



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 December 2017
EMA/666321/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Agenda – 12th industry stakeholder platform – operation of EU pharmacovigilance

24 November 2017, 10:00-13:30, Meeting room 2F

Co-Chairs: June Raine and Georgy Genov

Item	Preliminary draft agenda	Time
1.	Welcome and matters arising Including <ul style="list-style-type: none">• Signal Management GVP IX pilot on signals from MAHs<ul style="list-style-type: none">– <i>Agnieszka Szmigiel, EMA</i>– <i>Georgy Genov, EMA</i>• PRAC work plan for 2018<ul style="list-style-type: none">– <i>June Raine, PRAC chair</i>• PSUR Roadmap: Joint industry/assessors training<ul style="list-style-type: none">– <i>Feedback from the industry</i>• CMDh project on ideas for WS of assessment of RMPs and informal WS procedure for follow up requests after a PSUSA NAPs<ul style="list-style-type: none">– <i>Kora Doorduyn van der Stoep, MEB</i>	10:00-10:45
2.	EudraVigilance Auditable Requirement <ul style="list-style-type: none">• Launch of the new system<ul style="list-style-type: none">– <i>Sabine Brosch, EMA</i>– <i>Francois Domergue, EMA</i>	10:45-11:15



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3.	Good pharmacovigilance practices for the EU <ul style="list-style-type: none"> GVPs status, updates and plans for 2018 <ul style="list-style-type: none"> <i>Priya Bahri, EMA</i> GVP paediatric population and “direction of travel” <ul style="list-style-type: none"> <i>Roberto De Lisa, EMA</i> Discussion <ul style="list-style-type: none"> <i>All</i> 	11:15-11:40
	Coffee break	11:40-12:00
4.	Post-authorisation Safety Studies results <ul style="list-style-type: none"> Experience with post-referral imposed PASS studies – Importance of compliance and collaboration between MAHs in the conduct of studies <ul style="list-style-type: none"> <i>Irene Rager, Thomas Girard, EMA</i> <p>Discussion with Industry</p> <ul style="list-style-type: none"> <i>All</i> 	12:00-12:30
5.	United Kingdom’s withdrawal from the European Union preparedness activities – “ Q&A session on PhV Brexit related topic” <ul style="list-style-type: none"> Update <ul style="list-style-type: none"> <i>Marie-Helene Pinheiro, Georgy Genov, Maria Boulos, Radhouane Cherif</i> Q&A <ul style="list-style-type: none"> <i>All</i> 	12:30-13:15
6.	Conclusion and next steps	13:15-13:30
7.	Close of meeting	13:30