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Short communication

Pharmacovigilance audit ("remote") of the pharmacovigilance system of Replek Farm by an EU partner

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Introduction

Pharmacovigilance is the science and set of activities related to the detection, assessment, understanding, prevention and treatment of adverse drug reactions, as well as new information related to potential harm of the medicines use (MALMED). In the recent years, there has been a growing awareness of the importance of the safe use of medicines (WHO, 2004), thus emphasizing the role and importance of pharmacovigilance as a system that improves patient care and safety associated with medicines use (WHO, 2002).

Replek Farm as a manufacturer and holder of Marketing Authorizations for placing the medicines on the market has established Pharmacovigilance System (PV System) and is involved in all activities related to this issue, both in Republic of North Macedonia and in the partner countries with which it has concluded agreements for pharmacovigilance. According to the Drug Safety Agreement concluded with medac Gesellschaft fuer klinische Spezialpraeparate mbH, Theaterstraße 6; 22880 Wedel Germany (EU partner), by DREHM Pharma GmbH, an outsourcing company hired by medac, a regular annual Pharmacovigilance audit of Replek Farm's PV System was conducted. The aim was to ensure that the system complied with European regulatory requirements and standards (4), as well as the specific requirements of medac and the Drug Safety Agreement, which was confirmed during Pharmacovigilance audit ("remote") by EU partner.

Scope of activities

By request of DREHM Pharma GmbH, Replek Farm completed and sent a filled Questionnaire, with the following chapters: Company organization and responsibilities; Service Provider and Outsourced Activities; Training; Management of Safety Relevant information; Reconciliation; Periodic Safety Update Report (PSUR)/Risk Management Plan (RMP); Organized data collection; Recall; Pharmacovigilance system inspection; Archiving; Further questions and comments. This was "remote" Pharmacovigilance audit that was conducted on 17.09.2021 and took place through a video conference on the Microsoft Teams platform, based on a previously set agenda.

The regular annual Pharmacovigilance audit ("remote") was preceded by a Pharmacovigilance audit conducted in the same manner on 17.08.2020 in which the manager of the RA Department/Qualified Person for Pharmacovigilance took part and was with positive acceptance. The compliance of the PV System of Replek Farm with European requirements and standards, as well as medac requirements, was confirmed and resulted with a positive assessment (for the second time in continuation). The same procedure was repeated the next year during the presented Pharmacovigilance audit ("remote"), when in order of internal testing of the acquired knowledge the deputies of the Qualified Person for Pharmacovigilance participated.

A review of Replek Farm's complete PV System was performed by reviewing the following documentation: Detailed description of the Pharmacovigilance System (DDPS), Pharmacovigilance procedure and records and standard operating procedures (SOPs) arising from it. The organizational structure of the company, communication with local regulatory authorities (MALMED) and all other activities related to the system were also discussed. Emphasis was placed on the management of safety information, the responsibilities of employees especially their qualification, training and continuing education in the field of pharmacovigilance. The ICSR management process, the Periodic Safety Update Report (PSUR) legislation and how that document is prepared were

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reviewed. The subject of discussion was also the literature data research; detection and monitoring of signals for adverse drug reactions and how to proceed during reporting or recall of batch from the market. At the end of the Pharmacovigilance audit ("remote") was discussed the communication with regulatory authorities, how to respond to their requests and the implementation of the risk minimization measures of the adverse drug reactions. The "share screen" tool was used for review of the documentation.

Compliance of the PV system

After the detailed Pharmacovigilance audit ("remote") was performed by DREHM Pharma GmbH an evaluation report was received from them. One big remark, seven small remarks and two recommendations were noted. For their correction, a Corrective and Preventive Action Plan (CAPA plan) was prepared with precise terms for correction of the remarks.

The CAPA plan was accepted by DREHM Pharma GmbH. According to the CAPA plan, the following documentation was revised: DDPS, Pharmacovigilance procedure and the records and standard operating procedures (SOPs) arising from it. With this full compliance of the PV System of Replek Farm with European regulatory requirements and standards was achieved (EU-GVP, 2004), as well as with the specific requirements of medac and the Drug Safety Agreement. As a result, Replek Farm's PV System was assessed as compliant and the Pharmacovigilance audit ("remote") was successfully conducted.

Conclusion

This is an example of a Pharmacovigilance audit ("remote") of the Replek Farm's PV System conducted by medac (EU partner), through DREHM Pharma GmbH, an outsourcing company hired by medac. The Pharmacovigilance audit ("remote") was successfully conducted for the second time and the compliance of the PV System of Replek Farm with European regulatory requirements and standards, as well as the specific requirements of medac and the Drug Safety Agreement was confirmed.

Even in the new pandemic situation, this is a demonstration that the activities can precede without difficulties, using modern technology such as video conferencing on the Microsoft Teams platform and review of documentation through the tool "share screen".

References

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