

VICH/10/048
30 July 2010

ACTIONS AND DEADLINES
following the 24th Steering Committee meeting
June 23 & 26, Paris, France

<u>TOPIC</u>	<u>DECISION</u>	<u>ACTION</u>	<u>DEADLINE</u>
Discussion document on how the VICH GLs are implemented	JMAFF will provide a clarification to the SC at the next meeting.	JMAFF	Next meeting
Proposal for a revision of VICH GL 23	FDA should provide an update again at the next meeting. Meanwhile further consultation should take place between the experts from the VICH members.	FDA experts	Next meeting
Pharmacovigilance EWG	The Secretariat will inform and thank the EWG in accordance with the procedure	Secretariat	ASAP
	The SC agreed to adopt the CP by written procedure in order to confirm the mandate of the EWG	Secretariat	ASAP
	The secretariat will request all SC members to nominate their expert(s)	All	August 2010
Biologicals Quality Monitoring EWG	USDA will re-circulate the last version of the draft GL on Mycoplasma detection to the experts	USDA	ASAP
	IFAH Europe will re-circulate the last version of the draft GL on the detection of extraneous agents to the experts	IFAH Europe	ASAP
	Dr Oishi will liaise with EDQM on the logistical organisation of the meeting	Dr Oishi	ASAP
	The Chairman will sign the letter to PETA	Chairman	Done
MRK EWG	IFAH Europe will submit the paper with data sets to the EWG for discussion at its next meeting	IFAH Europe	ASAP
	The EU will contact with Dr Sheid on future work	EU	ASAP
Microbiological ADI EWG	The Secretariat will inform the chair of the request from the SC to receiving a progress report from the EWG by mid-October 2010	Secretariat	Done

Concept Paper from IFAH Europe for a VICH GL on potency test of rabies vaccines	The EU coordinator will arrange for contact to be made with Dr Fooks	EU	ASAP
Draft CP for the Establishment of an Expert Working Group to Elaborate the Requirements to Demonstrate Bioequivalence	FDA will provide the revised CP	FDA	Done
	The Secretariat will circulate this document for approval by written procedure	Secretariat	Done
	The Secretariat will ask SC members to nominate the experts to the BE EWG	All	Done
Publication of VICH Concept Papers	The SC requested the VICH Global Outreach Subgroup to recommend the principles and methodology for the publication of VICH CPs	Global Outreach subgroup	Next meeting
VICH Global Outreach	The SC authorised the VICH Global Outreach Subgroup to hold a face to face meeting	Global Outreach subgroup	Nov-Dec 2010
VICH Phase III Strategy	The EU and IFAH Europe agreed to revise the document and to provide a revised version by end of September for e-discussion	EU & IFAH Europe	End Sept.
	The SC asked the Global Outreach Subgroup to fine-tune the Action Plan	Global Outreach subgroup	Next meeting
Revision of VICH Guidelines	Each SC meeting's agenda should include an item covering "Review of VICH GLs"	Secretariat	Each meeting

Items for the 25th SC meeting

- Review of the proposal from the subgroup for the VICH global outreach strategy
- Adoption of the VICH Phase III Strategy
- Follow-up of the ESI EWG progress
- Review of the Quality EWG's progress
- Review of the BQM EWG progress
- Review of the Metabolism and Residue Kinetics EWG progress
- Review of the Microbiological ADI EWG progress
- Review of the Safety EWG progress
- Review of the Bioequivalence EWG progress
- Review of the Discussion Document from the TF with regard to the Concept Paper from IFAH Europe for a VICH GL on potency test of rabies vaccines
- Review of VICH GLs in light of an update of other organisation's GLs (ICH, OECD...)
- Review of the outcome of the VICH 4 Conference