# ACTIONS AND DEADLINES

following the 24th Steering Committee meeting

**June 23 & 26, Paris, France**

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

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**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