EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2017 PRAC Work Plan

10th Industry Stakeholder Platform – operation of EU Pharmacovigilance

3 February 2017

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PRAC Work Plan 2017 Overview

1. Optimising management and utility of reported adverse reactions
2. Life-cycle approach to pharmacovigilance and risk management
3. Process improvements and simplification
4. Special populations and product guidance
5. Partners and stakeholders
6. Strengthening links between assessment and inspection
7. Measuring the impact of pharmacovigilance activities

1. Optimise management & utility of reported adverse reactions

➢ Key objectives and activities

- **EudraVigilance functionalities**
  - adoption of recommendation on audit results
- **Signals**: new process for industry
  - prioritise and evaluate signals assessed by Industry
- **IMI-WEB-RADR project** - review relevant outputs

2. Life-cycle approach to pharmacovigilance and risk management

Innovation, PRIME, Real world data, patient registries, patients' value in benefit/risk

➢ Key objectives and activities

- Optimal PRAC input on risk management planning incl high value, high uncertainty products
  - Support life cycle development through risk management planning, use of real world data
  - Support accelerated assessment and PRIME
  - GVP module V on Risk Management systems
- Advise on inventory of real world data
- Contribute to task force on EMA patient registries
- Based on experience gained through ongoing pilot on effects tables in selected important benefit/risk reviews, agree on recommendations
- Improve scientific advice process for post-authorisation safety studies

3. Process improvements and simplification

➢ Key objectives and activities

- GVP module V : implement and operate the new format
- PSURs - continue implementation of PSUR Road Map including revision of GVP module VII
- Support implementation of publication of PSUR assessment reports/summary
- Continued support from PRAC efficiency group
- Continuous review of quarterly workload and performance measures, making recommendations
- SCOPE project: advise on implementation and maintenance of SCOPE output, embed/train and maintain in PRAC-related work
- Provide expert advice on optimal role of PRAC for safety related variations

4. Special populations and product guidance

➢ Key objectives and activities

- Develop GVP P.IV ‘Medicines use in **geriatric healthcare**’ for release for public consultation
- Develop GVP P.III ‘Product- or population-specific considerations: **pregnancy**’ for release for public consultation
- Finalise GVP special population on ‘conduct of pharmacovigilance for medicines used by the **paediatric population**’ (under lead of PDCO) for release for public consultation
- Support work of joint PDCO/PRAC working group on medicines for children: revision of mandate, give advice on products on an ad hoc basis, hold joint meeting with PDCO
- Finalise revision of ‘Guideline on safety and efficacy follow-up – Risk Management of **advanced therapy medicinal products**’ for release for public consultation (CAT lead)

5. Partners and stakeholders

Further engagement with the public

➢ **Key objective**

- Hold first public hearing

6. Inspections and compliance

➢ **Key objectives and activities**

- Strengthening links between assessment and inspection
- Advise on procedures of non-compliance
- Support training on pharmacovigilance inspection
- Inspectors to work on revision of PSMF – and involvement of PRAC

7. Measuring the impact of pharmacovigilance activities

➢ Key objectives and activities

- Apply prioritisation criteria for studies on impact to key public health decisions (referrals and signals)
- Contribute to methods of measuring impact of pharmacovigilance liaising with ENCePP Special Interest Group
- Review overall strategy in light of the recommendations of Impact workshop