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Current developments in pharmacovigilance from the regulator's perspective: A risk management, master file and dictionary evolution (REMS, PSMF and xEVMPD/IDMP)

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The decision of approving a medicinal product is based on its satisfactory balance between benefits and risks within the conditions specified in the product's labeling. This decision is also based on the limited information available at the time of approval. The huge exposure to the medicinal product in the post-marketing period will generate new information, which can have an impact on the benefits or risks of the medicinal products. This is the reason behind authorities' periodic safety data requirement and legislation developments. The EMA and the NCAs in the EU and the FDA in the US are empowered to impose certain obligations on authorizing medicinal products, to ensure the appropriate changes to medicinal product's labeling and to conduct post-authorization safety studies, when new safety information makes them necessary. The pharmacovigilance system in both areas demands expedited and obligations recording and reporting of all available data about the serious unexpected adverse events, medication errors and any suspected transmission of an infectious agent through the medicinal products. US legislation has been significantly enhanced by the title IX of the Food and Drug Administration Amendments Act of 2007 and with four different acts over the last two years, the EU has introduced several changes. Implementation of REMS, PSMF, PBRER, xEVMPD and IDMP are the main features of these changes. The current objective of these initiatives is to ensure that the agencies receive up-to-date, complete and high-quality data and maintaining the data so that it is kept up-to-date and of high quality.

Biography

Mohammad Wasif Khan has completed his MPharm from Jamia Hamdard University, New Delhi. He is the Pharmacovigilance Advisor of Yes Regulatory Healthcare Services India Pvt. Ltd; a premier Germany based service provider in Pharmacovigilance and Regulatory Affairs. He has worked for MAHs, Sponsors, service-providers and regulatory authority. His involvement with the regulatory authority included to review the reports submitted by MAHs/sponsors in line with the applicable regulatory authority guidelines and providing the findings and comments on the reports to the companies and providing resolution of their queries. He has also supported regulatory authority in drafting one of the modules of Good Pharmacovigilance Practices.

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