

VICH/13/036  
28 March 2013

**ACTIONS AND DEADLINES**  
*following the 28<sup>th</sup> Steering Committee meeting*  
**19 – 21 February 2013, Washington DC, USA**

<u>TOPIC</u>	<u>DECISION</u>	<u>ACTION</u>	<u>DEADLINE</u>
Participation of VICH Outreach Forum members in EWGs	Revise draft and submit to SC for written approval	IFAH-Europe	ASAP
VICH Explanatory document	Ensure update of translations	Secretariat	ASAP
VICH ad hoc Outreach subgroup	Lead the subgroup in preparing agenda and assisting the Secretariat in the organisation of Forum meetings	OIE	ASAP
SC subgroup on training strategy	Lead the subgroup in developing the strategy	FDA	ASAP
Update from the regions on how the VICH GLs are implemented	Place this item on the agenda in the same manner that it had been done previously	Secretariat	Ongoing
VICH GL 22 – Reproduction Toxicity Testing	Prepare a discussion document on revision of GL 22 to include OECD 1 generation reproduction toxicity study	EU	Before 29 <sup>th</sup> SC meeting
VICH GL 42 - Data Elements for Submission of AERs	Prepare a CP recommending a revision of GL 42 to update the IT issues	ESI EWG	<i>Done</i>
VICH GL 35 - Pharmacovigilance: ESTD	Determine implementation date	SC	29 <sup>th</sup> SC meeting
VICH revised GL 23 - Safety: genotoxicity	Address the comments based on the EFSA guideline to the EWG at this point in time	EU	ASAP
Electronic file formats EWG	Call for nomination of 1 expert and 1 advisor if desired	Secretariat	<i>Done</i>
VICH guideline on residue studies in honey	Create a separate e-mail address for this subgroup of the MRK EWG		ASAP
	Ask SC members if they wish to nominate additional advisors	Secretariat	<i>Done</i>

	Send Argentina the CP with the documents explaining the requirements for the experts		ASAP
ICH initiative to form a Pre-safety Group	Invite a representative of the EMA to the 30 <sup>th</sup> SC meeting.	IFAH-Europe	Before 30 <sup>th</sup> SC meeting
Climatic zones discussion	Update the Concept Paper	IFAH-Europe	ASAP
5th VICH Public Conference in Japan in fall 2015	Provide a more detailed proposal	JVPA	Before 29 <sup>th</sup> SC meeting
Application from South Africa	Acknowledge receipt to South Africa explaining that the SC has welcomed the application and that it is in the process of formal approval	Secretariat	<i>Done</i>
Upgrade of VICH Website	Provide a dummy website for review and comment	IFAH-Europe	When possible
EWGs messages	Request a "Read receipt" for all important e-mails	Chairmen	Ongoing
Reports from EWG chairmen to SC	Ensure that reports focus on specific issues and reports highlights for the SC	Coordinators	Ongoing
Revision of VICH Guidelines	Standing agenda item covering "Review of VICH GLs"	Secretariat	Each meeting

### **Items for the 29<sup>th</sup> SC meeting**

- Preparation of the 3<sup>rd</sup> VICH Outreach Forum meeting
- Preparation of a Outreach Forum session on training
- Review of the ESI EWG progress
- Review of the Quality EWG's progress
- Review of the BQM EWG progress
- Review of the Safety EWG progress
- Review of the Microbiological ADI EWG progress
- Review of the Bioequivalence EWG progress
- Review of MRK EWG progress
- Review of EFF EWG progress
- Determination of the implementation date of GL 35
- Review of a discussion document on revision of GL 22 to include OECD 1 generation reproduction toxicity study
- Review of VICH GLs in light of an update of other organisation's GLs (ICH, OECD...)
- Review of the draft programme for the 5<sup>th</sup> VICH Public Conference