



United Kingdom Country Update

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Medicines & Healthcare products Regulatory Agency





Overview

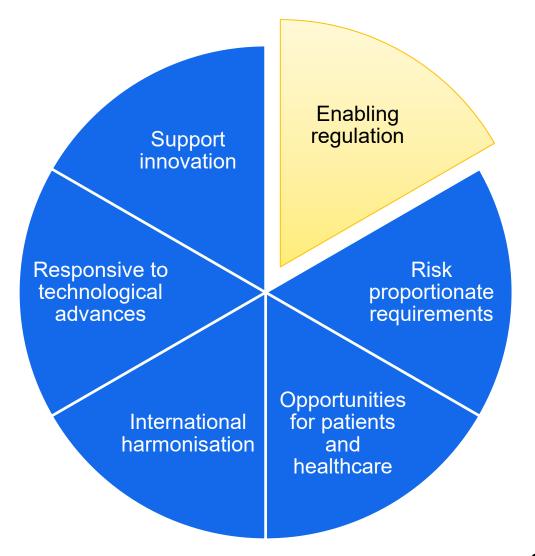
The UK is a hub for MedTech innovation...

- Medical Devices Regulatory Reform Roadmap
- Post-Market Surveillance legislation
- Pre-market Regulations legislation
- Pathway to the patient



A clear direction for the future

- Protect and improve public health
- Risk-proportionate regulation of medical products
- Use of scientific expertise to support innovation
- Predictable and timely outcomes







Medical Devices Regulatory Reform Roadmap

UDDATES	MUESTONES		2024		2025											2026	
UPDATES	MILESTONES	0	N	D	J	F	м	A	м	J	J	J A S		0	N	D	
1	STATUTORY INSTRUMENT (SI) DEBATED AND MADE LAW		-						~								
NEW REGULATIONS FOR POST- MARKET SURVEILLANCE (PMS)	PUBLICATION OF FIRST ITERATION OF PMS GUIDANCE	_			-												
	PMS REGULATIONS COME INTO FORCE 6 MONTHS AFTER BEING MADE				-						-						
(1 110)	PUBLICATION OF FINAL PMS GUIDANCE							_		-	-						
2	CONSULTATION ON IR, IVDs, MARKING AND ASSIMILATED EU LAW				_						_						
	PUBLISH RESPONSE ON ASSIMILATED EU LAW, LAY SI AND BRING INTO LAW																
	PUBLISH RESPONSE TO CTDA AND COMMON SPECS CONSULTATION																
NEW REGULATIONS FOR PRE- MARKET REQUIREMENTS	PUBLISH RESPONSE ON IR, IVDs AND MARKING																
	NOTIFICATION PERIOD FOR REGULATIONS ON WTO WEBSITE				_				-		-						
	IDENTIFICATION OF PRIORITY STANDARDS FOR DESIGNATION																
	INTRODUCTION OF SI INTO PARLIAMENT AND DEBATES							_									
	NEW PRE-MARKET SI IN FORCE SUBJECT TO TP, GUIDANCE PUBL.																-
3	DEVELOP & PUBLISH NEW EUA GUIDANCE			_													
POLICY	DEVELOP & PUBLISH POLICY INTENT FOR EARLY ACCESS AND INNOVATION																
DEVELOPMENT	REFINE POLICY AND GUIDANCE ON HIE TO ALIGN WITH GOVT STRATEGY										-						
	DEVELOP & PUBLISH IVD ROADMAP							-			_						
4	PUBLISH GUIDANCE FOR COMMENT ON																
SOFTWARE INCLUDING AI &	PUBLISH GUIDANCE FOR COMMENT ON AI DEVELOPMENT AND DEPLOYMENT																
DIGITAL MENTAL HEALTH PRODUCTS	PUBLISH SaMD GUIDANCE FOR CYBERSECURITY	_															
	DEVELOP & PUBLISH DRAFT GUIDANCE FOR DIGITAL MENTAL HEALTH TECH	-															

- Upcoming legislation
- Develop policy for early access and innovation
- Publish IVD roadmap



4



New Post-market surveillance legislation for Great Britain

Coming into force from 16 Jun 2025

legislation.gov.uk		THE NATIONAL ARCHIVES
Home Explore our collections Research	tools Help and guidance What's new About us Year: Number: Type:	English Cymraeg
	All UK Legislation (excluding originating from the EU)	Search Advanced Search
Regulations 2024 UK Statutory Instruments > 2024 No. 1368	ost-market Surveillance Requirements) (Amendme [•] Table of contents Explanatory Memorandum • Impact Assessments • More Resources •	nt) (Great Britain)
· · · · ·		-int Ontions
What Version Image: Constraint of the second seco	Status: This is the original version (as it was originally made). This item of legislation is currently on Introductory Text 1. Citation, commencement, extent and application 2. Amendments to the Medical Devices Regulations 2002 3. Amendment to regulation 2 (interpretation) 4. New Part 4A (post-market surveillance requirements) 5. Amendment to Schedule 2A 6. Saving provision Signature Explanatory Note	

- 3.2m medical device registrations
- Risk proportionate requirements
 for devices in use in Great Britain
- Safeguarding patient health
- Harmonisation across industry
- Support plans for new routes to market and improved access to devices





Guidance to support implementation

 $\underline{\mathsf{Home}} \geq \underline{\mathsf{Health}} \, \mathsf{and} \, \mathsf{social} \, \mathsf{care} \geq \underline{\mathsf{Medicines}}, \mathsf{medical} \, \mathsf{devices} \geq \underline{\mathsf{Medical}} \, \mathsf{devices} \, \mathsf{regulation} \, \mathsf{and} \, \mathsf{safety}$

Collection Medical devices: post-market surveillance

Information for manufacturers of medical devices on postmarket surveillance, reporting adverse incidents and field safety corrective actions to the MHRA.

From: <u>Medicines and Healthcare products Regulatory Agency</u> Published 26 January 2015 Last updated 15 January 2025 — <u>See all updates</u>



Post-Market Surveillance Guidance (Jan 2025)

- Detailed requirements
- Improved patient and public engagement
- Expanded scope for incident reporting
- Shortened timelines for reports
- Comprehensive trend reporting
- Pragmatic approach to custom-made devices





Upcoming changes to Pre-market regulations







Enhanced requirements for implantables supporting safe innovation



Improved traceability through mandated use of UDI

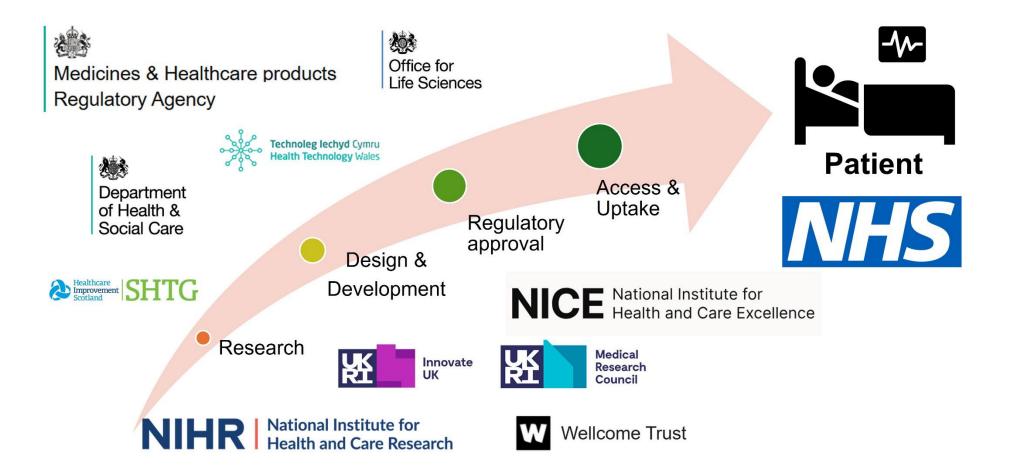


New routes to market including international reliance pathways





A connected network of expertise supporting innovative MedTech







The UK: The place for medical device innovators



- Facilitating scientific research and innovation
- Risk proportionate regulations that promote patient safety
- Enabling patient access
- Strong support from an
 interconnected healthcare network
- Open for adoption of new technologies





Thank you

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