

POLICY PAPER FOR THE ACCEPTANCE OF INTERESTED PARTIES IN VICH STEERING COMMITTEE MEETINGS

Background

Since the creation of the VICH in 1996, the founding members of VICH have agreed that the Steering Committee (SC), which is the decision making body of the VICH process where all strategic and management decisions are made, would be composed of full members (representing the EU, the governments from Japan and the USA, and the veterinary pharmaceutical and biological industry from the 3 active regions), 1 associate member (OIE) and 2 observers (representing the regulatory authorities from Australia - New Zealand and the veterinary pharmaceutical and biological industry from Australia - New Zealand). The organisational structure follows a precedent set by ICH on the human side where three major regions, EU, Japan and USA are home to over 80% of the research and development of human medicines; a similar situation prevails in the veterinary sector.

External public communication and publicity of the VICH process would be achieved through the VICH public web site, press releases produced after each SC meeting, regional meetings and events (organised by the parties in the regions), and VICH public conferences. The first VICH conference (VICH1) took place in Brussels in November 1999 and was considered very successful by organisers and participants alike, demonstrating the acute interest in the field of regulatory harmonisation in veterinary medicines. OIE, as an associate member, has committed to its pivotal role in communicating the proceedings of VICH to non-member countries, and actively promoting the awareness of VICH guidelines.

In the first 2 years of the VICH process, the public awareness of the VICH process outside of the small group of direct participants and Working Group experts was very low. But as the number of subjects has increased along with the number of Guidelines produced by the Working Groups (currently 26 draft or final Guidelines produced), the number of individuals and bodies aware of the VICH process and interested in its development increased.

Concerns about the transparency and the implications of the VICH process were formally voiced for the first time in late 1998. Since then, particularly at the time of the VICH1 conference, there has been an increase in the number of requests to the VICH SC to open its meetings to other bodies.

The VICH Steering Committee, at its 7th meeting in June 2000 in Tokyo, has therefore decided that accreditation of organisations as an Interested Party can proceed on the basis that it will enable organisations to attend at, but not participate in, meetings of the VICH Steering Committee. Furthermore, the Steering Committee has amended the VICH Organisational Charter (VICH/96/002 – Rev 5 – Final) in order to consider the attendance of Interested Parties at VICH Steering Committee meetings. It is however understood that, although transparency of proceedings is fundamental to the VICH process, the number of accredited Interested Parties will be limited in order to maintain the quality of VICH Steering Committee meetings as well as of the practical organisation of these meetings.

Policy

Accreditation to send 1 delegate to SC meetings will be granted to Interested Parties only if the following requirements are fulfilled:

- The request to attend SC meetings must be made in writing to the VICH secretariat at least 3 months prior to the first SC meeting the Interested Party wants to attend. The Interested Party must clearly state its specific interest in the VICH process.
- Each request shall be reviewed by the SC members by written procedure or in a SC meeting. A decision shall be reached by consensus.
- The accreditation to attend SC meetings shall be granted on a permanent basis.
- The Interested Party will be notified of the decision at least 6 weeks before the next SC meeting and, if an accreditation is not granted, of the reason(s). If this changes in time, the candidate Interested Party may request a new accreditation.
- Only 1 delegate per Interested Party will be authorised to attend SC meetings. The delegate shall be clearly identified at least 1 month before the SC meeting.
- The Interested Party shall be informed that if it fails to attend 2 consecutive meetings it will lose its accreditation as Interested Party.
- Interested Parties will not be authorised to attend any WG meetings.

The Interested Party shall furthermore:

- be a national or international organisation that represents individuals or bodies whose activities are related to the field of veterinary products registration, and have a clearly identified management and board ;
- provide a copy of its constitution to the VICH secretariat;
- agree to sign a confidentiality agreement stating that neither any of its members nor its delegate when he/she is not a member of the organisation shall publish information received from VICH before it will be published by VICH itself. It shall recognise that some information may need to be kept confidential at all times;
- agree to attend VICH Steering Committee meetings at its own expenses;
- recognise in writing that its delegate has no right to contribute to the discussions or intervene in the meetings as such in any way, unless requested by the chair to provide certain information;
- agree that the chairperson may ask at any moment during VICH SC meetings its delegate to leave the meeting;
- agree that that if it is proven that its delegate or membership has not respected the rules which have been set by the SC, it will be excluded from VICH SC meetings without any possibility of appeal;