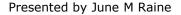


PRAC Work Plan 2018

13th Industry Stakeholder Platform – operation of EU Pharmacovigilance

20 March 2018







PRAC Work Plan 2018 adopted 31 January 2018

- Optimising management and utility of reported adverse reactions
- 2. Life-cycle approach to pharmacovigilance and risk management
- 3. Process improvements & simplification
- 4. Special populations & product guidance
- 5. Partners and stakeholders
- 6. Measuring impact of PhV activities
- 7. Regulatory science





PRAC Work Plan 2018 – highlights

- Optimising management and utility of reported adverse reactions
- Life-cycle approach to pharmacovigilance & risk management
- Information from real-world use
- Process improvements and simplification
- Special populations & product guidances
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PRAC Work Plan 2018 – highlights

- Optimising management and utility of reported adverse reactions
- Life-cycle approach to pharmacovigilance & risk management
- Information from real-world use
- Process improvements and simplification
- Special populations & product guidances
- Partners and stakeholders
- Measuring impact
- Regulatory science

Monitor operation of new EudraVigilance Functionalities; additional monitoring review Increasing involvement in innovation PRIME, SAWP, registries initiative Pilot network study (codeine), use of ENCePP PSUR Road map, optimise referrals conduct GVP P modules – pregnancy, the elderly Public hearing on fluoroguinolones June 18 Prioritisation, expert input to impact studies EMA regulatory science strategy – PV aspects



New activities for 2018

- Review the impact and value of the first PRAC **public hearing**
- Improve management of risk of hepatotoxicity in benefit risk management, based on work conducted by different delegations and PRAC independent experts (similar to the work done in 2017 for the management of severe cutaneous adverse reactions – SCARs - in benefit-risk)



Thank you for your attention

Further information

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