



# The European Medical Devices Regulations

What are the requirements for vigilance reporting  
and post-market surveillance?

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## Introduction

The publication of the stable text of the European Union (EU) Medical Devices Regulation<sup>1</sup> (MDR), and the In Vitro Diagnostic Medical Devices Regulation<sup>2</sup> (IVDR), in June 2016 documented political agreement between the three EU Institutions – the Commission, the Parliament and the Council – on the revision of the European Union legislation for medical devices. The text has now been reviewed for legal and language consistency. Formal publication of the ratified text in the Official Journal is expected in the second quarter of 2017, with entry into force of the two Regulations twenty days later. This starts the transition period of three years for the MDR and five years for the IVDR until the date of application of each regulation. You should note the meaning of terms used in the Regulations – ‘entry into force’ is the date when the regulation comes into effect and the transition period starts and the ‘date of application’ reflects the end of the transition period and the repeal of the Active Implantable Medical Devices Directive (AIMDD – 90/385/EEC), Medical Devices Directive (MDD – 93/42/EEC) and In Vitro Diagnostic Medical Devices Directive (IVDD – 98/79/EC).

BSI has published several white papers describing the MDR, the IVDR and how to start to prepare for them<sup>3-6</sup>.

One of the areas that has been changed substantially in the new Regulations relates to the ongoing oversight of marketed devices by the manufacturer of devices. This is the gathering of information from the post production phase referred to in EN ISO 14971<sup>7</sup>, the international and harmonized European standard for risk management. This paper focuses on vigilance and post-market surveillance (PMS) requirements from the European context. PMS is undertaken as a responsibility of the manufacturer and is in contrast to ‘market surveillance’, a term used in the Regulations to describe activities undertaken by, and coordinated between, the national competent authorities.

The current AIMDD, MDD and IVDD are repealed on the date of application of the MDR and IVDR, unless any provisions are specifically identified otherwise. There are no exceptions identified in the text with regards to requirements for vigilance or PMS from the Directives continuing to apply. Consequently, unless there is further guidance issued to provide additional interpretation, it would appear that the vigilance and PMS requirements apply to i) all devices from the date that they are CE marked under the MDR or IVDR, and, ii) any devices CE marked and legally marketed under the AIMDD, MDD or IVDD after the date of application of the Regulations.

This paper addresses a number of areas, including:

- PMS as an element of the management of clinical evidence throughout the device lifecycle;
- the PMS system, which is the comprehensive process used to collect, analyze and take action on PMS information;
- the PMS plan, which describes the application of the PMS system to a device or device family;
- preparation of a summary report of PMS information;
- complaint handling and reporting of vigilance; and,
- electronic submission of vigilance data and summary reports of PMS.

In many aspects the requirements of the IVDR parallel the MDR and the material presented here applies to both Regulations unless specifically indicated otherwise. An overview of the requirements for vigilance and PMS is summarized in Table 1.

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1. Council of the European Union, Interinstitutional File: 2012/0266 (COD) Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, 27 June 2016
  2. Council of the European Union, Interinstitutional File: 2012/0267 (COD) Proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices, 27 June 2016
  3. The proposed EU regulations for medical and in vitro diagnostic devices – An overview of the likely outcomes and the consequences for the market. Updated on 5 October 2015
  4. How to prepare for and implement the upcoming MDR – Dos and don'ts
  5. How to prepare for and implement the upcoming IVDR – Dos and don'ts
  6. Planning for implementation of the European Union Medical Devices Regulations – Are you prepared?
  7. EN ISO 14971:2012 Medical devices – Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

**Table 1 – Summary of the main vigilance reporting and PMS provisions of the Medical Devices Regulation and the In Vitro Medical Devices Regulation**

Element of the Regulation	Description	Medical Devices Regulation	<i>In Vitro</i> Medical Devices Regulation
<b>Post-market surveillance system</b> MDR – Article 83: Post-market surveillance system of the manufacturer MDR – Article 15: Person responsible for regulatory compliance IVDR – Article 78: Post-market surveillance system of the manufacturer IVDR –	Comprehensive system to gather experience from the use of devices	<ul style="list-style-type: none"> <li>Proactive and systematic</li> <li>Allows cooperation on vigilance and market surveillance</li> <li>Connects with corrective action or preventive action processes</li> <li>Allows update of technical documentation, including the risk-benefit determination and clinical evaluation.</li> <li>Part of the manufacturer's QMS</li> </ul>	
	Person responsible for regulatory compliance	<ul style="list-style-type: none"> <li>Fulfils minimum conditions of qualification</li> <li>Within the manufacturer's organization, except small manufacturers</li> <li>Permanently and continuously available to the authorized representative</li> <li>Ensures the requirements for PMS and vigilance are met</li> </ul>	
<b>Post-market surveillance plan</b> 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	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	<ul style="list-style-type: none"> <li>Part of the QMS and technical documentation;</li> <li>Defines indicators and thresholds for continuous reassessment of risk management and the risk-benefit analysis</li> <li>Incorporates information from complaint investigation and market experience;</li> <li>Describes methods to monitor trends, identify statistically significant increases in frequency or severity of incidents and provides trend reports;</li> <li>Defines methods of communication with competent authorities and notified bodies;</li> <li>Defines methods of communication with authorized representatives, importers, distributors, users and patients;</li> <li>Describes means of tracing and identifying devices;</li> <li>References the documented procedures for the –               <ul style="list-style-type: none"> <li>PMS system</li> <li>creation of the PMS Plan</li> <li>generation of the PSUR or PMS report, as applicable</li> <li>processes for corrections, corrective actions or preventive actions.</li> </ul> </li> </ul>	
<b>Post-market surveillance report</b> MDR – Article 85: Post-market surveillance report IVDR – Article 80: Post-market surveillance report	Summarizes the results and conclusions of analysis of the PMS data	<ul style="list-style-type: none"> <li>Includes rationale for, and description of, any preventive action or corrective actions taken;</li> <li>Updated when necessary and made available to the competent authority upon request.</li> </ul>	
		Applicable to Class I devices	Applicable to Class A and B devices

The references to the Regulations in the first column might change in the final published text

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Table 1 – Continued

Element of the Regulation	Description	Medical Devices Regulation	<i>In Vitro</i> Medical Devices Regulation
<p><b>Period Safety Update report</b></p> <p>MDR – Article 86: Periodic safety update report</p> <p>IVDR – Article 81: Periodic safety update report</p>	<p>Summarizes the results and conclusions of the analysis of PMS data with usage data</p>	<ul style="list-style-type: none"> <li>● Kept up to date throughout the lifetime of the device;</li> <li>● Part of the technical documentation;</li> <li>● Includes –                             <ul style="list-style-type: none"> <li>– conclusions to be used in risk-benefit determination;</li> <li>– main findings of any PMCF evaluation report;</li> <li>– volume of sales of devices with an estimate of the size of the population using the device;</li> <li>– rationale for, and description of, any preventive action or and corrective actions taken.;</li> </ul> </li> </ul>	
		<p><i>Class IIa devices</i></p> <ul style="list-style-type: none"> <li>● updated when necessary and at least every two years</li> </ul>	
		<p><i>Class IIb devices</i></p> <ul style="list-style-type: none"> <li>● updated when necessary and at least annually</li> <li>● made available to notified body and, upon request, to competent authorities</li> </ul> <p><i>For implantable devices</i></p> <ul style="list-style-type: none"> <li>● submitted electronically by means of Eudamed to notified body</li> <li>● notified body evaluation added with details of any action taken</li> <li>● PSUR and the notified body evaluation available to competent authorities through Eudamed.</li> </ul>	<p><i>Class C devices</i></p> <ul style="list-style-type: none"> <li>● updated when necessary and at least annually</li> <li>● made available to notified body and, upon request, to competent authorities</li> </ul>
		<p><i>Class III devices</i></p> <ul style="list-style-type: none"> <li>● updated when necessary and at least annually</li> <li>● submitted electronically by means of Eudamed to notified body</li> <li>● notified body evaluation added with details of any action taken</li> <li>● PSUR and the notified body evaluation available to competent authorities through Eudamed.</li> </ul>	<p><i>Class D devices</i></p> <ul style="list-style-type: none"> <li>● updated when necessary and at least annually</li> <li>● submitted electronically by means of Eudamed to notified body</li> <li>● notified body evaluation added with details of any action taken</li> <li>● PSUR and the notified body evaluation available to competent authorities through Eudamed.</li> </ul>

The references to the Regulations in the first column might change in the final published text

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Table 1 – Continued

Element of the Regulation	Description	Medical Devices Regulation	<i>In Vitro</i> Medical Devices Regulation
<b>Vigilance</b> 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		<ul style="list-style-type: none"> <li>● Exemption rules reduced</li> <li>● Temporary serious deterioration in health reportable</li> <li>● Establishes trend reporting</li> <li>● The timelines for reporting –               <ul style="list-style-type: none"> <li>– serious public health threats – 2 days</li> <li>– death or unanticipated serious deterioration in health have remained unchanged – 10 days</li> <li>– all other events – 15 days.</li> </ul> </li> </ul>	

The references to the Regulations in the first column might change in the final published text

## Definitions

As the Regulations introduce some new terms or modify some terms from the previous Directives, some key terms for vigilance and PMS are provided in Table 2.

The definitions in Table 2 are definitions in the Regulations or, in the absence of a definition, the explanatory text in an Article in the Regulations. The Regulations do not use the term 'family of devices' and refer to a 'category or group of devices' without a definition. The Regulations define a 'generic device group' although it does not use this term in relation to PMS but rather uses it in relation to conformity assessment and the responsibilities of the authorised representative. In this document the term 'device family', which is defined in ISO 12485:2016, is used as a synonym for 'category or group of devices'. A Notified Body might have developed characteristics that establish their criteria for establishing a device family.

## Clinical evidence and the device lifecycle

The Regulations emphasize the responsibilities of the manufacturer to update and maintain the clinical evaluation of their device and the resulting documentation throughout the device lifecycle. While these responsibilities were also a feature of the AIMDD, MDD and IVDD and the guidance in MedDev 2.7/1 Revision 4<sup>8</sup>, the Regulations provide significantly more detail and require the creation of specific plans and summary reports as well as, for certain classes of device or IVD device, submission of the summary report to the notified body. The lifecycle activities associated with clinical evidence for a medical device include:

- establishing clinical evidence through premarket clinical evaluations or clinical investigations;
- preparing and maintaining clinical evaluation reports (CERs);
- planning and conducting post-market clinical follow-up (PMCF), or documenting a justification why it is not applicable;

8. MEDDEV 2.7/1 revision 4 – June 2016 – Guidelines on Medical Devices – Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC.

Table 2 – Definitions

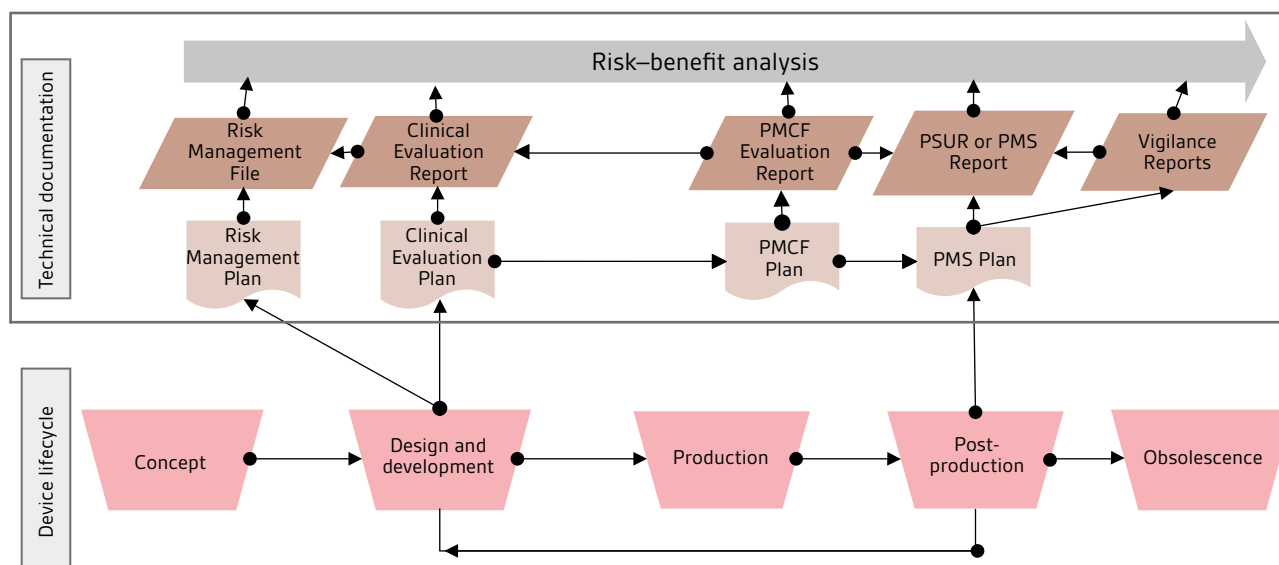
Term	Definition
Post-market surveillance (PMS)	All activities carried out by the manufacturer, in cooperation with other economic operators, to institute and keep up to date a systematic procedure to proactively collect and review experience gained from their devices placed on the market, made available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions
Market surveillance	Activities carried out and measures taken by competent authorities to check and ensure that devices comply with the requirements set out in the relevant legislation and do not endanger health, safety or any other aspect of public interest protection
Post-market clinical follow-up (PMCF)	Clinical investigation conducted to further assess, within the scope of its intended purpose, a device which already bears the CE marking
Periodic safety update report (PSUR)	Summary of the results and conclusions of the analyses of the gathered post-market surveillance data for each device or device family
Vigilance	Reporting of serious incidents and field safety corrective actions by manufacturers of devices, made available on the Union market, to the relevant competent authorities
Device family	Group of medical devices manufactured by or for the same manufacturer and having the same basic design and performance characteristics related to safety, intended use and function
Incident	Any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect
Serious incident	Any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person; (b) the temporary or permanent serious deterioration a patient's, user's or other person's state of health; or, (c) a serious public health threat.
Generic device group	Set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics

- planning and conducting PMS;
- documenting periodic safety update reports (PSUR) for:
  - class II and class III medical devices, and
  - class C or D IVD devices
- documenting PMS reports for:
  - class I medical devices, and
  - class A or B IVD devices;
- publishing a summary of safety and clinical performance (SSCP); and
- maintaining the risk-benefit analysis up-to-date based on the latest information.

Figure 1 illustrates how key stages in the device lifecycle and the ongoing risk-benefit analysis connect with the collection and monitoring of clinical evidence and the requirements for PMS and vigilance.

As a critical element of monitoring the safety and performance of the device, PMS data are used as an input into a number of processes used by the manufacturer to ensure the safety and performance of their device throughout its lifecycle. In particular, PMS data are intended to be used to:

**Figure 1** – Illustration of the relationship between device lifecycle, ongoing collection and monitoring of clinical evidence and requirements for vigilance and PMS



- input into risk management, including maintaining the risk-benefit determination;
- update design and manufacturing information, the instructions for use and the content of the labels;
- update the clinical evaluation report;
- update the SSCP;
- identify the need for preventive action, corrective action or field safety corrective action;
- identify improvements in usability, performance and safety of the device;
- contribute to PMS of other devices; and,
- detect and report trends indicating a statistically significant increase in the frequency or severity of i) incidents that do not meet the criteria for classification as serious incidents, or ii) expected undesirable side-effects, that could have a significant impact on the risk-benefit analysis.

Initial activities to prepare for the new requirements include:

- ✓ reviewing the lifecycle activities and their connections in the quality management system (QMS), in particular the connections between the risk management, generation of clinical evidence, PMS and the maintenance of the technical documentation;
- ✓ establishing the linkage mechanisms between the risk management plan, clinical evaluation plan, PMCF plan, PMS plan and their associated reports, how they feed into the technical documentation, and how they are maintained to be consistent throughout the lifecycle of the device.

## Post-market surveillance system

A comprehensive PMS system needs to be established, through which the manufacturer gathers experience from the use of their devices. The Regulations are explicit that this gathering of experience is proactive, involving actions to seek information, not simply reactive to complaints or other feedback received from the market.

A comprehensive, proactive PMS system needs to be established that is part of the QMS



The PMS system has to allow:

- systematic and active gathering of information;
- cooperation with the competent authorities responsible for vigilance and market surveillance;
- connection with the system for corrective action or preventive action to incorporate lessons learned; and,
- update of the technical documentation, including the risk-benefit determination and clinical evaluation.

The PMS system needs to be part of the manufacturer's QMS to allow an integrated, systems approach to be employed and connect with other processes of the QMS, including connections with the processes for risk management. This is consistent with the requirements in EN ISO 14971 on risk management and the requirements on measurement, analysis and improvement in EN ISO 13485:2016<sup>9</sup> to:

- document procedures for a feedback process including gathering data from post-production activities as input into risk management to maintain product requirements;
- gain specific experience from post-production activities and review this experience in the feedback process; and,
- identify and implement any changes necessary to ensure continued safety and performance of the device through the use of PMS.

As part of the manufacturer's QMS, PMS is subject to all the general QMS requirements including establishing, documenting and maintaining procedures that are implemented by competent personnel; providing adequate infrastructure and resources; subjecting PMS processes to internal audit and management review; and implementing correction, corrective action or preventive action to QMS processes or devices when necessary.

Post-market clinical follow-up (PMCF) is a continuous process to update the clinical evaluation. Whilst the Directives mention PMCF but provide little detail, the Regulations introduce specific PMCF requirements. PMCF is part of the PMS system and is described in a specific PMCF plan that is in turn an element of the PMS plan. When conducting PMCF, the manufacturer collects and evaluates clinical data proactively from the use of a CE marked device to i) confirm the safety and performance throughout the expected lifetime of the device, ii) ensure the continued acceptability of identified risks, and, iii) detect emerging risks. PMCF is an element of clinical evaluation that forms a bridge from clinical evidence collected in the premarket stage with PMS collected when the device is in regular use. PMCF is a broad topic closely connected with clinical evaluation and is not discussed further in detail here.

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9. EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes



## A qualified person responsible for regulatory compliance needs to be appointed



The Regulations require that, within the manufacturer's organization, a person responsible for regulatory compliance, who fulfils minimum conditions of qualification, is responsible for ensuring that the requirements for PMS and vigilance are met. The qualifications of this person are demonstrated by either i) formal qualification such as a diploma or certificate awarded on completion of a university degree, or equivalent course of study, in law, medicine, pharmacy, engineering or other relevant scientific discipline with at least one year of professional experience in regulatory affairs or QMS relating to medical devices or IVD devices as applicable; or, ii) four years of professional experience in regulatory affairs or in QMS relating to medical devices or IVD devices as applicable. Small manufacturers<sup>10</sup> are not required to have this person within their organization but the person has to be permanently and continuously available to them; this implies a contractual relationship that defines responsibilities and ensures availability to carry out these responsibilities. Where the manufacturer is located outside the European Union, their authorized representative also has to have a similarly qualified individual with the defined responsibilities for ensuring the requirements for PMS and vigilance are met either within their organization, or permanently and continuously available if they are not within their organization.

The responsibilities and authority of the person responsible for regulatory compliance should be documented in their job description and their interrelationships within the organization (shown in the organization charts). The person responsible for regulatory compliance should not be disadvantaged by the proper fulfilment of his or her responsibilities, regardless of whether or not they are employees of the organization. This implies that their independence should be guaranteed and their remuneration or career progression not limited by correctly fulfilling their responsibilities. The name, address and contact details of the person responsible for regulatory compliance is an element of the information to be submitted with the registration of the manufacturer or authorized representative.

Initial activities to prepare for the new requirements include:

- ✓ reviewing PMS activities against the requirements of the Regulation and identifying any gaps that need to be filled;
- ✓ documenting an overview of the future PMS system and the links to specific documented procedures for executing its elements;
- ✓ including the documented overview of the PMS system within the QMS;
- ✓ identifying the role that will act as the person responsible for regulatory requirements and the requirements for that position;
- ✓ updating the job description and job requirements for the person responsible for regulatory requirements.

10. As defined in Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

## Post-market surveillance plan

Under the Regulations, a PMS plan has to be established for each device or device family. The PMS plan describes the implementation of the PMS system for collecting information and characterizing the safety and performance of the device, or device family, with similar devices in the market, together with the methods and processes to assess the collected information. Potential information for use in PMS comes from a number of sources, including:

- investigations of serious incidents;
- investigations of incidents not meeting the criteria for classification as serious incidents;
- data on undesirable side effects;
- trend analysis and reporting;
- field safety corrective actions;
- reports in specialist or technical literature;
- reports or outputs from databases or registries;
- complaints provided by users, distributors and importers;
- other feedback including customer surveys, information provided as input into manufacturer's websites and reports in social media; and,
- publicly available data on events with similar devices provided by other manufacturers.

The PMS plan includes a description of indicators and thresholds for continuous reassessment of risk management and the risk-benefit analysis together with the means to:

- investigate complaints and market experience from the field;
- monitor trends, identify statistically significant increases in frequency or severity of incidents and provide trend reports;
- communicate with competent authorities and notified bodies;
- communicate with authorized representatives, importers, distributors, users and patients;
- trace and identify devices for which correction or corrective action might be necessary;

A PMS plan has to be established for each device or device family



The PMS plan should also reference the documented procedures describing i) the PMS system, ii) the creation of the PMS Plan, iii) the generation of the PSUR or PMS report, as applicable; and, iv) the processes for identification and implementation of corrections, corrective actions or preventive actions.

The PMS plan is an element of the technical documentation and so needs to be in place before the Declaration of Conformity to the applicable Regulation is drawn up and before the device can be CE marked under the Regulations.

Initial activities to prepare for the new requirements include:

- ✓ establishing a template for future PMS plans;
- ✓ identifying a sequence for creating or updating PMS plans into the new template for the portfolio of devices;
- ✓ creating or updating PMS plans and incorporating the plans into the technical documentation.

## Post-market surveillance reports

The Regulations contain new requirements to prepare summary reports of PMS information for all classes of devices.

### Medical devices in class I

The manufacturer prepares a report summarizing the results and conclusions of analysis of the PMS data together with a rationale for, and description of, any preventive action or corrective actions taken. The report is updated when necessary and made available to the competent authority upon request.

### Medical devices in classes IIa, IIb and III

The manufacturer has to prepare a PSUR for each device (or each device family) summarizing the results and conclusions of the analysis of PMS data together with a rationale for, and description of, any preventive action or and corrective actions taken. The PSUR needs to be kept up to date throughout the lifetime of the device and contain the:

- conclusions to be used in risk-benefit determination;
- main findings of any PMCF evaluation report; and,
- volume of sales of devices, an estimate of the size of the population using the device involved and, where practicable, the frequency of use of the device.

The PSUR forms part of the technical documentation.

The PSUR has to be updated when necessary but minimally the manufacturer of class IIb or class III devices is required to update the PSUR at least annually, whereas the manufacturer of class IIa devices updates the PSUR at least every two years. For class III devices or implantable devices in class IIb, the manufacturer submits the PSUR electronically by means of Eudamed to its notified body. The notified body reviews the report and adds its evaluation to Eudamed with details of any action taken. The PSUR and the notified body evaluation are available to competent authorities through Eudamed. For non-implantable class IIb devices, the manufacturer has to make the PSUR available to its notified body and, upon request, to competent authorities.

### IVD devices in classes A and B

As for class I medical devices, the manufacturer prepares a report summarizing the results and conclusions of the analyses of the PMS data together with a rationale for, and description of, any preventive action or corrective actions taken. The report is updated when necessary and made available to the notified body and the competent authority upon request.

The regulations contain new requirements to prepare summary reports of PMS for all classes of devices



## IVD devices in classes C and D

The requirements for class C and class D IVD devices parallel class II and class III medical devices. The manufacturer has to prepare a PSUR for each device or each device family summarizing the results and conclusions of the analysis of PMS data together with a rationale for, and description of, any preventive action or and corrective actions taken. The PSUR is kept up to date for the lifetime of the device and forms part of the technical documentation; the content of the PSUR is the same as for medical devices. The manufacturer updates the PSUR when necessary and at least annually.

For class D IVD devices, the manufacturer submits the PSUR electronically by means of Eudamed to its notified body. The notified body reviews the report and adds its evaluation to Eudamed with details of any action taken. The PSUR and the notified body evaluation are available to competent authorities through Eudamed. For class C IVD devices, the manufacturer has to make the PSUR available to its notified body and, upon request, to competent authorities.

Initial activities to prepare for the new requirements include:

- ✓ reviewing current reports of PMS activities against the requirements of the Regulations and identifying any gaps;
- ✓ creating template(s) for PSUR or PMS reports, as applicable;
- ✓ creating documented procedure(s) for creation of PSURs or PMS reports, as applicable, together with the associated roles and responsibilities;
- ✓ estimating the number of PSURs or PMS reports that will need to be prepared and the frequency at which they will need to be updated;
- ✓ establishing a timeline for creating or updating PSURs or PMS reports, as applicable; and,
- ✓ confirming the availability of the necessary resources.

## Complaint handling and vigilance reporting

The procedures for complaint handling and reporting of incidents are elements of the manufacturer's QMS. ISO 13485:2016 has created separate, identified subclauses for these two activities.

The manufacturer is required to establish, implement and maintain documented procedures for handling complaints in a timely manner. These procedures need to include requirements and responsibilities for:

- receiving and recording information;
- evaluating information to determine if the feedback constitutes a complaint;
- investigating complaints;
- determining the need to report to the appropriate regulatory authorities;
- handling complaint-related devices; and,
- determining the need to initiate corrections or corrective actions.

When the need to report to an appropriate regulatory authority is identified, the manufacturer is required to implement documented procedures for i) reporting adverse events that meet reporting criteria, ii) providing trend reports, and iii) reporting field safety corrective actions to regulatory authorities. They also need to keep records of such reports.

As the transition to ISO 13485:2016 has to be completed by the end of February 2019, actions to ensure compliance with these requirements should be in place.

In regards to the requirements for vigilance, information previously contained in guidance<sup>11</sup> has been included in the Regulations themselves. The exemption rules that obviate the need to report events have been reduced in number significantly; the only exclusion remaining is for expected side-effects that are clearly detailed in the product information and contained in the technical documentation. Furthermore, there is a requirement for trend reporting of incidents that are exempt from reporting; that is to report any statistically significant increase in the frequency or severity of incidents that do not meet the reporting criteria but could have a significant impact on the risk–benefit analysis and present unacceptable risks to the health or safety of patients, users or others. Consequently, the manufacturer has to:

- specify how to identify, record and analyze these incidents;
- document the foreseen frequency or severity of such incidents; and
- decide the criteria for identifying a statistically significant increase from this foreseen frequency or severity over a specific period of time.

Additionally, the scope of reporting has been increased as temporary serious deterioration in health is now reportable.

The timelines for reporting events that are considered serious public health threats or death or unanticipated serious deterioration in health have remained unchanged at two and ten days respectively, but the timeline for reporting all other events has been decreased from 30 days to 15 days. This reduces the time available to determine whether an event meets the reporting criteria. This could lead to submission of more initial reports when all the necessary information is not available in the shorter timescale and consequently more follow-up reports to provide additional information.

It is useful to note the change in terminology found in the Regulations: what were previously called reportable events are now called serious incidents, whereas incidents or non-serious incidents refer to what were previously called non-reportable events.

In addition to the changes in the requirements for vigilance reporting, the Regulations include an explicit requirement that, when conducting a Field Safety Corrective Action, the manufacturer has to inform the competent authority before implementing the action, unless this would cause a delay that could present a consequent risk to health.

Taken together, these changes are likely to lead to an increase in the number and types of reports submitted.

Initial activities to prepare for the new requirements include:

- ✓ reviewing the current procedures for vigilance against the requirements in the Regulations and identify any gaps;
- ✓ determining the methods to establish statistical increases in frequency and severity for trend reporting;

11. MEDDEV 2.12-1 – revision 8 – Guidelines on a Medical Devices Vigilance System

- ✓ reviewing a sample of previous vigilance reports against the revised exemption rules and timelines to estimate the likely increase in reporting that could result;
- ✓ reviewing resources for vigilance reporting against the projected future workload;
- ✓ identifying the changes needed to processes for complaint handling and vigilance reporting and the timeline for their implementation.

## Electronic submissions

Several aspects of the PMS system envisage electronic submission of information into Eudamed. Vigilance and PMS information intended to be submitted into Eudamed includes:

- vigilance reports;
- field safety notices;
- trend reports; and,
- PSURs for class III devices or implantable devices in class IIb and for class D IVD devices;
- notified body assessments of submitted PSURs.

Eudamed is intended to be fully functional by the date of application of the Regulations. The Commission is charged with publishing i) a plan for Eudamed 12 months after the Regulations come into force, and, ii) a notice that the functionality of Eudamed has been verified in the Official Journal at least two months before the date of application of the Regulation. However, if Eudamed is not fully functional by the date of application of the Regulations, the Commission publishes the notice when functionality has been verified and the requirements relating to Eudamed start to apply six months after that publication date. If there is delay in the availability of Eudamed, the text of the Regulations indicate that it is those elements of the requirements relating to Eudamed are postponed, not the full provisions of the affected Articles. Therefore, in the event that Eudamed is not available, it would seem likely that there will need to be additional guidance on submitting vigilance and PMS information for i) devices that are CE marked to the Regulation during the transition period before the date of application, and, ii) all devices after the date of application.

The implementation of Eudamed for vigilance and PMS establishes a centralized reporting process to replace reporting to the competent authority in which an incident occurs. It also establishes a consistent means of information exchange with notified bodies on PMS. In order to benefit from this standardization, the manufacturer will need establish processes for review and approval of documents for electronic submission and an interface between their internal systems and Eudamed. The detailed technical solution for these enhancements will depend upon the specification for Eudamed and the development of standardized templates for the data to be exchanged will be a key milestone.

As well as acting as the electronic system for collecting and sharing information on vigilance and PMS, Eudamed is the electronic system for:

- registration of devices;
- unique device identification (UDI);
- registration of economic operators (manufacturers, authorized representative, importers, distributors and assemblers of systems or procedure packs);
- notified bodies;
- certificates issued or withdrawn;
- clinical investigations; and,
- market surveillance by competent authorities.

Initial activities to prepare for the new requirements include:

- ✓ establishing mechanisms to remain informed of development of Eudamed, including the timelines and interface requirements;
- ✓ reviewing procedures to establish processes internal processes, including responsibility and authority for preparation and review of electronic submissions.

## Conclusion

The Medical Device and In Vitro Medical Device Regulations represent the most significant change to European legislation for medical devices in over 20 years. 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. Vigilance reporting and PMS are significantly affected by both the number and extent of the changes.

It might appear that there is plenty of time to implement the changes in vigilance reporting and PMS as they apply after CE marking a device to the applicable Regulation or at the end of the transition period – however, given the magnitude of change involved, it is prudent to start preparing for implementation as soon as possible. Timely preparation and implementation will allow you to understand fully the effect on your internal processes and accommodate external factors outside your direct control.

You need to monitor for the publication of the Regulation(s) in the Official Journal of the European Union, because they come into effect 20 days after publication when the transition period starts, as well as the progress in development of delegated and implementing acts and progress in establishing the Eudamed database.

BSI is grateful for the help of the following people in the development of the white paper series.

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Eamonn Hoxey, is a technical author, trainer and consultant on a range of life science areas including regulatory compliance, quality management, sterility assurance and standards development. Eamonn worked for Johnson & Johnson for 17 years in positions of increasing responsibility for Quality and Regulatory Compliance for medical devices, pharmaceuticals and consumer products including Vice President of Compliance, Vice President of Market Quality and Vice President of Quality & Compliance Strategic Programs leading quality implementation for the EU medical devices regulation for J&J's Medical Devices companies. Prior to joining J&J, Eamonn spent 16 years with the UK Medical Devices Agency, including six years as Head of Device Technology and Safety.

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Leo's firm specializes in helping clients through product safety, international regulatory and quality system processes. Leo is a Notified Body Auditor for NEMKO (previously for NSAI & TÜV PS). Leo is the convener of IEC SC62D JWG9 (IEC/ISO80601-2-58) and a committee member of US TAG for TC62, SC62A & SC62D. Leo is a registered professional engineer in safety and has 28 years' experience in product safety. Leo is a member of RAPS, AAMI, ASQ, & IEEE. He's manager of the LinkedIn discussion group IEC 60601 Series – Medical Electrical Equipment.

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Paul has worked in the healthcare industry for over 35 years, joining BSI in 2010 to lead the organization in Saudi Arabia where it had been designated as a Conformity Assessment Body. Later, he managed BSI's Unannounced Audits programme. Since October 2015 he has been working with both the Notified Body and Standards organizations looking at how best to use the knowledge, competencies and expertise in both.

Previously he held senior RA/QA leadership positions at Spacelabs Healthcare, Teleflex Medical, Smiths Medical, and Ohmeda (formerly BOC Group healthcare business). Paul is a member of the Association of British Healthcare Industries (ABHI) Technical Policy Group and Convenor of the ABHI ISO TC 210 Mirror Group. He is Convenor of the BSI Committee which monitors all of the work undertaken by ISO TC 210, and Convenor of the BSI Sub-committee dealing with Quality Systems. As UK Delegation Leader to ISO TC 210, he is also actively involved in the work of national, European and international standards' committees.

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Pete is the Director of the Surgical Materials Testing Laboratory (SMTL), based in Bridgend in South Wales, which is funded by the Welsh Government to test medical devices for the Welsh NHS and to provide technical advice on medical devices. He has worked in the medical devices field for 30+ years, and sits on a number of BSI, CEN and ISO medical device committees and groups. He chairs the Welsh Non-Luer Connectors Reference Group (WNCRG) for Welsh Government, which is coordinating the implementation of new ISO compliant non-Luer connectors across the Welsh NHS, and represents Welsh Government on medical devices on various other groups.



## Published white papers

*The Proposed EU Regulations for Medical and In Vitro Diagnostic Devices: An Overview of the Likely Outcomes and Consequences for the Market*, Gert Bos and Erik Vollebregt

*Generating Clinical Evaluation Reports – A Guide to Effectively Analysing Medical Device Safety and Performance*, Hassan Achakri, Peter Fennema and Ito Udofia

*Effective Post-market Surveillance – Understanding and Conducting Vigilance and Post-market Clinical Follow-up*, Ibim Tariah and Rebecca Pine

*What You Need to Know About the FDA's UDI System Final Rule*, Jay Crowley and Amy Fowler

*Engaging Stakeholders in the Home Medical Device Market: Delivering Personalized and Integrated Care*, Kristin Bayer, Laura Mitchell, Sharmila Gardner and Rebecca Pine

*Negotiating the Innovation and Regulatory Conundrum*, Mike Schmidt and Jon Sherman

*The Growing Role of Human Factors and Usability Engineering for Medical Devices: What's Required in the New Regulatory Landscape?* Bob North

*ISO 13485: The Proposed Changes and What They Mean for You*, Bill Enos and Mark Swanson

*The Differences and Similarities between ISO 9001 and ISO 13485*, Mark Swanson

*How to Prepare for and Implement the Upcoming MDR: Dos and Don'ts*, Gert Bos and Erik Vollebregt

*How to Prepare for and Implement the Upcoming IVDR: Dos and Don'ts*, Gert Bos and Erik Vollebregt

*Planning for Implementation of the European Union Medical Devices Regulations – Are you prepared?*, Eamonn Hoxey

*Cybersecurity of Medical Devices*, Richard Piggin

## Forthcoming white papers

*Medical Device Market Surveillance Requirements: Are you aware of your responsibilities?* (working title)

*Clinical Data – Away from Clinical Equivalence in Europe* (working title)

*General Requirements for Safety and Performance* (working title)

*Modifying, Creating and Maintaining Technical Documentation* (working title)

## About BSI Group

BSI (British Standards Institution) is the business standards company that equips businesses with the necessary solutions to turn standards of best practice into habits of excellence. Formed in 1901, BSI was the world's first National Standards Body and a founding member of the International Organization for Standardization (ISO). Over a century later it continues to facilitate business improvement across the globe by helping its clients drive performance, manage risk and grow sustainably through the adoption of international management systems standards, many of which BSI originated. Renowned for its marks of excellence including the consumer recognized BSI Kitemark™, BSI's influence spans multiple sectors including aerospace, construction, energy, engineering, finance, healthcare, IT and retail. With over 70,000 clients in 150 countries, BSI is an organization whose standards inspire excellence across the globe.

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This paper was published by BSI Standards Ltd

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