
PIPA EU Medical Device Vigilance Guidelines

(Version 1.0, 2021)

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Introduction

This document is provided only for guidance purposes and is not legally binding. It seeks to promote best practice in the pharmaceutical industry regarding medical device vigilance reporting and requirements.

On 5th April 2017, two new EU Regulations on medical devices were adopted, and entered into force on 25th May 2017 replacing the existing medical device directives.

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC¹
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU²

With a 3-year transition period extended to 4-years for the Medical Devices Regulation (MDR) and a 5-year transition period for the In Vitro Diagnostic Medical Devices Regulation (IVDR), the new requirements will not fully apply until 26th May 2021 and 26th May 2022 respectively.

During this transition period, Manufacturers (or their Authorised Representatives) can place their devices on the market under the current EU Directives. However, devices placed on the market after the transition period will need to fully comply with the new Regulations, unless manufacturers of those devices wish to make use of the extended period of CE certificate validity³.

All Manufacturers within the EU must meet the requirements in the relevant Regulation before their device(s) can be placed on the market.

These standards focus on the general safety and vigilance requirements of the MDR and IVDR Regulations. Adherence to the legislation is a legal requirement whereas adherence to the standards is voluntary.

Brexit

As the MDR and IVDR do not come into effect until after the end of the Brexit transition period, 31 December 2020, they will not be effective in Great Britain (England, Scotland and Wales). The current devices vigilance legislation therefore continues to be effective though the Medicines and Medical Devices Bill³, but allows the UK Government to amend the UK legislation regarding devices after the end of the transition period.

The MDR and the IVDR will be effective in Northern Ireland as a consequence of the Northern Ireland Protocol⁴, which requires that there be no regulatory border on the island of Ireland. For companies marketing and distributing medical devices in both Great Britain and Northern Ireland, these guidelines should be read in conjunction with the PIPA UK Medical Device Vigilance Standards.

¹ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.117.01.0001.01.ENG&toc=OJ:L:2017:117:TOC

² https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.117.01.0176.01.ENG&toc=OJ:L:2017:117:TOC

³ <https://services.parliament.uk/Bills/2019-21/medicinesandmedicaldevices.html>

⁴ [Revised_Protocol_to_the_Withdrawal_Agreement.pdf \(publishing.service.gov.uk\)](#)

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Definitions

See Article 2 in both the MDR and IVDR for a full set of relevant definitions.

Stakeholders

The Regulations extend the scope of the legislation beyond requirements of the Manufacturer. Additional requirements have been added to cover the supply chain responsibilities of other economic operators, namely the distributor, in all cases, and the importer, where the manufacturer is located outside the EU.

In addition, the Regulations have introduced the role of the Person Responsible for Regulatory Compliance.

Manufacturer

A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark. Their obligations include:

- Having at least one person responsible for regulatory compliance
- Having a quality management system that meets the requirements of the Regulations.

See Article 10 in both the MDR and IVDR for full details of the Manufacturer's obligations.

Authorised Representative (AR)

A natural or legal person established within the EU who has received and accepted a written mandate from a manufacturer, located outside the EU, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation. Their obligations include:

- Having at least one person responsible for regulatory compliance

- Where the manufacturer is not established in the EU and has not complied to its obligations, the AR shall be legally liable for defective devices on the same basis as the manufacturer.

See Article 11 in both the MDR and IVDR for full details of the AR's obligations.

Distributor

A natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.

See Article 14 in both the MDR and IVDR for full details of the Distributor's obligations.

Importer

A natural or legal person established within the EU that places a device from a third country on the EU market.

See Article 13 in both the MDR and IVDR for full details of the Importer's obligations.

Person Responsible for Regulatory Compliance

Manufacturers must appoint within their organisation at least one person responsible for regulatory compliance. The person responsible for regulatory compliance is responsible for, as a minimum:

- Quality management system
- Conformity of devices placed onto the market
- Ensuring technical documentation and declaration of conformity are compiled and maintained

- Post-market surveillance and vigilance
- Documentation relating to investigational devices.

The responsibilities can be shared between more than one person provided that the roles and responsibilities of each individual is clearly defined. For the Manufacturer, the person responsible for regulatory compliance has to be available within their organisation, that is, an employee. For Manufacturers that meet the definition of a small or micro enterprise, and for ARs, this person may be a contractor/consultant but must be permanently and continuously available to the Manufacturer or AR.

The person responsible for regulatory compliance must either have:

- A qualification in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices
- 4-years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

See Article 15 in both the MDR and IVDR for full details of the person responsible for regulatory compliance's obligations.

3 Post-market Surveillance

Post-market surveillance (proactive/preventative) is defined as:

- All activities carried out by Manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.

The key obligations for post-market surveillance are:

- Post-market surveillance system
 - Establish, implement and maintain a system to gather, record and analyse data on the quality, performance and safety of the device
 - Use the data, inter alia, to:
 - Update the risk/benefit assessment of the device
 - Update the design and use instructions
 - Update the clinical evaluation and summary of safety and clinical performance
 - Identify the need for field safety corrective actions (FSCA)
 - Implement appropriate corrective and preventative actions to ensure safe use of the device
 - Identify options to improve usability and safety of the device
 - Detect and report trends
 - Contribute to the safety of related devices
- Post-market surveillance plan
 - Describes the implementation of the post-market surveillance system for collecting information and characterising the safety and performance of the device
 - Includes the monitoring of the clinical and scientific literature
 - Describes the methods and processes to analyse and report the collected information
- Post-market surveillance report (PMS) report
 - Required for Class I medical devices and Class A and D in-vitro devices. To be updated as necessary. It contains data on post-market surveillance activities and their results. For example, what data has been collected and conclusions drawn regarding any changes to the risk/benefit profile of the device
- Post-Market Clinical / Performance Follow-Up (PMCF for MDR, PMPF for IVDR)
 - This is a continuous process that updates and maintains the clinical evaluation (for a medical device) or performance evaluation (for an in-vitro device) submitted as part of the initial application for a CE mark
 - This is documented in a PMCF/PMPF plan which clearly defines what data is to be collected, including from the clinical and scientific literature, and how it is to be evaluated and reported
- Periodic safety update report (PSUR)
 - Required for Classes II and III medical devices and Class C and D in-vitro devices. It contains the same information as the PMS report, plus a detailed assessment of the risk/benefit ratio, information on the results of the PMCF/PMPF, an overview of the patient exposure, FSCAs and CAPAs.
 - To be made available to the relevant notified body or competent authority upon request for Class IIb and Class C devices
 - To be uploaded into Eudamed* for Class II implantable, Class III and Class D devices for evaluation. The notified body's evaluation to be available to the competent authorities

- Summary of Safety and Clinical Performance (SSCP/SSP)
 - Required for Class III and implantable medical devices (SSCP) and Class C and D in-vitro devices (SSP)
 - Must be updated at least annually
 - Short report aimed directly at the user i.e. the patient
 - To be uploaded into Eudamed* after approval by the relevant notified body.
- For any identified incident, it will be processed, assessed and reported
- Incidents may require expedited reporting as well as reporting in the relevant post-market surveillance reports

Templates and guidance documents for some of the required documents have been, or are to be, developed by the Medical Device Coordination Group (MDCG)⁵.

See Chapter VII, Section 1 of the MDR and IVDR for more information.

Vigilance

Vigilance is the reactive monitoring and reporting of device safety.

The key obligations for vigilance are:

- Monitoring of device safety (incidents)
 - Incidents are defined as:
 - Any malfunction or deterioration in the characteristics or performance of a device made available on the market, including user-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect
 - Serious incidents are defined as:
 - Any incident that directly or indirectly led, might have led or might lead to any of the following:
 - the death of a patient, user or other person;
 - the temporary or permanent serious deterioration of a patient's, user's or other person's state of health; or,
 - a serious public health threat.
 - Manufacturers should have in place processes to ensure that any complaint is triaged to determine if there is an associated incident
- Reporting of serious incidents
 - Serious incidents require expedited reporting via Eudamed*, except expected side-effects already listed in the product information
 - The timelines are
 - 2 days for serious public health threats
 - 10 days for death or unanticipated serious deterioration in health
 - 15 days for all other serious incidents
 - Serious incidents require investigation and a risk assessment of the incident. This may lead to a field safety corrective action (FSCA)
- Field safety corrective actions (FSCA)
 - Corrective action taken by the Manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market
 - A field safety notice is a communication sent to users in relation to an FSCA
 - Manufacturers must have a process in place for the creation, approval and dissemination of FSCAs
- Trend reporting
 - Manufacturers must have a process for monitoring, analysing and reporting any increase in the frequency or severity of incidents
 - It is required for incidents that do not meet the reporting criteria, but which could have a significant impact on the risk/benefit analysis and present unacceptable risks to the health or safety of patients, users or others.

These are the activities of the competent authorities to ensure that devices comply with the requirements set out in the Regulations and do not endanger public health or safety.

5. https://ec.europa.eu/health/md_sector/new_regulations/guidance_en

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Market surveillance

See Chapter VII, Section 3 of the MDR and IVDR for more information.

Quality Management System

The QMS for device post-market surveillance and vigilance should include processes and procedures for the following:

- Role and responsibilities of the Person Responsible for Regulatory Compliance
- Receipt, processing and reporting of device incidents
- Creation and maintenance of post-market surveillance plans
- Preparation of PMS reports
- Preparation of PMCF/PMCP reports
- Preparation and submission of PSURs
- Creation and maintenance of SSCP
- Creation, approval and distribution of FSCAs
- Trend analysis and reporting.

*Eudamed (European database on medical devices) is not currently functional for electronic reporting by Manufacturers. Serious incident reports should continue to be reported to the relevant competent authority until further notice.

Annex.

Overview of the Regulations for Post-market Surveillance and Vigilance

Requirement	Regulation Article	MDR	IVDR
Person Responsible for Regulatory Compliance	MDR 15 IVDR 15		
Post-market surveillance	MDR Chapter VII, Section 1 IVDR Chapter VII, Section 1		
Summary of Safety (and Clinical) Performance	MDR 32 IVDR 29	<ul style="list-style-type: none"> • SSCP required 	<ul style="list-style-type: none"> • SSP required
Post-market surveillance system	MDR 83 IVDR 78		
Post-market surveillance plan	MDR 84 & Annex III IVDR 79 & Annex III		
Post-market surveillance report	MDR 85 IVDR 80	<ul style="list-style-type: none"> • Updated as necessary • Submitted to competent authority upon request 	
		Required for Class I device	Required for Class A & B devices
Periodic safety update report	MDR 86 IVDR 81	<ul style="list-style-type: none"> • Class I devices <ul style="list-style-type: none"> • Not required • Class IIa devices <ul style="list-style-type: none"> • When necessary and at least every 2 years • Class IIb devices <ul style="list-style-type: none"> • When necessary and at least every year • Made available to notified body and upon request to a competent authority • Notified body evaluation to be added • PSUR and notified body evaluation to be made available to competent authorities via Eudamed 	<ul style="list-style-type: none"> • Class A and B devices <ul style="list-style-type: none"> • Not required • Class C devices <ul style="list-style-type: none"> • When necessary and at least every year • Made available to notified body and upon request to a competent authority • Class D devices <ul style="list-style-type: none"> • When necessary and at least every year • To be submitted electronically to notified body via Eudamed • Notified body evaluation to be added • PSUR and notified body evaluation to be made available to competent authorities via Eudamed

Requirement	Regulation Article	MDR	IVDR
		<ul style="list-style-type: none"> • Class III devices • When necessary and at least every year • To be submitted electronically to notified body via Eudamed • Notified body evaluation to be added • PSUR and notified body evaluation to be made available to competent authorities via Eudamed 	
Vigilance	MDR Chapter VII, Section 2 IVDR Chapter VII, Section 2		
Reporting of serious incidents and field safety corrective actions	MDR Article 87 IVDR Article 82	<ul style="list-style-type: none"> • Report immediately via Eudamed after they have established a causal relationship between that incident and their device or that such a causal relationship is reasonably possible, and not later than • 2 days in the case of serious public health threats • 10 days in the case of death or unanticipated serious deterioration in health which has remained unchanged • 15 days for all other events • Does not apply for expected events 	
Trend reporting	MDR Article 88 IVDR Article 83		
Analysis of serious incidents and field safety corrective actions	MDR Article 89 IVDR Article 84		
Post-market Clinical/ Performance Follow-up	MDR Annex XIV Part B IVDR Annex XIII Part B	• PMCF required	• PMPF required



PIPA, PO Box 254
Haslemere
Surrey
GU27 9AF



pipa@pipaonline.org



<https://pipaonline.org/>

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