6th International Conference on Nanotechnologies and Biomedical Engineering
Proceedings of ICNBME-2023, September 20–23, 2023, Chisinau, Moldova
Volume 2: Biomedical Engineering and New Technologies for Diagnosis, Treatment, and Rehabilitation

The Surveillance System of Medical Devices, in Which the Responsible Individuals Have an Active Role, is the Guarantee of Patient and Medical Device User Safety

Gheorghe Gorceag, Victor Sontea

https://doi.org/10.1007/978-3-031-42782-4_8

Abstract

The surveillance of medical devices is defined as a system for collecting, storing, scientifically evaluating, and assessing incidents resulting from the use of medical devices, as well as reporting them to the competent authorities for the purpose of continuous monitoring of the risk-benefit ratio and the adoption of necessary measures to reduce occurrences. The medical devices used in medical procedures must be safe, of high quality, and efficient. This is the goal of states and their competent authorities, who have recognized and implemented the management of medical technologies at the healthcare system level, which includes reporting any malfunction or deterioration in the characteristics and performance of a device that may or has led to the death or severe deterioration of a patient's or user's health condition. Following the non-reporting of incidents involving medical devices and not taking corrective actions to prevent incidents, the medical devices that are used, does not guarantee security and performance parameters. Thus, it is very important that there are, at regulatory level, tools and methods to report incidents and to prevent their occurrence or reoccurrence. On the other hand, the best international practices, regulates the fact that for the successful functioning of the vigilance system, users are must have an active role in the surveillance system of medical devices. Safety cannot be guaranteed without a medical device surveillance system, as well as the proper involvement of responsible individuals who will ensure and guarantee the

use of safe medical devices with an appropriate level of performance and security parameters.

Keywords: medical devices, medical device vigilance system, medical devices safety, medical device users

References

1. EU Medical Device Directives: Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Official Journal of the European Communities, L 331 (1998)
2. EU Medical Device Directives: Council Directive 93/42/EEC on Medical Devices (MDD). Official Journal of the European Communities, L 169 (1993)
3. EUMedicalDeviceDirectives:Council Directive 90/385/EEC on Active ImplantableMedical Devices (AIMDD). Official Journal of the European Communities, L 189 (1990)
4. Law No. 102/2017 on medical devices. The Official Journal of the Republic of Moldova, 244, pp. 389 (2017)
5. Order of the Ministry of Health, Labour, and Social Protection No. 211/2018 regarding the medical device surveillance system. The Official Journal of the Republic of Moldova, 126, p. 517 (2018)
6. Post-market Surveillance of Medical Devices by the European Medicines Agency, Draft 1, (2020). https://www.who.int/docs/default-source/essential-medicines/in-vitro-diagnostics/draft-public-pmsdevices.pdf?sfvrsn=f803f68a_2
7. Broucher, J., Gaba, M.., Deem Mark, E., Termini, E., Auchincloss, K.: A practical guide to navigating the medical device industry: advice from experts in industry. Law, Intellect. Property Academia **2**(4) (2011)
8. Medical Devices Regulation (MDR): 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/EEC. Official Journal of the European Union, L 117 (2017)

9. Guidance Regulating medical devices in the UK. London: Medicines and Healthcare Products RegulatoryAgency (MHRA).https://www.gov.uk/guidance/regulating-medical-devices%20in-the-uk#contents (2020)

10. Outline of Post-marketing Safety Measures. Tokyo: Pharmaceutical and Medical Device Agency (PMDA). https://www.pmda.go.jp/english/safety/outline/0001.html (2021)