ABHI Regulatory Round-up – September 2024

Contents

ABHI

ABHI Regulatory Round-up – September 2024

ABHI

ABHI Regulatory Round-up – September 2024

Introduction

In this regulatory round-up, you will find updates from UK, EU, US and internationally as well as some upcoming dates for your diary.

We have included new and updated MHRA notices, some training events from TOPRA and RAPS, plus international updates from industry and regulators across the world. There are also a few member opportunities. If you have any updates that you want us to consider for a future edition, please get in touch.

Regulatory Updates are provided in collaboration with MedBoard, the data intelligence platform monitoring regulatory news from 225+ Countries in 15+ Regulatory Areas, in real time. Visit www.MedBoard.com to learn more about the cloud platform and its regulatory, clinical, and market solutions to stay on top and manage information and data within the MedTech industry.

MedBoard

ABHI

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

Upcoming regulatory group meetings

IVD Regulatory

- 28th November 2024 2-4pm
- 27th February 2025 2-4pm
- 29th May 2025 2-4pm
- 4th September 2025 2-4pm
- 27th November 2025 2-4pm

MD Regulatory

- 3rd December 2024
- More dates tbc

ABHI

ABHI Regulatory Round-up – September 2024

ABHI Briefing: Data Collection on EU v US HealthTech Regulatory Systems

You can find past ABHI regulatory resources by clicking 'regulation' in the ABHI resource hub.

Professional Associate Member Offers If you are an ABHI Professional Associate Member company and would like to extend an offer to our wider membership, get in touch with communications@abhi.org.uk

If you have provided any regulatory events (training sessions, webinars etc) or publications that you think would be of interest to ABHI members, then please get in touch so it can be included in the next regulatory round-up.

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

MHRA

New

Subject	Relevance
MHRA consultation on statutory fees - proposals on ongoing cost recovery	New consultation ending 24th October. ABHI will host a webinar on 10th October to finalise the industry submission
Medicines and medical devices: Key back-to-school tips	Reference to use of asthma inhalers and adrenaline autoinjectors
MHRA Data Strategy 2024 – 2027	5 Strategic themes for data and digital technology.
MHRA Strategy for Improving Safety Communications	Implementing recommendations from last year's consultation
Post Market legislation	Baroness Merron announced the government's commitment to lay draft regulations before Parliament later this year.
Application route for performance studies under the In Vitro Diagnostics Regulations in Northern Ireland	Applications for IVDR performance studies in Northern Ireland can now be submitted.
AI Airlock pilot call for applications	Applications are now being accepted for the MHRA AI airlock programme. Closing date is 7th October.

ABHI Regulatory Round-up – September 2024

MHRA MedRegs Blog	Latest update on UK regulatory reform confirms that MHRA will: • Lay post-market legislation by the end of this year • Lay pre-market legislation next year following a targeted consultation (inc detailed proposals for international reliance, self-assessment of class B IVDs, the need for a physical UKCA mark, pre-determined change control plans for software/AI, etc)

Updates

Subject	Update	Relevance
AI Airlock: the regulatory sandbox for AIaMD	Link to July webinar video added.	The webinar describes the AI airlock pilot now open to applicants. Join the mailing list at aiairlock@mhra.gov.uk
Notify MHRA about a clinical investigation for a medical device	Updated to include new template for quarterly summary reports (QSR)	Administrative
Notify MHRA about a clinical investigation for a medical device	Updated 'In Vitro Diagnostic Medical Devices (IVDs)' section.	Requirement for a UK mark of conformity for assays used in clinical trials has been dropped.
Clinical investigations guidance	Updated section on 'Amendments' to reflect changes to the process.	Administrative

Other UK Government updates

Department of Science Innovation and Technology (DSIT) UK innovation diffusion and adoption survey

Team AB

Team-AB welcomes the announcement on post-market regulations.

Upcoming events from TOPRA & RAPS

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

ABHI

Medical Devices/IVDs Symposium 1 - 2 October 2024 Rotterdam

Post-Market Surveillance and Vigilance for Medical Devices 23 - 25 October 2024 London/online

CRED IVD Regulatory Affairs for Global Markets 19-20 November 2024 London/online

TOPRA Awards for Regulatory Excellence 28 November 2024 London

Essentials of European Medical Device Regulatory Affairs 29 November 2024 Berlin/online

RAPS events

RAPS Workshop: Global Expedited Pathways (US/Global) – Medical Devices 21 Oct 2024 online

RAPS European Clinical, Risk, and Postmarket Surveillance Conference 22-24 October 2024 Barcelona

Sponsored Webcast: QMSR Blueprint: Complying with the FDA's New Medical Device Regulation 29 Oct 2024 online

AI Summit 12th November 2024 Ohio

RAPS Workshop: Survivor: The FDA 510(k) Program Edition 12th November online

Standards

ABHI have been working with BSI standards to ensure that membership of the individual UK-based standards committees is appropriate.

In the past, ABHI have 'sponsored' membership of BSI working groups, depending on the expertise of interested individuals from within appropriate ABHI Working Groups, although this practice has relaxed in recent years. Whilst membership of standards working groups is voluntary, the personal rewards with regards to personal development and networking are significant. Indeed, National standards involvement can lead to international and/or global exposure, as BSI recommend standards experts at the European and Global level.

If any member of ABHI would like to be considered for standards work, please contact Phil, Steve and Lindsey Ferrari at BSI.

ABHI Regulatory Round-up – September 2024

EU news - MedTech Europe

COCIR and MedTech Europe support focus on the medical technologies regulatory system for Health Commissioner

MedTech Europe's views on the AI Act

Closing innovation launch gaps in health is key to Europe's prosperity and competitiveness

A vision for Europe's medtech future: Safeguarding Europe's access to medtech and innovation

EU news – European Commission

ISTITUTO SUPERIORE DI SANITA (NB 0373), 13th Notified Body designated under IVDR (EU) 2017/746
The future of European competitiveness – A competitiveness strategy for Europe
Monitoring the availability of medical devices on the EU market -survey for health service providers (individual health professionals, health institutions and medical device procurement bodies)
Commission Implementing Regulation (EU) .../... amending Implementing Regulation (EU) 2022/1107 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council - Annexes I to XIII
SCHEER - Minutes of the Working Group meeting on Brain stimulators of 5 September 2024
MDCG 2021-4 Rev. 1 Application of transitional provisions for certification of class D in vitro diagnostic medical devices according to Regulation (EU) 2017/746 September 2024

ABHI

ABHI Regulatory Round-up – September 2024

EU news - Team NB

TEAM NB Position Paper on IVD Transfer Agreement for Surveillance of Legacy Devices V1

Team-NB Code of Conduct for Notified Bodies V5

EU news – Team PRRC

TEAM-PRRC THIRD ANNUAL SUMMIT 17 – 18 October 2024 Malaga

ABHI

ABHI Regulatory Round-up – September 2024

US news – AdvaMed

AdvaMed Achieves National Accreditor's Endorsement to Develop Medical Device Standards

US news – FDA

Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff
Biocompatibility Testing of Medical Devices - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program : Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff
The Accreditation Scheme for Conformity Assessment (ASCA) Program: Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff
Chemical Analysis for Biocompatibility Assessment of Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff
Appeal Options Available to Mammography Facilities Concerning Adverse Accreditation Decisions, Suspension/Revocation of Certificates, or Patient and Referring Provider Notification Orders: Guidance for Mammography Facilities and Food and Drug Administration Staff
Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle: Draft Guidance for Industry, Food and Drug Administration Staff, and Other Interested Parties
Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers: Guidance for Industry and Food and Drug Administration Staff

ABHI

ABHI Regulatory Round-up – September 2024

	Mammography Quality Standards Act and Regulation Amendments: Small Entity Compliance Guide: Guidance for Industry and Food and Drug Administration Staff
	Electronic Submission Template for Medical Device De Novo Requests: Guidance for Industry and Food and Drug Administration Staff
	FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act: Guidance for Industry and Food and Drug Administration Staff
	Predetermined Change Control Plans for Medical Devices: Draft Guidance for Industry and FDA Staff
	Acceptable Media for Electronic Product User Manuals: Guidance for Industry and FDA Staff
	Electronic Submission Template for Medical Device De Novo Requests; Guidance for Industry and Food and Drug Administration Staff; Availability
	Medical Devices; General Hospital and Personal Use Devices; Classification of the Intravenous Catheter Force-Activated Separation Device
	Medical Devices; Immunology and Microbiology Devices; Classification of the Device To Detect and Identify Selected Microbial Agents That Cause Acute Febrile Illness
	Webinar – FDA's Total Product Life Cycle Approach to In Vitro Diagnostic Products (IVDs)

ABHI

ABHI Regulatory Round-up – September 2024

International news – GMDN Agency

GMDN FOCUS - Summer 2024

GMDN Agency publishes white paper on the future of medical device nomenclature

The importance of a universal definition for medical devices

International news – IMDRF

IMDRF Document Implementation Report

International news – GHWP

Call for Comments on the Proposed Document 'Guidelines on Development of GHWP Documents - Part 2: Structure and Drafting'

Call for Comments on the Proposed Document 'Guidelines on Development of GHWP Documents - Part 1 Procedure for Development'

Call for Comments on the Proposed Document 'Guidance Document for Medical Device Organizations-Product Localisation for Manufacturing and Importation'

Call for Comments on the Proposed Document 'Comparison Study of new ISO13485 vs. QMS requirements in GHWP member economies'

Call for Comments on the Proposed Document 'Software as a Medical Device (SaMD) Pre-Market Submission Requirement – Comparison of requirement from Key jurisdictions'

ABHI

ABHI Regulatory Round-up – September 2024

International news – APACMed

Towards MedTech Efficiency & Sustainability through e-Label & e-IFU

International news – WHO

WHO urges rapid access to mpox diagnostic tests, invites manufacturers to emergency review

"Get it right, make it safe!": WHO highlights safe diagnosis during global campaign for patient safety

International news – national regulators

Switzerland (Swissmedic)	Go-live of the SwissGMDP database
Spain (AEMPS)	The AEMPS assesses the results of the survey of Spanish manufacturers on the implementation of the In Vitro Diagnostic Regulation
China (NMPA)	Medical Device Management Law of the People's Republic of China (Draft for Comments)
Singapore (HSA)	Guidance on Change Management Program (CMP) for SaMD

ABHI