EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 February 2016
EMA/148594/2016
Procedure Management & Business Support Division

PRAC work plan - FINAL

2016 – adopted by the Committee on 11 February 2016

List of abbreviations

ADR: Adverse drug reaction

ADVANCE: Accelerated development of vaccine benefit-risk collaboration in Europe

CAT: Committee for advanced therapies

EMA: European Medicines Agency

EC: European Commission

ENCePP: European network of centres for pharmacoepidemiology and pharmacovigilance

EU: European Union

GVP: Good pharmacovigilance practice

HCP: Healthcare professional

IMI: Innovative medicines initiative

ISO: International Organization for Standardization

PAES: Post-authorisation efficacy studies

PASS: Post-authorisation safety studies

PDCO: Paediatric committee

PRAC: Pharmacovigilance risk assessment committee

PRIME: Priority medicines

PROTECT: Pharmacoepidemiological research on outcomes of therapeutics by a European consortium

PSUR: Periodic Safety Update Report

PSUSA: PSUR Single Assessment

RADR: Recognising Adverse Drug Reactions

RMP: Risk management plan

SMART: Signal management review technical

SCOPE: Strengthening Collaborations for Operating Pharmacovigilance in Europe

1. Evaluation activities for human medicines

1.1. Pre-authorisation activities

1.1.1. Special populations and product guidances

Certain specific population groups including children, pregnant women and the elderly require specific consideration in the conduct of pharmacovigilance. Likewise certain product types bring specific issues that necessitate additional focus. This PRAC work topic will therefore channel PRAC's expertise into the development of population specific and product-type specific guidance.

Key objectives

- Strengthen pharmacovigilance by industry and regulators through dedicated guidance on specific populations
- Strengthen pharmacovigilance by industry and regulators through dedicated guidance on specific product types.

Activities in 2016

PRAC activities to achieve the objectives set for this area:

- Expert input in the development of GVP P.IV – 'Medicines use in geriatric healthcare' for release for public consultation
- Expert input in the development of GVP P.III – 'Product- or population-specific considerations: pregnancy' for release for public consultation
- Expert input (under the lead of the PDCO) on the revision of the 'Guideline on conduct of pharmacovigilance for medicines used by the paediatric population' release for public consultation
- Support the work of the joint PDCO/PRAC working group on medicines for children
- Expert input in the development of GVP P.II – ' Product- or population-specific considerations: biological medicines' for release for public consultation
- Expert input (under the lead of CAT) in the revision of the guideline on safety and efficacy follow-up – Risk Management of advanced therapy medicinal products for release for public consultation.

PRAC topic leader: June Raine

Other Committee participants:

Member/alternate	Name	Member state or affiliation
Member	Jolanta Gulbinovič	LT (Paediatrics)
Member	Kirsti Villikka	FI
Member	Ulla Wändel Liminga	SE (Pregnancy)
Member	Julie Williams	UK (ATMP)
Member	Sabine Straus	NL (Biologicals)
Member	Dolores Montero Corominas	ES (Geriatric)
Alternate	Kirsten Myhr	Representative of HCPs (Geriatric and pregnancy)[1]
Expert	Philip Bryan	UK (Biologicals)

[1] Subject to EC re-nomination

1.1.2. Life-cycle approach to pharmacovigilance and risk management

By ensuring robust, feasible and risk proportionate planning of pharmacovigilance activities including risk minimisation and further collection of data and information, the work of the PRAC supports the protection and promotion of public health. The work of the PRAC also underpins innovation throughout the product lifecycle thereby and supporting the delivery of new treatments to patients, fulfilling unmet medical needs.

Key objectives

- Strengthen public health promotion and protection
- Support innovation and the fulfilment of unmet medical needs of patients.

Activities in 2016

PRAC activities to achieve the objectives set for this area:

- Review of the Scientific Advice pilot on non-imposed PASS protocols
- Finalise the approach for PRAC consultation of Scientific Advice responses related to PRAC's mandate but outside the pilot for non-imposed PASS protocols
- Optimise RMP content and process through finalisation of the revision of GVP module V 'Risk management systems'
- Expert input into the creation of a common understanding on optimal PRAC input on risk management planning for high value, high uncertainty products. This activity should support the accelerated assessment, PRIME and Adaptive Pathways initiatives
- Expert input into the finalisation of the PAES scientific guideline
- Pilot the use of the effects tables in selected important benefit/risk reviews.

PRAC topic leader: Margarida Guimarães

Other Committee participants:

Member/alternate	Name	Member state or affiliation
Member	Almath Spooner	IE
Member	Jolanta Gulbinovič	LT
Member	Martin Huber	DE
Member	Julie Williams	UK
Member	Ulla Wändel Liminga	SE
Alternate	Rafe Suvarna	UK
Alternate	Leonor Chambel	PT
Alternate	Valerie Strassmann	DE
Alternate	Miroslava Matíková	SK
Alternate	Qun-Ying Yue	SE
Expert	Eva Segovia	ES

1.2. Initial-evaluation activities

Not applicable.

1.3. Post-authorisation activities

1.3.1. Information from real-world clinical use of medicines

Collection and analysis of data and information from the real-world use of medicines is important in supporting the assessment and decision-making on how medicines are used, their effectiveness and their safety. Use of epidemiological approaches is key and enablers include access to electronic health and insurance records, clear governance, and collaboration across stakeholders including academia. Data and information from the real-world use of medicines is a key enabler for access to new treatments and will support the PRIME and Adaptive Pathway initiatives.

Key objectives

- Strengthen the input of the network and academic research as a source of data and information in PRAC assessments
- Improve collaboration within the network to deliver focussed results of assessment of information from clinical use.

Activities in 2016

PRAC activities to achieve the objectives set for this area:

- Review of learnings from the pilot involving EMA, Spain and the UK, initiated following finalisation of the reflection paper 'Strategy for supporting PRAC assessment with best evidence'
- Recommendation on maximising utility of ENCePP network to PRAC assessment. See 1.5.3.
- Expert input to the EMA initiative of registries
- Informed by input of the ADVANCE project on vaccine benefit risk, make recommendations on any need for further guidance or capacity for vaccine surveillance.

PRAC topic leader: Marie Louise (Marieke) De Bruin; Dolores Montero Corominas; Julie Williams

Other Committee participants:

Member/alternate	Name	Member state or affiliation
Member	Tatiana Magalova	SK
Member	Ulla Wändel Liminga	SE

1.4. Arbitrations and referrals

Not applicable.

1.5. Pharmacovigilance activities

1.5.1. Optimising management and utility of reported adverse reactions

During 2016 the EudraVigilance database will undergo an audit to verify that the additional functionalities adopted in December 2014 have been delivered. EU legislation requires that PRAC gives its recommendation on the independent audit report to inform a decision by the EMA Management Board on whether the functionalities have been delivered. The consequence of this decision is that 6–months after the decision the Marketing Authorisation Holders will report suspected adverse drug reaction reports to EudraVigilance only and this will be in the new ISO data format.

Key objectives

- Enhanced adverse reaction collection and management system (EudraVigilance) that delivers better health protection through simplified reporting, better quality data and better searching, analysis and tracking functionalities. Enhanced detection of new or changing safety issues allows more rapid action to protect public health.

Activities in 2016

PRAC activities to achieve the objectives set for this area:

- PRAC recommendation on the independent audit report of EudraVigilance
- Expert input in the revision of GVP module VI 'Management and reporting of adverse reactions to medicinal products' and release for public consultation
- Review relevant outputs from IMI-WEB-RADR project.

PRAC topic leader: Jean-Michel Dogné

Other Committee participants:

Member/alternate	Name	Member state or affiliation
Alternate	Miroslava Matíková	SK
Expert	Edurne Lázaro	ES

1.5.2. Signal detection and management

Key PRAC tasks include prioritisation, assessment and recommendations on safety signals. This key public health domain has delivered important outputs during PRAC's first three-years of activity and there is an opportunity to further enhance the effectiveness and efficiency of these activities based on important regulatory science results from the PROTECT project and learnings from operation of the processes to date. Furthermore, in 2017 Marketing Authorisation Holders will have access to EudraVigilance data and the process for the resulting signal management needs to be defined.

Key objectives

- Apply evidence-based new methodologies for signal detection
- Improve signal management processes based on experience
- Achieve efficient and effective industry input to signal detection and management.

Activities in 2016

PRAC activities to achieve the objectives set for this area:

Supported by the SMART working group:

- Provide expert input into the revision of the signal detection methods guidance
- Provide expert input the revision of GVP module IX 'Signal management'
- Deliver a user guide on electronic reaction monitoring reports.

PRAC topic leader: Sabine Straus; Lennart Waldenlind

Other Committee participants:

Member/alternate	Name	Member state or affiliation

Member/alternate	Name	Member state or affiliation
Member	Margarida Guimarães	PT
Member	Martin Huber	DE
Member	Isabelle Robine	FR
Alternate	Leonor Chambel	PT
Alternate	Miroslava Matíková	SK

1.5.3. Measuring the impact of pharmacovigilance activities

Measuring impact allows regulators to determine what activities are successful and which are not, and therefore identifies enablers and barriers for generating positive impacts which would contribute to an effective pharmacovigilance system for health and innovation. Measuring impact can also inform the review of the benefits and risks of individual medicines that have been the subject of major risk minimisation efforts (e.g. post referral).

Key objectives

- Improve pharmacovigilance through feedback on impact
- Strengthen targeted product assessment through measuring the impact of regulatory action taken
- Achieve a better understanding of stakeholder views.

Activities in 2016

PRAC activities to achieve the objectives set for this area:

- Share network information and contribute on activities linked to the work of impact of pharmacovigilance activities
- Establish a virtual PRAC special interest group on impact
- Adopt criteria for prioritising studies into the impact of pharmacovigilance activities
- Provide expert advice on the research questions for at least four impact studies
- Provide expert advice on stakeholder surveys in pharmacovigilance
- Support a stakeholder workshop focussed on impact measurement methods.

PRAC topic leader: Marie Louise (Marieke) De Bruin; Dolores Montero Corominas; Sabine Straus; Almath Spooner; June Raine

Other Committee participants:

Member/alternate	Name	Member state or affiliation
Member	Margarida Guimarães	PT
Member	Sabine Straus	NL
Member	Martin Huber	DE
Member	Julie Williams	UK
Member	Tatiana Magalova	SK
Member	Carmela Macchiarulo	IT
Member	Isabelle Robine	FR
Member	Ulla Wändel Liminga	SE
Member	Julia Pallos	HU
Member	Ingebjørg Buajordet	NO

Member/alternate	Name	Member state or affiliation
Alternate	Leonor Chambel	PT
Alternate	Valerie Strassmann	DE
Alternate	Torbjorn Callreus	DK
Alternate	Miroslava Matíková	SK
Alternate	Amelia Cupelli	IT
Alternate	Qun-Ying Yue	SE

1.6. Other specialised areas and activities

Not applicable.

2. Horizontal activities and other areas

2.1. Committees and working parties

Not applicable.

2.2. Inspections and compliance

Not applicable.

2.3. Partners and stakeholders

2.3.1. Engage patients

The engagement of patients is important for effective pharmacovigilance. Patients can be involved throughout the process from risk management planning, through reporting of suspected adverse drug reactions, managing safety signals, assessments and decision e.g. through PSURs and referrals and on benefit risk communications. For the PRAC key engagement has included membership of the committee, patient reporting, involvement in ad-hoc expert groups and scientific advisory groups.

Key objectives

- Achieve adoption of the PRAC rules of procedure for public hearings
- Improve engagement of patients through availability of public hearings.

Activities in 2016

PRAC activities to achieve the objectives set for this area:

- Finalisation of the rules of procedures on public hearing
- Conduct of a preparatory public hearing.

PRAC topic leader: Albert van der Zeijden[2]

Other Committee participants:

Member/alternate	Name	Member state or affiliation
Member	Julia Pallos	HU
Member	Margarida Guimarães	PT

[2] Subject to EC re-nomination

Member/alternate	Name	Member state or affiliation
Member	Albert van der Zeijden	Representative of patients organisations[3]
Alternate	Marco Greco	Representative of patients organisations[4]
Alternate	Kirsten Myhr	Representative of HCPs[5]
Alternate	Leonor Chambel	PT

2.4. Data-management support

Not applicable.

2.5. Process improvements

The PRAC has an important role in continuous improvement of its processes. Key processes through PRAC include risk management plans, post-authorisation study protocols and results, signal management, referrals, periodic safety update reports including single assessment procedures, and variations. Observations from running these processes combined with feedback from stakeholders and outputs from the SCOPE project provide opportunities for such improvement.

Key objectives

- Improve processes involving the PRAC
- Increase the efficiency of PRAC plenary discussion
- Strengthen the quality of PRAC recommendations.

Activities in 2016

PRAC activities to achieve the objectives set for this area:

- Provide expert input into review of content and process for PSURs/PSUSA (based on the Roadmap for PSURs adopted by PRAC in 2015)
- Review of quarterly workload and performance measures, making recommendations where appropriate
- Establish a PRAC virtual group to make recommendations on efficiency and effectiveness improvements for PRAC plenary meetings
- Provide expert advice on optimal role of PRAC for safety related variations
- Review outputs from the SCOPE project.

PRAC topic leader: Martin Huber; Menno van der Elst

Other Committee participants:

Member/alternate	Name	Member state or affiliation
Member	Margarida Guimarães	PT
Member	Ingebjørg Buajordet	NO
Member	Jolanta Gulbinovič	LT
Member	Julie Williams	UK

[3] Subject to EC re-nomination
[4] Subject to EC re-nomination
[5] Subject to EC re-nomination

Member/alternate	Name	Member state or affiliation
Member	Tatiana Magalova	SK
Member	Carmela Macchiarulo	IT
Member	Dolores Montero Corominas	ES
Member	Isabelle Robine	FR
Member	Ulla Wändel Liminga	SE
Alternate	Leonor Chambel	PT
Alternate	Rafe Suvarna	UK
Alternate	Miroslava Matíková	SK
Alternate	Amelia Cupelli	IT
Expert	Charlotte Backman	SE