EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PRAC Work Plan 2018

13th Industry Stakeholder Platform – operation of EU Pharmacovigilance

20 March 2018

Presented by June M Raine

PRAC Work Plan 2018 adopted 31 January 2018

1. 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

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31 January 2018
EMA/PRAC/139104/2018
Procedure Management and Committees Support Division

Pharmacovigilance Risk Assessment Committee (PRAC): Work Plan 2018

Adopted by the Committee on 31 January 2018

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

PRAC Work Plan 2018 – highlights

Optimising management and utility of reported adverse reactions	Monitor operation of new EudraVigilance Functionalities; additional monitoring review
Life-cycle approach to pharmacovigilance & risk management	Increasing involvement in innovation PRIME, SAWP, registries initiative
Information from real-world use	Pilot network study (codeine), use of ENCePP
Process improvements and simplification	PSUR Road map, optimise referrals conduct
Special populations & product guidances	GVP P modules – pregnancy, the elderly
Partners and stakeholders	Public hearing on fluoroquinolones June 18
Measuring impact	Prioritisation, expert input to impact studies
Regulatory science	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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