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Procedure Management and Committees Support Division

PRAC work plan

2015 – Adopted by the Committee on 25 June 2015

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List of abbreviations

CAT: Committee for advanced therapies

CHMP: Committee for medicinal products for human use

DHPC: Direct healthcare professional communication

EMA: European Medicines Agency

ENCePP: European network of centres for pharmacoepidemiology and pharmacovigilance

EU: European Union

GVP: Good pharmacovigilance practice

HCP: Healthcare professionals

HMA: Heads of Medicines Agencies

IMI: Innovative medicines initiative

PAES: Post-authorisation efficacy studies

PASS: Post-authorisation safety studies

PDCO: Paediatric committee

PgWP: Pharmacogenomics working party

PMG: Project and maintenance group

PRAC: Pharmacovigilance risk assessment committee

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

SAWP: Scientific advice working party

SMART: Signal management review technical

Priorities

Following the priorities set out in the Agency Work Programme 2014 and 2015 the PRAC will concentrate its activities towards enhanced quality and consistency of reviews, focusing in best evidence generation underpinning decisions on individual medicines or class of medicines, to increase the quality of advice in PRAC assessments.

The PRAC will also support product lifecycle management through best use of the tools provided by the new pharmacovigilance legislation which will be taken to its final phase of implementation, application of new methodologies for signal detection from spontaneous reports, production of guidance in key evolving fields.

1. Evaluation activities for human medicines

1.1. Pre-authorisation activities

See 1.5.1.

1.1.1. Special populations and pharmacovigilance

Activity areas

Focus on guidance on the conduct of pharmacovigilance for special populations and their specific needs.

Key objectives

- Analyse the need of special populations in terms of pharmacovigilance activities;
- Complete the set of guidance describing the special measures for the conduct of pharmacovigilance in selected patients' populations;
- Investigation of strategies (e.g. registries, PAES, PASS) to acquire data in the older population, particularly with respect to collection of post-approval data in frail/comorbid/very old people; coordination of geriatric activities across CHMP/PRAC/SAWP.

Activities in 2015

PRAC activities to achieve the objectives set for this area:

- Input in the development of GVP P. IV – 'Medicines used in geriatric healthcare';
- Input on the finalisation of GVP P.III - 'Product- or population-specific considerations: pregnancy';
- Cooperation (under the lead of PDCO) on revision of the 'Guideline on conduct of pharmacovigilance for medicines used by the paediatric population';
- Contribution (under the lead of PgWP) in the revision of the 'Guideline on key aspects for the use of pharmacogenomic methodologies in the pharmacovigilance evaluation of medicinal products' following public consultation.

PRAC topic leaders and contributors:

Member/alternate	Name	Member state or affiliation
Member	Jane Ahlqvist Rastad	Independent scientific expert (for geriatrics)
Member	Jolanta Gulbinovič	LT (for paediatrics)
Member	Dolores Montero Corominas	ES (for geriatrics)
Member	Julia Pallos	HU (for paediatrics)
Member	Adam Przybylkowski	PL (for paediatrics)
Member	Almath Spooner	IE (for geriatrics)
Member	Amy Tanti	MT (for paediatrics)
Member	Ulla Wändel-Liminga	SE (for pregnancy)
Alternate	Qun-Ying Yue	SE (pharmacogenomics)

1.2. Initial-evaluation activities

None

1.3. Post-authorisation activities

1.3.1. Benefit-risk decision-making

Activity area

Focus on PRAC's contribution on methodologies for benefit-risk decision-making process.

Key objectives

- In collaboration with CHMP, contribute to further develop and review potential methodology for decision-making, solicitation of patient values, and visualisation to communicate the decisions reached;
- Explore applicability of agreed benefit-risk assessment project approaches to PRAC's recommendations including values and visual displays through interaction with academia and consortia (e.g. IMI-PROTECT);
- Increase patients and healthcare professionals' involvement during the benefit-risk evaluation of medicines.

Activities in 2015

PRAC activities in collaboration to achieve the objectives set for this area:

- Contribute to an enhanced interaction with patients and consumers by further integrating patients' values in the work of the PRAC with consideration of activities in this area taking place in other Committees/Working Parties;
- Explore the implementation of the benefit-risk assessment methodology into PRAC decision-making, in assessment reports of referral procedures. Conduct and evaluate a pilot of the use of effects benefit-risk table;
- Explore utility of summary tables and/or graphical representations in supporting the communication of decision making in the context of PRAC recommendations on benefit-risk.
- Review deliverables from PROTECT.

PRAC topic leader: Almath Spooner

Other PRAC contributors:

Member/alternate	Name	Member state or affiliation
Member	Filip Babylon	Representative of HCPs
Member	Jean-Michel Dogné	BE
Member	Stephen J. W. Evans	Independent scientific expert
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Member	Albert van der Zeijden	Representative of patients organisations

1.3.2. Strengthening science and evidence base: best evidence, best expertise

Activity area

Focus on scientific robustness of post-authorisation evidence and strengthening evidence underpinning decisions on individual medicines or class of medicines to increase quality of advice and consistency of elements in PRAC assessments.

Key objectives

- Strengthen methodology for pharmacovigilance decision-making at PRAC; input in strategies developed to support use of high quality data and best evidence in critical assessments of risk and benefit-risk to maximise benefits to public health;
- Optimise use of expertise through collaboration with other Committees, ENCePP.

Activities in 2015

PRAC activities to achieve the objectives set for this area:

- Contribution to reflection paper: 'Strategy for supporting PRAC assessment with best evidence' (common to PMG2)
- Review experience with ENCePP collaboration and deliver option for enhancement of interaction PRAC – EnCePP;
- Develop mandate and scope for joint PDCO/PRAC working group.

PRAC topic leader: Dolores Montero Corominas

Other PRAC contributors:

Member/alternate	Name	Member state or affiliation
Member	Stephen J. W. Evans	Independent scientific expert
Alternate	Corinne Fechant	FR
Alternate	Miguel-Angel Macia	ES

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Alternate	Kirsten Myhr	Representative of HCPs
Member	Adam Przybylkowski	PL
Member	Julie Williams	UK

1.3.3. Post-authorisation safety studies (PASS) and post-authorisation efficacy studies (PAES)

Focus on undertaking of joint PASS by MAHs to address research questions raised during the evaluation of new safety issues involving more than one product or substance; and encouraging joint studies by MAHs and use of registries measuring the effectiveness and safety of medicinal products in the routine treatment of diseases. Develop guidance for PAES.

Key objectives

- Work on past experience in order to inform development of future practices for both PASSs and joint studies;
- Explore initiatives to facilitate dialogue across relevant stakeholders;
- Develop a scientific guidance on PAES.

Activities in 2015

PRAC activities to achieve the objectives set for this area:

- Supplement GVP Module VIII – Post-authorisation safety studies module with more practical measures;
- Coordination with ENCePP which builds capacity in the delivery of post-authorisation studies. See also 1.3.2. ;
- Contribution to the draft 'EU collaborative framework for patient registries proposal for strategy and pilot phase';
- Advise on EMA scientific guidance on PAES.

PRAC topic leader: Almath Spooner (PAES)

Other PRAC contributors:

Member/alternate	Name	Member state or affiliation
Member	Ingebjørg Buajordet	NO
Alternate	Amelia Cupelli	IT
Member	Marie Louise (Marieke) De Bruin	Independent scientific expert
Member	Stephen J. W. Evans	Independent scientific expert
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1.4. Referrals

1.4.1. Pharmacovigilance referrals

Activity area

PRAC's work towards enhanced quality and consistency of reviews under urgent union procedures under Article 107i of Directive 2001/83/EC and Article 31 of Directive 2001/83/EC in terms of process and content. This area is also linked to 1.3.1. and work on deliverables will be conducted in parallel.

Key objectives

- Optimise three main phases of the process to ensure optimal input and deliver robust output:
  - Definition of scope;
  - Identification of data sources and formulation of questions;
  - Experts and non-industry stakeholders involvement.
- Support interactions with other Committees with regard to implementation and feasibility of proposed measures.

Activities in 2015

PRAC activities to achieve the objectives set for this area:

- Develop a best practice guide;
- Contribute to the revision of processes and tools: revision of assessment report template; design of new business process; establish training programme.

PRAC topic leader: Jean-Michel Dogné

Other PRAC contributors:

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Expert	Charlotte Backman	SE
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Member	Jan Neuhauser	AT
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Member	Isabelle Robine	FR
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1.5. Pharmacovigilance activities

1.5.1. Product lifecycle support: pharmacovigilance planning, effectiveness of risk management and risk minimisation

Activity area

PRAC's role in support of product lifecycle management - as knowledge of safety evolves - through planning of appropriate studies, evaluation of effectiveness of risk minimisation and evaluation of the impact of pharmacovigilance decisions.

Key objectives

- Optimisation of proactive life-cycle management of medicines through:
  - Effective risk management planning;
  - Best use of regulatory tools.

- Increase patients and healthcare professionals' involvement during the benefit-risk evaluation of medicines;
- Ensuring effectiveness of risk minimisation;
- Explore approaches and methodologies for the evaluation of public health impact of the outcomes delivered;
- Develop a strategy to strengthen assessment of risk minimisation proposals.

Activities in 2015

- Contribute in targeted training for the assessors on RMPs;
- Contribute in the enhancement of GVPs:
  - Review GVP Modules linked to risk management planning (GVP Module V – 'Risk management systems' and Module XVI – 'Risk minimisation measures') with a view to facilitating utility of the tools;
  - Contribute to the development of GVP Module XII – 'Regulatory options';
- Contribute to reflection paper on measuring the impact of pharmacovigilance in the EU;
- Develop a concept paper concerning guidance on educational materials.

PRAC topic leader: Sabine Straus

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Alternate	Qun-Ying Yue	SE

1.5.2. Signal management

Progress and support the SMART's work; consideration on methodologies for signal detections in special population and special areas.

Key objectives

- Support SMART's work and oversee progress based on defined indicators;
- Apply new methodologies for signal detection from spontaneous reports (including patient reports) and signal confirmation, in the general and in special populations (e.g. paediatrics, elderly, medication errors).

Activities in 2015

PRAC activities to achieve the objectives set for this area:

- Provide input in the scope of revision and draft revised guidance for GVP Module IX – 'Signal management';
- Consolidate consideration of all results from PROTECT project relevant to signal management;
- Provide advice on the signal detection methods guidance in 2015.

PRAC topic leader: Sabine Straus

Other PRAC contributors:

Member/alternate	Name	Member state or affiliation
Member	Stephen J. W. Evans	Independent scientific expert
Member	Margarida Guimarães	PT
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Alternate	Kirsten Myhr	Representative of HCPs
Alternate	Magda Pedro	PT
Member	Sabine Straus	NL

1.5.3. Biologicals, vaccines and pharmacovigilance

Activity areas

Focus on guidance on the conduct of pharmacovigilance for biologics and vaccines.

Key objectives

- Define key elements of pharmacovigilance of biologicals that would need to be further developed;
- Revise pharmacovigilance plan in case of a pandemic (in view of the changes in the pharmacovigilance processes and of the PRAC's mandate).

Activities in 2015

PRAC activities to achieve the objectives set for this area:

- Contribute to the drafting of the GVP module related to the concept paper on guideline on GVP 'Product- or Population specific consideration II: Biological medicines';
- Contribute to any EMA guidance paper on 'enhanced safety surveillance for vaccines in case of influenza pandemic'.

PRAC topic leaders: Sabine Straus (Biologicals)

Other PRAC contributors:

Member/alternate	Name	Member state or affiliation
Member	Ingebjørg Buajordet	NO
Member	Stephen J. W. Evans	Independent scientific expert
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1.5.4. Medication errors

Activity areas

Focus on developing guidance on coding, reporting and assessment of medication errors leading to adverse reactions, including guidance on risk minimisation and prevention of medication errors.

Key objectives

- Provide support and advice on the key deliverables of the HMA agreed action plan on medication errors with good practice guides;
- Promote international debate on strategies for minimisation of medication errors;
- Support the production of guidance for specific issues.

Activities in 2015

PRAC activities to achieve the objectives set for this area:

- Contribution to coding and reporting and on the risk management good practice guides;
- Consultation on a concept paper for a medication error working group and on two papers developed through SCOPE (awareness campaign on reporting requirements and communication toolbox for health care delivery);
- Create a guidance in relation to labelling terminology (e.g. dose steps, units), pack design, patient and HCP education, product distribution modalities and communication to manage the risk of medication errors with the new generation (high strength) insulins.

PRAC contributors:

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Member	Stephen J. W. Evans	Independent scientific expert
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Member	Sabine Straus	NL
Member	Amy Tanti	MT

1.5.5. Safety communication

Activity areas

Focus on benefit-risk communication and on strategies to enhance accessibility for safety information.

Key objectives

- Optimise communication of medicines information, particularly safety information, within the network and with international partners. The work takes into account ongoing work within the SCOPE project as well as EMA's work on implementation of the pharmacovigilance legislation within PMG3.
- Explore innovative approaches in communication of PRAC activities and outcomes.

Activities in 2015

PRAC activities to achieve the objectives set for this area:

- Update of GVP module XV – 'Safety communication'; particularly regarding the DHPC process and communication plan;
- Defining criteria for consistent communication on topics other than referrals in the PRAC highlights;
- Preparing a report on experiences so far of EMAs coordination of safety announcements.

PRAC topic leader: Jane Ahlqvist Rastad

Other PRAC contributors:

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2. Transversal activities and other areas

2.1. Partners and stakeholders

Activity areas

Focus stakeholder interactions with patients, healthcare professionals, industry organisations and wider stakeholders engagement.

Key objectives

- Optimise interaction with stakeholders on procedures discussed at PRAC. See also 1.5. ;
- Contribute to the concept and development of 'Public hearings'.

Activities in 2015

PRAC activities to achieve the objectives set for this area:

- Revision of comments and finalisation of 'Rules of procedures on the organisation and conduct of public hearings at the Pharmacovigilance Risk Assessment Committee (PRAC)' after public consultation.
- Perform a review of the experience following conduct of the first public hearings

PRAC contributors:

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