



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 October 2020
EMA/342512/2020

Agenda – 15th Industry Stakeholder Platform – Operation of EU Pharmacovigilance

30 October 2020, 09:00-13:00, Virtual meeting: WebEx

Co-Chairs: Sabine Straus and Evdokia Korakianiti

Item	Agenda	Time
1.	Welcome and matters arising	09:00-09:10 10 min
2.	Monitoring of COVID-19 products (vaccines and therapeutics) - Georgy Genov, Xavier Kurz, Emil Cochino (all EMA) Monitoring of COVID-19 products with focus on vaccines – Industry perspective (Joint presentation by EFPIA and Vaccines Europe) - Vincent Bauchau (VE/ GSK)	09:10-10:00 50 min
3.	GVPs update - Priya Bahri (GVPs updates incl. GVP XVI and PASS addendum) on behalf of Nuria Semis-Costa, Thomas Goedecke and Xavier Kurz - Corinne de Vries (GVP P.III) All speakers EMA.	10:00-10:40 40 mins
	Coffee break	10:40-10:50 10 min
4.	EudraVigilance Operational Plan (Milestones 2020 to 2022) Rodrigo Postigo (EMA)	10:50-11:20 30 min

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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5.	Preparations for the end of Transition Period for UK's withdrawal from the EU - Marie-Helene Pinheiro, Monica Dias (both EMA)	11:20-11:50 30 min
6.	Paper on the Reference Safety information (RSI) by Medicines for Europe - Dr. Klaudija Marijanovic Barac – (Joint presentation by Medicines for Europe, EFPIA and AESGP) - Kora Doorduijn-van der Stoep (CMDh chair/ MEB) - Menno van der Elst (PRAC/ MEB)	11:50-12:35 45 min
7.	Summary and follow-up items Close of meeting END	12:35-12:50 15min

Participants List

Participants List

Chairs: - Sabine Straus, Chair of PRAC

- Evdokia Korakianiti, Head of Quality and Safety of Medicines Department, EMA

- **CMDh**

- Kora Doorduijn-van der Stoep (CMDh chair/ MEB)

- **PRAC**

- Martin Huber (PRAC Vice chair / BfArM)

- Menno van der Elst (PRAC / MEB)

- **European Commission**

- Alexandra Opalska (EC)

- **European Medicines Agency**

- Georgy Genov, Head of Pharmacovigilance Office, Quality and Safety of Medicines Department

- Agnieszka Szmigiel, Signal Management Lead, Pharmacovigilance Office, Quality and Safety of Medicines Department

- Marie-Helene Pinheiro, Industry Liaison Officer, Public and Stakeholders Engagement Department

- Rodrigo Postigo, Scientific Management Lead, Pharmacovigilance Office, Quality and Safety of Medicines Department

- Priya Bahri, Principal Scientific Administrator, Pharmacovigilance Office, Quality and Safety of Medicines Department

- Viola Sarinic Macolic, PRAC Scientific Committee Lead, Human Medicines Division

- Thomas Goedecke, Principal Scientific Administrator, Pharmacovigilance Office, Quality and Safety of Medicines Department

- Corinne de Vries, Head of the Science and Innovation Support Office, Regulatory Affairs and Science and Innovation Support Department

- Nuria Semis-Costa, Risk Management Specialist, Office of therapies for immune and inflammatory diseases, Human Medicines Division

- Matthias Sennwitz, Committee manager, Meeting secretariats Office, Committees and Quality Assurance department

- Emil Cochino, Risk Management Specialist, Office of vaccines and therapies for infectious diseases, Human Medicines Division

- Xavier Kurz, Head of Data Analytics workstream, Data analytics and Methods Task Force

- Monica Dias, Crisis Coordinating Officer, Policy and Crisis Management, Office of Deputy Executive Director

Industry Stakeholder Organisations

AESGP

Christelle Anquez-Traxler
Wendy Booth
Agnieszka Majcher-Dann
Leonie Zimmermann
Stephan Köhler
Mia Bengtstrom
• Albert Dorninger

EFPIA

Vicki Edwards
Judith Weigel
Valerie Simmons
Sabine Hackel
Magnus Ysander
Giovanna Rizzetto
Achint Kumar
Sumit Munjal
Eric Teo
Sabine Jeck Thole

EUCOPE

Wendy Huisman
Jörg Plessl
Peter de Vreene
Joanne Webbe
Antti Miikki
Sigrid Lang

EuropaBIO

Barbara de Bernardi
David Lewis
Almath Spooner
Laura Liebers
Jill Morrell
Lara Sutton
Budhesh Dhamija

Medicines for Europe

Susana Almeida
Sebastian Horn
Klaudija Marijanovic Barac Pliva
Marcus Metternich
Augusto Eugénio Filipe
Attila Oláh
Michael Forstner
Katja Pecjak
Andreas Iwanowitsch

Vaccines Europe

Guy Demol
Solange Rohou
Nicolas Praet
Andrew Moore
Corinne Jouquelet-Royer - **speaker**
Alexandra Dederichs
Vincent Bauchau - **speaker**
Patty Price-Abott
Anna Czwarno

Europharm SMC

Laura Davenport
Paul Gilbert
Dr. Graeme Ladds