Post-market surveillance

bsi. Compliance Navigator
for Medical Devices

Background to changes

The Medical Devices Regulation (MDR) (Regulation (EU) 2017/745) and In Vitro Medical Device Regulation (IVDR) (Regulation (EU) 2017/746) are significant changes to European legislation for medical devices. Understanding the requirements is essential to your ability to provide the European Union market with safe medical devices that perform as intended and comply with the Regulations. One of the areas that has been changed substantially in the new Regulations relates to the ongoing oversight by the manufacturer of devices once they are on the market. This is consistent with the gathering of information from the post-production phase referred to in ISO 14971:2019, the international and European standard for risk management. EN ISO 13485:2016, the standard for quality management systems (QMS) for medical devices, also references using data from post-production activities in feedback processes as well as requiring that post-market surveillance (PMS) is used to maintain the safety and performance of medical devices.

PMS is undertaken as a responsibility of the manufacturer – it is different from 'market surveillance', which is used to describe activities to monitor compliance with the Regulations undertaken by, and coordinated between, national competent authorities.

The current Active Implantable Medical Devices Directive (AIMDD) (90/385/EEC), Medical Devices Directives (MDD) (93/42/EEC) and In Vitro Diagnostic Medical Devices Directive (IVDD) (98/79/EC) are repealed on the date of application of the MDR and IVDR, unless any provisions are specifically identified otherwise. Article 120 of the MDR and Article 110 of the IVDR, Transitional provisions, allow that a device with a valid certificate that was issued in accordance with the MDD, AIMD or IVDDD can be placed on the market or put into service for a defined period after the date of application of the Regulations, provided the device continues to comply with those Directives and there are no significant changes in the design and intended purpose.

However, the requirements of the Regulations relating to (1) post-market surveillance, (2) market surveillance, (3) vigilance, (4) registration of economic operators[1] and (5) registration of devices[1], apply in place of the corresponding requirements in the Directives from the date of application.

- For the MDR, the transition period is four years. The transition period of the MDR ends on the date of application, 26th May 2021.
- For the IVDR, the transition period is five years and so the date of application for the IVDR, and the end of its transition period, is 26th May 2022.

Therefore, the vigilance and PMS requirements in the MDR and IVDR apply to:

1. all devices from the date that they are CE marked under the MDR or IVDR, whether applied during the transition period or after the entry into force; and
2. any devices CE marked and legally marketed under the Medical Devices Directive or In Vitro Diagnostic Medical Devices Directive after the date of application of the Regulations.

In many aspects, the requirements of the IVDR parallel the MDR; this guidance is intended to be as generic as possible and apply to both Regulations unless specifically indicated as applicable to medical devices or in vitro diagnostic (IVD) devices specifically.

An overview of the requirements for vigilance and PMS is summarized in Table 1.

[1]This will not apply until Eudamed becomes available which may not be on the date of application of the Regulation.

Element of the Regulation	Description	MDR	IVDR
Post-market surveillance system MDR Article 83: Post-market surveillance system of the manufacturer MDR Article 15: Person responsible for regulatory compliance	Comprehensive system to gather experience from the use of devices	✓ Proactive and systematic ✓ Allows cooperation on vigilance and market surveillance ✓ Connects with corrective action or preventive action processes ✓ Allows update of technical documentation, including the risk-benefit determination and clinical evaluation/performance evaluation. ✓ Part of the manufacturer's QMS	
IVDR Article 78: Post-market surveillance system of the manufacturer IVDR Article 15: Person responsible for regulatory compliance	Person responsible for regulatory compliance		✓ Fulfils minimum conditions of qualification ✓ Within the manufacturer's organization, except small manufacturers ✓ Permanently and continuously available to the authorized representative ✓ Ensures the requirements for PMS and vigilance are met

<table>
<tr><th>Element of the Regulation</th><th>Description</th><th>MDR</th><th>IVDR</th></tr>
<tr><td>Post-market surveillance plan

MDR Article 84: Post-market surveillance plan

MDR Annex III: Technical documentation on post-market surveillance

IVDR Article 79: Post-market surveillance plan

IVDR Annex III: Technical documentation on post-market surveillance</td><td>Describes the implementation of the PMS system for collecting information and characterizing the safety and performance of the device, or family of devices, and the methods and processes to assess the collected information</td><td colspan="2">✓ Part of the QMS and technical documentation

✓ Defines indicators and thresholds for continuousreassessment of risk management and the risk-benefit analysis

✓ Incorporates information from complaint investigation and market experience

✓ Describes methods to monitor trends, identify statistically significant increases in frequency or severity of incidents and provides trend reports

✓ Defines methods of communication with competent authorities and notified bodies

✓ Defines methods of communication with authorized representatives, importers, distributors, users and patients

✓ Describes means of tracing and identifying devices

✓ References the documented procedures for the –
• PMS system;
• creation of the PMS plan;
• generation of the PSUR or PMS report, as applicable; and
• processes for corrections, corrective actions or preventive actions.</td></tr>
<tr><td rowspan="2">Post-market surveillance report

MDR Article 85: Post-market surveillance report

IVDR Article 80: Post-market surveillance report</td><td rowspan="2">Summarizes the results and conclusions of analysis of the PMS data</td><td colspan="2">✓ Includes rationale for, and description of, any preventive action or corrective actions taken

✓ Updated when necessary and made available to the competent authority upon request</td></tr>
<tr><td>Applicable to class I devices</td><td>Applicable to class A and B devices</td></tr>
</table>

<table>
<tr><th>Element of the Regulation</th><th>Description</th><th>MDR</th><th>IVDR</th></tr>
<tr><td rowspan="2">Period safety update report

MDR Article 86: Periodic safety update report

IVDR Article 81: Periodic safety update report</td><td rowspan="2">Summarizes the results and conclusions of the analysis of PMS data with usage data</td><td colspan="2">✓ Kept up to date throughout the lifetime of the device
✓ Part of the technical documentation
✓ Includes –
• conclusions to be used in risk–benefit determination;
• main findings of any PMCF/PMPF evaluation report;
• volume of sales of devices with an estimate of the size of the population using the device; and
• rationale for, and description of, any preventive action or and corrective actions taken.</td></tr>
<tr><td>Class IIa devices
✓ Updated when necessary and at least every two years

Class IIb devices
✓ Updated when necessary and at least annually
✓ Made available to notified body and, upon request, to competent authorities</td><td>Class C devices
✓ Updated when necessary and at least annually
✓ Made available to notified body and, upon request, to competent authorities</td></tr>
</table>

Element of the Regulation	Description	MDR	IVDR
		For implantable devices ✓ Submitted electronically by means of Eudamed[2] to notified body ✓ Notified body evaluation added with details of any action taken ✓ PSUR and the notified body evaluation available to competent authorities through Eudamed[2] Class III devices ✓ To update when necessary and at least annually ✓ Submitted electronically by means of Eudamed[2] to notified body ✓ Notified body evaluation added with details of any action taken ✓ PSUR and the notified body evaluation available to competent authorities through Eudamed[2]	Class D devices ✓ Updated when necessary and at least annually ✓ Submitted electronically by means of Eudamed[2] to notified body ✓ Notified body evaluation added with details of any action taken ✓ PSUR and the notified body evaluation available to competent authorities through Eudamed[2]

[2]This will not apply until Eudamed becomes available which may not be on the date of application of the Regulation.

Element of the Regulation	Description	MDR	IVDR
Vigilance MDR Article 87: Reporting of serious incidents and field safety corrective actions MDR Article 88: Trend reporting MDR Article 89: Analysis of serious incidents and field safety corrective actions IVDR Article 82: Reporting of serious incidents and field safety corrective actions IVDR Article 83: Trend reporting IVDR Article 84: Analysis of serious incidents and field safety corrective actions		✓ Exemption rules reduced ✓ Temporary serious deterioration in health reportable ✓ Establishes trend reporting ✓ Manufacturers must report immediately 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; and • 15 days for all other events.	

Actions

All the above points mean that you need to review your existing processes and improve their efficiency and effectiveness, as well as look at resource needs to implement the changes and then sustain compliance. You need to develop an effective implementation plan for these changes that are integrated within your overall programme to move to compliance with all the aspects of the Regulations.

Get in Touch

Smart Support is designed to outline the impact of the new regulatory changes, in order for your business to prepare to navigate the transition and implement the new requirements.

Each Smart Support topic is written by an industry expert and reviewed by a topic expert and advisory panel, providing you with:

- An executive summary suitable for senior management
- Detailed practical guidance on what has changed and what this means for your organization
- Actions to take now and a summary of what is still to change

To access the full text of the MDR/IVDR Smart Support and find out more about Compliance Navigator, contact us today.

T: +44 (0)20 8996 7029
E: cservices@bsigroup.com
bsigroup.com/complinav