EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections and Human Medicines Pharmacovigilance

Workshop: measuring the impact of pharmacovigilance activities

Call for expressions of interest

5 - 6 December 2016
European Medicines Agency, London, United Kingdom

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An agency of the European Union

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Workshop objectives

The workshop will bring together the partners and stakeholders involved in the performance of pharmacovigilance activities or impacted by pharmacovigilance with the following objectives:

1. Review the PRAC approach for measuring the impact of pharmacovigilance activities and regulatory decisions.
2. Identify enablers and barriers to measure the impact of pharmacovigilance activities.
3. Share and develop methodologies for measuring impact of individual product specific pharmacovigilance activities on clinical practice including intermediate indicators and health outcomes.
4. Share and develop methodologies for measuring the impact of the different pharmacovigilance processes.
5. Engage partners and stakeholders in collaborative efforts to measure the impact of pharmacovigilance activities.

Scope

EU pharmacovigilance systems have been established to fulfil the tasks and responsibilities of EU pharmacovigilance legislation, to monitor the safety of authorised medicinal products and to detect and manage any change to their risk-benefit balance. Pharmaceutical companies and regulators have access to a variety of post-marketing surveillance tools that allow for systematic monitoring of the benefits and risks of medicinal products throughout the life-cycle. Pharmacovigilance activities include risk management planning and the detection, assessment, evaluation and management of drug-related adverse effects. They are designed to prevent harm caused by medicines and to enable their safe and effective use. In January 2016 the Pharmacovigilance Risk Assessment Committee (PRAC) has adopted a strategy[1] for measuring the impact of pharmacovigilance activities which relies on a collaborative approach between stakeholders. Measuring the impact of key pharmacovigilance activities will allow those responsible for pharmacovigilance to determine which activities are most successful and to identify enablers and barriers for generating positive health impacts. Together, these will contribute to the further development of proactive pharmacovigilance systems and to promote best practice across the EU.

The aim of this workshop is to facilitate the implementation of the PRAC strategy through the objectives outlined above, with a particular focus on the development of methodologies and on stakeholder collaboration.

[1] Pharmacovigilance Risk Assessment Committee. PRAC strategy on measuring the impact of Pharmacovigilance activities (EMA/790863/2015).

Who the workshop might be of interest to

The presentations and discussions will include experts and stakeholders in the following areas:

- Regulatory bodies: EU and national regulatory agencies, international regulatory bodies.
- Public bodies: national health authorities, the European Commission, the WHO.
- Academia and learned societies, including experts in methodologies.
- Healthcare professional organisations' representatives.
- Patient and consumer organisations' representatives.
- Pharmaceutical industry associations' representatives.

Programme Committee

June Raine (PRAC), Tomas Salmonson (CHMP), Peter Bachmann (CMDh), Dirk Mentzer (PDCO), Marieke De Bruin (PRAC), Almath Spooner (PRAC), Dolores Montero (PRAC), Isabelle Moulon (EMA), Michael Berntgen (EMA), Xavier Kurz (EMA), Peter Arlett (EMA).

Call for expression of interest

Attendance at this workshop is free; however, due to limited space, pre-registration is required. The Agency will consider expressions of interest to participate and will ensure that there is a reasonable balance of representatives of different partners and stakeholder groups.

Should you be interested in attending this workshop, please send an email indicating any particular areas of interest to: pharmacovigilance.impact@ema.europa.eu.

Deadline for receipt of requests to participate

30 September 2016.

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Workshop venue and secretariat

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