European Medicines Agency
Communications and Networking

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Session Report: Pharmacovigilance

Martin Terberger (European Commission) provided a summary on how the new pharmaceutical legislation will strengthen the pharmacovigilance activities with the aim of further increasing the safe use of medicines across the EU. As one of the main pillars of pharmacovigilance, Thomas Goedecke (EMEA) presented the EudraVigilance system and its key functionalities to monitor adverse reactions and to perform signal detection for medicinal products authorised in the EU. Stella Blackburn (EMEA) introduced the concept of EU risk management plans and the central role of pharmacovigilance planning based on the product-specific safety specification including both routine and additional risk minimisation measures for identified and potential risks.

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