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EU MDR 2017/745 will reduce the Risk of Medical Devices. Does MDCG got it Right?

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Abstract

Under the new European Union Medical Device Regulation (EU MDR), framed by Medical Device Coordination Group (MDCG), for each device manufacturers must have a documented risk management plan, identify and analyse the known and foreseeable hazards, estimate and evaluate the associated risks and eliminate or control those risks. In contrast with the MDD, the new EU MDR contains an explicit obligation in the new Article 10 (2), that manufacturers establish, document, implement and maintain a system for risk management. The detailed requirements of which are listed in the new Annex I Chapter I.

Compared to MDD there is more emphasis on Post Market Surveillance (PMS) activities with the inclusion of European Databank or European Database for Medical Devices (EUDAMED) and mandatory submission of Periodic Safety Update Report (PSUR) to all the actors in the possession with the medical devices.

A poll conducted by Aegis Lifesciences Pvt. Ltd, Ahmedabad, India concludes that the relevant annexures and sections in MDR 2017/745 have more emphasis on PMS, Vigilance, PSUR, EUDAMED, tracking, Implantation card etc. that are directed in regard to the safety of the Medical Device.

Keywords: EU MDR, PMS, European Database for Medical Devices (EUDAMED), Medical Device Directives (MDD), Post Market Surveillance (PMS), Risk Management.

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1. Introduction

After a one-year delay due to the global coronavirus pandemic, the European Union Medical Device Regulation (EU MDR) 2017/745 went into effect on 26 May 2021. The regulation was introduced to resolve and address a number of deficiencies in the two Medical Device Directives (MDD) - the Active Implantable Medical Device (AIMD) Directive - 90/385/EEC established in 1990 and the Medical Device Directive (MDD) - 93/42/EEC established in 1993. The EU MDR 2017/745 consolidates both these directives into one medical device regulation. The EU MDR 2017/745 is a legally binding regulation across the EU member states. (1, 2)

The regulation has a major focus on safety and risk management, post-market surveillance (PMS) activities, and specific requirements for notified bodies. Article 10, "General Obligations to Manufacturers", requires manufacturers to ensure compliance to their Quality Management Systems and establish, implement, document and maintain a system for risk management as described in Section 3 of Annex I.

The expectation of notified bodies has for many years been that manufacturers have a risk management system which conforms to EN ISO 14971. However, the current Medical Device Directive (MDD) does not explicitly require that. While the MDD Annex I Chapter I (2) does require that the risks associated with an individual device be eliminated or reduced, that adequate protection measures are taken in relation to risks that cannot be eliminated, and that users are informed about any residual risks. The MDD does not contain an explicit requirement to employ risk management, other than for software devices. There is no Article of the MDD that requires manufacturers to have a risk management system.

In contrast with the MDD, the new EU Medical Device Regulation (EU MDR) contains an explicit

obligation in the new Article 10 (2), that manufacturers establish, document, implement and maintain a system for risk management. The detailed requirements of which are listed in the new Annex I Chapter I. (3)

Under the new EU MDR, **for each device**, manufacturers must have a documented risk management plan, identify and analyse the known and foreseeable hazards, estimate and evaluate the associated risks and eliminate or control those risks. Additionally, in the "production phase", evaluate the impact of new information and if necessary amend control measures accordingly.

If all of the above reads like a paraphrasing of the requirements of EN ISO 14971: 2019, it clearly is. Even to the point of adopting terms like "production phase" rather than post market phase. But it's not a verbatim copy and paste of EN ISO 14971, because that wouldn't allow the use of other approaches or for the risk management solutions to be developed and improved over time. Nevertheless, the new Article 10 (2) obligation on manufacturers to establish a risk management system, combined with the explicit requirements for each device contained in the new Annex I Chapter I (3), mean that the current state of the art in device risk management (EN ISO 14971: 2019) will become the new minimum standard for device risk management under the new EU MDR. (2-4)

2. Sections, articles and annexures from (EU MDR) 2017/745 that should be covered in ISO 13485

Table 1. Chapter 7 – Post-Market Surveillance, Vigilance, And Market Surveillance

Section 1 – Post-Market Surveillance	
Article 83	Post-market surveillance system of the manufacturer
Article 84	Post-market surveillance plan
Article 85	Post-market surveillance report
Article 86	Periodic safety update report
Section 2 – Vigilance	
Article 87	Reporting of serious incidents and field safety corrective actions
Article 88	Trend reporting
Article 89	Analysis of serious incidents and field safety corrective actions
Article 90	Analysis of vigilance data
Article 91	Implementing acts
Article 92	Electronic system on vigilance and on post-market surveillance
Section 3 – Market Surveillance	
Article 93	Market surveillance activities
Article 94	Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance
Article 95	Procedure for dealing with devices presenting an unacceptable risk to health and safety
Article 96	Procedure for evaluating national measures at Union level
Article 97	Other non-compliance
Article 98	Preventive health protection measures
Article 100	Electronic system on market surveillance

Annexures

- Annexure 3 – Technical documentation on post-market surveillance
- Annexure 8 – Classification rules
- Annexure 14 – Clinical evaluation and post-market clinical follow-up

3. Regulation EU MDR 2017/745 and its relationship to EN ISO 14971:2019

The risk management requirements in Annex I, Chapter l of the regulation mirror those detailed in EN ISO 14971. Although the regulation does not specifically mention the medical device risk management standard EN ISO 14971, it does require compliance to harmonized standards.

Recital 22 states "compliance with harmonized standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council (2) should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as those relating to quality and risk management, laid down in this Regulation."

Article 2 (70) defines a harmonized standard as "a European standard as defined in point (1)(c) of Article 2 of Regulation (EU) No 1025/2012". The document

Commission Implementing Decision (EU) 2020/437 of 24 March 2020 on the harmonized standards for medical devices drafted in support of Council Directive 93/42/EEC published the Official Journal of the European Union lists all the standards applicable to medical devices. This includes EN/ISO 14971, and also includes other relevant standards like EN/IEC 62366, EN/ISO 10993, EN/IEC 60601 and EN/IEC 623049. (2, 5,6)

4 Requirements for Risk Management to be included in the EU MDR

Sections 1 to 5 of Annex I (General Safety and Performance Requirements), Chapter I (General Requirements) clearly layout the requirements for risk management. These include:

- Ensure that devices during normal use are suitable for their intended use
- Risks which may be associated with device use constitute acceptable risks when weighed against the benefits to the patient
- Reduce risk as far as possible. The requirement to reduce risk as far as possible means reduction of risks without adversely affecting the benefit-risk ratio
- Establish, implement, document and maintain a risk management system.

5. Opinion poll of Quality Assurance/Regulatory Affairs personnel in Medical Device field on MDR 2017/745 and Risk management

5.1 Methodology of Survey

A poll conducted on LinkedIn (Professional networking) by Aegis Lifesciences Pvt. Ltd, Ahmedabad, and survey question was published and authorized QA/RA experts in the medical device industry to poll their answer within 14 days. The subject matter was shared to 1267 LinkedIn contacts and 986 contacts participated and responded in the poll.

5.2 ***Question on the subject matter***

Is MDR new wine in old bottle of MDD? What's good of MDR over MDD to the manufacturer? (Does New regulations of MDR 2017/745 will reduce the risk posed by Medical Devices compared to MDD?)

Option 1: No, it addresses more safety

Option 2: Yes, its the same restructured

Option 3: MDR is all about PMS, tracking or EUDAMED

Option 4: MDR is for EARs to earn

5.3 Analysis

Poll results were analysed on the subject matter whether new regulations of MDR 2017/745 will reduce the risk posed by Medical Devices compared to MDD?

Total contacts shared: 1267

Total votes polled: 986

Voting Pattern is as below:

Option 1: No, it addresses more safety: 425 votes (43%)

Option 2: Yes, it's the same restructured: 0 votes (0%)

Option 3: MDR is all about PMS, tracking, EUDAMED: 561 votes (57%)

Option 4: MDR is for EARs to earn: 0 votes (0%).

6. Questions are answered in MDR 2017/745 on Risk Management by the survey conducted by Aegis Lifesciences Pvt. Ltd.

a. Is EN ISO 14971:2019 and MDR risk management the same?

No, but similar and in harmony *(Unlike EN ISO 14971:2019 vs MDD where there are a lot of differences)*

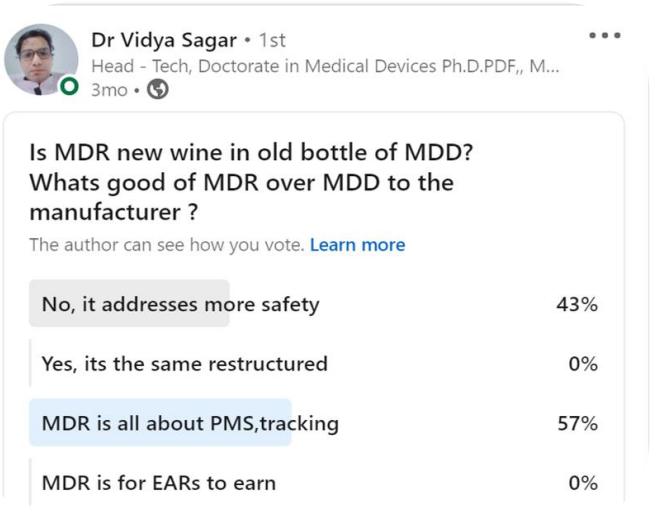

Figure 1. Showing the results of the poll conducted on LinkedIn

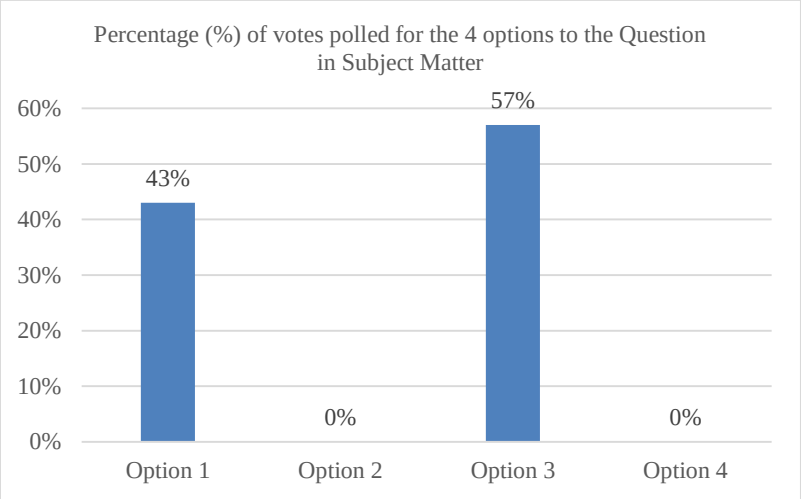

Figure 2. Showing the results of the poll conducted on LinkedIn on the question on the subject matter

b. Do we have to reduce risk As Far as Possible?

Yes, as long as it does not adversely affect the benefit-risk ratio, Acceptable or Unacceptable only, there is Change in Risk matrix (In EN ISO 14971:2019/MDD where it is As Low As Reasonably Practicable, ALARP/Insignificant/ unacceptable, complex risk matrix)

c. Can we reduce risk As Far As Possible (AFAP)?

Yes, and without economic considerations *(ISO EN 14971:2019/MDD is with economic considerations)*

d. Do we have to perform benefit-risk analysis for all risks?

Yes, not only that, it should be mentioned in numerical/quantified *(In EN ISO 14971:2019/MDD where discussion is only on ALARP or unacceptable risks after Risk Mitigation)*

e. Can information for safety reduce risk?

Yes, but we have to prove that it does. We can provide information for safety or risk mitigation (With IFU - warnings/precautions/contra-indications, labels, etc.) and, where appropriate, training to users. *(But in EN ISO 14971:2019/MDD – Risk mitigation was not allowed through IFU - warnings/precautions/contra- indications or training to users)*

f. Will risk management according to MDR result in medical devices with lower risk?

May not be, Fingers crossed, but more work on technical part

7. Conclusion

The relevant annexures and sections in MDR 2017/745 have more emphasis on PMS, Vigilance, PSUR, EUDAMED, tracking, Implantation card etc. and all are directed in regard to the safety of the Medical Device.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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