



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 November 2017
EMA/117206/2018
Pharmacovigilance and Epidemiology Department

Agenda – 13th industry stakeholder platform – operation of EU pharmacovigilance

20 March 2018, 09:30-13:30, Meeting room 2F

Co-Chairs: June Raine and Peter Arlett

| Item | Preliminary draft agenda | Time |
|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| 1. | Welcome and matters arising | 9:30-09:40 |
| 2. | New EudraVigilance system <ul style="list-style-type: none">• Industry experience<ul style="list-style-type: none">– <i>Industry speakers</i>• Progress update from EMA<ul style="list-style-type: none">– <i>Sabine Brosch, Francois Domergue</i>• Discussion | 9:40-10:40 |
| 3. | Pilot of MAH EudraVigilance Signal detection <ul style="list-style-type: none">• Initial experience from industry<ul style="list-style-type: none">– <i>Industry speakers</i>• Update from EMA including plan for pilot evaluation<ul style="list-style-type: none">– <i>Georgy Genov, Julie Durand</i>• Discussion | 10:40-11:40 |
| | Coffee break | 11:40-12:00 |
| 4. | PRAC Work Plan for 2018 <ul style="list-style-type: none">– <i>June Raine</i> | 12:00-12:30 |



| Item | Preliminary draft agenda | Time |
|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| 5. | GVPs update <ul style="list-style-type: none"> General update <ul style="list-style-type: none"> <i>Priya Bahri</i> GVP Paediatrics highlights <ul style="list-style-type: none"> <i>Roberto De Lisa</i> | 12:30-13:00 |
| 6. | United Kingdom's withdrawal from the European Union preparedness activities <ul style="list-style-type: none"> General update <ul style="list-style-type: none"> <i>Tony Humphreys, Marie-Helene Pinheiro</i> | 13:00-13:15 |
| 7. | Conclusion and next steps | 13:15-13:30 |
| 8. | Close of meeting | 13:30 |

Topics for next meetings

- Risk Minimisation Measures
- Patient Support Programmes
- Medical Literature Monitoring