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

VICH/11/010 17 November 2011 FINAL

Terms of Reference for the VICH Outreach Forum

The VICH Organisational Charter clearly states in its objectives that as well as establishing and implementing harmonised regulatory requirements for veterinary medicinal products in the VICH regions, the programme should "<u>work towards providing a basis for wider international harmonisation of registration requirements"</u>.

As VICH has re-iterated this objective of wider international harmonisation in the priorities for the years 2011-2015 set out in its Strategy for Phase III: 2011-2015, VICH will progress its objective of wider international harmonisation of registration requirements, which is aimed at the wider dissemination and acceptance of VICH guidelines and co-operation on a more global level.

The matter was a major discussion point at the 4th VICH Public Conference in Paris held at the OIE headquarters in June 2010. A first contact meeting with 11 non-VICH countries and 3 non VICH regional organisations was held under the chairmanship of OIE on 15 November 2011 in the margins of the 26th VICH Steering Committee meeting in Tokyo from 14-17 November 2011. Following this meeting the Steering Committee agreed to set up a VICH Outreach Forum, which is intended to be comprised of participants from regulatory authorities of non-VICH countries and regions invited by VICH which comply with agreed criteria as well as representatives from the Steering Committee and OIE.

The main objective for the VICH Outreach Forum is to provide a basis for wider international harmonization of registration requirements, improve information exchange and raise awareness of VICH and VICH guidelines with non-VICH countries/regions. The criteria for participation are:

- Regulation for marketing authorisation in place;
- Willingness to work towards accepting and implementing VICH guidelines;
- Paying for participation (travel costs, accommodation and translation, if needed);
- Regular participation.

The VICH Outreach Forum is a VICH initiative, and will be chaired by VICH in collaboration with OIE, recognising the OIE's membership in VICH as well as its broader mandate. The VICH Outreach Forum will meet in the margins of VICH Steering Committee meetings, which take place every 9-10 months at a location in one of the VICH member countries/regions. Matters identified that will be addressed at the VICH Outreach Forum will be:

- Collating comments on concept papers and draft guidelines and making them available to VICH
- Discussing practical issues related to VICH guidelines arising in the participants' countries/regions and providing feedback to the Forum

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- Collaborating and sharing of translations of guidelines
- Providing feedback on acceptance of existing guidelines

Concept papers and draft guidelines for consultation will continue to be distributed to non-VICH countries and regions through OIE and VICH.

The VICH Steering Committee will review potential involvement in guideline development in the future for forum participants.

In light of the discussions at the Forum meetings the VICH Steering Committee will review other questions arising and may add or amend tasks and roles or composition of the Forum.