Short communication

The EU Pharmacovigilance System Master File (PSMF)

Abstract:

Pharmacovigilance (PV) is the science relating to collecting, detecting, assessing, monitoring, and preventing adverse effects with pharmaceutical products. [1] The urgent need for this field within the pharmaceutical world became apparent after the two catastrophic events with sulphanilamide and thalidomide. Pharmacovigilance evolved drastically over the last few decades thanks to the experts creating legislations to properly control the safety, efficacy and quality of medicinal products. Despite that, new challenges are emerging. The year 2010 significantly shaped the currently known Pharma world introducing various updates to statutory and strengthening them. The newly introduced Directive 2010/84/EU amending Directive 2001/83/EC obliges each Market Authorisation Holder (MAH) with the EEA to have a socalled PSMF document in place for each Market Authorisation Application (MAA). The PSMF is a modular document describing the PV system which is utilised for the medicinal product by the MAH. It also supports the conduct of audits and inspections, confirms compliance of the PV system, highlights deficiencies in the system or non-compliance with the requirements, and highlights risks or actual failure in the conduct of specific aspects of PV. It is a key instrument and vital for a MAH, a dynamic document that also evolves with the MAH, and each section has to provide a detailed description of a specific aspect of the PV system. Due to its above-described nature, this document has to be provided to Competent Authorities upon request within seven days, if not otherwise specified. Although the information expected to be included within the PSMF is very well outlined in the legislation - GVP Module 2, findings identified during inspections suggest that some aspects of the legislation can be misunderstood.

Biography:

Erika graduated with a master degree in Biology (research sector) in 2015 in Hungary. She started her career in Pharmacovigilance in the same year. Before joining Market Authorisation Holders, Erika used to work for PV service providers such as TCS and Quintiles IMS as a PVA and PV Officer on projects such as Bayer. In 2018, she joined Sanofi S.A where she was already responsible for the management of all PV data, including the PV inbox, individual (including tracking and follow-up) and aggregate reports, SUSAR management, safety agreements, local signal detection and literature monitoring, reconciliation, quality checks and local risk management and compliance activities. In 2019, Erika was awarded her second master's degree in Pharmaceutical Medicine from Trinity College. She joined Ayrton Saunders as a Deputy QPPV for six months, following which she has been promoted to EU/EEA QPPV. She was in charge of all aspects of Pharmacovigilance (PV) activities and followed applicable regulations, guidelines and industry best practices. She acted as the single point of contact for PV on a 24-hour basis in the EEA for Competent Authorities for PV related matters, maintained an overview of the safety profiles of the company medicinal products and any emerging safety concerns, and maintained oversight of the PV system and its performance. At the end of 2020, Erika joined Jenson R+ as an EU/EEA QPPV and serving as an EU and UK QPPV. She is also a certified Lead Pharmaceutical Auditor. Erika is also a member of both the International Society of Pharmacovigilance (ISoP) and the Pharmaceutical Information & Pharmacovigilance Association (PIPA).

Note: This work is partly presented at Webinar on Pharmaceutics and Drug Discovery (March 29, 2021 GMT+1)