

EMA Report on Pharmacovigilance Tasks (2019-2022)

TRENDING TOPICS

The [report](#) on PV tasks from EU Member States and EMA published in June 2023 specifies all the key factors that allowed the European medicines regulatory network to effectively respond to the Covid-19 pandemic: the preparedness for intensified monitoring, methodologies based on established PV tools as well as on innovative approaches and the flexibility and commitment of all the stakeholders involved.

The report describes how EMA is leveraging real world evidence (RWE) as part of the [Big Data Steering Group work plan](#), to accelerate medicine development, improve treatment outcomes and facilitate earlier patient access to new treatments. It also provides an overview of key activities carried out from 2019 to 2022 and metrics by area, namely: PRAC activities, adverse reaction reporting, signal management, RMPs, PASS, PSUR, safety referrals and inspections.

Next steps

Experience during the public health emergency has highlighted a number of areas for improvement:

1. An upgrade of EudraVigilance (EV) data analysis (EVDAS) system is underway* to achieve a higher level of automation, increased flexibility and enhanced data extraction and query functionalities.
2. To leverage real-world data (RWD) for decision-making and rapidly generate evidence on the safety and effectiveness of medicines, the range of available tools should be widened and the collection and analysis of health data across the EU harmonised.
3. Earlier engagement with healthcare professionals through the PRAC Risk Minimisation Alliance (PRISMA) will help identify the barriers and enablers of risk minimization measures implementation in clinical practice.
4. Further engagement with national immunisation technical advisory groups, the national expert bodies advising on vaccination programmes coordinated by the European Centre for Disease Prevention and Control (ECDC), is also envisaged to harmonise public health recommendations at time of crisis.

*A pilot is on-going whereby MAHs of selected active substances must monitor them in EV and inform EMA and NCAs of validated signals with their medicines. In July 2022, the European Commission decided to further extend the pilot until the end of 2023, pending the update of the Commission Implementing Regulation based on the experience gained with the pilot.

Keywords: EMA, pharmacovigilance tools, intensified monitoring, EVDAS, PRISMA, RMMs, Big Data

