# ABHI Regulatory Round-up – June 2025

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ABHI

11 July 2025

# ABHI Regulatory Round-up – June 2025



ABHI

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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. I've also added some new 'spotlight sessions' that I hope will be of interest.

*If you saw June's interim round-up, new UK information is marked with *

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')

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.

**Advance notice: ABHI HealthTech Conference 2025**

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*"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

**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.

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NIHR HRC Community Healthcare "**Introduction to the EU Medical Device Regulation (EU) 2017/745 – Interactive workshop**" Tuesday**, 08 July 2025**, 10am to 12.15pm

Compliance with **medical device software standard - IEC 62304** - remains a costly pinch-point for software-enabled devices. One emerging solution is an automated formal-verification suite from UK developer D-RisQ. According to D-RisQ CEO, Nick Tudor, the toolset auto-generates verification and certification evidence artefacts, potentially cutting development effort by up to 80% while aligning with IEC 62304 for UK, EU and US regulatory compliance. Pilot studies covered gas pumps, temperature and other control systems and report faster development cycles and higher code assurance. D-RisQ offers licensing, training and subcontract models. Further information: drisq.com/medical-systems-software .

West Midlands **IVD Innovation & Adoption** Conference 2025 https://uobevents.eventsair.com/wmivdiac2025/ Edgbaston Park Hotel 17th and 18th July 2005

***PUBLISHED:** NHS 10-Year Plan Published, With **HealthTech Vital To Delivering The Vision**: Many of the plan's ambitions closely reflect the priorities ABHI has long championed through our Manifesto for HealthTech. In particular, the Plan echoes ABHI calls to:
**Professionalise innovation and adoption**, embedding technology into care pathways at scale.

**Deliver a world-leading regulatory system**, supporting safe, rapid access to cutting-edge solutions.
**Adopt a longer-term, sustainable approach to investment in HealthTech**, ensuring companies have the certainty to drive continuous improvement.

*Capturing Gender Equality in **HealthTech – 2025 Report** This year, over 110 professionals contributed to the survey, offering honest reflections on representation, organisational culture, and career progression. Though signs of progress are clear, the data also highlights persistent challenges

*Defining The Size Of **The Health Innovation Prize.** Reducing ill-health and making better use of health innovations could add billions to economic growth in the UK, a new report has revealed.

**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

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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

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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## Spotlight Session – MHRA's new MIR form

From **Monday 16 June 2025** every manufacturer or UK Responsible Person must notify the MHRA of the relevant details of serious incidents occurring in Great Britain according to the new UK post market surveillance requirements. MHRA continues to update their guidance in light of feedback. They also provide a new GB-specific Manufacturer's Incident Report (MIR) form which mirrors EU MIR v 7.2.1 but introduces national data requirements: it asks for UK Approved Body identification and certificate numbers, full Unique Device Identifier details (including the issuing entity), estimates of the number of devices placed on the market and users affected in Great Britain, mandatory IMDRF codes, UK Responsible Person contact information, and it limits device nomenclature to GMDN terms while stripping out EUDAMED reference fields.

The MHRA also allows v7.2.1 of the EU MIR form to be used (with GB-specific data) for a four-month transition period until **16th October** after which MHRA will only accept reports conforming to the GB-specific (7.2.1) MIR form. To support implementation, the MHRA has updated its MORE portal and released revised *XSD files*, help text and user guidance, together with options for *manual, XML and API submission routes*. Incidents that occur in Northern Ireland must continue to be submitted under EU rules, with a move to the new EU MIR 7.3.1 form in line with the European Commission's timetable. We understand that MHRA will consider a further transition to a GB-specific 7.3.1 MIR form in the future.

If like me you sometimes struggle to get your head round all the different ways of submitting reports to MHRA, I asked a chatbot to 'ELI5' **(explain like I'm 5)**

*Think of an XML Schema Definition (XSD) as the picture on a Lego box. It shows which bricks are allowed and where each must sit, so everyone shares the same reference. When someone builds an XML message, that picture is the standard used to decide whether the model is acceptable.*

*Filling in an online form feels like building in front of a teacher. Each time you place a brick, the teacher glances at the box for confirmation and corrects you immediately if it is wrong. Behind the scenes the form assembles an XML file, and the server checks every field against the XSD before it stores the submission. This ensures consistency across manual, file and API paths.*

*Using the file-upload route is like constructing the model at home. You carry it to school, set it on the desk, and only then does the teacher compare the entire model with the picture. If even one brick is misplaced or the wrong colour, the model comes back for rebuilding. In practice you create an XML file locally, upload it to a portal, and the portal validates the document against the same XSD in one pass.*

*An API call resembles a small robot passing the finished model through a window. The teacher reviews it against the picture, but the hand-off is instant and needs no people. A machine-to-machine request carries the XML payload, and the service validates it against the XSD before processing. When the picture changes, builders need to fetch the updated image and rebuild.*

*Whether you build under supervision, build at home, or send a robot, judgement always comes from the same picture on the box. The submission routes differ only in how the model is prepared and delivered; the rules for a valid model never change.*

# ABHI Regulatory Round-up – June 2025

## Spotlight Session – MHRA plans for the future

**Top Headlines from Rob Reid's presentation at this month's MedTech Summit in Berlin**

1. Draft legislation for pre-market requirements (including international reliance routes) is expected to be notified to WTO soon, laid in Parliament by end of 2025 and come into force mid-2026. A 12-month transition for international reliance is planned.
2. MHRA aims to accept approvals from comparable regulators (EU, US, Canada, Australia) with "seamless and barrier-free" access to the UK market for most devices.
3. UKCA mark will be reformed to support UK-specific innovation opportunities in a pragmatic, flexible way.
4. MHRA will launch an early advice service to help innovators navigate NHS/MHRA requirements and expand "sandbox" models like AI Airlock for experimental technologies.
5. Learnings from the Innovative Devices Access Pathway (IDAP) pilot are being reviewed to potentially inform standard regulatory processes. (see also MHRA UCNA process published recently)
6. Ongoing MHRA work includes sustainability (e.g., remanufacturing Class I devices), refining health institution exemptions, and early access policy development.
7. Given rapid evolution, MHRA will focus on producing detailed guidance (not legislation) to help industry meet requirements in digital mental health and AI technologies.
8. A key consultation response (on international reliance, IVD routes, and UKCA) was delayed due to UK-EU reset talks but is expected "in the next few weeks".

# MHRA

**New**

| Subject | Relevance |
|---|---|
| *MHRA publishes final Business Plan for 2023-2026 Corporate Plan | The new Business Plan sets out priorities for 2025–26: Protecting public safety and maintaining public trust; delivering efficient, predictable services through regulatory excellence; being an agile organisation that drives innovation; being a great place to work and providing excellent customer service. |
| *MedRegs Blog: Exploring AI in Healthcare: Insights from the AI Airlock Pilot and associated news item | MHRA signals a major step in aligning the UK's regulatory system for AI in healthcare with global standards. The launch of the AI Airlock, CERSIs, and a new international network are intended to support safe innovation, accelerating AI-enabled medical technologies' adoption. The AI Airlock pilot explored regulatory approaches for AI as a Medical Device (AIaMD), testing real-world technologies in a safe, controlled sandbox. It focused on challenges like explainability, clinical validation, and data quality. These findings will help to shape future UK guidance and AI regulations, offering a critical opportunity to engage with evolving frameworks, support innovation, and inform regulatory clarity for AI-driven health technologies entering the UK market. |
| *UK MHRA leads safe use of AI in healthcare as first country in new global network | Starting as a global network of 1, MHRA expects others will join to help shape international rules for AI in healthcare – speeding up access to safe, effective technologies into the NHS and worldwide. |
| *AI Airlock Phase 2 application | The call for application for phase 2 of the AI Airlock is now open until **14th July** |
| Notification of **interruption or discontinuation of the supply** of a medical device for manufacturers based in **Northern Ireland** (article 10a MDR/IVDR) | Importers, distributors and manufacturers established in Northern Ireland, or manufacturers with their authorised representative established in Northern Ireland, must inform the MHRA if they anticipate an interruption or discontinuation of the supply of a medical device. MHRA reference the EU form and the EU Q&A document. |
| Fast, Expert and Open – how the MHRA is poised to become a global leader in risk-proportionate regulation | MHRA CEO **puts safety, accelerated access and innovation** at the centre of agency's refreshed strategic direction. |
| First major overhaul of medical device regulation comes into force across Great Britain | New **Post-Market Surveillance (PMS) regulations** have taken effect across Great Britain, requiring medical device manufacturers to proactively monitor the safety and performance of their products once on the market. |

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|---|---|
| NHS red tape blitz delivers game-changing new cancer treatment | Patients to benefit from new era in cancer treatment, as the government slashes red tape to unleash life-saving innovation.<br>And many congratulations to ABHI member **Histosonics** for the first **IDAP** success story |

**Updates**

| Subject | Update | Relevance |
|---|---|---|
| **Post Market Surveillance (new GB forms: MIR and FSCA) – see also this month's Spotlight Session** | Implementation of data requirements under the new Post-Market Surveillance regulations | **General guidance:** MHRA has updated its processes and procedures to ensure that trends, patterns or signals that may reveal new risks or safety concerns are identified more efficiently.<br>As part of this work, the data schemas for transmission of Manufacturer Incident Reports (MIR) and Field Safety Corrective Action (FSCA) reports have been updated to support GB submissions under the new requirements. |
| | Documentation for implementation of data requirements | Documentation to support new GB-specific updates PMS reporting forms **MIR and FSCA forms** |
| | MORE implementation | Guidance on new GB-specific updates PMS reporting forms **MIR and FSCA forms** |
| | Updated MORE reference guide | Updates related to PMS requirements, and removal of references to **legacy MORE system** and interim guidance related to **transition to current MORE system.** Version 4, June 2025: |
| | Medical devices: periodic safety update report | Information and recommendations for approved bodies on the presentation and review of a periodic safety update report (PSUR). |
| | *Standardised format for periodic safety update report (PSUR) | This document is intended to guide manufacturers on what data to include within |

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|---|---|---|
| | | a periodic safety update report (PSUR). It is not mandatory to include sections which do not apply, and data may be displayed in an alternative form if appropriate. |
| | Device Specific Vigilance Guidance | **NEW** Coronary Stents **NEW**<br>**NEW** IVC filters **NEW**<br>**NEW** Heart Valves **NEW**<br>**NEW** Cardiac Implantable Devices **NEW**<br>Blood Glucose meters<br>Intraocular lenses<br>Joint Replacements<br>Neurostimulators<br>Breast Implants<br>Insulin pumps/meters<br>Cardiac ablation<br>SaMD |
| Borderline products: medical devices and other products | "Removal of paragraph 20**. In-house manufacturing** from the Borderlines page. This content is superseded on other published guidance pages." (presumably here) | If you supply products to health institutions who then use them to manufacture medical devices or IVDs, be aware of this minor change. |
| The IDAP Unmet Clinical Need Authorisation (UCNA) | ABHI member Histosonics has been successful in navigating the MHRA IDAP process | This new regulatory process arising from IDAP allows non-UKCA or non-CE devices to be placed on the Great Britain (GB) market in the interest of the protection of public health. |
| ***Register medical devices to place on the market** | The statutory fee will increase to £261 effective 16 July 2025. | Note this planned change to registration fees |

***MHRA SoGATS Workshop Registration** 24–26 September 2025

MHRA Science Campus, South Mimms (Hybrid format)

Relevant for IVD and molecular diagnostics manufacturers, this MHRA workshop offers insights into standardisation plus engagement opportunities with regulators and EQA providers.

The 2025 Standardisation of Genome Amplification Techniques and Serology (SoGATS) Workshop will bring together scientists, regulators, EQA providers and manufacturers to discuss current developments in reference materials and standards for infectious disease diagnostics. Key themes include high-throughput sequencing, digital PCR, and pandemic preparedness.

Free to attend (in person or online). To register, email your name, affiliation, and attendance mode to: sogat@nibsc.org

**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 |
| **NEW** ▶ Post-market Surveillance and Vigilance of Medical Devices **NEW** | May 2025 |
| **UPDATED** ▶ RegulatoryConnect Programme update **UPDATED** | May 2025 |

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

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*Independent report **Review of patient safety across the health and care landscape** Dr Penny Dash's review of patient safety across the health and care landscape in England, which was commissioned by the Department of Health and Social Care.

The latest DHSC review calls out the complexity of the current patient safety system and sets the stage for changes. While MHRA isn't directly under review, the direction is: coordination, oversight, and use of data. For ABHI members right now, this means a continued focus on UK requirements for post-market surveillance and incident reporting.

## *BSI updates

**Attention: Decontamination leads, medical device manufacturers, and reprocessing service providers.**

BS EN ISO 15883-1 on washer-disinfectors is now published, setting out general requirements, terms and definitions, and test methods for cleaning and disinfection of reusable medical devices. Co-developed with support from ABHI, this vital resource ensures safer, standardised reprocessing practices. Ensure your practices align with the latest best-in-class standard.

Explore the standard here: BSI Knowledge

**Update on Projects June 2025**

| Status | Closing Date | Description | Committee |
|---|---|---|---|
| Published standard | | BS EN ISO 7376:2020+A1:2025 Anaesthetic and respiratory equipment. Laryngoscopes for tracheal intubation | CH/121/5 - Airways and related equipment |
| Published standard | | BS EN ISO 16671:2025 Ophthalmic implants. Irrigating solutions for ophthalmic surgery | CH/172/7 - Eye implants |
| Published standard | | BS ISO 23317:2025 Implants for surgery. Materials. Simulated body fluid (SBF) preparation procedure and test method to detect apatite formation in SBF for initial screening of bone-contacting implant materials | CH/150/1 - Materials for surgical implants |
| Published standard | | BS EN IEC 60601-2-83:2019+A1:2025 Medical electrical equipment. Particular requirements for the basic safety and essential performance of home light therapy equipment | CH/62/4 - Particular medical equipment, software, and systems |
| Published standard | | BS EN ISO 14889:2025 Ophthalmic optics. Spectacle lenses. Fundamental requirements for uncut finished lenses | CH/172/3 - Spectacles |
| 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 |

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| 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 | BS EN ISO 16571:2024/DAmd 1 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 60601-2-93 Ed. 1.0. 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 |
| Draft for public comment | 30/07/2025 | BS EN IEC 60601-2-57:2023/prAA:2025 Medical electrical equipment. Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring, cosmetic and aesthetic use | EPL/76 - Optical radiation safety and laser equipment |
| Draft for public comment | 30/07/2025 | BS EN IEC 60601-2-22:2020/prAA:2025 Medical electrical equipment. Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment | EPL/76 - Optical radiation safety and laser equipment |
| Draft for public comment | 04/08/2025 | BS ISO 13926-1 Cartridge systems. Part 1: Glass cylinders for cartridge-type needle-based injection systems (NIS) for medical use | CH/212 - IVDs |
| Draft for public comment | 10/08/2025 | BS EN ISO 10328 Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods | CH/168 - Prosthetics and orthotics |
| Draft for public comment | 11/08/2025 | BS EN ISO 8325:2023/Amd 1 Dentistry. Test methods for rotary instruments. Amendment 1 | CH/106 - Dentistry |
| Draft for public comment | 13/08/2025 | BS EN 60601-1/FRAG8 ED4 Medical electrical equipment. Part 1: General requirements for basic safety and essential performance - Thermal and fire hazards (Fragment 8) | CH/62/1 - Common aspects of medical equipment, software, and systems |
| Draft for public comment | 13/08/2025 | BS EN 60601-1/FRAG7 ED4 Medical electrical equipment. Part 1: General requirements for basic safety and essential performance - Mechanical hazards (Fragment 7) | CH/62/1 - Common aspects of medical equipment, software, and systems |

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|---|---|---|---|
| Draft for public comment | 13/08/2025 | BS EN 60601-1/FRAG6 ED4 Medical electrical equipment. Part 1: General requirements for basic safety and essential performance - Electrical hazards (Fragment 6) | CH/62/1 - Common aspects of medical equipment, software, and systems |
| Draft for public comment | 13/08/2025 | BS EN 60601-1/FRAG5 ED4 Medical electrical equipment. Part 1: General requirements for basic safety and essential performance - PEMS related hazards (Fragment 5) | CH/62/1 - Common aspects of medical equipment, software, and systems |
| Draft for public comment | 18/08/2025 | BS EN ISO 11135 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices | CH/198 - Sterilization and Associated Equipment and Processes |

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## *Upcoming events from TOPRA & RAPS

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

- Essentials of **In-Vitro Diagnostics Regulatory** Affairs 11 July, London/online
- Meet Our Chief Executive Dr Samantha Atkinson 16 July
- Sponsored Webinar-Transforming Regulatory Processes 22 July
- **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
- Successful and Skilful Communication 23 September
- 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: EU Medical Device Regulation 2017/745 2-5 September
- Sponsored Webcast: Smarter Regulatory Projects: Agile Methods and AI in Action 4 September
- RAPS Workshop: **Global Expedited Pathways** (US/Global) – Medical Devices 09 September online
- RAPS Workshop: The Future of Wearable Medical Devices: A Regulatory Perspective 19 September
- RAPS Workshop: Clinical Evaluation for Medical Devices 20 October
- RAPS Workshop: Seamless Integration of Design and Development and Human Factors 21 October
- RAPS Workshop: Software as a Medical Device 25 October
- RAPS Workshop: The Role of the PRRC Under the MDR and IVDR 10 November

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## 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**



Just published: amending **electronic Instructions for Use** regulation for medical devices

Medtech Europe IVD Clinical Evidence Working Group recently shared an article on 'project COMBINE' that they say is a helpful **recap of key points regarding the pilot for the combined studies** with the participation of an **IVD** (PS) and **medicinal product** (CT).

In summary, the article describes the EU's new pilot under the COMBINE project which introduces a unified application process for combined drug and IVD trials, aiming to streamline regulatory review across member states. Sixteen countries are participating, with key roles played by Austria, Germany, Ireland, and others. Sponsors can submit a single application via the EU Clinical Trials Information System, reducing duplication and aligning decisions between authorities and ethics committees.

For UK developers operating in the EU, this offers faster trial approvals, clearer procedures, and expanded access to multinational studies—especially important for companion diagnostics. Though the UK isn't part of the pilot, the approach provides a potential model for future UK frameworks. Alignment with or adaptation of similar streamlined processes could boost global competitiveness and enable UK-based IVD companies to more effectively collaborate and bring products to both EU and domestic markets, supporting faster innovation and patient access to new diagnostics.

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## EU news – MDCG

AIB 2025-1 MDCG 2025-6 - FAQ on Interplay between the Medical Devices Regulation & In vitro Diagnostic Medical Devices Regulation and the **Artificial Intelligence Act** (June 2025)

MDCG 2025-5 - Questions & Answers regarding **performance studies of in vitro diagnostic medical devices** under regulation (EU) 2017/746

MDCG 2019-11 Rev. 1 - Guidance on **Qualification and Classification of Software** in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

MDCG 2025-4 - Guidance on the safe making available of **medical device software (MDSW) apps on online platforms** (June 2025)

## EU news – European Commission



Commission Implementing Regulation (EU) 2025/1234 of 25 June 2025 amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the **instructions for use may be provided in electronic form**

Expert decision and opinion in the context of the **Clinical Evaluation Consultation Procedure** (CECP)

**COMBINE Project 1 – pilot "all-in-one" coordinated assessment**

**Manufacturer Incident Report (MIR) template version 7.3.1** (Updated)

SMEMDN Project **EMDN Helpdesk** Platform

## EU news – Team NB

TEAM NB Position Paper on **Software classification under the IVDR** V2

**Code of Conduct for Notified Bodies** under Regulations (EU) 2017/745 and (EU) 2017/746 "Improving implementation of the European CE certification of medical devices through the harmonisation of Notified Bodies v5.1

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## 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

**Cybersecurity in Medical Devices**: Quality System Considerations and Content of Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff

Unique Device Identifier Requirements for **Combination Products**: Draft Guidance for Industry

Conducting **Remote Regulatory Assessments** Questions and Answers: Guidance for Industry

**Hernia Mesh** – Package Labeling Recommendations: Draft Guidance for Industry and Food and Drug Administration Staff

**Transfer of a Premarket Notification (510(k)) Clearance** – Questions and Answers: Draft Guidance for Industry and Food and Drug Administration Staff

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## International news – IMDRF

Voluntary Withdrawal of **GHWP**

IMDRF 28th Session, September 15-19 2025, Sapporo Japan – **Registration is open**

## International news – GHWP

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

**Sponsorship opportunities** of the 29th GHWP Annual Meeting & GHWP Technical Committee Meeting are now open



## International news – GMDN

GMDN FOCUS - June 2025

Blog - Manufacturers: The '**Closest Match' Term Dilemma** for Devices

## 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**

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## International news – national regulators

| | |
|---|---|
| South Korea (MFDS) | Guide-1029-04: Guidance on procedures, methods, and standards for designating **innovative medical devices** |
| Australia (TGA) | Therapeutic Goods Legislation Amendment (**Fees and Other Measures**) Regulations |
| Singapore (HSA) | Introducing "SHARE" - Your **digital portal for Medical Devices** |
| South Africa (SAHPRA) | MD05-2025/2026: Regulatory Requirements for **Veterinary Medical Devices** (Including in-vitro Diagnostic Veterinary Medical Devices) |
| Malaysia (MDA) | MDA/GD/0062: **Harmonised classification of Medical Devices** in ASEAN v3 |
| Canada (HC) | Cancellation of MDELs for non-compliance with annual licence review requirements: 2025 |
| Slovenia (JAZMP) | Official Gazette of the Republic of Slovenia, No. 40/2025 the Medical Devices Act (ZMedPri-1) |