EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on PRAC Work Plan and Impact Strategy

11th Industry Stakeholder Platform – operation of EU Pharmacovigilance

2nd June 2017

Presented by June M Raine

PRAC Work Plan 2017 published 23rd March 2017

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. Strengthening links between assessment and inspection
7. Measuring impact of PhV activities


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23 March 2017
EMA/PRAC/213230/2017
Procedure Management and Committees Support Division

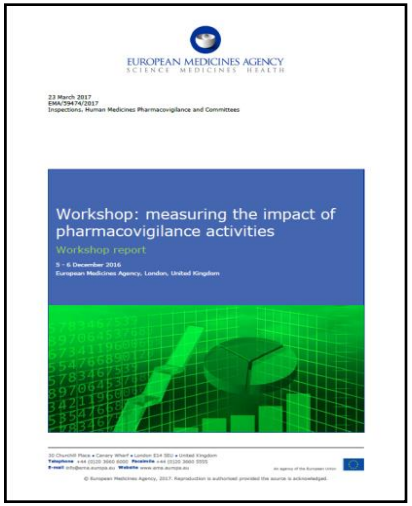
Pharmacovigilance Risk Assessment Committee (PRAC): Work Plan 2017

Adopted by the Committee on 23 March 2017

PRAC Work Plan 2017 – headline progress

Optimising management and utility of reported adverse reactions	Adopted recommendation on auditable requirements for EV full functionality 3/05/17
Life-cycle approach to pharmacovigilance & risk management	GVP V revision 2 published 31/3/17 Increasing involvement in SAWP, PRIME
Process improvements and simplification	Subgroup of cross–Committee Brexit TF
Special populations & product guidance	GVP Paediatric Pharmacovigilance agreed
Partners and stakeholders	Public hearing on valproate referral Oct 17
Strengthening links between assessment and inspection	Strategic review commenced under Malta Presidency

Impact Strategy update - Workshop recommendations



Key recommendations
1. Revision of the framework for impact evaluation
2. Systematic collection of impact relevant data considering the need for, the nature of and the approach to collection
3. Robust methodologies for measuring health impacts of pharmacovigilance activities
4. Establishing collaboration with novel information technology providers
5. Active engagement and capacity building with patient communities and healthcare professional bodies to support impact research
6. Development of a process for identifying relevant intended (and unintended) public health outcomes of regulatory decisions

Impact Strategy achievements - PRAC Interest Group

Reflection paper on criteria for prioritising collaborative impact research;

Under revision to include recommendations of a 6-month pilot Dec 16-May'17 applying criteria to signals & referrals → 4 potential topics identified

Planned: publication of criteria on EMA website for reference purposes

Tender for 2 EMA commissioned impact studies (framework contract) relaunched in Apr'17:

Diclofenac & cardiovascular risks – evaluation of impact of RMM following 2013 Art 31 referral : drug utilisation & prescribing trends, inc alternative medicines, prescribers' compliance

Hydroxyzine & pro-arrhythmogenic potential – evaluation of impact of RMM following 2015 Art 31 : drug utilisation & prescribing trends, inc alternative medicines, prescribers' compliance

Opportunities for collaboration with industry

- Re-activate 'EMA Industry Stakeholder Group on Impact'
- 'Platform' for sharing impact relevant data
  - PASS protocols and results, effectiveness studies among MAHs and EU regulatory network
  - Survey on industry held non-public impact relevant data sources to support collaborative impact research
- Collaboration on methods of measuring impact of pharmacovigilance activities and for effectiveness studies

Thank you for your attention

Further information

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