Market authorization services for healthcare products
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A short comparison of Risk Management Plan (RMP), Periodic Safety Update Report (PSUR) and Addendum to the Clinical Overview (ACO)

RMP	***PSUR***	***ACO***
The main documents of post-approval pharmacovigilance (should be updated throughout the whole life cycle of drug product)		It is formed as a single time action (provided to obtain the Marketing Authorization (MA) of unlimited validity)
In which cases is submitted to Competent Authorities (CA)		
- during MA obtaining/renewal; - in case of the changes requiring a new registration (new dosage form, new route of administration, new manufacturing process for biotechnological medicinal product, pediatric indications and other substantial changes in indications, etc.); - in case of the new risks occurrence (change of the specification, change PV plan, plan of the risk minimization, benefit/risk ratio); - at the request of the CA.	Periodically during the post-approval period: For the first approved DP: • every 6 months (2 years), • every year (2 years), • every 3 years (from the marketing approval date) or Then: • according to EMA reference dates or • according to the terms of registration certificate, • at the CA request.	During MA renewal.
Document content:		
Consists of seven parts: I. Overview; II. Safety specification: - Epidemiology of the indication(s) and target population(s); - Non-clinical part of the safety specification; - Clinical trial patient exposure; - Populations not studied in clinical trials; - Post-authorization experience; - Additional Ukraine's, EU requirements; - Identified and potential risks; - Summary of the safety concerns; III. Pharmacovigilance plan; IV. Plans of post-authorization efficacy studies V. Risk minimization measures; VI. Summary of risk management plan; VII. Annexes.	Consists of twenty parts: I. Introduction; II. Worldwide marketing authorization status; III. Actions taken in the reporting interval for safety reasons; IV. Changes to the reference safety information; V. Estimated exposure and use patterns; VI. Data in summary tabulations; VII. Summary of the significant findings from clinical trials during the reporting interval; VIII. Findings from non-interventional studies; IX. Information from other clinical studies and sources; X. Non-clinical data; XI. Literature; XII. Other periodic safety update reports; XIII. Lack of the efficacy in the clinical trials; XIV. Late-breaking information; XV. Overview of signals (new, ongoing or closed); XVI. Signal and risk evaluation; XVII. Benefit evaluation; XVIII. Integrated benefit-risk analysis for registered indications; XIX. Conclusions and actions; XX. Appendices to the periodic safety update report.	Consists of fourteen parts: 1. History of pharmacovigilance inspections; 2. Worldwide marketing authorization status; 3. Actions taken in the reporting interval for safety reasons; 4. Changes to the reference safety information ; 5. Meaningful differences between the DP Reference Information and the SmPC; 6. Estimated exposure and use patterns; 7. Data in the summary tabulations; 8. Summary of the significant safety and efficacy findings from clinical trials and non-interventional studies during review period; 9. Literature; 10. Risk evaluation; 11. Benefit evaluation; 12. Benefit/risk balance; 13. Late-breaking information; 14. Clinical Expert Statement.