HOW DOES VICH WORK?

Beginning with a VICH Steering Committee decision to pursue a new topic for which harmonised guidance is deemed necessary (based on a concept paper submitted by a VICH member), the VICH Steering Committee assigns the **new topic** to an Expert Working Group. That group then conducts face-to-face meetings, email exchanges and teleconferences to develop **a draft guideline.** After approval of the draft guideline by the Steering Committee, VICH publishes the draft for **public consultation,** typically for six months, through the public display processes of the member regulatory agencies and through the VICH website. Through the support and network of the World Organisation for Animal Health (OIE), countries that are not part of VICH are also invited to provide comments about each draft guideline. After these public consultations, the draft returns to the Expert Working Group, which reviews the comments, finalises the guideline appropriately and submits it to the Steering Committee for final approval. **The approved VICH guideline then becomes the official recommended guideline in the VICH member countries, replacing previously existing national guidelines.**

As of April 2011 VICH has completed 45 guidelines, and nine more are in process. The VICH Steering Committee is also working towards providing a basis for wider international harmonisation of registration requirements through **a global outreach programme.** The objective is to communicate the role of VICH, the benefits of harmonised registration requirements and facilitate the efficient use of resources in **non-members of VICH.** The aim is to **provide support,** in close cooperation with OIE, for the governance of veterinary medicinal products globally and to **enable broad access to high quality veterinary medicines** for all livestock producers, veterinarians, and pet owners in other parts of the world.

For more details see the VICH website at: **www.vichsec.org**

SECRETARIAT

c/o IFAH
rue Defacqz, 1
B-1000 Brussels (Belgium)
Tel. +32-2-543.75.72
Fax +32-2-543.75.85
Email: sec@vichsec.org

www.vichsec.org

HARMONISING THE GLOBAL PROCESSES FOR AUTHORISING VETERINARY MEDICINES

For 15 years, VICH has worked to ensure the quality, efficacy (effectiveness) and safety of veterinary medicines and has also, where feasible, reduced the number of animal tests required and associated costs. Here's how VICH works.

High-quality veterinary medicines, that is medicines and vaccines for animals, are an indispensable tool for veterinarians and animal owners to treat and prevent diseases and suffering in pets and farm animals around the world. To ensure these medications are appropriately produced, countries require that animal health products be manufactured to specific **standards of quality, safety and efficacy.** Before a veterinary medicine - whether it be an antibiotic, an anti-parasitic or some other pharmaceutical, a vaccine, or a similar product - can be manufactured, sold or used, the responsible authority in the country where it will be used must legally authorise its use.

That **marketing authorisation,** sometimes also known as **"registration" or "licence"**, signifies to the veterinarian, the animal owner and/or the general public that the responsible authority has not only **approved the product** to be marketed, but also the details of **the conditions under which the product will be used,** including:

- **The active substance,** its purity and concentration, as well as the complete composition of the medicine;
- **The form** the medicine will be delivered in (e.g. tablet, powder, cream, solution for injection) and the way it will be given to the animal, whether by injection, by mouth, in feed or water, or by topical application;
- **The animals** for which it can be used, including specific ages and weights;
- What **diseases or conditions** it can used to prevent, treat or control, also known as the "indications";
- **The dosages** for each indication;
- **The duration** of treatment and the withdrawal period, which means the number of days the medication must be withheld from farm animals prior to their produce entering the food system;
- **Other conditions of use,** including storage, shelf life, safety and disposal instructions and possible contra-indications.

These details and instructions become part of the labelling, packaging and promotion of the product. These conditions and their compliance are essential to ensure that the medicine is safe and efficacious. Authorisation also dictates manufacturing controls for the active substance(s) and the final product, to ensure continued monitoring once the medicine has been approved and is being manufactured. Once authorisation is granted, products are monitored by tracking any unexpected adverse reactions, sampling and testing of products, and regular manufacturing site inspections. Also, many countries require monitoring systems to ensure that any residues of the medicine in food from use in food-producing animals remain below established **safe levels for the consumer** (Maximum Residue Limits – MRLs).

In order to obtain authorisation, the company that will bring the veterinary medicine to the market must formally apply to the country's authority using a comprehensive and often complex package of scientific data to ensure the quality, safety and efficacy. This data package, **"application", or "dossier"**, is developed by the sponsor and is based on the testing requirements and standards for the data required by the authorising legislation – often after a series of submissions, questions, and resubmissions – until regulators are satisfied that the benefits of the medicine regarding public health, animal health and the environment outweigh any risks associated with its use.

As trade in veterinary medicines has become more globalised, issues arising over trans-boundary trade differences have become much more common. Discrepancies concerning the data requirements for authorisation of veterinary medicines **can inhibit access to safe and effective veterinary medicines.** Because the world is becoming a smaller more interconnected place, it makes sense that **regulations** which sometimes differ in relatively insignificant ways **should be harmonised** to the extent possible **without affecting product quality, safety, or efficacy.** Also, in this way national regulators can work together and facilitate cooperation between countries in order to simplify authorisation processes, because decisions will be made on the basis of harmonised or common requirements. As a consequence, there will be a more equal access to quality, safe, and effective veterinary medicines around the world. For developers of veterinary medicines it means that instead of having to repeat similar tests to meet slightly differing requirements, **one test based on the harmonised criteria will satisfy regulators around the world** – a great opportunity to save resources and reduce animal testing.

THE ROLE OF VICH

To improve the coordination and cooperation in that international process, the animal health industry and the regulators from the European Union, Japan and the United States in 1996 formed **the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products,** known as **VICH**; with Australia/New Zealand and Canada joining as Observers. VICH was modelled on a similar international effort to harmonise technical requirements for human medicines called the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH. The guidelines overseen by VICH make uniform and consistent the guidance for sponsors to follow in developing data for application dossiers as well as for post-marketing safety monitoring. VICH does not generally address issues concerning the assessment of data; with only a few exceptions, that important task is reserved for the regulatory authorities in each of the VICH countries.
The overall work of VICH is intended to:

- **Harmonise regulatory requirements** in the VICH regions to ensure high quality, safety and efficacy standards, even as it reduces the number of animals needed for testing and the associated costs.
- **Provide a basis for wider international harmonisation** of registration requirements.
- **Monitor and maintain existing VICH guidelines.**
- **Ensure the processes operate smoothly,** in order to maintain and monitor consistent interpretation of data requirements within VICH guidelines.
- **Encourage constructive technical dialogue** between regulators and industry to enable response to significant emerging global veterinary medical issues.