International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

VICH/11/030 4 April 2011

## ACTIONS AND DEADLINES following the 25<sup>th</sup> Steering Committee meeting February 23 & 24, 2011, Washington DC, USA

| TOPIC   | DECISION  | ACTION                         | DEADLINE                        |
|---|---|--------------------------------|---------------------------------|
| VICH Strategy Phase   | To circulate draft 8 for final adoption by written procedure  | Secretariat                    | Done                            |
| Proposal for public<br>disclosure of VICH<br>Concept Papers | To circulate the final draft for final adoption by written procedure  | Secretariat                    | Done                            |
| VICH Global<br>Outreach Strategy                            | To work with OIE to contact the appropriate<br>veterinary medicine authorities in the identified<br>countries/regions and to provide a final<br>proposal with the identified countries and<br>regions | Global<br>Outreach<br>Subgroup | mid-April<br>2011               |
|   | To develop further an information/<br>communication action plan   | Global<br>Outreach<br>Subgroup | ASAP                            |
| Revision of VICH<br>GL 23                                   | To revise by written procedure  | Safety<br>EWG                  | ASAP                            |
| Pharmacovigilance –<br>ESI implementation<br>EWG            | To provide a written progress report to the SC  | Dr Brown                       | Before<br>EWG f to f<br>meeting |
| SOP on VICH procedures                                      | To re-circulate to all EWG chairmen   | Secretariat                    | ASAP                            |
| MRK EWG   | Residue studies with biopharmaceuticals:<br>VICH members to review this suggestion within<br>their respective organisations and provide their<br>positions  | All SC<br>members              | Before next<br>SC meeting       |
| Policy on consultation at step 4                            | To circulate the revised document   | Secretariat                    | ASAP                            |
| Implementation of<br>VICH GLs in the<br>regions             | Standing agenda item for update by SC members at each meeting   | Secretariat                    | Each<br>meeting                 |
| Revision of VICH<br>Guidelines                              | Standing agenda item covering "Review of VICH GLs"  | Secretariat                    | Each<br>meeting                 |

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## Items for the 26<sup>th</sup> SC meeting

- Discussion of the outcome of the meeting with non-VICH countries/organisations
- Review of the proposal from the subgroup for a VICH global outreach strategy
- Review of the ESI EWG progress
- Review of the Quality EWG's progress
- Review of the BQM EWG progress
- Review of the CP on Residues in Fish
- Review of the Safety EWG progress
- Review of the Bioequivalence EWG progress
- Review of the recommendation 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...)