCP, and better access to high-quality data with strong privacy protections. The roadmap urges Medicare and CMS to create clear reimbursement pathways for AI and digital therapeutics, while opposing mandatory third-party assurance labs. It advocates globally harmonized, innovation-friendly policies that enhance patient care and expand access to AI-enabled health technologies.

US news – FDA

Requests for Feedback and Meetings for Medical Device Submissions: **The Q-Submission Program**: - Final Guidance for Industry and Food and Drug Administration Staff

Electronic Submission **Template for Medical Device Q-Submissions**: Draft Guidance for Industry and Food and Drug Administration Staff

FDA Launches Elsa – an Agency-Wide AI Tool

ABHI Regulatory Round-up – May 2025

International news – IMDRF

IMDRF/MC/N2FINAL:2025 (Edition 13): IMDRF **Standard Operating Procedures v2** describes the procedures that the IMDRF follows when revising the membership of the IMDRF Management Committee (MC), Official Observers and Affiliates, establishing Subcommittees or Working Groups, developing IMDRF documents or managing documents previously developed under the GHTF

International news – GHWP

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

International news – GMDN

GMDN **FOCUS - May 2025**

International news – WHO

WHO **Diagnostics Coalition** launched with MedTech Europe representing GMTA

International news – Other Global Trade Associations

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

ABHI Regulatory Round-up – May 2025

International news – national regulators

Brazil (ANVISA)	SIUD User Manual Unique Medical Device Identification System (**UDI-ANVISA**)
Saudi Arabia (SFDA)	MDS-G022-V2.0/250518: Guidance on the development of **IVDs for in-house use v2**
Australia (TGA)	Understanding regulatory requirements for in vitro diagnostic (IVD) **companion diagnostics (CDx)**
South Korea (MFDS)	Guide-0612-05: **Medical Device Software Licensing** Guidelines
Switzerland (Swissmedic)	BW630_30_829: **Guideline for In-house Medical Devices v1**
Switzerland (Swissmedic)	ZL000_00_036e_WL Guidance document for formal requirements v16 (does not apply to medical devices)