



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance and Committees

Workshop: measuring the impact of pharmacovigilance activities

Final programme

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



Introduction

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) 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 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).

Welcome to participants

Dear colleagues,

On behalf of the European Medicines Agency I am pleased to welcome you to this international workshop on measuring the impact of pharmacovigilance activities.

Pharmacovigilance systems have been established to monitor the safety of authorised medicinal products and to detect and manage any change to their risk-benefit balance. The EU has the most advanced pharmacovigilance systems in the world and we share a responsibility to ensure that key pharmacovigilance activities and processes are effective and efficient. We also share a responsibility to continuously improve.

In January 2016 PRAC adopted a strategy for measuring the impact of pharmacovigilance activities. This relies on the collaboration between stakeholders to assess whether pharmacovigilance systems are fully achieving their public health objectives, and to identify areas for improvement. We are committed to working with all our stakeholders to deliver on this strategy.

This workshop is an excellent opportunity to bring together the available expertise from partners and stakeholders, including regulatory and public bodies, healthcare-professional and patient-consumer organisations, academia, learned societies and the pharmaceutical industry.

The workshop's objective is to develop methods in impact research and to identify enablers and barriers to measuring the impact of pharmacovigilance. Particular focus will be on new methods for measuring the impact of product-specific pharmacovigilance activities on clinical practice and health outcomes, as well as the impact of individual pharmacovigilance processes.

We believe that a focused dialogue between regulators and stakeholders is crucial to foster collaboration and to engage the scientific community in efforts to measure the impact of pharmacovigilance activities.

Only by measuring the impact of what we do can we ensure we are effective and continuously get better. Working together I am certain we can develop better methods for measuring pharmacovigilance impact and therefore better contribute to promoting and protecting public health.

I look forward to meeting you in London!



Guido Rasi

Executive Director

Scope

This workshop will be of interest to all stakeholders involved in pharmacovigilance activities and the public health impact of pharmacovigilance systems: health authorities; healthcare professionals; patient associations; regulators; pharmaceutical industry; academics; civil-society organisations; corporate decision-makers.

Sessions

Session 1 Importance of measuring the impact of pharmacovigilance.

Session 2 Approaches for measuring impact of pharmacovigilance and regulatory decisions.

Session 3 Parallel breakout sessions:

3.1 Enablers and barriers to measuring impact – patient and healthcare professional engagement.

3.2 From regulatory outputs to health outcomes.

3.3 Measures of impact of pharmacovigilance processes.

Session 4 Reports from breakout sessions: gaps and observations.

Session 5 Way forward and next steps.

Outputs

A synopsis of the workshop will be made publicly available. In addition, the workshop will support the delivery of recommendations on methodologies for measuring the impact of pharmacovigilance activities in line with the PRAC strategy.

Programme Committee

June Raine	Medicines and Healthcare products Regulatory Agency, United Kingdom
Tomas Salmonson	Medical Products Agency, Sweden
Peter Bachmann	Federal Institute for Drugs and Medical Devices, Germany
Dirk Mentzer	Paul-Ehrlich-Institute, Germany
Marieke De Bruin	University of Copenhagen, Denmark
Almath Spooner	Health Products Regulatory Authority, Ireland
Dolores Montero	Spanish Agency of Medicines and Medical Devices, Spain
Agnes Kant	Netherlands Pharmacovigilance Centre Lareb, Netherlands
Isabelle Moulon	European Medicines Agency
Michael Berntgen	European Medicines Agency
Xavier Kurz	European Medicines Agency
Peter Arlett	European Medicines Agency

Programme details

Monday, 5 December 2016 – Room 3A

12.00 **Registration**

Welcome and opening

13.00 **Opening remarks**
Guido Rasi
European Medicines Agency

13.10 **Introduction and objectives of the workshop**
Xavier Kurz (conference chair)
European Medicines Agency

Session 1: Importance of measuring the impact of pharmacovigilance

Session co-chairs: Almath Spooner and Marco Greco

13.20 **Why measuring the impact of regulatory actions?**
June Raine
Medicines and Healthcare products Regulatory Agency, United Kingdom

14.00 **Regulatory initiatives for measuring the impact of pharmacovigilance**
Dolores Montero
Spanish Agency of Medicines and Medical Devices, Spain

14.20 **The PRAC strategy for measuring impact of pharmacovigilance activities**
Thomas Goedecke
European Medicines Agency

14.40 **Panel discussion**

15.00 **Coffee break**

Session 2: Approaches for measuring impact of pharmacovigilance and regulatory decisions

Session co-chairs: Agnes Kant and Julie Williams

15.20 **FDA experience with measuring the impact of pharmacovigilance**
Gerald Dal Pan
Food and Drug Administration, United States

15.40 **PMDA experience with measuring the impact of pharmacovigilance**
Shinobu Uzu
Pharmaceuticals and Medical Devices Agency, Japan

- 16.00** **Health Canada experience with measuring the impact of pharmacovigilance**
John Patrick Stewart
Health Canada, Canada
- 16.20** **How is industry approaching the impact of pharmacovigilance activities?**
Robert Reynolds
Pfizer Inc., United States
- 16.40** **Challenges and opportunities to measuring the impact of regulatory actions**
Sabine Straus
Medicines Evaluation Board, Netherlands
- 17.00** **Panel discussion**
- 17.20** **End of day 1**
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Tuesday, 6 December 2016 – Room 2D, 2E, 3A

Session 3: Parallel breakout session – Brainstorming & Discussion

For Session 3 discussion topics please refer to the Annex (page 13)

9.00 **3.1 Enablers and barriers to measuring impact – patient and healthcare professional engagement** (Room 2D)

Martin Huber (chair)

Federal Institute for Drugs and Medical Devices, Germany

Patrick Brown (co-chair)

University of Amsterdam, Netherlands

9.00 **3.2 From regulatory outputs to health outcomes** (Room 2E)

Margarida Guimarães (chair)

National Authority of Medicines and Health Products, Portugal

Saad Shakir (co-chair)

Drug Safety Research Unit, United Kingdom

9.00 **3.3 Measures of impact of pharmacovigilance processes** (Room 3A)

Marieke De Bruin (chair)

University of Copenhagen, Denmark

Agnes Kant (co-chair)

Netherlands Pharmacovigilance Centre Lareb, Netherlands

10.30 **Coffee break**

10.50 **Session 3: Parallel breakout session – Wrap-up**

Parallel breakout sessions 3.1, 3.2 and 3.3 continue with discussions and preparation of break-out session reports in rooms 2D, 2E and 3A.

12.00 **Lunch break**

Session 4: Reports from breakout sessions: gaps and observations

Session co-chairs: Dolores Montero and Nawab Qizilbash

13.00 **Report on 'Enablers and barriers to measuring impact – patient and healthcare professional engagement'**

Martin Huber

Federal Institute for Drugs and Medical Devices, Germany

Thomas Goedecke

European Medicines Agency

13.20 **Report on 'From regulatory outputs to health outcomes'**

Margarida Guimarães

National Authority of Medicines and Health Products, Portugal

Daniel Morales

European Medicines Agency

13.40 **Report on 'Measures of impact of pharmacovigilance processes'**

Marieke De Bruin

University of Copenhagen, Denmark

Xavier Kurz

European Medicines Agency

14.00 **Panel discussion**

14.30 **Coffee break**

Session 5: Way forward and next steps

Session co-chairs: June Raine and Marieke De Bruin

14.50 **How can researchers contribute to measuring impact?**

Agnes Kant

Netherlands Pharmacovigilance Centre Lareb, Netherlands

15.10 **How can patients and caregivers contribute to generate data on behavioural changes?**

Elisa Ferrer

European Organisation for Rare Diseases (EURORDIS), France

15.30 **How can healthcare professionals contribute to generate data on behavioural changes?**

Jamie Wilkinson

Pharmaceutical Group of the European Union, Belgium

15.50 **How can pharmaceutical industry contribute to measuring impact?**

Vicki Edwards

AbbVie Ltd., United Kingdom, on behalf of European Federation of Pharmaceutical Industries and Associations (EFPIA)

16.10 **Pharmacovigilance system impact – EU regulatory network collaboration and initiatives**

Julie Williams

Medicines and Healthcare products Regulatory Agency, United Kingdom

16.30 **Panel discussion**

Closing remarks

16.50 **Closing remarks and next steps**

Xavier Kurz

European Medicines Agency

17.00 **End of conference**

List of speakers, chairs and panellists

Marin Banovac	European Medicines Agency
Patrick Brown	University of Amsterdam, Netherlands
Gerald Dal Pan	Food and Drug Administration, United States
Marieke De Bruin	University of Copenhagen, Denmark
Vicki Edwards	AbbVie Ltd., United Kingdom
Stephen Evans	London School of Hygiene and Tropical Medicine, United Kingdom
Elisa Ferrer	European Organisation for Rare Diseases (EURORDIS), France
Thomas Goedecke	European Medicines Agency
Amie Goulbourne	Biogen, United Kingdom
Marco Greco	European Patients' Forum, Belgium
Margarida Guimarães	National Authority of Medicines and Health Products, Portugal
Martin Huber	Federal Institute for Drugs and Medical Devices, Germany
Agnes Kant	Netherlands Pharmacovigilance Centre Lareb, Netherlands
Xavier Kurz	European Medicines Agency
Terri Madison	Mapi Group, United States
Dolores Montero	Spanish Agency of Medicines and Medical Devices, Spain
Daniel Morales	European Medicines Agency
Nawab Qizilbash	Oxon Epidemiology, United Kingdom
Guido Rasi	European Medicines Agency
June Raine	Medicines and Healthcare Products Regulatory Agency, United Kingdom
Robert Reynolds	Pfizer Inc., United States
Judith Sanabria	Biomedical Research Institute, University Hospital of Malaga, Spain
Rachel Sobel	Pfizer Inc., United States
Saad Shakir	Drug Safety Research Unit, United Kingdom
Almath Spooner	Health Products Regulatory Authority, Ireland
John Patrick Stewart	Health Canada, Canada
Sabine Straus	Medicines Evaluation Board, Netherlands
Maia Uusküla	State Agency of Medicines, Estonia
Shinobu Uzu	Pharmaceuticals and Medical Devices Agency (PMDA), Japan
Eric van Ganse	Red Cross Hospital Lyon Cedex, France
Jamie Wilkinson	Pharmaceutical Group of the European Union (PGEU), Belgium
Julie Williams	Medicines and Healthcare products Regulatory Agency, United Kingdom

Practical information

Venue

The European Medicines Agency can be reached:

- By Docklands Light Railway (DLR)
The European Medicines Agency is a short walk from Canary Wharf station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton.
- By Underground
The nearest stop for the European Medicines Agency is Canary Wharf station on the Jubilee Line.
- By bus
Canary Wharf is serviced by local bus numbers D3, D7, D8, 135 and 277.
- By boat
River services run between Embankment, London Bridge and Canary Wharf throughout the day.
- From London City Airport
The European Medicines Agency is a 10-minute walk from Blackwall or Poplar station on the DLR. Alternatively, change at Canning Town to the Jubilee Line to Canary Wharf station.

Getting to the Agency

A map showing travel connections to the Agency can be found [here](#).

Entering the building

The Agency operates a stringent security policy. Upon arrival at the ground-floor reception, you will be given a security pass that will allow you to make your way to meeting room 3A on the 3rd floor. Please show your ID or a credit card in your name. Tea and coffee will be available on your arrival in the 3rd floor foyer.

Physical disability

Let us know if you would like any specific help or information that would make your stay more comfortable. We will be very happy to help.

Registration

We would advise you to arrive up to one hour before the start of the workshop (i.e. at 12:00) to allow sufficient time for registration and settling down. Registration will take place in the foyer on the 3rd floor.

Meeting room

This workshop will benefit from a full house and a seating plan with your name will be available for room 3A. For the parallel breakout session 3 on 6th December you will be assisted by EMA staff and a list with your name and parallel breakout session will be available.

Presentations

We will not circulate printouts of speakers' presentations. However, you will be able to download the presentations from the Agency's website approximately two weeks after the end of the workshop.

Catering

The Agency has a restaurant and a deli bar that offer a variety of food and drinks during the day. They both operate a cashless payment system. No cash or credit/debit cards are accepted.

You will be able to purchase a visitor card at the registration desk. In addition, visitor card terminals are available in the 4th floor restaurant.

At the end of your visit, simply reinsert the card in one of the visitor card terminals and the deposit plus any account balance will be refunded. If visiting the Agency frequently, visitors may wish to retain the card for future use.

Please note that the machine refunds in GBP coins only. For this reason, we encourage you to retain the card for future use or not to load it with more than £20.

Please note the industry representatives do not have access to the EMA restaurant.

Media disclaimer

The Agency records or broadcasts a number of its meetings, including some virtual meetings. This is part of the Agency's commitment to the principle of transparency as enshrined in the Treaty on European Union. The Agency herewith informs attendees that this particular meeting will be live broadcast and recorded.

By attending this meeting you consent to any broadcast and recording.

Conference venue and secretariat

European Medicines Agency
30 Churchill Place, Canary Wharf
London E14 5EU, United Kingdom

Telephone +44 (0)20 3660 6000

E-mail pharmacovigilance.impact@ema.europa.eu

Website www.ema.europa.eu

Annex – Parallel session 3 topic list

Tuesday, 6 December 2016, 9.00 – 12.00

Session 3.1 Enablers and barriers to measuring impact – patient and healthcare professional engagement (Room 2D)

Session co-chairs: Martin Huber and Patrick Brown

09.00 Defining engagement – awareness and perception of public health measures

Patrick Brown

University of Amsterdam, Netherlands

09.20 ISPE paper “Evaluating the Effectiveness of Additional Risk Minimisation Measures via Surveys in Europe: Challenges and Recommendations”

Rachel Sobel

Pfizer Inc., United States

Terri Madison

Mapi Group, United States

09.40 Patient reporting in EudraVigilance – a measure of patient engagement?

Marin Banovac

European Medicines Agency, EU

10.00 Discussion and recommendations (continued after coffee break)

All participants

Session 3.2 From regulatory outputs to health outcomes (Room 2E)

Session co-chairs: Margarida Guimarães and Saad Shakir

09.00 Methods to go from process outcomes to health outcomes (e.g. use of surrogate measures and interrupted time series)

Stephen Evans

London School of Hygiene and Tropical Medicine, United Kingdom

09.20 Study of liver function monitoring in patients receiving agomelatine in the Estonian Health Insurance (EHI) database

Maia Uusküla

State Agency of Medicines, Estonia

09.40 Modelling methods to estimate the public health impact of regulatory decisions

Saad Shakir

Drug Safety Research Unit, United Kingdom

10.00 Discussion and recommendations (continued after coffee break)

All participants

Session 3.3 Measures of impact of pharmacovigilance processes
(Room 3A)

Session co-chairs: Marieke De Bruin and Agnes Kant

- 09.00 Challenges of measuring impact of new pharmacovigilance processes**
Judith Sanabria
Biomedical Research Institute, University Hospital of Malaga, Spain
- 09.20 Measuring impact: a review of survey studies to evaluate the effectiveness of additional risk minimisation measures in Europe**
Nawab Qizilbash
Oxon Epidemiology, United Kingdom
- 09.40 Measuring time from identification of a new risk to regulatory action with focus on signalling tools and processes**
Amie Goulbourne
Biogen, United Kingdom
- 10.00 The risks of asthma therapy as assessed from real-life data: ASTRO-LAB & SNIIRAM**
Eric van Ganse
Red Cross Hospital Lyon Cedex, France
- 10.20 Discussion and recommendations** (continued after coffee break)
All participants