10th Pharmacovigilance Conference

25 January 2017

Radisson Blu Portman Hotel
22 Portman Square, London W1H 7BG, UK

Wednesday 25 January

08:00 - 09:00	**Registration and welcome coffee**
09:00	**Opening address** | ***Adrian van den Hoven**, Director General, Medicines for Europe*
09:10	**Session 1 – Pharmacovigilance legislation: what are the next steps?** **Chair** | ***June Raine**, PRAC Chair, Director of Vigilance and Risk Management of Medicines, Medicines and Healthcare products Regulatory Agency (MHRA), UK* **3-year report on Pharmacovigilance related activities** | ***Helen Lee**, DG SANTE, European Commission (invited)* **Scanning the horizon 2016 – 2018** | ***Peter Arlett**, Head of Pharmacovigilance Department, European Medicines Agency (EMA)* **Industry's role in patients' safety and 2017 priorities** | ***Wendy Huisman**, Medicines for Europe PhV Working Group Chair, EU QPPV, TEVA* **Questions & answers**
10:20	**Social media and technology supporting patients' safety: opportunities and pitfalls** | ***David J. Lewis**, Global Head of Pharmacovigilance, Novartis Pharma AG*
10:45	**Panel discussion** *with **Phil Tregunno**, Signal Management & Quality Standards Unit Manager, Medicines & Healthcare products Regulatory Agency (MHRA), session speakers and interaction with the floor*
11:00	**Networking coffee break**
11:30	**Session 2 – Enhanced EudraVigilance and Signal detection: how to prepare for the upcoming milestones** **Chair** | ***Industry representative** (invited)* **Overview of the new process for Signal Detection and Management** | ***Georgij Genov**, Head of Signal Management, European Medicines Agency (EMA)* **EudraVigilance stakeholder change management plan – how to prepare for the changes** | ***Sabine Brosch**, Principal Scientific Administrator, European Medicines Agency (EMA)* **Industry Readiness for the New EudraVigilance - how can companies ensure smooth implementation?** | ***Industry representative** (invited)*
12:45	**Panel discussion** *with session speakers and interaction with the floor*
13:00 - 14:00	**Networking buffet lunch**

PLEASE NOTE that during online registration you will be asked in which of the following 5 workshops you wish to participate. As seats for each topic are limited, your choice will be subject to availability. To change your choice after registration please contact Lucia Romagnoli before 16 January 2017 at lucia@medicinesforeurope.com

14:00 **Session 3 – Mini Workshops: how to improve pharmacovigilance activities**
Chair | ***Sabine Straus**, Dutch representative of the PRAC, Head of Pharmacovigilance, Medicines Evaluation Board (MEB)*

Topic 1: Educational material – is there a more efficient way to educate? | ***Wendy Huisman**, Medicines for Europe PhV Working Group Chair, EU QPPV, TEVA*
Invited: ***Jamie Wilkinson**, Pharmaceutical Group of the European Union (PGEU)*
Is the way we are handling educational material effective and efficient? What is our experience and how can we improve?

Topic 2: Medical Literature Monitoring – service improvements after one year implementation | ***John Barber**, QPPV and Director, Head of Pharmacovigilance, European Operations, Dr. Reddy's*
Invited: ***Tom Paternoster-Howe**, European Medicines Agency (EMA)*
With nearly 1.5-years since the introduction of the EMA's MLM service, this session will look at what has changed in that time, what further changes are planned, and what changes would we like to see.

Topic 3: Inspections and compliance – is there a more efficient way when companies are auditing each other? | ***Julia Appelskog**, QPPV, Head of Pharmacovigilance, Bluefish Pharmaceuticals AB*
Invited: ***Joanna Harper**, Inspector at UK Department of Health (invited)*

Topic 4: Signal detection – what changes to implement and how? | *Nicole Lang, Senior Director, PhV TA Group Leader, Biologics, Respiratory & IM, Global Patient Safety & Pharmacovigilance, TEVA*
Invited: *to be defined*

Topic 5: Pharmacovigilance of biologicals – implementation of GVP P.II recommendations | ***Michael Forstner**, Global Head of Pharmacovigilance, Acino Pharma AG*
Invited: *to be defined*

15:20 **Networking coffee break**

15:50 **Brief summary of the workshops** | ***Sabine Straus**, Dutch representative of the PRAC, Head of Pharmacovigilance, Medicines Evaluation Board (MEB), NL and **topic leads***

16:45 **Closure of the day** | ***Katarina Nedog**, Safety & Regulatory Manager, Medicines for Europe*

17:00 **End of day cocktail**

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Follow the event on twitter #PHV17
For further information and to register on-line, please visit www.medicinesforeurope.com/events

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Registrations close officially on 16 January 2017 and are subject to availability.