



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 July 2012
EMA/PRAC/239375/2012
Patient Health Protection

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda of the inaugural plenary meeting 19-20 July 2012

Centre Albert Borschette, Conference Room AB-0C

Rue Froissart 36, 1040 Brussels, Belgium

Thursday 19 July 2012, 10.00 - 18.00 (CET)

Chaired by Guido Rasi

	1	Introduction
10.00 - 10.10	1.1	Welcome and keynote address by the EMA, Executive Director Speaker: Guido Rasi
10.10 - 10.20	1.2	Keynote address by the European Commission, Director General of DG Health and Consumers Speaker: Paola Testori
10.20 - 11.15	1.3	Membership of the Committee Tour de Table / Introduction and Expertise
<i>11.15 - 11.30</i>		<i>Coffee Break</i>
11.30 - 12.00	1.4	General Introduction to the EU Regulatory Framework and Opportunity offered by the new Pharmacovigilance Legislation Speaker: Peter Arlett (EMA) Questions and Answers
12.00 - 12.30	1.5	Presentation of EMA, its Scientific Committees and key interactions between PRAC, CHMP and CMDh Speaker: Anthony Humphreys (EMA) Questions and Answers
<i>12.30 - 13.30</i>		<i>Lunch</i>
13.30 - 14.15	1.6	Key processes and deliverables of the PRAC Speaker: Peter Arlett (EMA) Questions and Answers



14.15 – 14.45	1.7	Transparency aspects Speaker: Roberto De Lisa (EMA) Questions and Answers
	2	Rules of Procedure of the PRAC Discussion led by Noel Wathion (EMA)
14.45 - 16.15	2.1	Draft Rules of Procedure - Mandate - Membership and Chairmanship - Voting process - Rapporteurship Speakers: Anthony Humphreys (EMA), Sheila Kennedy (EMA) Questions and Answers
<i>16.15 – 16.30</i>		<i>Coffee Break</i>
16.30 - 18.00	2.2	Draft Rules of Procedure - PRAC tasks - Roles and responsibilities of the PRAC and EMA Secretariats - Other arrangements Speakers: Roberto De Lisa (EMA), Geraldine Portier (EMA) Questions and Answers

Friday 20 July 2012, 9.00 - 12.30 (CET)

Chaired by Guido Rasi

9.00 - 9.30	2.3	Adoption of the Rules of Procedures
9.30 - 10.00	2.4	EMA Policy for handling of Conflict of Interests and Confidentiality Agreement Guarantees of Independence and Code of Conduct Speaker: Sheila Kennedy (EMA) Questions and Answers
	3	Orientation on key tasks
10.00 – 10.30	3.1	Rapporteurship Appointment and process Speaker: Anthony Humphreys (EMA) Questions and Answers
10.30 – 11.00	3.2	- PhVWP Legacy - List of Union Reference Dates and frequency for submission of Periodic Safety Update Reports (EURD list) Speaker: Geraldine Portier (EMA) Questions and Answers
<i>11.00 - 11.15</i>		<i>Coffee Break</i>
11.15 - 11.45	3.3	- Signal Management and Additional Monitoring - Black Symbol Speaker: Peter Arlett (EMA) Questions and Answers

	4	Organisational matters
11.45 - 12.15	4.1	<ul style="list-style-type: none"> - Operational aspects related to the handling of unforeseen Safety Issues (possibilities for ad-hoc PRAC and operation of the Incident Review Group) - PRAC meeting dates in 2012 - Preparation of the PRAC meeting of 3-6 September 2012 <p>Questions and Answers</p>
12.15 - 12.30	4.2	Any Other Business
12.30	5	Close of the meeting