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ABHI REGULATORY ROUND UP

April 2026

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

EXECUTIVE HIGHLIGHTS

UK	• CE recognition remains central to GB market access; MHRA processes are becoming more defined across registration, fees, clinical investigations, digital and AI, with increasing emphasis on post-market systems
EU	• Focus shifts to implementation and readiness, including EUDAMED, vigilance updates and targeted MDR/IVDR revisions to improve efficiency
International	• Regulatory reliance moves from concept to practice, with growing expectations around PMS, change management and data reuse
Spotlights & resources	• Practical member-focused spotlight sessions, alongside extensive UK, EU and global regulatory and standards resources. Spotlight Sessions continue, with an open call for short contributions on practical regulatory topics.

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SPOTLIGHT SESSION -
SHARING REGULATORY INSIGHTS ACROSS THE ABHI COMMUNITY

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

We continue to build on the concept of spotlight sessions - short, focused articles to highlight a specific regulatory topic relevant to ABHI members. These sessions are intended to provide practical insights and interpretation of regulatory changes and feature expert perspectives from across ABHI membership. Whether you are new to ABHI, new to the industry or you've seen all these changes come and go before, if you have an idea for a Spotlight Session, please drop me a line.

Suggested topics:

- Continued CE recognition
- UKCA transition planning
- PMS in EU and UK
- Real World Evidence

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

> Include author name and affiliation.
> Ensure factual accuracy and cite sources where appropriate.
> ABHI will provide the title and key takeaway, but contributors may suggest their own.
> Submit by the middle of the previous month with earlier suggestions welcome.

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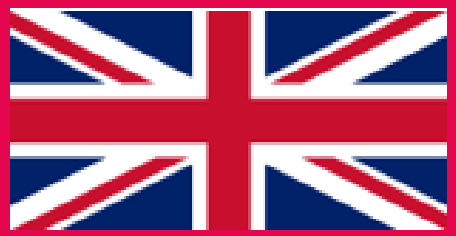
UK Updates



UK updates – in summary

- **CE recognition remains central:** MHRA consultation on indefinite CE recognition has closed. ABHI position supports long-term, all-class CE acceptance. Members should avoid premature changes to GB regulatory stra
- **Registration and fees now bedded in:** MHRA updates reduce friction for routine changes, reinforce portfolio-base fees, encourage GMDN rationalisation, and clarify divergence between GB and Northern Ireland routes from May 2026.
- **More predictable GB clinical investigations:** Clearer MHRA guidance confirms fixed 60-day GB assessments with no clock-stop, increasing the importance of high-quality submissions first time.
- **NI continues to follow EU MDR and IVDR:** Sponsors operating across GB and NI must plan for different procedures and timelines, particularly for clinical investigations and IVD studies.
- **Digital and AI regulation is incremental, not disruptive:** Continued MHRA investment in AI Airlock and increased focus on evidence quality, particularly for digital mental health technologies. No immediate new requirements.
- **Reliance is moving into implementation:** International focus is shifting to post-market surveillance, change management, inspections, and regulatory data reuse, with gradual adoption expected.
- **Horizontal legislation is accumulating:** Sustainability, packaging, chemicals and AI workplace rules increasingly intersect with device and IVD compliance.
- **High volume of standards activity:** New and draft standards across software, AI, IVDs and active devices will shape future regulatory expectations. Members should monitor relevance to their portfolios.

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UPDATES FROM MHRA - general

Webpage	UPDATE	RELEVANCE
Register medical devices to place on the market	Various fees updates including • changes that will no longer be charged • Northern Ireland fees • New video tutorials • Use of GMDN terminology	Reduced friction and cost for routine administrative updates Annual, portfolio-based fee model now fully embedded Stronger incentive to review and rationalise GMDN category use Clear divergence between GB and NI registration routes from May 2026
Regulating medical devices in the UK (see also Regulation of medical devices in **Northern Ireland**)	Revised guidance on Northern Ireland. Reduced or removed sections (UKNI and NI protocol). Simplified registration guidance.	No changes to policy – but some background detail has been removed.
UK **Clinical Research Delivery** key performance indicators: methodology	This webpage sets out the methodology used by DHSC to measure national performance in UK clinical research delivery that can include medical device and IVD studies. It focuses on how these indicators are defined, collected and quality-assured rather than on making policy or regulatory changes, and applies across commercial clinical research conducted in the UK.	UK government benchmarks and public reporting on UK clinical research performance, which feeds into the wider narrative on UK attractiveness for device and diagnostics development and supply.
Medical devices regulations: targeted consultation on the indefinite **recognition of CE** marked devices	MHRA is inviting members of the public to provide their views on proposals for the approach to recognising CE marked medical devices in Great Britain.	The consultation closed on 10th April. ABHI submitted a response on behalf of the healthtech industry in the UK. Please get in touch if you'd like a copy of our response.
Strength of Evidence to Support Decision-Making on the Use of **Digital Mental Health Technologies** in NICE Evaluations: Cross-Sectional Analysis of Studies	MHRA DMHT team article for JMIR Mental Health "Digital mental health technologies (DMHTs) are playing an increasing role in mental health services. The quality of evidence for DMHTs is variable, and there are concerns that evidence is not sufficient to support decision-making."	MHRA have identified that evidence gaps need to be addressed to provide a stronger case for adoption of Digital Mental Health Technologies.

UPDATES FROM MHRA - general

Webpage	UPDATE	RELEVANCE
AI Airlock: the regulatory sandbox for AIaMD	The second phase of the airlock is due to complete in Spring 2026 and reports due in Summer 2026. Multi-year funding will enable the AI Airlock programme to support longer-term testing models for regulatory pathway for future AI medical technologies.	For members developing AIaMD this signals sustained MHRA support for sandbox testing and evolving regulatory pathways, with outputs that may shape future UK requirements and expectations.
UK and US deepen regulatory cooperation on medical devices	The Medicines and Healthcare products Regulatory Agency and the US Food and Drug Administration are strengthening cooperation on medical device regulation, to support faster access to safe, innovative technologies for patients in both countries.	a signal of future engagement rather than an immediate new route to market
MHRA **governance**	The next MHRA Board Meeting held in public will be conducted virtually by webinar on Tuesday, 7 July 2026 from 10:00AM until 12.30PM (GMT).	The public MHRA Board meeting provides members with transparency on MHRA priorities, resourcing and strategic direction that may affect regulatory policy and delivery.
Guest blog – Prof Dr Chua (Singapore HSA) Shaping the Future of Healthcare Through Global **Regulatory Innovation** blog post	Emerging technologies like AI and advanced therapies are transforming healthcare, and through international collaboration with partners such as Singapore's HSA, the MHRA is accelerating patient access to innovative treatments and medicines.	Reinforces MHRA's commitment to international collaboration and regulatory innovation, aligning with member interests in global convergence and reliance.
Medical devices: get **regulatory advice** from the MHRA	How to apply for a regulatory advice meeting on medical devices and in vitro diagnostic devices.	Relevant for members seeking early regulatory clarity, as it sets out how to access MHRA advice to de-risk product development and market access for devices and IVDs.

UPDATES FROM MHRA – clinical studies

SUBJECT	UPDATE	RELEVANCE
The MHRA approval process for **clinical investigations**		
Submitting a clinical investigation proposal for MHRA assessment	The guidance clarifies validation criteria, statutory timelines and documentation expectations for submissions, including use of IRAS and what constitutes a valid application before the review clock starts.	This is directly relevant to sponsors as incomplete or low-quality submissions will delay review start dates and increase the risk of objections.
Clinical investigations in Great Britain	The guidance re-states that clinical investigations in Great Britain are regulated under the UK Medical Devices Regulations 2002, with a fixed 60-day MHRA assessment period that does not stop for requests for further information	This provides greater predictability for planning GB-only investigations but places more emphasis on getting submissions right first time.
Clinical investigations in Northern Ireland	The guidance confirms that investigations in Northern Ireland continue to follow EU MDR and IVDR requirements, with different timelines and clock-stop rules where additional information is requested.	Members operating in or across Northern Ireland need to factor in EU-aligned procedural requirements and timelines alongside GB processes
Clinical investigations for electrically powered devices	The guidance consolidates requirements relating to electrical safety, risk management and supporting technical evidence for electrically powered investigational devices.	This is particularly relevant to manufacturers of active devices, as gaps in electrical safety evidence are a common cause of MHRA questions.
Clinical investigations: investigators' responsibilities	The guidance reinforces investigator obligations around conduct of the investigation, safety reporting and compliance with the approved clinical investigation plan.	Sponsors should ensure investigator agreements and training are aligned with these expectations to avoid non-compliance during inspections.
Clinical investigations: statistical considerations	This is relevant for manufacturers seeking efficient evidence generation, as weak statistical justification may undermine acceptability of clinical data.	The guidance clarifies expectations for statistical design and justification, including alignment between endpoints, sample size and the study objective.
Medical devices that need a clinical investigation	The guidance consolidates criteria for when a device requires a clinical investigation, particularly for higher-risk, novel or non-equivalent devices.	This helps members assess evidence strategy early and reduces uncertainty when planning conformity assessment routes.
Determining if a clinical investigations is required	The guidance brings together decision factors for assessing whether existing clinical data are sufficient or whether a new investigation is needed.	This supports early regulatory decision-making and may help sponsors avoid unnecessary studies where robust clinical data already exist
Clinical trials that include an in vitro diagnostic device (Updated March 2026)	The guidance updates how clinical trials involving IVDs should be assessed, including interaction with IVDR requirements where applicable.	This is particularly relevant for members running combined drug-device or diagnostic-led studies, where regulatory pathways can be easily misaligned.

SPOTLIGHT SESSION - MHRA Adoption of EU MIR 7.3.1

Key Takeaway: MHRA will implement the updated EU MIR 7.3.1 (SB 11010) on 29 April 2026, ahead of the EU mandatory date, for Northern Ireland incident reporting. Manufacturers using XML or API reporting via MORE must ensure systems are updated in time, as earlier versions will no longer be compatible. GB reporting remains unchanged. Early technical readiness is important to avoid disruption to mandatory vigilance reporting.

MHRA has shared the following message for ABHI members:

The MHRA will be implementing the latest changes to the EU MIR 7.3.1 (SB 11010) on Wednesday 29 April ahead of the mandatory date for use in the EU of Friday 1 May. The decision to implement the new version before the mandatory date was made to reduce the risk of deploying on a Friday of a bank holiday weekend in the UK and to ensure we can provide support, if needed.

After the 29 April implementation, the earlier EU MIR 7.3.1 version originally scheduled by the EC for release in November 2025, and supported by MORE since 3 November 2025, will no longer be compatible with MHRA systems.

The updates will be available in the MORE test environment on 15 April. Anyone that does not have access to this environment but wishes to do so can contact AIC@mhra.gov.uk

The reporting form in MORE will be updated to match the updated schema on 29 April. Reporters who utilise this feature will be unaffected and can continue to report as normal. Reporters who utilise 'post xml' or an API should switch to the latest update of EU MIR 7.3.1 (SB 11010) from this date. If reporters are unable to switch before 1 May but need to report to meet regulatory timelines, please use the MORE web reporting form.

Please note that EU MIR 7.3.1 should only be used for reporting incidents in respect to Northern Ireland. GB reports should continue to be reported on GB MIR 7.2.1 which has no changes.

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UK key updates

UKCA and CE product marking

- UK government overview of current product marking approaches
- Context for UK and EU market access, alignment and recognition discussions

ABHI regulatory member groups

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

Upcoming regulatory group member meetings

(meeting packs and minutes from past meetings are available to members)

- 25th June (**Confirmed** MD&IVD Regulatory combined in-person in Manchester

Kindly hosted by Caroline Alexander, (Genedrive)

- 15th September (MD Regulatory)
- 24th September (IVD Regulatory)

- 1st December (MD Regulatory)
- 3rd December (IVD Regulatory)

ABHI Regulatory Groups

IVD Regulatory

Co Chairs:

- Sue Spencer (Compliance Connextions)
- Megha Iyer (ThermoFisher Scientific)

Vice Chair:

- Erin Wigglesworth, (Cepheid)

Medical Device Regulatory

Chair:

- Cait Gatt, (Boston Scientific)

Vice Chairs:

- Clare Huntington, (Pennine Healthcare)
- Roland Back, (Abbott)
- Darren Thain, (Smith & Nephew)

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ABHI Regulatory Event Highlights | Q1 2026

MHRA SME Roundtable (25 February)	•An ABHI-convened roundtable with MHRA focused on practical regulatory challenges faced by SMEs and where more structured dialogue could add value. Discussion explored priority problem areas, optimal timing across the product lifecycle, and which stakeholders need to be involved.
ABHI x Veeva Digitalisation Event (4 March)	•An in-person executive roundtable examined the digitalisation of regulatory submissions for medical devices and IVDs, including electronic submissions and emerging global approaches. The session focused on how more structured, system-readable submissions could support alignment and reliance across regulatory systems.
Medical Devices Regulatory Group Meeting (10 March)	•The MD Regulatory Group met to discuss current UK regulatory developments, including ABHI's emerging position on MHRA CE mark recognition. Member feedback was used to refine draft policy positions ahead of wider consultation engagement.
Chairs and Vice-Chairs Meeting (19 March)	•ABHI Chairs and Vice-Chairs met with the ABHI Board to discuss cross-cutting regulatory priorities and coordination across member groups. The session supported strategic alignment and information exchange across the association's governance structure.
IVD Regulatory Group Meeting (26 March)	•A member webinar and panel Q&A focused on recent UK and EU regulatory developments affecting IVDs and diagnostics. The meeting provided an opportunity for members to raise practical questions and share perspectives ahead of ongoing policy discussions.
MHRA CE Recognition Member Briefing (30 March)	•A member briefing set out the scope and key issues in the MHRA consultation on CE mark recognition. The session focused on policy intent, potential impacts on industry, and how members could engage through ABHI's consultation response.
ABHI x FPM Companion Diagnostics (15th April)	•A joint ABHI–Faculty of Pharmaceutical Medicine webinar examining how companion diagnostics are moving from single test–drug pairings to platform-based, data-driven enablers of precision medicine and the resulting implications for NHS commissioning, regulation and infrastructure.
ABHI presentation to IBMS quality managers (16 April)	•ABHI presented on IVDR and the UK regulatory approach. Laboratory members raised practical concerns around post-market surveillance, data sharing constraints and fragmented reporting routes, alongside significant gaps in regulatory training for laboratory managers.

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Future events planning: Q2 and beyond

RAPS EuroConvergence	• Lisbon Congress Centre • 5-8th May
Fundamentals of Clinical Trials	Nottingham Clinical Trials Unit 11th - 15th May 2026
Workshop: Medical Device Software Development	• Firefinch Software Leeds • 16th June
MedTech Summit	JW Marriott Hotel Berlin, Berlin, Germany, In-Person or Digital 15 - 18 June 2026
ABHI & Q BIOMED Webinar: Quantum Sensing in Healthcare	• Online event • Thursday, June 25 • 12 PM - 1 PM *(clash with our in person member group!)*
ABHI Member Briefing	• Online event • Friday 3 July • 10 – 12
ABHI Annual Parliamentary Reception 2026	• Terrace Pavilion, House of CommonsLondon • Monday, July 6 • 6:30 PM - 8:30 PM
ABHI Digital Health Conference 2026	• Covington & Burling LLPLondon, England Wednesday 16 September • 9:30 - 18:30
UKHSA Conference 2026	Manchester Central 22-23 September
ABHI Sustainability Conference 2026	• Conference Centre at Coin StreetLondon, England • Wednesday 30 September • 9:30 - 16:30
2026 TOPRA Symposium	• Utrecht, the Netherlands 19 to 21 October
ABHI UK HealthTech Conference	• Save The Date! • 9 - 10 November 2026

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UPDATES FROM ABHI

Webpage	UPDATE
Women in Clinical Trials: Why Representation Matters	Despite women making up over half of the population, women have historically been underrepresented in clinical trials, creating gaps in understanding how conditions present, progress and respond to treatment. ABHI's Clinical Advisor, Dr Nina Wilson sits down with Roberta (Bobbi) Chapman, MD, FACC, FACP, FHFSA, Vice President, Heart Failure, J&J MedTech, to discuss the importance of recruiting an appropriate number of women into clinical trials and research.
Better Representation, Better Outcomes. **Women in Clinical Trials**	
ABHI's **Quarterly Communications Report:** Q1 2026	In our latest update, we showcase a strong start to 2026, marked by progress on key regulatory issues, including support for indefinite CE marking recognition, and continued advocacy to improve the UK's competitiveness.
Pulse of the Sector 2025	Survey findings show cautious optimism about the UK's long-term potential, supported by continued confidence in research strengths and the direction of regulatory reform. Companies also highlight areas where delivery can be supported further, including adoption pathways, procurement approaches and the practical implementation of sustainability requirements.

What did you ask?

You asked...	ABHI answered ...
Will GB recognise CE-marked MDR and IVDR devices long term?	Members should continue to work on the basis that CE-marked MDR and IVDR devices are acceptable for the GB market and avoid making premature changes to regulatory strategy. ABHI's view is that Great Britain should recognise CE-marked MDR and IVDR devices on an indefinite basis and for all classes. Conditions linked to classification are not seen as a proportionate way to manage risk, which is better addressed through post-market surveillance, vigilance, and enforcement. Alignment with EU transition provisions remains important to avoid supply disruption and market fragmentation.
When will UK regulatory reform actually take effect?	Members should monitor developments closely but avoid assuming firm timelines until legislation and guidance are confirmed. We are in direct discussion with MHRA leadership and consistently calling for early and unambiguous clarity on the timing, scope, and transitional arrangements for UK regulatory reform. While reform is supported where it improves the system, it must be sequenced and communicated in a way that increases predictability and avoids duplication, as predictability underpins investment and long-term planning.
How different are GB post-market surveillance requirements from the EU?	GB post-market surveillance is generally familiar to existing EU MDR and IVDR processes, with some GB-specific adaptations. From ABHI members' perspective, the GB PMS framework remains largely aligned with the EU. Taken together, registration, PMS, and vigilance requirements already provide MHRA with lifecycle oversight, and ABHI continues to ask for greater transparency on how associated fees translate into regulatory value.
What evidence will MHRA expect under UK reform?	Members should continue to prepare evidence strategies that are risk-based and aligned with MDR and IVDR expectations. Currently, we do not assume fundamentally new GB requirements. ABHI's position is that UK evidence expectations should remain proportionate and aligned wherever possible. Greater use of lifecycle evidence and real-world data should reduce unnecessary duplication, and GB-specific evidence requirements would not be supported without a clear patient safety justification.

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What did you ask?

You asked ...	ABHI answered ...
How will EU MDR and IVDR revisions affect the UK?	We're still working on this. For now, members supplying the GB market should follow updates to EU MDR and IVDR revisions closely, as these changes are likely to remain relevant through CE recognition. In ABHI's view, CE recognition and EU regulatory reform cannot be separated when considering GB market access. Moves toward greater proportionality, digitalisation and simplification are broadly welcomed, and ABHI supports a managed model that maintains patient safety while preserving market access.
What does the UK–US regulatory cooperation announcement mean in practice?	Members should treat the UK–US announcement as a signal of future engagement rather than an immediate new route to market and should avoid changing regulatory plans on this basis alone. ABHI sees the announcement primarily as a strategic signal of intent, with practical impact dependent on clear scope, operational detail and timelines. UK–US cooperation is supported especially where it complements EU recognition.
Will regulators accept digital and structured regulatory submissions?	Members anticipate a gradual shift toward more digital and structured regulatory interactions under CE MDR/IVDR revision. ABHI believes digitalisation of conformity assessment and technical documentation is both necessary and overdue. Internationally aligned approaches, including IMDRF dossier structures, offer a practical way to reduce duplication, provided digitalisation focuses on system efficiency rather than GB-specific platforms.
How do new horizontal rules apply to devices and IVDs?	Members should expect horizontal legislation to affect devices and IVDs and plan for cross-cutting compliance, while looking for opportunities to reuse data and documentation. ABHI's position is that such rules should be applied coherently across HealthTech, with clear guidance on interaction with device and IVD regulation, and with maximum reuse of evidence, PMS data, and technical documentation across regimes.

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MEMBERS 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**

NEW ***RAPS publications and online products*** – 10% **discount**

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

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UPDATE ON BRITISH STANDARDS PROJECTS – Published Standards

Call for experts: Projects of AI in Healthcare
ISO/IEC PWI 26313 Information technology — Artificial intelligence — Classification and use cases of generative AI in healthcare
ISO/IEC PWI 26319 Information technology — Artificial intelligence — Evaluation framework for safety and reliability of generative AI in healthcare
ISO/IEC AWI 22989-2 Artificial intelligence — Concepts and terminology — Part 2: Healthcare
ISO/IEC AWI TS 26312 Information technology — Artificial intelligence — Identification and treatment of bias in AI by healthcare organizations
ISO/IEC CD TR 18988 Artificial intelligence — Application of AI technologies in health informatics
These projects are under development in ART/1, the horizontal committee of Artificial Intelligence. *If you are interested in contributing as an expert, or wish to receive more information, please contact Gavin Jones* gavin.jones@bsigroup.com

Closing Date	Description	Committee
28/02/2026	BS EN IEC 62083:2026 Medical device software — Requirements for the safety of radiotherapy treatment planning systems	CH/62/3 - Equipment for radiotherapy, nuclear medicine and radiation dosimetry
31/03/2026	PD IEC PAS 63621:2026 Artificial intelligence enabled medical devices - Data management	CH/62 - Medical equipment, software, and systems
31/03/2026	PD ISO/TR 4234:2026 Non-active surgical implants — Implant coating — Best practices for coating system assessment	CH/150 - Implants for surgery
31/03/2026	BS EN ISO 11979-1:2026 Ophthalmic implants. Intraocular lenses. Vocabulary	CH/172/7 - Eye implants
31/03/2026	BS EN ISO 18777-1:2026 Transportable liquid oxygen systems for medical use. Common requirements and particular requirements for base units	CH/121/6 - Medical gas supply systems
31/03/2026	BS EN ISO 11979-4:2026 Ophthalmic implants — Intraocular lenses. Labelling and information	CH/172/7 - Eye implants

UPDATE ON BRITISH STANDARDS PROJECTS – Public drafts

Closing Date	Description	Committee
04/04/2026	BS EN ISO 3826-2 Plastics collapsible containers for human blood and blood components — Part 2: Graphical symbols for use on labels and instruction leaflets	CH/212 - IVDs
04/04/2026	BS EN ISO 3826-3 Plastics collapsible containers for human blood and blood components — Part 3: Blood bag systems with integrated features	CH/212 - IVDs
04/04/2026	BS EN ISO 3826-4 Plastics collapsible containers for human blood and blood components — Part 4: Aphaeresis blood bag systems with integrated features	CH/212 - IVDs
06/04/2026	BS ISO 11040-5 Prefilled syringes — Part 5: Plunger stoppers for injectables	CH/212 - IVDs
07/04/2026	BS ISO 23399 Determination of antibacterial activity and efficacy of water-absorbent polyacrylate for urine absorbing products	CH/173 - Assistive products for persons with disability
08/04/2026	BS ISO 13404-1 Prosthetics and orthotics. External orthoses and orthotic components. Part 1: Uses, functions, classification and description of lower limb orthoses	CH/168 - Prosthetics and orthotics
08/04/2026	BS ISO 6474-1 Implants for surgery — Ceramic materials — Part 1: Ceramic materials based on high purity alumina	CH/150/1 - Materials for surgical implants
11/04/2026	BS ISO 25096 Cryogenic pipeline systems with automatic nitrogen supply and distribution systems. Design, installation, and testing	CH/121/6 - Medical gas supply systems
12/04/2026	BS EN ISO 3843 Dentistry. Dental attachments. Measurement of placement and removal forces	CH/106/2 - Prosthodontic materials
12/04/2026	BS EN ISO 10555-5 Intravascular catheters. Sterile and single-use catheters. Part 5: Over-needle peripheral intravenous catheters	CH/84 - Catheters and syringes
12/04/2026	BS EN ISO 10555-3 Intravascular catheters. Sterile and single-use catheters. Part 3: Central venous catheters	CH/84 - Catheters and syringes
15/04/2026	BS EN IEC 60601-2-92 ED.1 Medical electrical equipment. for use with electron accelerators for use with electron accelerators	CH/62/3 - Equipment for radiotherapy, nuclear medicine and radiation dosimetry
18/04/2026	BS EN ISO 3630-1 Dentistry. Endodontic instruments. Part 1: General requirements	CH/106 - Dentistry
22/04/2026	BS ISO 24645 General requirements for Luer activated needle-free connectors (LANCs) for intravascular applications	CH/212 - IVDs

UPDATE ON BRITISH STANDARDS PROJECTS – Public drafts

Closing Date	Description	Committee
26/04/2026	BS EN ISO 8836 Anaesthetic and respiratory equipment. Suction catheters for use in the respiratory tract	CH/121/5 - Airways and related equipment
29/04/2026	BS EN ISO 11737-1 Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	CH/198 - Sterilization and Associated Equipment and Processes
09/05/2026	BS EN ISO 7260 Dentistry. Protective filtering devices intended for use with powered polymerization activators	CH/106 - Dentistry
11/05/2026	BS EN ISO 3823 Dentistry. Rotary instruments. Steel and carbide dental burs	CH/106 - Dentistry
12/05/2026	BS EN 13704 Chemical disinfectants. Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. Test method and requirements (phase 2, step 1)	CH/216 - Chemical disinfectants and antiseptics
13/05/2026	BS ISO 24051-1 ISO 24051-1 Medical laboratories. Part 1: General principles for the application of artificial intelligence in medical laboratories	CH/212 - IVDs
18/05/2026	BS EN ISO 29022 Dentistry. Adhesion. Notched-edge shear bond strength test	CH/106/1 - Dental restorative and orthodontic materials
26/04/2026	BS EN ISO 8836 Anaesthetic and respiratory equipment. Suction catheters for use in the respiratory tract	CH/121/5 - Airways and related equipment
29/04/2026	BS EN ISO 11737-1 Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	CH/198 - Sterilization and Associated Equipment and Processes
09/05/2026	BS EN ISO 7260 Dentistry. Protective filtering devices intended for use with powered polymerization activators	CH/106 - Dentistry
11/05/2026	BS EN ISO 3823 Dentistry. Rotary instruments. Steel and carbide dental burs	CH/106 - Dentistry
12/05/2026	BS EN 13704 Chemical disinfectants. Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. Test method and requirements (phase 2, step 1)	CH/216 - Chemical disinfectants and antiseptics
13/05/2026	BS ISO 24051-1 ISO 24051-1 Medical laboratories. Part 1: General principles for the application of artificial intelligence in medical laboratories	CH/212 - IVDs
18/05/2026	BS EN ISO 29022 Dentistry. Adhesion. Notched-edge shear bond strength test	CH/106/1 - Dental restorative and orthodontic materials

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EU News

UPDATES FROM THE EU

UPDATE
EUDAMED becomes mandatory from 28 May 2026 MedTech Europe is supporting organisational readiness through onboarding webinars.
The **European Health Data Space Regulation** entered into force on **26 March 2025**, establishing a phased framework to strengthen citizens' rights over electronic health data and to enable cross-border primary use and regulated secondary use of health data, with key obligations applying from 2027 onwards.
The European Commission has published an **updated MIR form version 7.3.1** with technical corrections, which becomes mandatory for vigilance reporting from 1 May 2026
The Commission has adopted a delegated regulation expanding the list of class IIb implantable medical devices considered **well-established technologies**, allowing notified bodies to assess technical documentation on a sampling basis rather than for every individual device
The **HTA Coordination Group has published its 2025 Annual Report**, outlining the first year of implementation of the EU HTA Regulation and confirming preparatory work to start joint clinical assessments for medical devices and IVDs in 2026
Team-NB has issued a position paper setting out harmonised notified body expectations on how manufacturers should demonstrate safety and performance when **IVD reagent devices are intended to be used in combination with other devices or equipment under the IVDR**.
Team-NB has published a position paper on the **proposed targeted MDR and IVDR revisions**, supporting measures that improve efficiency and digitalisation while cautioning against reforms that could reduce regulatory scrutiny and patient safety

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US NEWS

UPDATES FROM THE US

UPDATE
The **FDA's Quality Management System Regulation**, which replaces most of the existing QSR and incorporates ISO 13485:2016 by reference, became effective on 2 February 2026 and is now being used for FDA inspections.
In January 2026, FDA finalised updated guidance clarifying when **clinical decision support software** **and** **low-risk general wellness** products fall outside the medical device definition, with a stronger emphasis on transparency, intended use and user independence.
FDA published final **updated cybersecurity guidance** in February 2026 aligning premarket and quality system expectations with the new QMSR and Section 524B requirements, superseding earlier versions
In February 2026, FDA issued final guidance **on computer software assurance**, confirming a risk-based, least-burdensome approach for software used in production and quality systems in support of compliance with 21 CFR Part 820
In March 2026, FDA finalised updated guidance expanding how **voluntary patient preference information** may be collected and used across the total product life cycle, replacing the 2016 guidance and reflecting an MDUFA V commitment.
On 25 March 2026, FDA issued a final order reclassifying **optical melanoma detection devices and electrical impedance spectrometers** from class III to class II with special controls, renaming them as software-aided adjunctive diagnostic devices, effective from 24 April 2026.
In March 2026, FDA proposed classifying **blood irradiators** intended to prevent transfusion-associated graft-versus-host disease as class II devices subject to special controls, while proposing class III classification for devices intended to prevent metastasis.
In March 2026, FDA issued final guidance setting out its current expectations for non-clinical testing, clinical study design and benefit-risk assessment to support premarket submissions for **medical devices with weight-loss-related indications**.

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INTERNATIONAL NEWS

INTERNATIONAL REGULATORS

IMDRF and MDSAP
IMDRF published the final guidance IMDRF/AET WG/N86 on 26 February 2026, setting out global principles for the consistent selection and use of IMDRF **adverse event terminologies** to support harmonised vigilance and post-market reporting across jurisdictions
IMDRF published GRRP WG/N89, providing a practical playbook for regulators on designing and implementing medical device **regulatory reliance** programmes, including governance models, maturity assessment and risk management considerations.
IMDRF published draft guidance setting out common definitions and high-level principles for **clinical evidence and performance evaluation for IVDs**, aiming to support greater global consistency in evidence expectations across regulatory systems.
The MDSAP audit approach document AU P0002.010 continues to define how conformity assessment audits are structured and conducted under MDSAP, supporting **consistent application of ISO 13485-based audits** across participating jurisdictions.
The **MDSAP audit report template** (AU F0019.1.009) specifies the standardised format for documenting audit findings, non-conformities and regulatory conclusions, enabling streamlined information sharing between MDSAP regulators.

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SPOTLIGHT SESSION - Towards Operational Reliance

Key Takeaway: In future, we can expect more incremental, pilot-based adoption of reliance and increasing expectations around PMS and transparency to realise efficiencies.

The International Medical Device Regulators Forum (IMDRF) met in Singapore in March 2026 for its 29th Management Committee meeting, Industry Joint Workshop and Stakeholder Forum. Across sessions, the emphasis was clear: regulatory reliance is moving from concept to implementation. Discussion focused on how reliance can be applied in a credible, legally robust and operationally workable manner. This has direct relevance for manufacturers of medical devices, IVDs and digital health technologies supplying the UK, EU and global markets.

A key reference point was the IMDRF Reliance Playbook, published in February 2026. The Playbook is positioned as a practical, non-prescriptive framework that distinguishes reliance from convergence or harmonisation and reaffirms that regulators retain full sovereignty and accountability for decisions. Three reliance approaches were repeatedly referenced: work sharing, abridged review and recognition.

From an industry perspective, reliance was framed as a mechanism to reduce duplicative regulatory activity, improve predictability and mitigate risks to continuity of supply. Regulators highlighted that the most significant efficiency gains may sit beyond initial market entry. Post market change management, vigilance, inspections and quality management system oversight were consistently identified as priority areas for expanded reliance activity.

Trust and legal underpinning were central themes. Regulators stressed that effective reliance depends on clear legal authority, transparency and access to high quality regulatory outputs from reference authorities. Reliance does not remove regulatory judgement but shifts how it is exercised. Several authorities described phased approaches, beginning with limited pilot initiatives and expanding scope as confidence and experience develop.

Post market surveillance and change management featured prominently. Divergent interpretations of significant versus non-significant change were identified as a major friction point for global manufacturers. Regulators shared risk-based frameworks intended to support reliance on prior approvals where appropriate. The Medical Device Single Audit Program was cited as an established reliance mechanism, particularly where regulators have access to full audit reports rather than certificates alone. IMDRF also reinforced the enabling role of international standards and digitalisation. ISO and IEC standards were described as a shared technical foundation, while locally specific standards were seen as barriers to reliance. Regulators acknowledged the need to move beyond digitised documents towards more structured and reusable regulatory data to support scalable reliance models.

For ABHI members, the direction of travel is clear. Regulatory reliance is now embedded in international strategy, with implementation a clear priority. Manufacturers should anticipate greater focus on post market systems, change management and regulatory data transparency, alongside further IMDRF consultations during 2026.

INTERNATIONAL REGULATORS

Authority	Update
Argentina (ANMAT)	Provision 236/2026 Regulates Decree No. 892/25 and defines a system of notification, accreditation of regulatory equivalence and post-marketing control for **products of foreign origin**
Australia (TGA)	Understanding how we regulate **software-based medical devices**
Australia (TGA)	Complying with the **Unique Device Identification** requirements for medical devices (Updated Feb 2026)
Bhutan (MOH)	Public Consultation on "Guideline for Post-market and market surveillance of medical device: **Management of adverse events**"
Brazil (ANVISA)	Anvisa **Normative Instruction** No. 426, of 02/13/2026
Chile (ISP)	Resolution no. E1243 approves "guide for the evaluation of the **transport of medical devices and in vitro medical devices with cold chain**," prepared by the national medical devices agency department
China (NMPA)	Announcement of the State Food and Drug Administration, the National Health Commission, and the National Health Insurance Administration on the Implementation of **Unique Identification of Medical Devices** for Subsequent Varieties (No. 21 of 2026)
China (NMPA)	Announcement of the State Food and Drug Administration on Matters Concerning the Implementation of **Unique Identification of Medical Devices** in Specific Situations (No. 15 of 2026)
Hong Kong (MDD)	[TR-007] **Software Medical Devices and Cybersecurity** (Updated Feb 2026)
Hong Kong (MDD)	[TR-008] **Artificial Intelligence Medical Devices** (AI-MD) (Updated Feb 2026)
India (CDSCO)	Guidance for **Import of In-Vitro Diagnostic Medical Device** For submission of Import licence applications to online portal
India (CDSCO)	CDSCO/IVD/FAQ/04/2022 **In-Vitro Diagnostic (IVD) Medical Devices Division Frequently Asked Questions**

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INTERNATIONAL REGULATORS

Authority	Update
Malaysia (MDA)	MDA/GD/0006 **Definition of Medical Device** v2
Malaysia (MDA)	MDA/GD/0071 Application for confirmation status of **obsolete and discontinued medical device**
Malaysia (MDA)	MDA/GD/0043 Import and/or supply of unregistered medical devices under **special access exemption** application v3
Nigeria (NAFDAC)	NAFDAC **Medical Devices, including In-vitro Diagnostics and Related Products Regulations**, 2026
Pakistan (DRA)	No. F.13-1/2025-LA **Draft Therapeutic Goods (Import and Export) Rules** 2026 (For Comments)
Singapore (HSA)	GN-15-R13 Guidance on **Medical Device Product Registration** rev 13
South Africa (SAHPRA)	SAHPGL-MD-21 Guideline for **Medical Device Certificate of Free Sale**
South Korea (MFDS)	**Medical Device Good Manufacturing Practice (GMP)** Regulations
South Korea (MFDS)	Instructions-1081-02 Guidelines for **Handling Foreign Matter Mixture in Medical Devices**
Switzerland (Swissmedic)	BW600_00_016e_MB **Performance studies with IVD** v5.2
Thailand (FDA (MoPH))	Hearing comments on the principles of raising (draft) the Notification of the Ministry of Public Health on **Standards of Medical Devices Required by Manufacturers or Importers**, B.E
Thailand (FDA (MoPH))	Hearing comments on the principles of the Ministry of Public Health's Announcement on Criteria Methods and conditions for importing medical devices exempted under Section 100 of the Regulation on **Import of Medical Devices Exempted under Section 100** of the T 27 (8) of the Medical Devices Act, B.E. 2551 (No. .), B.E

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Resource Library

UK Resources

Legislation

- Legislation.gov.uk – https://www.legislation.gov.uk
- The Medical Devices Regulations 2002 - https://www.legislation.gov.uk/uksi/2002/618/contents
- UK Government Web Archive -https://www.nationalarchives.gov.uk/webarchive/
- UK Approved Bodies – https://www.gov.uk/government/publications/uk-approved-bodies-for-medical-devices
- UKCA designated standards – https://www.gov.uk/government/publications/ukca-designated-standards
- MHRA PARD - https://pard.mhra.gov.uk/
- Information Commissioner's Office – https://ico.org.uk

Guidance

- MHRA – https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency MHRA medical devices guidance – https://www.gov.uk/government/collections/medical-devices-guidance
- Software and AI as a Medical Device – https://www.gov.uk/government/collections/software-and-ai-as-a-medical-device-guidance
- MHRA device registration (DORS) – https://www.gov.uk/guidance/register-a-medical-device-with-the-mhra
- MHRA Drug and Device Alerts – https://www.gov.uk/drug-device-alerts

Standards

- British Standards - https://knowledge.bsigroup.com

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EU resources

Legislation

•EUR-Lex – https://eur-lex.europa.eu
•Official Journal of the European Union (EUR-Lex) - https://eur-lex.europa.eu/oj/direct-access.html
•NANDO database – https://ec.europa.eu/growth/tools-databases/nando
•EUDAMED – https://health.ec.europa.eu/medical-devices-eudamed_en

Guidance

•European Commission medical devices sector – https://health.ec.europa.eu/medical-devices-sector_en
•Medical Devices - Topics of Interest - https://health.ec.europa.eu/medical-devices-topics-interest_en
•Medical Device Coordination Group (MDCG) – https://health.ec.europa.eu/medical-devices-sector/medical-device-coordination-group-mdcg_en
•Medical Devices - Dialogue between interested parties - Latest updates - https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/latest-updates_en
•Medical Devices - Clinical investigations and performance studies - https://health.ec.europa.eu/medical-devices-clinical-investigations-and-performance-studies_en
•CAMD – https://www.camd-europe.eu
•EMA - https://www.ema.europa.eu/en/homepage
•Horizon Europe - https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en
•GOG dashboard - https://app.powerbi.com/view?r=eyJrIjoiNDVmMWY0YTgtNzY1ZS00ZDU5LTlmNTAtZDM4MjBjNjIzYTU5IiwidCI6ImIyNGM4YjA2LTUyMmMtNDZmZS05MDgwLTcwOTI2ZjhkZGRiMSIsImMiOjh9

Standards and specifications

•Harmonised standards (MDR/IVDR) – https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en
•Common Specifications – https://health.ec.europa.eu/medical-devices-vitro-diagnostics/common-specifications_en
•CEN/CENELEC – https://www.cencenelec.eu
•EMDN – https://health.ec.europa.eu/medical-devices-sector/emdn_en

Industry

•MedTech Europe – https://www.medtecheurope.org
•COCIR - https://www.cocir.org/
•Team NB - https://www.team-nb.org/

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International resources

United States

Legislation

•FDA CDRH – https://www.fda.gov/medical-devices
•FDA medical device guidance – https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products
•FDA MAUDE – https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm
•FDA GUDID – https://accessgudid.nlm.nih.gov
•FDA recognised consensus standards – https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
•Federal Register – Daily Journal of the US Govt - https://www.federalregister.gov/

Industry

•AdvaMed – https://www.advamed.org

Australia

Legislation

•TGA medical devices – https://www.tga.gov.au/products/medical-devices
•TGA software-based medical devices – https://www.tga.gov.au/products/medical-devices/software-medical-device

Industry

•MTAA – https://www.mtaa.org.au

Canada

Legislation

•Health Canada medical devices – https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices.html
•Health Canada guidance documents – https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/guidance-documents.html
•Health Canada SaMD guidance – https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/applications-submissions/guidance-documents/software-medical-device.html

Industry

•MedTech Canada – https://www.medtechcanada.org

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International resources

International (RoW)

International policy

•IMDRF – https://www.imdrf.org/documents
•WHO medical device regulation – https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/regulations
•WHO Global Benchmarking Tool – https://www.who.int/teams/regulation-prequalification/regulatory-systems-strengthening
•GMDN Agency - https://www.gmdnagency.org/
•GHWP – https://www.ghwp.org

Standards and specifications

•ISO – https://www.iso.org
•IEC – https://www.iec.ch
•GMDN Agency – https://www.gmdnagency.org
•CLSI – https://clsi.org

Industry

•GMTA - https://www.globalmedicaltechnologyalliance.org/index.html
•DITTA - https://globalditta.org/
•GDA - https://www.globaldiagnosticsalliance.org/
•APEC LSIF RHSC – https://www.apec.org/Groups/SOM-Steering-Committee-on-Economic-and-Technical-Cooperation/Working-Groups/Life-Sciences-Innovation-Forum
•Mecomed - https://www.mecomed.com/
•Swiss MedTech - https://www.swiss-medtech.ch/en

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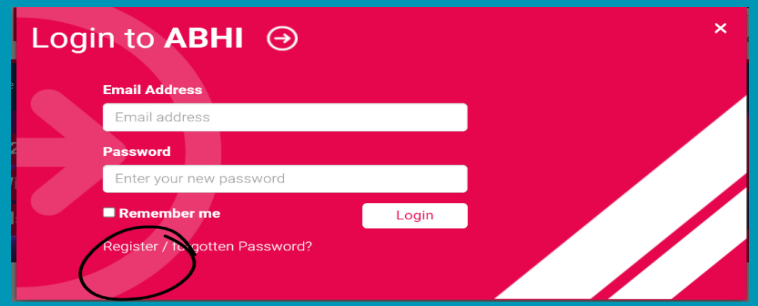
SPOTLIGHT SESSION - MAXIMISING YOUR ABHI MEMBERSHIP

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

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



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

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

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

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