



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

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Mandate of the ENCePP Special Interest Group (SIG) on Measuring the Impact of Pharmacovigilance Activities

Background

The PRAC Strategy on Measuring the Impact of Pharmacovigilance Activities ([EMA/790863/2015](#)) was adopted by PRAC in January 2016. It established an approach for measuring the impact of pharmacovigilance activities that will deliver data, information and knowledge on major specific product related actions, on key pharmacovigilance processes and on enabling factors. The strategy proposes the conceptual approach, principles, stakeholders and priorities for this work.

One of the strategy's pillars is the development of robust methods for measuring health outcomes of regulatory decisions in collaboration with the ENCePP network.

Composition of the ENCePP SIG on Impact

The SIG is composed of ENCePP partners with a special interest in the impact of EU pharmacovigilance activities and experience in relevant methodologies. Additional experts, including EMA staff may join the group on an ad-hoc basis. The EMA will provide the link with the impact work conducted by PRAC, EU regulators and stakeholders and will provide the secretariat of the SIG.

Mandate

The mandate of the ENCePP SIG on Impact is to provide recommendations (e.g. in form of guidance documents or publications in peer-reviewed journals) to the PRAC Interest Group (IG) on Impact on the key methodologies for measuring health outcomes of pharmacovigilance activities which contribute to the overall evaluation of the impact of pharmacovigilance systems in line with the PRAC strategy outlined above.

The following specific activities will be undertaken:



- Develop and review methods for modelling health outcomes of pharmacovigilance activities based on parameters such as population attributable risk, prevalence of exposure, behavioural changes, switching therapies etc., including data requirements and relevant data sources.
- Provide recommendations for revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology.

Operational aspects

Meetings will be held as teleconference with ad-hoc face to face meetings in the margins of ENCePP plenary depending on budget availability. EMA will provide administrative support and prepare agendas and minutes in collaboration with the SIG Chair and core members.