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HPRA MEDICAL DEVICES
NEWSLETTER

ISSUE 57

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Contacting the HPRA

- Medical device adverse incident reporting, information regarding serious risk, falsified devices and any issue regarding device safety: devicesafety@hpra.ie
- Medical device registration and other queries: devices@hpra.ie

HPRA UPDATES

EU Commission proposal to improve the availability of *in-vitro* diagnostics

On 23 January, the European Commission published a legislative proposal to introduce a number of actions to improve the availability of *in-vitro* diagnostics and medical devices.

These include:

- a staggered extension to the transitional provisions under IVDR based on device risk class which is subject to certain criteria.
- new requirements for manufacturers to share information on supply interruptions.
- bringing forward the mandatory use of EUDAMED modules on a roll out basis.

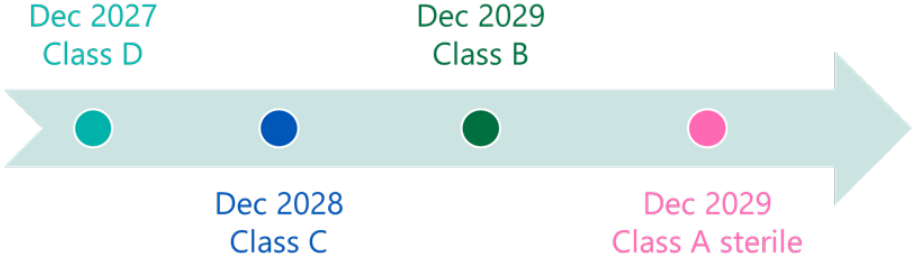
Under the current IVDR provisions, the transitional periods are set at May 2025 for high-risk class and May 2027 for lower risk class. The extended timelines under the proposal are outlined in Figure 1.

The EU Commission also proposed an additional requirement for manufacturers to provide at least 6 months prior notice of any interruption in the supply of IVDs or medical devices. While this is a new provision, manufacturers will have a six-month transition timeline following official publication before the notification requirement comes into force.

The proposal has been adopted by the EU Council and is currently with the European Parliament for consideration. If adopted, the legislative measures on the transitional provisions will come into force upon publication in the Official Journal of the EU.

We are encouraging stakeholders to review the proposal and the accompanying documents published with the EU Commission press release.

Figure 1: Proposed extended transitional periods under IVDR.



1. Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)

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HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

EUDAMED Update

Updated times and mandatory use

In accordance with the EU legislative proposal that is under review by the EU Parliament, it is expected that the mandatory use of EUDAMED modules which are already complete will be brought forward. Timelines for this will depend on the adoption of the legislation and will be published on the EU Commission website.

EUDAMED environments

The EUDAMED Platform currently has three "Environments":

1. The EUDAMED Production System – contains the modules that can be used on a voluntary basis relating to:
   - Actor registration
   - Unique Device Identification (UDI) and Device registration
   - Notified Bodies and Certificates

2. The EUDAMED Public Database – has information from the EUDAMED Production System that is publicly accessible.

3. The EUDAMED Playground – is a test environment and can be used by stakeholders to gain an understanding of the system and to test local procedures that are being developed or implemented. It currently contains six modules relating to:
   - Actor Registration,
   - Unique Device Identification (UDI) and Device registration,
   - Notified Bodies and Certificates,
   - Clinical Investigations and Performance Studies,
   - Vigilance and Market Surveillance.

There are very useful resources from the EUDAMED development team available to assist all actors in becoming familiar with the system and integrating the system into your local processes.

EU horizontal legislation

EU proposal to ban per- and polyfluoroalkyl substances (PFAS)

Background

PFAs are a large class of synthetic chemicals that come in gas, liquid, and solid forms. PFAs have widespread use across all industries. They are found in most types of medical devices including coatings for stents and catheters, orthopaedic components, tubing, blood bags etc. PFAs are commonly used due to their beneficial properties e.g., they are stable under high temperatures, they reduce wear and erosion, and they can improve biocompatibility, flexibility, and durability.

Environmental and human concerns

There are significant concerns regarding the impact of PFAs on both humans and the environment. These chemicals persist in the environment, can be toxic in both humans and animals and can bioaccumulate in organisms. PFAs are released directly and indirectly into the environment from industrial facilities and through the use of consumer products e.g. cosmetics, clothing. Despite the concerns, PFAs continue to have critical use in the MedTech sector due to the lack of suitable PFA-free substitutes available.

Regulation of PFA

PFAs are regulated under the EU regulation 1907/2006 for the registration, evaluation, authorisation and restriction of chemicals (REACH). There have been restrictions on the use of some PFAs in place for ten years and there have been further compounds restricted in recent years.

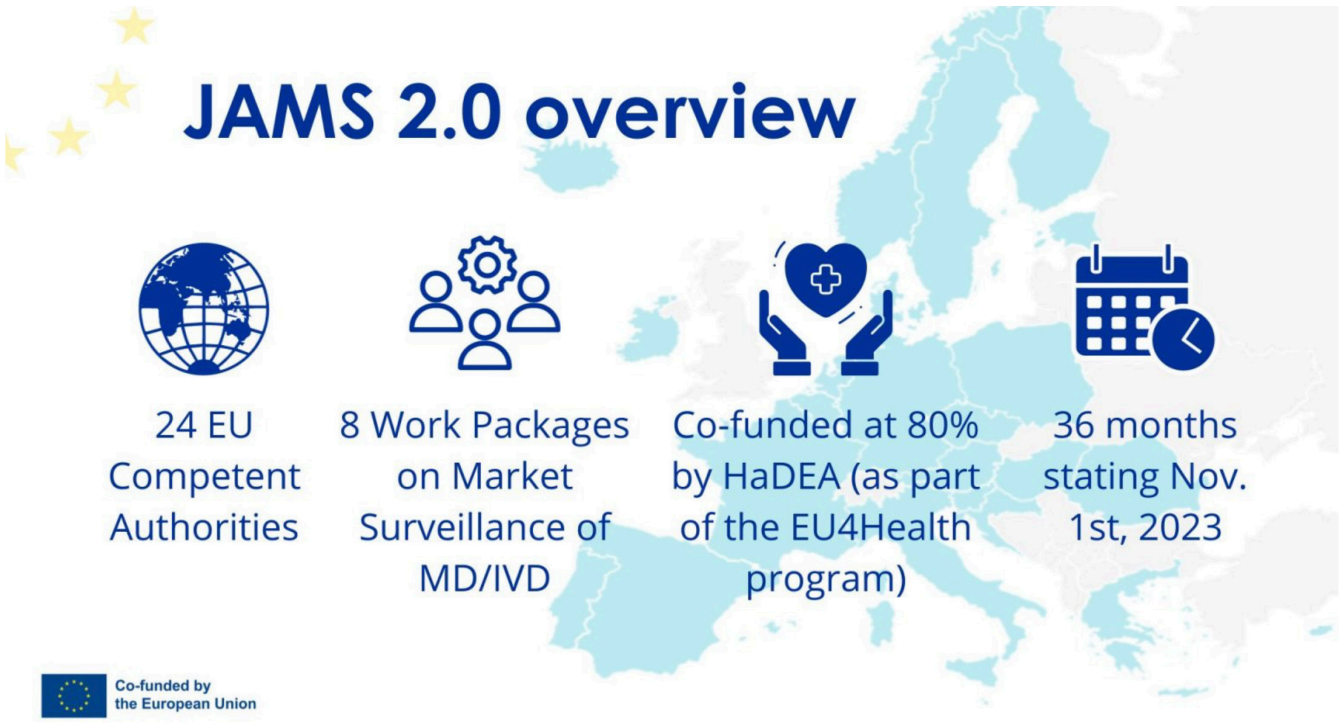
Regulatory proposal to ban all PFAs in the EU

In January 2023, Germany, Sweden, Demark, and Norway, submitted a proposal to the European Chemicals Agency (ECHA) to ban the use of all per- and polyfluoroalkyl substances. The proposal was published in February and a six-month consultation period opened in March. ECHA scientific committees are reviewing the comments received and their opinions will be submitted to the European Commission for review before issuing a decision on the proposal.

Raising awareness for medical devices and in vitro diagnostic devices

HRPA are informing stakeholders of this proposal to raise awareness of the impact of a potential complete ban on PFAs for the devices sector. Discussions are ongoing at an EU level to assess how this proposal could affect the manufacturing and supply of devices in Europe. Manufacturers experiencing significant challenges with raw material availability should raise awareness of the impact of the PFAs ban on the MedTech sector with the Department of Enterprise, Trade and Employment.

Overview of JAMS 2.0: Joint Action on Reinforced Market Surveillance of Medical Devices and *In Vitro* Medical Devices



JAMS 2.0 is a project co-funded by the European Health and Digital Executive Agency (HaDEA) under the EU4Health programme. The project aims to reinforce the market surveillance of medical devices between member states and to harmonize approaches across the European Union. The project is divided into 8 work packages (WP) covering different aspects of market surveillance. HPRA are taking part in work packages 5,6 and 8. Each work package, provides opportunities under which information on best practices, knowledge, and resources will be shared between competent authorities.

Work packages 1-4 are "cross-cutting" and involve activities to ensure the implementation and completion of the Joint Action. Work packages 5-8 are technical work packages covering different aspects of market surveillance.

WP1 – Coordination	WP 5 – Signal detection and vigilance
WP2 - Communication and dissemination	WP 6 - Inspection
WP3 – Evaluation	WP 7- Market Surveillance Campaigns
WP4 - Sustainability	WP 8 – MD/IVD University

The project will strengthen coordination for medical device safety and ensure aligned and consistent working method between competent authorities. The project began in November 2023 and will run for 3 years up to October 2026. The project is being carried out by 24 national competent authorities across Europe. Further details on the work packages and additional information on the JAMS project can be found on the CAMD webpage.

HPRA Custom-Made Device Webinar

The HPRA hosted a webinar on 19 October 2023 for custom-made device manufacturers. The webinar was designed to give an overview of the Medical Devices Regulation (MDR) and how it applies to custom-made devices. It focused on providing practical information regarding the application of the MDR for custom made device manufacturers in the areas of:

- qualification and classification
- conformity assessment
- manufacturer requirements
- quality management systems and technical documentations
- post-market surveillance and vigilance

The webinar was well-attended and there was an engaging question and answer session where a number of different topics were addressed. Each of our live sessions including the questions and answers have been recorded and the recordings are now available on the HPRA YouTube account. The link to the YouTube account can be found on the HPRA website.

Considerations when planning to carry out a clinical investigation in Ireland

Our medical devices team presented at the HRB National Clinical Trials Office (NCTO) workshop and networking event which took place in October 2023. The content of the workshop was aimed at innovators performing clinical research for devices.

We provided advice relating to the planning and the application process of clinical investigations. There was an engaging discussion on some of the common questions that are raised during the assessment period.

The summary below, while not exhaustive, outlines some of the key areas addressed with workshop participants.

Clinical Investigation Plan (CIP)/ Protocol	
✓	The CIP/Protocol should be adapted based on the type of clinical investigation and the type and development stage of the investigational medical device.
✓	The requirements of Chapter II of Annex XV in MDR must be addressed or indicated as "not applicable" with a justification.
Clinical Investigation Plan (CIP)/ Protocol	
✓	The current state of the art or standard of care
✓	Where the clinical investigation fits into the clinical development of the device
✓	The statistical design and proposed analysis of the clinical investigation
✓	Reference to any specific European, national, or other guidelines
✓	Additional safety measures where required for early studies and new/high risk devices
✓	Investigator's Brochure (IB) including a summary of benefit-risk analysis
✓	All appropriate design verification testing should be complete prior to submission
Guidance documents and resources	
✓	**MDCG 2021-8** provides a template for compiling your relevant general safety and performance requirements (GSPR) checklist.
✓	**MDCG 2020-10/1** guidance document should be used and referenced when defining and reporting adverse events during a clinical investigation.
✓	ISO14155 is the international standard for good clinical practice when conducting clinical investigations of medical devices.
✓	The European Commission have written draft guidance on both the content of the CIP and IB which will outline the type of information expected to be submitted in both documents.
✓	HPRA Guide to clinical investigations carried out in Ireland

We strongly encourage sponsors to have a pre-submission meeting before submitting an application. This support is free of charge and to apply, we ask that sponsors complete our 'Request for Clinical Investigation Pre-submission meeting' form and send it to devices@hpra.ie

Published documents

MDCG guidance documents that have been published during H2 2023 are listed in the table below. For the latest published MDCG guidance visit the EU Commission website.

Title and link	Publication date
2023/C 163/06 Commission Guidance on the content and structure of the summary of the clinical investigation report.	May 2023
European Commission Q/A Rev.1 Q/A on practical aspects related to the implementation of Regulation (EU) 2023/607-Extension of the MDR transitional period and removal of the "sell off "periods.	July 2023
Commission Delegated Regulation Commission Delegated Regulation (EU) 2023/2197 of 10 July 2023 amending Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards the assignment of Unique Device Identifiers for contact lenses.	July 2023
Manual on Borderline and classification under Regulations (EU) 2017/745 and 2017/746 v3.	September 2023
MDCG 2020-3 Rev.1 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD.	September 2023
European Commission Q/A Q/A on transitional provisions for products without an intended medical purpose covered by annex XVI of the MDR.	September 2023
MDCG 2023-4 Medical Device Software (MDSW)-Hardware combinations Guidance on MDSW intended to work in combination with hardware components.	October 2023
MDCG 2022-11 Rev-1 MDCG Position Paper: Notice to manufacturers and notified bodies to ensure timely compliance with MDR and IVDR requirements.	November 2023
Commission Implementing Regulation Commission Implementing Regulation (EU) 2023/2713 of 5 December 2023 designating European Union reference laboratories in the field of in vitro diagnostic medical devices.	December 2023
MDCG 2021-6 - Rev.1 Questions & Answers regarding clinical investigation.	December 2023
MDCG 2023-5 Guidance on qualification and classification of Annex XVI products - A guide for manufacturers and notified bodies.	December 2023
MDCG 2023-6 Guidance on demonstration of equivalence for Annex XVI products - A guide for manufacturers and notified bodies.	December 2023
Update on MDCG 2021-27 - Rev.1 Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746.	December 2023
MDCG 2023-7 Guidance on exemptions from the requirements to perform clinical investigations pursuant to Article 61(4)-(6) MDR.	December 2023