ABHI Regulatory Round-up - Summer 2024

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Introduction

The Summer is finally here. If you have not already taken your summer vacation, then here is some holiday reading for you. In this regulatory round-up, you will find updates from UK, EU, US and internationally as well as some upcoming dates for your diary.

We have included a list of current BSI standards projects, 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.

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Regulation remains a key priority for ABHI and is mentioned in every letter that we have sent to new Government Ministers so far. We have raised the subjects of international recognition and UKCA in discussions with Government officials from DHSC, MHRA, OLS, HMT and DBT. Our focus is on how the Government can deliver certainty and clarity to devices industry in the UK.

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

- ABHI's Quarterly Communications Report: Q2 2024
- Summer Update from ABHI: Key Developments and Future Direction
- Engaging with the New Government on HealthTech
- Call for evidence for Lord Darzi Review of Health and Care
- ABHI Responds to Wes Streeting's DHSC Growth Department Commitment

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The Defra REACH consultation closed on 25th July. Following briefings for members by McDermott Will & Emery and TSG we received some very helpful member input for the ABHI response.

Upcoming regulatory group meetings

- 5th September 2024 (IVD Regulatory)
- 28th November 2024 (IVD Regulatory)
- 4th September 2024 (MD Regulatory)
- 3rd December 2024 (MD Regulatory)

The ABHI UK HealthTech Conference

30th September to 1st October

With the goal of providing a comprehensive overview of the UK landscape and insights for your business, we are convening industry leaders and experts for two days of unparalleled networking and learning opportunities.

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

Member opportunities

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

Currently OMC, Psephos and TOPRA all have offers for ABHI members

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.

MHRA

New

Top Tips for summer

MHRA annual report and accounts 2023 to 2024.

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Updates

Medical devices given exceptional use authorisations during the COVID-19 pandemic

Notify MHRA about a clinical investigation for a medical device

New section 'Regulatory advice meetings' added to this page.

Updates to clarify the fees and payment process, addition of guidance on early terminations and temporary halts in GB and NI and clarification that Annex XVI applications cannot be accepted in GB.

Export medical devices

Updated 'Certificates of Free Sale for Medical Devices' to reflect changes to the registration and Certificates of Free Sale system.

Register medical devices to place on the market

Updated 'Account Management Reference Guide' & 'Device Registration Reference Guide' to reflect changes to the registration system.

Account Management Reference Guide *Version August 2024 v1*

Device Registration Reference Guide *Version August 2024 v1*

MHRA Board meetings in 2024

Updated dates and papers for Board meetings in public

MHRA performance data for assessment of clinical trials and established medicines

Updated to include medical device clinical investigation metrics

Implementation of medical devices future regime

Updated with MHRA response to WTO comments on PMS legislation (update now removed to the archive)

Other UK Government updates

Funding competition UK RS&IN Implementation Phase: Human Health (CERSIs)

Life sciences sector data: Annual data on the life sciences sector in the UK and other countries. 2024 report published.

UK Standards for Microbiology Investigations

New consultation: Infectious syndromes affecting the genitourinary tract and reproductive organs from 31/07/2024 to 28/08/2024

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Team AB

no updates

Upcoming events from TOPRA & RAPS

11th September TOPRA Regulatory Careers Live 2024 - UK In-Person
17th to 19th September RAPS convergence
24th September TOPRA CRED Successful and Skilful Communication*
25th September RAPS Sponsored Webcast: Advancing Medical Device Compliance Through Regulatory Management Systems and AI
1st to 2nd October TOPRA Medical Devices/IVDs Symposium 2024
**Remember to use the 10% off TOPRA courses for ABHI members*

BSI standards update

BSI Standards - Update on Projects August 2024

Status	Closing date	Standard	Committee
Published standard	17/07/2024	PD ISO/TS 6838:2024 Ophthalmic optics — Contact lenses — Tolerances and methods for measurement of multifocal contact lens addition power	CH/172/9 - Contact lenses and contact lens care products
Published standard	24/07/2024	BS EN ISO 21536:2024 Non-active surgical implants. Joint replacement implants. Specific requirements for knee-joint replacement implants	CH/150/4 - Surgical Implants - Bone and Joint Replacements
Published standard	24/07/2024	BS EN ISO 21535:2024 Non-active surgical implants. Joint replacement implants. Specific requirements for hip-joint replacement implants	CH/150/4 - Surgical Implants - Bone and Joint Replacements
Published standard	26/07/2024	PD ISO/TR 11826:2024 Ophthalmic optics. Spectacle lenses. Aspects of three-dimensional properties and reference markings	CH/172/3 Spectacles

Published standard	29/07/2024	BS ISO 17256:2024 Anaesthetic and respiratory equipment. Respiratory therapy tubing and connectors	CH/121/5 - Airways and related equipment
Published standard	31/07/2024	BS EN ISO 5362:2024 Anaesthetic and respiratory equipment. Anaesthetic reservoir bags	CH/121/5 - Airways and related equipment
Published standard	31/07/2024	BS EN ISO 23500-2:2024 Preparation and quality management of fluids for haemodialysis and related therapies. Water treatment equipment for haemodialysis applications and related therapies	CH/150/2 - Cardiovascular implants
Draft for public comment	10/08/2024	BS EN ISO 10993-7 Biological evaluation of medical devices. Part 7: Ethylene oxide sterilization residuals	CH/194 - Biological evaluation of medical devices
Draft for public comment	11/08/2024	BS EN ISO 13504 Dentistry. General requirements for instruments and related accessories used in dental implant placement and treatment	CH/106 Dentistry
Draft for public comment	12/08/2024	BS EN ISO 4823 Dentistry. Elastomeric impression and bite registration materials	CH/106/2 - Prosthodontic materials
Draft for public comment	12/08/2024	BS EN ISO 10993-12:2021/Amd 1 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials - Amendment 1: Biological evaluation of medical devices — Part 12: Sample preparation and reference materials — Amendment 1	CH/194 - Biological evaluation of medical devices
Draft for public comment	13/08/2024	BS EN ISO 14155 Clinical investigation of medical devices for human subjects. Good clinical practice	CH/194 - Biological evaluation of medical devices
Draft for public comment	17/08/2024	BS EN ISO 10993-1 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	CH/194 - Biological evaluation of medical devices
Draft for public comment	20/08/2024	BS EN 16128 Ophthalmic optics. Reference method for the testing of spectacle frames and sunglasses for nickel release	CH/172/3 Spectacles
Draft for public comment	20/08/2024	BS EN ISO 18374 Dentistry. Artificial intelligence (AI) and augmented intelligence (AuI) based 2D radiograph analysis. Data generation, data annotation and data processing	CH/106 Dentistry
Draft for public comment	31/08/2024	BS ISO 23317 Implants for surgery. Materials. Simulated body fluid (SBF) preparation procedure and test method to detect apatite formation in SBF for initial screening of bone-contacting implant materials	CH/150/1 - Materials for surgical implants
Draft for public comment	02/09/2024	BS EN ISO 11980 Ophthalmic optics. Contact lenses and contact lens care products. Guidance for clinical investigations	CH/172/9 - Contact lenses and contact lens care products

Draft for public comment	09/09/2024	BS EN ISO 19490 Dentistry. Sinus membrane elevator	CH/106 Dentistry
Draft for public comment	17/09/2024	BS ISO 18192-3 Implants for surgery. Wear of total intervertebral spinal disc prostheses. Part 3: Impingement-wear testing and corresponding environmental conditions for test of lumbar and cervical prostheses	CH/150/5 - Surgical Implants - Osteosynthesis and spinal devices
Draft for public comment	18/09/2024	BS EN ISO 15087 Dentistry. Dental elevators	CH/106 Dentistry
Draft for public comment	24/09/2024	BS EN ISO 4074 Natural rubber latex male condoms. Requirements and test methods	CH/157 - Non-systemic contraceptives and barrier prophylactics

NOTE: no new proposals for the period

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EU news - MedTech Europe

European Commission survey for healthcare professionals: Electronic Instructions for Use for medical devices
MedTech Europe urges the European Commission to prioritise the competitiveness of the medical technology industry for the benefit of patients in Europe
Manufacturer's Declaration in relation to Regulation (EU) 2024/1860

EU news – EMA

New pilot programme to support orphan medical devices

EU news – CAMD

Consensus statement from the EU Competent Authorities to the EU Commission

EU news – European Commission

List of hyperlinks to publicly available notified bodies' standard fees
Template for notified body confirmation letter in the framework of Reg EU 2024/1860
Dashboard monitoring availability of devices in the EU
Survey on Electronic Instructions For Use (eIFUs) for medical devices

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Commission Implementing Decision (EU) 2024/2120 of 30 July 2024 renewing the designation of issuing entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of medical devices
Template for notified body confirmation letter of the status of a formal application, written agreement, and appropriate surveillance in the framework of Reg EU 2024/1860
MDCG and MDCG subgroups meetings planning (Version: 23/07/2024)
Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act)
Eudamed Updated Timeline - Current planning for gradual roll out and modules' functionality view
Regulation (EU) 2024/1860 Of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices
Q&A on practical aspects related to the implementation of the extended transitional period provided for in the IVDR, as amended by Regulation (EU) 2024/1860 of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices
Extension of the MDR Transitional Period and Removal of the 'Sell Off' Periods: Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 - Rev. 2
NBCG-MED 2024-1: Application of hybrid audits to quality management system assessments under MDR/IVDR – operational elements
MDCG 2020-16 rev.3 Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746
MDCG 2021-5 Rev. 1: Guidance on standardisation for medical devices

EU news - Team NB

Survey on Electronic Instructions For Use for medical devices
UDI issuing entities
Seventh session : MDR Technical Documentation Training for Manufacturers
Team-NB Position Paper Transfer Agreement for Surveillance of Legacy Devices V2

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US news – AdvaMed

Guardant Health's Shield™ Blood Test Approved by FDA
Opportunities, Challenges of AI Facing Medtech Innovators
AdvaMed Statement on Dr. Jeff Shuren's Retirement
AdvaMed Signs New MOU with British Medtech Association

US news – FDA

MDSAP AU P0002: Audit Approach - Version: 009
Discussion Paper: Health Equity For Medical Devices
Reprocessed Single-Use Devices: Frequently Asked Questions
Extension of Remote and Hybrid Auditing Pilot - MDSAP AU P0036
Medical Device User Fee Rates for Fiscal Year 2025
Blog: A Lifecycle Management Approach toward Delivering Safe, Effective AI-enabled Health Care
Standards Newsletter from the Division of Standards and Conformity Assessment
Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers: Draft Guidance for Industry and Food and Drug Administration Staff

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International news – IMDRF

IMDRF 26th Session | September 16-20, 2024 | Seattle, Washington
Consultation open Good machine learning practice for medical device development - Guiding Principles Closing date Friday, 30 August 2024

International news – GHWP

28th GHWP ANNUAL MEETING. 9th to 12th December 2024 KL Malaysia
Proposed Document 'Adverse Event Reporting Guidance
Proposed Document 'Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices

International news – national regulators

Australia (TGA)	Guidance: Varying entries in the ARTG: medical devices and IVDs - Version 5.0, July 2024
Canada (HC)	Notice on Health Canada's proposed changes to the guidance on recognized standards for medical devices
Switzerland (Swissmedic)	Go-live for the swissdamed Actors module
WHO	MeDevIS platform announced to boost access to medical technologies and devices
Germany (Bundestag)	Medical Research Act - Bundestag passed the "Medical Research Act" in 2nd/3rd reading.

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