# ABHI REGULATORY ROUND UP

Summer 2025

*A concise 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.*

# ABHI Regulatory Round-Up – Summer 2025



ABHI

5th September 2025

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ABHI

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*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](http://www.MedBoard.com) to learn more about the cloud platform and its regulatory, clinical, and market solutions to stay on top and manage information and data within the MedTech industry.*

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# ABHI Regulatory Round-Up – Summer 2025

## Executive highlights

UK Regulatory Highlights

- CE Mark Recognition: MHRA confirms intent to accept CE-marked devices in GB indefinitely.
- Reliance Pathways: New routes for US, Canada, and Australia approvals progressing.
- PMS Fee Reform: New annual fee from April 2026; simplified model based on GMDN Level 2.
- Electronic Labelling: CE-marked devices accepted with eIFUs; UKCA-marked IVDs should have risk-based justification.
- Health Institution Exemption: MHRA survey open; ABHI encourages member input.
- Digital Health: MHRA updates on SaMD, mental health tech, and AI Airlock pilot closure.

EU Regulatory Highlights

- IVDR Sampling: MedTech Europe proposes risk-based approach.
- eIFU Regulation: Amended to support broader use of electronic instructions.
- UDI Guidance: MDCG updates on Master UDI-DI timelines and implementation.
- Governance: CAMD and Team NB publish positions on future EU regulatory coordination.



International Regulatory Highlights

- WHO Listing: MHRA designated as WHO-Listed Authority (medicines/vaccines).
- Global Engagement in IMDRF, GHWP, and bilateral reliance pilots.
- TGA Visit: MHRA–TGA collaboration focuses on AI and regulatory convergence.
- Singapore–Malaysia MOU: Launch of regulatory reliance pilot for medical devices.

Training & Events

- ABHI HealthTech Conference: 11–12 Nov 2025 (Day 1: UK Market, Day 2: Regulation).
- TOPRA/RAPS UK MDR Conference: 5–6 Nov 2025, London.
- TOPRA Apprenticeships: Final intake before levy changes closes 23 Oct.
- MHRA SoGATS Workshop: 24–26 Sept 2025 – focus on IVD standards and pandemic readiness.

## Spotlight Session - Sharing Regulatory Insights Across the ABHI Community

**Key Takeaway: 📌 Introducing Spotlight Sessions. 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.**

In this edition, we build on the concept of spotlight sessions piloted in the last Round-Up. These are 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.

**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 (mid-September for the October Round-Up) with earlier suggestions welcome.

# ABHI Regulatory Round-Up – Summer 2025

## UK Updates

### ABHI

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)*

IVD Regulatory

- 4th September 2-4pm
- 27th November 2-4pm
- 2026 dates agreed at the 4th September meeting

MD Regulatory

- 9th September 10.30-12.30pm

**ABHI Regulatory Group Leadership**

*IVD Regulatory*

Co Chairs: Sue Spencer (Compliance Connextions) & Megha Iyer (ThermoFisher Scientific)

Vice Chair: Erin Wigglesworth, (Cepheid)

*Medical Device Regulatory*

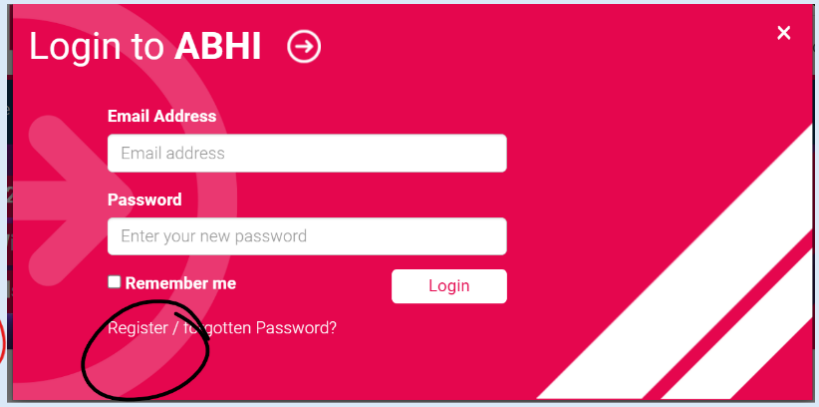
Chair: Cait Gatt, (Boston Scientific)

Vice Chairs: Clare Huntington, (Pennine Healthcare), Roland Back, (Abbott), & Darren Thain, (Smith & Nephew)

## 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.

# ABHI Regulatory Round-Up – Summer 2025

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**

*"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)

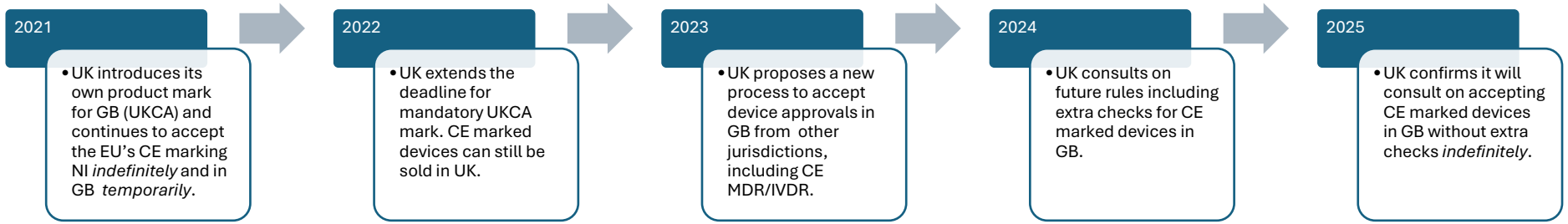
ABHI Strengthens Diagnostics Leadership **with Appointment of Ravi Chana**. Ravi will take up this full-time role on 1st September 2025.

Life Sciences Sector Plan Launched **- Delivery Is Now Key** - ABHI welcomes the Life Sciences Sector Plan, developed with industry input. The Plan prioritises regulatory reform, including reliance on trusted approvals and early access pathways. It acknowledges HealthTech's distinct R&D needs and calls for sustained investment in infrastructure. Adoption of innovation within the NHS remains a key challenge, requiring financial alignment and committed NHS engagement. Delivery must be collaborative, addressing persistent barriers. ABHI and its members will support implementation and alignment with the 10 Year Health Plan.

Prevent the Risks of **Ransomware Attacks on Tech Companies** "Ransomware is no longer a hypothetical risk – it's an urgent reality for tech and medtech businesses."

Andrew Davies, ABHI digital health lead writes "*Now the summer is over, I'd really appreciate completion of the survey to ensure that the **Digital Health Group** remains fit for purpose to support member needs, align with recent government policy announcements and support continued growth of the group. Many have already and the stats show it does indeed only take about 2mins. Thanks for your support*."

**A history of CE recognition** in **five bullet points.**






***Shaping the Future of Lung Diagnostics - Join the TPP Conversation***

ABHI member, LifeArc are working with Asthma + Lung UK to understand what new tests are needed in primary and community care to speed up diagnosis of chronic lung conditions. LifeArc have a developed a TPP (target product profile) – a list of instructions for new test developers to ensure the most needed tests reach the clinic quickest. More information here Simple Lung Test TPP: Developing a patient focused target product profile (TPP) for to accelerate diagnosis of chronic lung conditions - LifeArc.

***Have your say: Mark your diary.*** Have LifeArc accurately described the most needed test? What have they missed? Surveys go live on September 15th on the website above. Please register your interest in completing the survey by emailing critc@lifearc.org with the title 'survey'.

# ABHI Regulatory Round-Up – Summer 2025

## 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

## Spotlight Session – Electronic instructions - dual requirements for CE and UKCA

**Key Takeaway: 📌 MHRA confirms CE-marked devices can use eIFUs in GB and NI if compliant with EU rules. UKCA-marked general medical devices may use e-labelling under Regulation 4J, but UKCA-marked IVDs require a risk-based justification via MEDDEV 2.14/3. Dual-marked devices may face added complexity due to overlapping obligations.**

💾📜 We are preparing a policy paper on **electronic labelling** for MHRA that covers the views of the healthtech industry in the UK. Thank you for all your contributions so far.

In the meantime, in a recent letter from MHRA on electronic labelling, they said to us:

**"For *UKCA marked devices***

*As you correctly mention, the EU electronic IFU Regulation (EU) 2021/2226 does not apply to UKCA marked devices. Manufacturers wishing to apply the UKCA mark to their medical devices must follow the requirements of The Medical Devices Regulations 2002 (MDR 2002).*
*Under Regulation 4J of the MDR 2002, manufacturers of certain types of medical devices and accessories are allowed to provide electronic instructions for use if they wish, provided certain conditions are met. Further guidance on the use of electronic instructions for use for UKCA marked devices under MDR 2002 can be found here - Guidance on the regulations for electronic instructions for use of medical devices - GOV.UK.*

***"For CE-marked devices***

*CE-marked devices will continue to be accepted onto the GB market, until at the latest 30 June 2030, depending on the type of device and which EU legislation it complies with. To place a CE-marked device onto the GB market it must be compliant with the relevant EU regulations. In the EU manufacturers may choose to provide electronic instructions for use, and if so, must comply the relevant EU regulations (e.g. Regulation (EU) 2021/2226 or Regulation (EU) No 207/2012 as per the transition periods set out in Regulation (EU) 2021/2226).*

*"As such, if a CE-marked device is compliant with the relevant EU regulations, including regulation on the use of eIFU, it will continue to be accepted onto the GB market in line with the timelines set out here."*

This has some important implications for ABHI members depending on your regulatory route onto the UK market:

**CE Mark Recognition Route Only (inc NI)**
If your device is placed on the GB or NI market using CE marking under MDR/IVDR, you should continue to follow EU requirements for electronic labelling. MHRA will accept CE-marked devices with electronic IFUs as long as they comply with the relevant EU regulations.

**UKCA GB Domestic Route Only**
If your *general medical device* is UKCA-marked only and not CE-marked under MDR, you must follow *UK MDR 2002 Regulation 4J* requirements

for electronic labelling. Regulation 4J of UK MDR 2002 retains the provisions of relevant EU regulations (now without the original revocation date). The rules for regulation 4J and for EU regulations are broadly the same though the MHRA guidance includes specific conditions for eIFU for UKCA marked *general medical devices*.

Although not mentioned by MHRA in their letter, the scope of EU regulations on electronic instructions does not apply to *IVDs* and therefore nor does Regulation 4J of UK MDR 2002. Furthermore, *IVDs* are specifically excluded from the scope of MHRA's 2013 guidance. Therefore, if your *IVD* is UKCA-marked only and not CE-marked under IVDR, instead of using the MHRA guidance, manufacturers should refer to EU MEDDEV 2.14/3 to support a risk-based justification for eIFU for UKCA marked *IVDs*.

**Dual Marking (UKCA + CE)**

MHRA has not yet clarified its expectations for dual-marked devices. While there may be valid strategic reasons for manufacturers to pursue dual marking, ABHI members should be aware that dual marking may introduce:

- Dual compliance obligations and costs
- Separate operational and documentation pathways
- Increased regulatory and marketing complexity
- Separate post market surveillance obligations

ABHI continues to monitor MHRA's direction of travel, including the planned consultation for ongoing recognition of CE marking beyond 2030.

## News from MHRA

| Subject | Relevance |
|---|---|
| The head of Australia's **Therapeutic Goods Administration** (TGA) visited MHRA. | MHRA and TGA talked about strengthening global regulatory collaboration including the role of AI in regulatory frameworks. |
| **MHRA Safety Roundup: August 2025** | Summary of the latest safety advice for medicines and medical device users including articles on self-sampling and cosmetic breast augmentation |
| **Self-sampling at the point-of-care** | RCPath article co-authored by MHRA.<br>AI summary of the article: "***Self-sampling at the point of care*** *offers improved access and patient autonomy, especially for underserved groups. Adoption remains limited despite clinical and operational benefits.*"<br>To help build confidence in new pathways and support safe, effective deployment, **ABHI members** may wish to support innovation in self-sampling by ensuring that performance and compliance of your devices are aligned with alternate sample types (capillary, venous etc). |
| **Cosmetic Breast Augmentation Risk Awareness Tool** | MHRA's **Cosmetic Breast Augmentation** Risk Awareness Tool addresses risk communication and informed consent for patients and healthcare professionals. |
| **Health Institution Exemption – Stakeholder survey** | MHRA is consulting on the use of **devices that are made and used within a health institution** (currently fully exempt from GB device regulations). Although the survey is mostly fact finding aimed at health institutions, we have heard from MHRA that they would also welcome input from industry - this may include your thoughts on the current legislation and the future policy direction. Please consider engaging with the survey - see *Spotlight Session* |
| **MHRA designated as WHO-Listed Authority** | WHO listed authority designation replaces the older 'stringent regulatory authority' concept. The recent designation of MHRA applies to medicines and vaccines only. |
| **New review highlights untapped potential of the vaginal microbiome in women's health** | The bacteria living naturally in people's bodies could be a powerful tool for personalised, non-invasive treatment and earlier diagnosis. The review highlights opportunities for ABHI members in developing microbiome-based diagnostics and advancing regulatory and clinical innovation in **women's health**. |
| **MHRA MedRegs blog – Summer 2025** | The MHRA's Summer 2025 MedRegs blog outlines progress on UK regulatory reform, including **new reliance pathways** for devices approved in the US, Canada, and Australia, and plans to consult on **indefinite CE mark recognition**. It aligns with the 10-Year Health Plan and Life Sciences Sector Plan, emphasising agile, risk-proportionate regulation, international harmonisation, and support for innovation—particularly AI as a medical device. **Post-market surveillance** regulations introduced in June |

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| | underpin these changes. Draft legislation for pre-market measures is being finalised for WTO notification. These developments are directly relevant to ABHI members navigating UKCA, CE, and global market access strategies. |
| MHRA begins recruitment for new digital roles at Leeds hub to drive innovation and smarter regulation | MHRA's **Leeds Digital Hub** will enhance regulatory data and digital capabilities, that could support smarter regulation and faster innovation in the future. |
| Report on Adverse Event (AE) reporting in digital mental health technologies (DMHTs) and the development of updates to regulatory guidance | MHRA's report on **adverse event reporting in digital mental health technologies** highlights gaps in post-market surveillance and signals updates to regulatory guidance - relevant for ABHI members developing or supplying SaMD in mental health. |
| Statement of Policy Intent: Early Access to Innovative Medical Devices<br>MHRA outlines intent to speed up patient access to innovative medical devices | MHRA's policy statement outlines **plans for an Early Access service** to enable time-limited, conditional access to innovative medical devices addressing unmet clinical needs. Built on the IDAP pilot and UCNA tool, it aims to support faster, risk-proportionate market entry, especially for diagnostics. ABHI members should note its relevance to future regulatory strategy, evidence generation and NHS adoption pathways. |
| Summer ready: MHRA issues updated guidance on medicines and medical devices during holiday season | MHRA issues **advice to users** of blood glucose monitors and people with implants ("*Most body scanners are safe…*") |
| MHRA announces proposals to improve access to world's best medical devices for patients and to boost economic growth in Britain's med tech sector | MHRA has announced reforms to improve patient access to high-quality medical devices and reduce regulatory burden. Key reforms are set to include<br>• **new international reliance routes** (US, Canada, Australia),<br>• **indefinite CE mark recognition**, and<br>• **refocusing UKCA on first-in-market innovations** like AI.<br>ABHI members will by now be very familiar with these three concepts and should note implications for market access, regulatory planning, and product strategy.<br><br>ABHI statement: "*This announcement marks a significant step towards a more agile, internationally aligned regulatory system. ABHI has consistently called for the indefinite recognition of CE-marking, and it is encouraging to see this, along with a number of other long-standing ABHI recommendations, reflected in* |

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| | *government thinking. We particularly welcome the positive engagement with the new MHRA leadership and their commitment to reducing barriers to market entry and enabling faster, risk-proportionate, and predictable regulatory pathways."* |
| Medicines and Medical Devices Act 2021 – Stakeholder survey | **Shape the Future of UK HealthTech Regulation – Share Your Voice.**<br>Please respond to this MHRA survey by 19th September |
| MHRA CEO Lawrence Tallon welcomes Life Sciences Sector Plan | MHRA CEO welcomed the **Life Sciences Sector Plan** and noted MHRA's role in enabling safe, effective innovation. Lawrence emphasised continued collaboration across the sector to support public health and maintain the UK's attractiveness for HealthTech development. |
| Government to align with European specifications on high risk in vitro diagnostic devices to reduce regulatory burden | MHRA intend to align with **EU Common Specifications for high-risk IVDs**, streamlining approvals and reducing duplication. This includes **repealing the CTDA process** and introducing an accelerated route for CE-marked COVID-19 tests. ABHI IVD members should benefit from reduced regulatory burden and improved UK–EU market alignment. |
| Common specification requirements for in vitro diagnostic devices | |

## Spotlight Session – Sue Spencer of Compliance Connextions offers her perspective on the MHRA's HIE survey.

**Key Takeaway:** 📌 MHRA is gathering evidence on the Health Institution Exemption. ABHI members can submit input via appended documents to help shape future guidance and ensure a balanced approach that supports innovation without undermining regulatory integrity.

MHRA have launched a stakeholder survey on the Health Institution Exemption Stakeholder Survey . Why is MHRA running the survey? The first thing to note is that this is a survey not a consultation, so it does not contain specific plans but is a call for evidence to inform MHRA policy and guidance. The government recently issued their 10-year plan with the aim of enhancing access to innovative technology closer to home. The challenge is how to balance patient safety and timely patient access to new technology, particularly for rare diseases or niche conditions whilst not creating a loophole to inappropriately bypass regulations. Technology is advancing and moving outside the hospital and into the clinic and into patients' homes, this was not envisaged in the current MHRA guidance.

The survey is aimed at health institutions to gather information about whether they have or use an exemption, what devices are covered and how many, what approvals or accreditations the institution holds and whether they conduct PMS and vigilance. Whilst the survey is focused on the health institutions ABHI is advised other stakeholders can provide an input by appending a document to the survey.



Another contentious topic in GB as well as Europe has been, what is the definition of a health institution. In Europe there is an MDCG guidance but practically each member state makes their own decision about how this is applied and overseen. For example, some member states may require institutions to be registered which provides visibility to the competent authority. It is important to note that under the Windsor Agreement Northern Ireland must follow the health institution exemption requirements described in the MDR and IVDR plus the associated MDGC guidance not the GB requirements.

The compliance bar is lower for in-house exempt devices, it was intended for small scale rapid access to support unmet need especially where devices provide significant benefit to the patient and would not be commercially viable or if modifications were needed to support a particular population, it was not intended to be used on an "industrial scale". The health institution exemption enables flexibility for hospitals to manufacture, modify or change the use of a device to accommodate the population or need of the patients within the institution whilst clarifying that the institution becomes accountable for the changed device.

Medtech companies manufacture devices whilst some supply the in-house markets so a balanced view is important, it can be an important vehicle to support the rapid access of new technology provided patient safety is appropriately considered, and provided it is not abused. Can MHRA take leadership and create a suitable balance for GB to establish an appropriate level regulatory playing field which does not disadvantage innovative device manufacturers who are often SMEs and are expected to conduct expensive clinical studies? In order for MHRA to have a balanced view it's important that all stakeholders provide evidence to this survey.

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## Updates from MHRA

| Subject | Update | Relevance |
|---|---|---|
| Consultation outcome - **MHRA consultation on statutory fees - proposals on ongoing cost recovery** | The long-awaited fees update. MHRA will introduce the first stage of a new annual post-market surveillance (PMS) fee from April 2026, replacing the current £261 registration fee. Following ABHI's input, the fee will be based on broader GMDN categories (Level 2), estimated at £300, rather than granular codes. MHRA expects many smaller manufacturers to pay one fee annually, though this will vary. | The revised model aims to ensure sustainable PMS funding for MHRA with a lower administrative burden for manufacturers compared with the previous model.<br><br>These new fees will directly affect regulatory planning and importantly link to broader recognition and reliance goals. |
| **MORE Submissions - user reference guide** | **Online reporting** updated the PSR submission process to reflect the resumption of uploads via the MORE portal. | Good to know if you use MHRA's 'Periodic Summary Reports' |
| **MHRA Performance Data for July 25** | MHRA continues to meet targets for assessment of **clinical investigation applications** | Good to know if you are running clinical investigations for medical devices in the UK. |
| **MORE Submissions - user reference guide** | Revised the SAE section to include additional guidance on **Quarterly Safety Reports** (QSRs). | |
| **Clinical investigations for medical devices** | Revised wording in the 'Payment for a clinical investigation' section to remove reference to **'amendments to a clinical investigation'.** | MHRA no longer apply fees to amendments of clinical investigations. **This is a fee reduction.** |
| **Clinical investigations for medical devices** | Added new flow chart and guidance documentation for UK and Northern Ireland. | This updated guidance helps decide if a study involving a medical device should be notified to MHRA (includes advice on application of the **health institution exemption**) |
| **Digital mental health technology** | Added link in 'Guidance' section to 'Report on Adverse Event (AE) reporting in **digital mental health technologies (DMHTs)** and the development of updates to regulatory guidance' | MHRA continue their work on digital mental health technologies. This report covers challenges for MHRA in adverse event reporting. |
| **Our governance** | Update to members of Board and Executive Committee Video recording of 8th July meeting added | Note how **MHRA leadership** is evolving since Lawrence Tallon came on board |
| **The Yellow Card scheme: guidance for healthcare** | Updated to reflect that the **Northern Ireland Adverse Incident Centre (NIAIC) incident and reporting function** | MHRA has replaced the Northern Ireland Adverse Incident Centre with a new Yellow |

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| professionals, patients and the public<br>Yellow Card centre launched in Northern Ireland to strengthen patient safety<br>Regulation of medical devices in Northern Ireland | **will be closing.** From the 1st August 2025, healthcare professionals in Northern Ireland will report adverse incidents involving medical devices to the Yellow Card scheme in accordance with their organisations medical device policies and procedures. | Card Centre, aligning device safety reporting with the rest of the UK. For ABHI members, this supports more consistent post-market surveillance and may improve data quality through enhanced local engagement. |
| Consultation on Medical Devices Regulations: Routes to market and in vitro diagnostic devices | MHRA response to consultation on international reliance, UKCA marking and in vitro diagnostic devices consultation proposal. | See news story above and various ABHI updates |
| AI Airlock Phase 2 application CLOSED | The call for applications for phase 2 of the **AI Airlock** is now closed. | To note |
| Register medical devices to place on the market | - Statutory Registration fee increase to £261 from 16 July 2025<br>- Review Registration section updated to include Northern Ireland regulations | To note |
| MHRA fees from 16th July | Updated the following fees sections to reflect increases from 16 July 2025:<br>- 9. Clinical investigations for devices: fees<br>- 42. Medical Device Approved Body Fees<br>- 44. Devices Regulatory Advice meeting (new section added)<br>Also updated: Payment easements and waivers for small and medium companies | To note |
| Medical devices: list of UK approved bodies | TUV SUD BABT Unlimited (0168) designation for IVDs | To note |
| Digital mental health technology: qualification and classification | Multiple updates including when DMHTs do not qualify as Software as a Medical Device (SaMD) and aligning classification with EU MDCG 2019-11 Rev 1. | To note |

## Spotlight Session - MHRA SoGATS Workshop

**Key Takeaway:** 📌 **IVD manufacturers have direct access to MHRA and EQA experts to discuss standards for infectious disease diagnostics, with a focus on sequencing, digital PCR, and pandemic readiness.**

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 |
| Post-market Surveillance and Vigilance of Medical Devices | May 2025 |
| RegulatoryConnect Programme update | May 2025 |

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

## Spotlight Session - MHRA Annual Report 2024 to 2025

**Key Takeaway:** 📌 **MHRA's annual report highlights progress in post-market surveillance, digital health innovation, and international engagement, signalling a regulator beginning to balance reform with delivery across devices, IVDs, and AI.**

MHRA published their annual report and their impact report on 21st July. Overall, the documents convey transparency, regulatory accountability and operational progress. They reflect a regulator seeking to balance delivery against reform, with a measured confidence in its direction of travel. Here are some key regulatory outputs and numbers relevant to medical devices, IVDs, and digital health products.

### *Key regulatory outputs '24-'25*

**Regulatory Frameworks**

- Post-Market Surveillance (PMS) Regulations introduced.
- IVDR implemented in Northern Ireland with MHRA designated as responsible authority.
- New application process for IVD performance studies in NI launched.
- Extension of assimilated law for CE-marked devices in place.
- New guidance developed on patient and public involvement in device regulation.
- New Patient and Public Community launched

**Innovation and Digital Health**

- AI Airlock pilot launched: regulatory sandbox for AI as a medical device.
- Innovative Devices Access Pathway (IDAP) pilot completed.
- UK Centres of Excellence for Regulatory Science and Innovation (UK-CERSIs) established.
- SafetyConnect programme for device surveillance updated
- Signal detection programme for devices expected in Q3 2025/26.

**International Engagement**

- Active participation in IMDRF.
- WHO-endorsed standards for HIV-1 p24 antigen and lung cancer mutations

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***MHRA's year in numbers '24-'25***

***PreMarket Activity***

- *370+* clinical investigation applications
- *222* humanitarian device applications
- *12* exceptional use authorisations.

***Safety and Surveillance***

- *~56,000* medical device incidents assessed.
- *677* Field Safety Notices reviewed.
- *91* safety alerts and *21* safety updates issued.

***Compliance and Enforcement***

- *11* Approved Body audits
- *4* "for cause" manufacturer audits
- *14* device inspections arising from investigations
- *1.5 million* unregulated online listings blocked.

## Other UK news

*The **Life Sciences Innovative Manufacturing Fund** (LSIMF) is making up to £520 million of grants available to support businesses investing in manufacturing projects in the UK.*

*The fund is designed to strengthen the UK's health resilience and deliver economic benefits, with a particular focus on projects that contribute to pandemic preparedness. This includes:*

- *Production of point-of-care and high-volume diagnostics.*
- *Diagnostics that enable preventative medicines.*
- *Technologies that have a significant positive impact on population health, particularly through addressing chronic diseases.*

*The deadline for the current application round has been extended to 12 September 2025 and more information is available here.*

*Eligible projects must have a total cost of at least £8 million (including capital expenditure), and government funding will typically cover 10–20% of total project costs.*



**New chief executive appointed at UKHSA** Professor Susan Hopkins is appointed as the new Chief Executive Officer of the UK Health Security Agency (UKHSA).

**UKHSA conference**: Manchester 22/23 September 2026.

**Committing to better inclusion of older adults in health research** UKRI and health funders pledge to improve inclusion of older adults in research, with implications for clinical evidence and regulatory relevance.

**Policy paper Transforming the UK clinical research system: August 2025 update** The August 2025 update to Lord O'Shaughnessy's 2023 UK Clinical Research Recovery and Resilience programme highlights reforms to improve research delivery across the NHS, including better integration of digital tools, streamlined governance, and enhanced support for diverse study types. While the 150-day trial set-up target is primarily aimed at pharmaceutical sponsors, broader system changes may benefit HealthTech developers seeking efficient pathways for clinical validation and regulatory alignment.

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**UK REACH: Extending dossier submission deadlines for transitional registrations** The UK government is consulting on extending transitional registration deadlines under UK REACH, due to delays in implementing the Alternative Transitional Registration model (ATRm). ABHI plans to submit a response and is seeking member input by **27 August**. The consultation closes on **8 September**.

The **NHS Supply Chain** have updated their **information on the need for a certified quality management system** in the contract and tender process.

The exact requirements are on the NHS SC website, but in essence they can be summarised as:

- Suppliers must hold relevant QMS certification from a body accredited by UKAS (or another IAF-recognised body).
- Certification must cover all relevant activities (sales, manufacturing, storage, distribution).
- Subcontractors/distributors must also be certified.
- Valid certificates (or letter from Certification Body) are required at bid submission. Commitment alone is insufficient.
- All devices need a Declaration of Conformity.
- All devices (except class A IVDs/ class I MDs) need a conformity assessment certificate
- All devices must be registered with MHRA.

## Spotlight Session - Apprenticeships: Regulatory Affairs Specialists

**Key Takeaway:** 📌 !Act now! Enrol staff in regulatory apprenticeships before levy funding ends for those aged 22+ on 1 January 2026; TOPRA's final intake closes 23 October.

From 1 January 2026, apprenticeship levy funding will no longer be available for individuals aged 22 and over. This change will impact access to funded training, including regulatory skills development. If your organisation is considering enrolling staff in regulatory apprenticeships, now is the time to act. The current TOPRA intake closes on 23 October 2025, providing a final chance to utilise levy funding before the change takes effect. TOPRA – the professional membership organisation for individuals engaged in regulatory affairs for human and veterinary medicines and medical devices worldwide – offers a highly regarded Level 7 Regulatory Affairs Apprenticeship. Several ABHI members are already benefitting from the programme.
See TOPRA webpage for more details - https://www.topra.org/TOPRA/TOPRA_Member/Apprenticeships_in_Regulatory_Affairs.aspx

## Upcoming courses and events from TOPRA & RAPS

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

Design Development and Certification of Medical Devices 8-10 September London/Online
Regulatory **Careers** Live 2025 – 9 September, London
Sponsored Webinar-Navigating **AI Innovation in RA** 11 September
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 *****

***** TOPRA is seeking a **module leader and speakers** for this *IVD Regulatory Affairs* module. This is an opportunity for ABHI members to support regulatory education, share expertise, and engage with future professionals. If you or a colleague are interested, please contact Valeria Riscanu, Postgraduate Administrator Tel +44 (0) 20 7510 2560; E: Valeria.Riscanu@topra.org for details. *****

**Leadership and Strategic Management** in Regulatory Affairs London/Online 10-12 November
Essentials of **European Medical Device Regulatory Affairs** London/online 26 November

The **Awards for Regulatory Excellence** 2025 27 November 2025, 6pm-11pm Plaisterers' Hall, London

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 Convergence 2025** 7-9 October 2025 Pittsburgh USA

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

## Joint event: TOPRA/RAPS

**UK MDR Regulatory Conference** **5-6 November Hilton London Wembley**
Join experts from MHRA, health authorities, medical device regulatory professionals, and other key industry stakeholders to explore the UK MDR landscape.

## Spotlight session- ISO 15223-1 and the Authorized Representative Symbol

**Key Takeaway:** 📌 **The Authorized Representative symbol in ISO 15223-1 has been updated. This change aims to reduce translation needs, optimize label space, and support compliance across multiple regulatory jurisdictions.**

On March 5, 2025, ISO 15223-1:2021/Amd 1:2025 introduced a significant change to the Authorized Representative symbol, altering the [EC] part of the symbol to [XX]. This change allows the symbol to be used globally, not just within the European Union, by replacing [XX] with country codes or other recognized text. This change is intended to minimize translation needs, free up label space, and meet various regulatory requirements. In her recent blog, Lena Cordie-Bancroft describes the change to ISO 15223-1 - a crucial standard for medical device manufacturers, providing symbols to convey information about devices without relying on text.

# ABHI Regulatory Round-Up – Summer 2025

## Update on British Standards Projects July and August 2025

| Status | Closing Date | Description | Committee |
|---|---|---|---|
| Published standard | | BS EN ISO 15883-1:2025 Washer-disinfectors. General requirements, terms and definitions and tests | CH/198 - Sterilization and Associated Equipment and Processes |
| Published standard | | BS ISO 18193:2021+A1:2025 Cardiovascular implants and artificial organs — Cannulae for extracorporeal circulation | CH/150/2 - Cardiovascular implants |
| Published standard | | BS EN ISO 7396-3:2025 Medical gas pipeline systems. Proportioning units for the production of synthetic medical air | CH/121/6 - Medical gas supply systems |
| Published standard | | BS ISO 5834-4:2025 Implants for surgery. Ultra-high-molecular-weight polyethylene. Oxidation index measurement method | CH/150/1 - Materials for surgical implants |
| Published standard | | BS ISO 5834-1:2025 Implants for surgery. Ultra-high-molecular-weight polyethylene. Powder form | CH/150/1 - Materials for surgical implants |
| Published standard | | BS ISO 5834-3:2025 Implants for surgery. Ultra-high-molecular-weight polyethylene. Accelerated ageing methods after gamma irradiation in air | CH/150/1 - Materials for surgical implants |
| Published standard | | BS ISO 5834-2:2025 Implants for surgery. Ultra-high-molecular-weight polyethylene. Moulded forms | CH/150/1 - Materials for surgical implants |
| Published standard | | BS ISO 5834-5:2025 Implants for surgery. Ultra-high-molecular-weight polyethylene. Morphology assessment method | CH/150/1 - Materials for surgical implants |

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| Published standard | | BS EN IEC 61847:2025 Ultrasonics. Surgical systems. Measurement and declaration of the basic output characteristics | EPL/87 - Ultrasonics |
| Published standard | | BS ISO 18193:2021+A1:2025 Cardiovascular implants and artificial organs — Cannulae for extracorporeal circulation | CH/150/2 - Cardiovascular implants |
| Published standard | | BS EN ISO 7396-3:2025 Medical gas pipeline systems. Proportioning units for the production of synthetic medical air | CH/121/6 - Medical gas supply systems |
| Published standard | | BS ISO 5834-4:2025 Implants for surgery. Ultra-high-molecular-weight polyethylene. Oxidation index measurement method | CH/150/1 - Materials for surgical implants |
| Published standard | | BS EN ISO 14607:2025 Non-active surgical implants. Mammary implants. Specific requirements | CH/150 - Implants for surgery |
| Published standard | | BS EN ISO 12870:2025 Ophthalmic optics. Spectacle frames. Requirements and test methods | CH/172 - Ophthalmic optics |
| Published standard | | BS EN ISO 8536-16:2025 Infusion equipment for medical use. Infusion sets for single use with volumetric infusion controllers | CH/212 - IVDs |
| Published standard | | BS ISO 7207-2:2025 Implants for surgery. Components for partial and total knee joint prostheses. Articulating surfaces made of metal, ceramic and plastics materials | CH/150/4 - Surgical Implants - Bone and Joint Replacements |
| Published standard | | BS EN ISO 19211:2025 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 | 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 |

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|---|---|---|---|
| Draft for public comment | 06/08/2025 | BS EN 60601-1/FRAG10 ED4 Medical electrical equipment. Part 1: General requirements for basic safety and essential performance - Ionizing radiation hazards (Fragment 10) | CH/62/1 - Common aspects of medical equipment, software, and systems |
| 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 | 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 |
| Draft for public comment | 27/08/2025 | BS EN IEC 60050-881 ED2 International Electrotechnical Vocabulary (IEV). Part 881: Radiology and radiological physics | CH/62 - Medical equipment, software, and systems |
| Draft for public comment | 27/08/2025 | BS EN IEC 60601-2-22/AMD1 Amendment 1 - 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 | 30/08/2025 | BS EN ISO 8637-2 Extracorporeal systems for blood purification. Part 2: Extracorporeal blood and fluid circuits for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators | CH/150/2 - Cardiovascular implants |
| Draft for public comment | 30/08/2025 | BS ISO 8637-1 Extracorporeal systems for blood purification. Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators | CH/150/2 - Cardiovascular implants |
| Draft for public comment | 30/08/2025 | BS ISO 8637-3 Extracorporeal systems for blood purification. Part 3: Plasmafilters | CH/150/2 - Cardiovascular implants |

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| Draft for public comment | 02/09/2025 | BS ISO 11040-8 Prefilled syringes. Part 8: Requirements and test methods for finished prefilled syringes | CH/212 - IVDs |
| Draft for public comment | 21/09/2025 | BS EN ISO 11608-1:2022/Amd 1 ISO 11608-1:2022/DAmd 1 Needle-based injection systems for medical use. Requirements and test methods. Part 1: Needle-based injection systems. Amendment 1 | CH/84 - Catheters and syringes |
| Draft for public comment | 06/09/2025 | BS ISO 11249 Copper-bearing intrauterine contraceptive devices. Guidance on the design, execution, analysis and interpretation of clinical studies | CH/157 - Non-systemic contraceptives and barrier prophylactics |
| Draft for public comment | 10/09/2025 | BS ISO 17191 Urine-absorbing products for incontinence. Measurement of airborne respirable polyacrylate superabsorbent materials. Determination of dust in collection cassettes by sodium atomic absorption spectrometry | CH/173 - Assistive products for persons with disability |
| Draft for public comment | 17/09/2025 | BS EN 60976 ED3 Medical electrical equipment - Medical electron accelerators - Functional performance characteristics | CH/62/3 - Equipment for radiotherapy, nuclear medicine and radiation dosimetry |
| Draft for public comment | 20/09/2025 | BS ISO 11140-5 Sterilization of health care products. Chemical indicators. Part 5: Type 2 indicators for Bowie and Dick-type indicators and indicator systems | CH/198 - Sterilization and Associated Equipment and Processes |
| Draft for public comment | 21/09/2025 | BS EN ISO 11608-1:2022/Amd 1 Needle-based injection systems for medical use. Requirements and test methods. Part 1: Needle-based injection systems. Amendment 1 | CH/84 - Catheters and syringes |
| Draft for public comment | 21/09/2025 | BS EN ISO 11140-3 Sterilization of health care products. Chemical indicators. Part 3: Type 2 indicators for use in the Bowie and Dick-type steam penetration test | CH/198 - Sterilization and Associated Equipment and Processes |
| Draft for public comment | 22/09/2025 | BS EN ISO 11140-4 Sterilization of health care products. Chemical indicators. Part 4: Type 2 indicator systems as an alternative to the Bowie and Dick-type test for the detection of steam penetration | CH/198 - Sterilization and Associated Equipment and Processes |

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| Draft for public comment | 27/09/2025 | BS EN ISO 21611 Dentistry. Vocabulary for Source Conclusion for Human Identification by Dental Evidence | CH/106/5 - Terminology |
| Draft for public comment | 27/09/2025 | BS EN ISO 10079-1:2022/A1 Medical suction equipment. Part 1: Electrically powered suction equipment. Amendment 1: Ingress of water | CH/121/5 - Airways and related equipment |
| Draft for public comment | 28/09/2025 | BS EN ISO 5361:2023/A1 Anaesthetic and respiratory equipment. Tracheal tubes and connectors. Amendment 1: Reinstatement of third edition S1 dimensions | CH/121/5 - Airways and related equipment |
| Draft for public comment | 04/10/2025 | BS EN ISO 28399 Dentistry. External tooth bleaching products | CH/106/7 - Oral hygiene products |
| Draft for public comment | 06/10/2025 | BS EN ISO 5364 Anaesthetic and respiratory equipment. Oropharyngeal airways | CH/121 - Anaesthetic and respiratory equipment |
| Draft for public comment | 07/10/2025 | BS EN 1865-1 Patient handling equipment used in ambulances. Part 1: General stretcher systems and patient handling equipment | CH/239 - Rescue systems |
| Draft for public comment | 11/10/2025 | BS EN ISO 11608-3:2022/Amd 1 Needle-based injection systems for medical use. Requirements and test methods. Part 3: Containers and integrated fluid paths. Amendment 1 | CH/84 - Catheters and syringes |
| Draft for public comment | 21/10/2025 | BS ISO 24996 Traditional Chinese medicine. General requirements for the basic safety and essential performance of the transcutaneous electrical acupoint stimulators | CH/100 - Healthcare and Medical Equipment |
| Draft for public comment | 21/10/2025 | BS ISO 5833 Implants for surgery — Acrylic resin cements | CH/150/1 - Materials for surgical implants |
| Draft for public comment | 03/11/2025 | BS EN ISO 11607-3 Packaging for terminally sterilized medical devices —. Part 3: Requirements for process development for forming, sealing and assembly | CH/198 - Sterilization and Associated Equipment and Processes |

# ABHI Regulatory Round-Up – Summer 2025

## EU news

### MedTech Europe

Simplification of **EU digital legislation**: MedTech Europe proposal to ensure coherent implementation

**Sampling** under In Vitro Diagnostics Regulation: MedTech Europe proposal for a more risk-based approach



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

Revision of **Standardisation** Regulation 1025/2012

### MDCG

MDCG 2025-7 - Position Paper: Timelines of implementation of **'Master UDI-DI' to contact lenses and spectacle frames, s**pectacle lenses and ready-to-wear reading spectacles
MDCG 2024-14 - rev.1 - Guidance on the implementation of the Master UDI-DI solution for contact lenses (August 2025)

### CAMD

**Coordination and governance of the regulatory system for medical devices** at the EU level: publication of a consensus statement from the EU Competent Authorities to the EU Commission

# ABHI Regulatory Round-Up – Summer 2025

## EMA

Medical device **expert panels**

## European Commission

Commission Implementing Decision (EU) 2025/1324 of 7 July 2025 amending Implementing Decision (EU) 2019/1396 as regards certain administrative aspects related to ex
designation of **an additional expert panel in the field of medical devices**

POLSKIE CENTRUM BADAN (1434), **Notified Body designated under IVDR** 2017/746

**EUDAMED Workshops**: 8 October 2025, Rome, Italy - 3 December 2025, Brussels, Belgium

Commission Delegated Regulation (EU) 2025/788 of 16 April 2025 amending Delegated Regulation (EU) 2023/2197 as regards the date of application (Assignment of **Uniqu
lenses**)

**COMBINE Project 1** – pilot "all-in-one" coordinated assessment: The call for expression of interest will close on **21 September 2025** (extended from previous deadline of 31

Updated - **Notified bodies survey** on certifications and applications

**MDR - Language requirements** for manufacturers - Rev. 3 (August 2025)



## Team NB

Tenth session : **MDR Technical Documentation Training** for Manufacturers

Team-NB **Position Paper list** (update July 17th 2025)

Team-NB Position Paper - **Orphan In-vitro diagnostics medical device**s

Notified Body Perspective on **Future Governance** in the EU Medical Device Sector

New session : **MDR Clinical Training** for Manufacturers

# ABHI Regulatory Round-Up – Summer 2025

## US news

### AdvaMed

AdvaMed Releases White Paper on **Medical Imaging Cybersecurity**



AdvaMed Welcomes **MDUFA** VI Discussion Kickoff at FDA Public Meeting

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

### FDA

Medical Device **User Fee Small Business** Qualification and Determination: Guidance for Industry, Food and Drug Administration Staff and Foreign Governments

Marketing Submission Recommendations for a **Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software** Functions: Guidance for Industry and Food and Drug Administration Staff

Animal Studies for **Dental Bone Grafting Material Devices** - Premarket Notification (510(k)) Submissions: Guidance for Industry and Food and Drug Administration Staff

# ABHI Regulatory Round-Up – Summer 2025

## International news

### IMDRF

**IMDRF 28th Session,** September 15-19 2025, Sapporo Japan

Day 1 IMDRF/Industry sessions: Conformity Assessment, Classification and RWE



Day 2 IMDRF Stakeholder Updates plus a session on UDI

Day 3 agenda – closed sessions with industry and others

### GHWP

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

### GMDN

Graham Nash joins GMDN Agency as **Health Data Strategy Lead**

**GMDN FOCUS** - Summer 2025

### International regulators

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|---|---|
| Australia (TGA) | Therapeutic Goods (Medical Devices) Regulations 2002 **Compilation** No. 68 |
| Australia (TGA) | Preparing for **Good Clinical Practice (GCP) inspections** (Updated) |

# ABHI Regulatory Round-Up – Summer 2025

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| Australia (TGA) | **Changing the sponsor** of a therapeutic good (Updated) |
| Australia (TGA) | **TGA Business Plan** 2025-26 |
| Australia (TGA) | TGA Report: Clarifying and strengthening the **regulation of Medical Device Software including Artificial Intelligence (AI)** |
| Australia (TGA) | **eCTD** AU module 1 and regional information v3.2 |
| Australia (TGA) | Meeting **3D printing (additive manufacturing)** rules for medical devices |
| Australia (TGA) | Reporting of medical device adverse events by **healthcare facilities** |
| Australia (TGA) | Understanding **regulation of software-based medical devices** |
| Canada (HealthCanada) | **The eSTAR pilot:** Health Canada is launching a second pilot that expands the scope of submission types. |
| Canada (HC) | **The eSTAR pilot**: Notice to industry |
| Switzerland (Swissmedic) | Implementation in Switzerland of EU Commission Implementing Regulation on **instructions for use in electronic form** |
| Switzerland (Swissmedic) | New in **swissdamed**: Medical device registration now available |
| Singapore (HSA) | GN-21: **Guidance on Change Notification** for Registered Medical Devices v6 |
| Singapore (HSA) | Guidelines on **Risk Classification of SaMD and Qualification of Clinical Decision Support Software** (CDSS) |
| Singapore (HSA) | GN-15: Guidance on Medical Device **Product Registration** Revision 12 |
| Singapore (HSA) & Malaysia (MDA) | Malaysia and Singapore Sign Memorandum of Understanding and Launch Medical Device **Regulatory Reliance** Pilot to Fast Track Medical Device Market Access |
| Malaysia (MDA) | Announcement Update : Implementation of the Malaysia - China Medical Device **Regulatory Reliance Programme** (Pilot Phase 1 : 30 July - 30 September 2025) |
| Japan (MHLW) | Conformity checklist for designated **highly-controlled medical devices, etc. (**Part 33) |
| Japan (PMDA) | Updated information on **companion diagnostics** |
| Saudi Arabia (SFDA) | MDS-G-011-V2/250707: Draft Guidelines for **Manufacturing Pathways** for Medical Devices and Supplies v2 |
| India (CDSCO) | Addendum 02 to **FAQ on Medical Devices** Rules 2017 |
| Oman (MoH) | Ministerial Resolution No. 54 of 2025 regarding the adoption of **national standards for endoscopy services** |
| Brazil (ANVISA) | Manual for Regularization of **Medical Equipment and Software as Medical Devices** at Anvisa |
| Brazil (ANVISA) | Anvisa changes the way the validity of the **Certificate of Good Practices i**s calculated |
| Cuba (CECMED) | Regulatory Provision (DR) E132-2025, CECMED's **Policy for the regulation of medical devices** |
| Cuba (CECMED) | Regulation E 133-25 - **Essential principles of safety and performance** of medical devices and in vitro diagnostic medical devices (Edition 2) |

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| South Africa (SAHPRA) | MD08-2025/2026 - Regulatory Requirements of **Artificial Intelligence and Machine Learning (**AI/ML) Enabled Medical Devices |
| Mexico (COFEPRIS) | Agreement establishing **simplification actions** for procedures carried out before the Federal Commission for the Protection against Health Risks |
| South Korea (MFDS) | Manual for Issuing **English Certificates for Medical Devices**, etc. |
| South Korea (MFDS) | Administrative Notice on the Establishment, Revision, and Abolition of **Korean Industrial Standards** in the Medical Product Sector |

## Appendix - Resource Library

ABHI Regulatory Round Up – past issues

- June 2025
- May 2025
- April 2025
- March 2025
- February 2025
- December 2024
- September 2024
- Summer 2024

ABHI briefing papers

- HealthTech Regulations - Driving Economic **Growth and Patient Safety In The UK**
- Regulation of Medical Devices and In **Vitro Diagnostic Medical Devices in Northern Ireland**
- Electronic Labelling for **Medical Devices and IVDs**
- How to Best Implement the **EU IVDR – Dos and Don'ts**
- Overview of Main Changes **Brought About by the IVDR**
- Update on the UKCA **Mark: A Rapidly Evolving Landscape**
- International Regulatory Recognition **in the UK**

UK legislation

- Medicines and Medical Devices Act 2021
- The Medical Device Regulations 2002. UK Statutory Instrument no 618 (UK MDR 2002)
- The National Archives *"... capture, preserve and make accessible UK central government information published on the web. The Web Archive includes videos, tweets, images and websites dating from 1996 to the present day."*

MHRA

- MHRA gov.uk website
- MedRegs Blog
- Public Access Registration Database (PARD)
- MHRA careers hub