

Wednesday 29 January 2020

08.00
09.00



REGISTRATION AND WELCOME COFFEE

09.00
09.15



OPENING ADDRESS

Adrian van den Hoven, Director General, Medicines for Europe

09.15
10.35



SESSION 1 – GLOBALISATION AND PHARMACOVIGILANCE: WHERE ARE WE GOING?

CHAIRS

- **Sabine Straus**, PRAC Chair, MEB (NL)
- **Sebastian Horn**, Head Patient Safety, Sandoz International and Chair of the Medicines for Europe Pharmacovigilance Working Group

SPEAKERS

- **Sabine Straus**, PRAC Chair, MEB (NL)
- **Shanti Pal**, Group Lead, Medicines Safety, WHO
- **Sebastian Horn**, Head Patient Safety, Sandoz International and Chair of the Medicines for Europe Pharmacovigilance Working Group
- **Kaisa Immonen**, Director of Policy, European Patients' Forum

TOPICS

- How globalisation is impacting pharmacovigilance
- What's in it for patients?
- Measuring the impact of pharmacovigilance activities
- The role of smart safety surveillance

10.35
11.00



NETWORKING COFFEE BREAK

11.00
13.15



SESSION 2 – WATCH THIS SPACE IN THE NEAR FUTURE!

CHAIRS

- **Martin Huber**, PRAC Vice-Chair, Bfarm (DE)
- **Uwe Gudat**, Head of Clinical Safety & Pharmacovigilance Biosimilars, Fresenius Kabi SwissBioSim GmbH

KEY NOTE SPEECH

- **Peter Arlett**, Head of Pharmacovigilance and Epidemiology Department, EMA

SPEAKERS

- **Martin Huber**, PRAC Vice-Chair, Bfarm (DE)
- **Sophie Radicke**, Pharmacovigilance Inspector, MHRA
- **Fakhredin Sayed Tabatabaei**, Senior Assessor, MEB (NL)
- **Andrew Donaldson**, IQVIA
- **Uwe Gudat**, Head of Clinical Safety & Pharmacovigilance Biosimilars, Fresenius Kabi SwissBioSim GmbH

TOPICS

- The role of big data in patient safety
- Lifecycle approach in pharmacovigilance
- Latest inspection trends
- How automation and robotisation can help us
- Electronic Patient Information: where are we?

13.15
14.10



NETWORKING BUFFET LUNCH

For those interested there will be a working lunch on “Extended analysis of validated signals via EVDAS” accessible for all Pharmacovigilance attendees (limited seats).

14.10
15.20



SESSION 3 – SIGNAL DETECTION AND EUDRAVIGILANCE IN THE YEARS AHEAD

CHAIR

- **Andreas Iwanowitsch**, Head Global Pharmacovigilance Unit, STADA Arzneimittel AG

SPEAKERS

- **Georgy Genov**, Head of Signal and Incident Management, EMA
- **Peter Arlett**, Head of Pharmacovigilance and Epidemiology Department, EMA
- **Andreas Iwanowitsch**, Head Global Pharmacovigilance Unit, STADA Arzneimittel AG

TOPICS

- Signal detection: lessons learned from the pilot and next steps
- Eudravigilance: proposals for next steps
- Where will industry go?

15.20
15.45



NETWORKING COFFEE BREAK

15.45
17.00



SESSION 4 – BOOSTING EFFICIENCY THROUGH WORKSHARING

CHAIRS

- **Kora Doorduyn-van der Stoep**, Vice-Chairperson CMDh and NL-CMDh Member/Senior Policy Adviser, MEB (NL)
- **Klaudija Marijanović Barać**, Senior Director, Teva Periodic reports & risk management Centre (TPC), Teva Pharmaceuticals

SPEAKERS

- **Benedicte Lunddahl**, Head of European Pharmacovigilance, Danish Medicines Agency
- **Paul Fleming**, Technical Director, BGMA
- **Kora Doorduyn-van der Stoep**, Vice-Chairperson CMDh and NL-CMDh Member/Senior Policy Adviser, MEB (NL)
- **Klaudija Marijanović Barać**, Senior Director, Teva Periodic reports & risk management Centre (TPC), Teva Pharmaceuticals

TOPICS

- Progress on the RMP HaRP project
- Communication with healthcare professionals: can we improve the experience for everyone involved?
- Reference safety information: opportunities for streamlining the process

17.00
17.15



CLOSURE OF THE CONFERENCE

Susana Almeida, Clinical Development and Safety Director, Medicines for Europe

17.15
18.00



END OF CONFERENCE COCKTAIL

MEDIA PARTNERS



Follow the event on twitter **#PHV20**

For further information <https://www.medicinesforeurope.com/events>