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from diagnosis to cure

Submission of Vigilance Reports to Notified Bodies under EU MDR & IVDR

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Background

According to the Medical Devices Regulation (EU) 2017/745 (MDR), and the *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR)[1] Annex VII section 4.10, third indent "*The notified body shall have documented procedures <…> to review vigilance data to which they have access under [MDR Article 92(2) / IVDR Article 87] in order to estimate its impact, if any, on the validity of existing certificates. The results of the evaluation and any decisions taken shall be thoroughly documented*." In practice, some Notified Bodies interpret that to comply with this paragraph they must review every vigilance report a manufacturer submits. However, it is not specified in the regulations that Notified Bodies need to perform a single vigilance case review; this is the responsibility of the competent authorities per Article 89(2) MDR and Article 84(2) IVDR.

In this paper, MedTech Europe argues that the challenges created by the current practice of duplicate vigilance case review by Notified Bodies and competent authorities are not aligned with the intention and requirements listed in the regulations, it has little added value in ensuring patient safety and creates unreasonable burdens and costs on manufacturers. MedTech Europe calls on the European Commission and the Medical Device Coordination Group (MDCG) to streamline vigilance data evaluation processes to eliminate duplicate reviews of vigilance cases. Repeated vigilance case reviews are straining manufacturers who are already struggling to bring and keep medical devices and IVDs on the EU market.

[1] Further in this document 'MDR/IVDR' is referred to as 'regulations', unless otherwise specified.

According to recent data, many manufacturers are no longer prioritising the EU as a preferred geography and are stopping or planning to stop the supply of their devices to the EU market due to high regulatory costs, of which additional unpredictable vigilance costs are a significant part [2,3]. Based on a recent MedTech Europe IVDR and MDR Survey, manufacturers pay 285 € on average to a Notified Body per one vigilance report reviewed. The yearly costs for vigilance report evaluation performed by the Notified Body could be as high as 600 000 € or more (depending on the number of vigilance cases and a Notified Body)[2]. Therefore, it is paramount to support an effective system for reporting serious incidents to protect the health and safety of medical devices and IVDs on the market, while ensuring that manufacturers can dedicate their time/resources towards ensuring that medical devices and diagnostics remain available for European patients and healthcare professionals.

The role of Notified Bodies in the vigilance system

Section 2 of Chapter VII of MDR and IVDR outlines the roles and responsibilities of each actor within the vigilance system. However, none of the articles in this section dedicated to vigilance indicate that Notified Bodies have to replicate the role of competent authorities in evaluating individual serious incident reports.

Each actor involved in the vigilance system has a role to fulfil:

- The manufacturer must report serious incidents to the relevant competent authority and perform the necessary investigations while cooperating with the competent authorities and, where relevant, the Notified Body concerned[4]. Once the vigilance module in EUDAMED is declared functional, these serious incident reports shall be submitted through EUDAMED.
- The competent authority must evaluate serious incident reports, if possible, together with the manufacturer, and, where relevant, the Notified Body concerned, assess the risk arising from the reported serious incident, as well as monitor the manufacturer's investigation and intervene where necessary (Article 89 and Article 84 IVDR).

As mentioned above, the main actors foreseen by the regulations in the vigilance process are the manufacturer and the relevant competent authority. It is the role of the competent authority to evaluate the risks arising from the reported serious incident, and, where necessary, intervene in a manufacturer's investigation.

Conversely, it is not specified in the regulations that Notified Bodies must perform individual vigilance case reviews, instead "*The notified body shall have documented procedures: <…> to review vigilance data <..> in order to estimate its impact, if any, on the validity of existing certificates*". The Notified Body's assessment of the impact of vigilance

[2] MedTech Europe 2024 Regulatory Survey: key findings and insights
[3] Based on the Gesundheit Österreich GmbH (GÖG) survey on the monitoring of the availability of devices, 3 out of 5 main reasons for MD and IVD manufacturers having stopped or planning to stop production/marketing/supply of some IVDs to the EU market are related to costs (i.e. products with low sales volumes, product revenue does not justify cost to reapprove device under the IVDR, products with low profitability)
[4] Art 87 (1)(a) MDR, Art 82 IVDR (1)(a) and (Article 89(1) MDR/Article 84(1) IVDR.

data on certification is done during the surveillance audit. The competent authority may decide to consult the Notified Body where relevant for individual serious incidents (e.g. when the certification granted by the Notified Body might be at risk), but, in most cases, it is not required.

Under the directives[5] as well as under the regulations, the role of the Notified Body was and remains to assess the impact of vigilance data on existing certificates. The role of the Notified Body with regard to vigilance, as specified in the regulations' Annex VII, has not substantially changed in comparison to the directives and MEDDEV 2.12-1, Rev 8 (Chapter 7). The MEDDEV document specified that the Notified Body had a role in assessing the impact of vigilance issues on the certificate granted. Similarly to the regulations, the competent authority could have engaged the Notified Body under the directives in individual serious incidents where specific investigations or audits were needed. The requirements in the regulations may be more specific overall, but they do not include additional details on obligations for Notified Bodies related to vigilance.

While Notified Bodies must have access to vigilance data to assess its impact on certification, the review of single vigilance cases is outside the scope of what is currently stated in the regulations. Moreover, the initial goal of the regulations was to increase transparency by giving access to vigilance data to Notified Bodies through EUDAMED, rather than adding additional responsibilities to assess single vigilance reports[6]. The vigilance cases that may impact certification are to be reviewed by Notified Bodies during surveillance audits, not through all reports continuously throughout the year.

Holistic Post-Market Surveillance system to ensure patient safety

Vigilance reports are only one part of a systematic and integrated post-market surveillance (PMS) system established through the regulations to ensure the safety of medical devices. In the current post-market surveillance system, manufacturers must systematically and actively collect, analyse and review experience gained from devices placed on the EU market. This helps to identify any need to immediately take any necessary corrective or preventive actions. The enlarged, more frequent and more detailed reporting obligations for manufacturers under the regulations, as opposed to the directives, add an additional layer of oversight next to the reporting of vigilance cases. Some of the examples of the additional requirements include:

- Trend Reporting, which aims at catching any statistically significant increase in the frequency or severity of non-serious incidents;
- Periodic Safety Update Reports for higher class devices, which summarise the results and conclusions of the analyses of post-market surveillance data which is used to update the benefit-risk profile of the device;

[5] 'Directives' refer to Directive 93/42/EEC (MDD), Directive 90/385/EEC (AIMDD) and Directive 98/79/EC (IVDD), unless otherwise specified
[6] Medical devices: European Commission calls for immediate actions - tighten controls, increase surveillance, restore confidence (link)

- Continuous processes to update the performance/clinical evaluation through Post-Market Performance/Clinical Follow-Up;
- Notification of changes of the device or of the quality system to the Notified Body whereby the Notified Body must assess if the change requires a supplement to the certificate or a new conformity assessment procedure.

Therefore, vigilance reports are not standalone reports but rather one element within a holistic and proactive post-market surveillance system which ensures that device issues are caught on time. Risk analysis in line with the regulations is not limited to vigilance reports but is based on a comprehensive review of PMS data collected via the various elements of the post-market surveillance system, which helps to ensure the safety of devices available in the public health system.

Conclusion

Notified Bodies do not serve as primary operational actors in the vigilance system established by the regulations; instead, they play a supportive role. The primary responsibility for reporting and evaluating serious incident reports lies with manufacturers and competent authorities. The Notified Bodies should not duplicate the work of competent authorities, especially as the regulations do not require their assessment of single vigilance reports. Instead, Notified Bodies contribute to the vigilance system by auditing the implementation of vigilance procedures, assessing vigilance data which may have an impact on certification as part of their audits, and liaising with competent authorities when relevant.

A holistic Post-Market Surveillance and Vigilance system under the regulations creates a well-grounded process to ensure the safety of medical devices and IVDs for public health. Duplicate vigilance case review has little benefit to fulfilling this objective but creates a profound administrative burden which is unpredictable and costly for manufacturers, and which further risks aggravating the current situation of the availability of medical devices and IVDs in Europe[2,3].

In light of recent calls from the European Commission for less bureaucracy and better enforcement[7], MedTech Europe urges the European Commission and the MDCG to reconsider how Annex VII section 4.10 is currently being interpreted and streamline vigilance data review practices.

[7] Statement at the European Parliament Plenary by President Ursula von der Leyen, candidate for a second mandate 2024-2029

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

www.medtecheurope.org.

For more information, please contact:

Petra Zoellner

Director, Regulatory Affairs (IVDR & MDR)

p.zoellner@medtecheurope.org