VICH/09/043
7 April 2009

ACTIONS AND DEADLINES

following the 22nd Steering Committee meeting
February 25 & 26, 2009, Ottawa, Canada

TOPIC	DECISION	ACTION	DEADLINE
VICH Strategy Phase II – Future VICH topics	The EU will develop a more detailed Discussion Document for a VICH GL on statistical evaluation of stability data.	EU	15 Sept 2009
Strengthening the partnership OIE - VICH	The VICH Subgroup to reflect further	Subgroup	Sept 2009
Enhancement of the VICH global outreach	The Subgroup will prepare a questionnaire for the non-VICH countries All to provide further target addresses to OIE The Subgroup will assess the needs and expectations of the countries regarding training and capacity building and refine the objectives	Subgroup All Subgroup	15 April ASAP Sept 2009
VICH 4 Conference	The Organising team composed of IFAH Europe, the EU, FDA, OIE and the Secretariat to fine-tune the draft programme and address issues between SC meetings All members were asked to reflect on potential speakers	Organising team All	Ongoing Next meeting
Review of final GLs at step 9	GL 18 - The SC requested the Quality EWG to work by written procedure only, to provide a step 2 document. GL 36 – The SC members were requested to send their nominations for the Microbiological ADIs EWG to the Secretariat. The EWG chairman should evaluate rapidly if the GL could be revised by written procedure only.	Quality EWG All EWG chair	February 2010 15 April ASAP
Biologicals Quality Monitoring	All regions to confirm to the EDQM that their results will be provided before next 1st September.	All	ASAP
Metabolism and Residue Kinetics EWG	the SC encouraged the EWG to try to solve the outstanding issue by written procedure.	EWG	End May 2009

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Draft CP for the Establishment of an Expert Working Group to Elaborate the Requirements to Demonstrate Bioequivalence	The SC agreed that a thorough electronic discussion should be pursued within the SC in order to identify all the current requirements in the regions and to enable FDA to further refine the Concept Paper by addressing issues such as timelines, resources, and other matters.	All FDA	 15 Sept 2009
Draft CP for the Harmonisation of the Target Animal Batch Safety Test for immunological veterinary medicinal products	The EU will draft a first proposal with the criteria for the initial phase of the work, as well as suggestions for further broadening at a later stage. All SC members were asked to identify their additional advisors and inform the VICH Secretariat	EU All	15 Sept 2009 Before next SC meeting
Draft Concept Paper for the Harmonisation of the Studies to Establish an Acute Reference Dose	SC members were requested to nominate their experts and to inform the Secretariat	All	1st June 2009
Electronic Presentation of Regulatory Documents	IFAH Europe asked to be informed of any change in the regions	All	ongoing
Communication within VICH and between Steering Committee meetings	The Secretariat will improve the lay-out of this web page and ensure that the word documents are kept up to date SC members and coordinators to ensure that all changes of personal contact details and experts' details are communicated promptly to the Secretariat	Secr. All	*Done* ongoing

Items for the 23rd SC meeting

- Review of the proposal from the Subgroup for the Enhancement of the VICH global outreach
- Review of the proposal from the Subgroup for the strengthening of the OIE - VICH partnership
- Adoption of the final programme for the VICH IV Conference
- Review of the progress on the draft Concept Paper for review at Step 9 of VICH GL 23
- 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
- Follow-up of the finalisation of the Pharmacovigilance GLs
- Review of a discussion Document for a VICH GL on statistical evaluation of stability data
- Review of the revised Concept Paper for the Establishment of an Expert Working Group to Elaborate the Requirements to Demonstrate Bioequivalence
- Adoption of the revised Concept Paper for the Harmonisation of the Target Animal Batch Safety Test for immunological veterinary medicinal products