



5 May 2015
EMA/CVMP/161959/2015

DRAFT - CVMP Interested Parties' Meeting

6 May 2015, 17:00-19:00, Room 2A

Chair: David Mackay

Item	Preliminary draft agenda	Initials	Mins
1.	Adoption of draft agenda	All	-
2.	Minutes of last meeting and report on actions arising	All	5'
3.	Application of 3R principles in the authorisation of medicines <ul style="list-style-type: none">Update from the Agency on their efforts- incl. at ICH, VICH and Jc3Rs	ICAPPP/ EMA	10'
4.	Pharmacovigilance <ul style="list-style-type: none">building blocks for an improved pharmacovigilance system	Stakeholders and CVMP	20'
5.	Environmental Risk Assessment - how to avoid duplication and redundancy of ERA within the EU authorisation system	Stakeholders and CVMP	20'
6.	SPC harmonisation with a focus on withdrawal periods	Stakeholders and CVMP	20'
7.	How stakeholders prepare responses to CVMP consultations	IFAH-Europe EGGVP	10'
8.	Update on progress with VICH GL52 on Bioequivalence: blood level bioequivalence study	EMA at request of EGGVP	5'
9.	AOB		
10.	Close of the meeting		

