



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Contact meeting on wider international harmonisation of VICH guidelines

Tokyo, 15 November 2011

What is a VICH guideline – their role in the
authorisation/registration of veterinary medicinal products

Presented by: Kornelia Grein
EU co-ordinator

An agency of the European Union





Issues addressed

- Objectives of VICH
- Principles for marketing authorisation for veterinary medicinal products
- Application dossier for a marketing authorisation/registration
- Example for studies required for a marketing authorisation
- What is the role of a VICH guideline – and what not
- Conclusions



Objectives of VICH (1)

- Establish and implement **harmonized regulatory requirements** for veterinary medicinal products in the VICH regions, which meet high quality, safety and efficacy standards and minimize the use of test animals and costs of product development.
- Provide a basis for wider international harmonization of registration requirements.
- Monitor and maintain existing VICH guidelines, taking particular note of the ICH work programme and, where necessary, update these VICH Guidelines.



Objectives of VICH (2)

- Ensure efficient processes for maintaining and monitoring consistent interpretation of data requirements following the implementation of VICH guidelines.
- By means of a constructive dialogue between regulatory authorities and industry provide technical guidance enabling response to significant emerging global issues and science that impact on regulatory requirements within the VICH regions.



Principles for marketing authorisation/ registration for veterinary medicines (1/5)

- Before a veterinary medicinal product can be sold or used, it should be authorised by the country where it will be used
- Marketing authorisation (or 'registration' or 'licence') : Approval by the responsible authority in the country concerned that the product can be sold and used
- A marketing authorisation includes specification of:
 - the **details of the medicine** (e.g. name, **name of active** substance, **animals** for which it can be used, **indications** for use, **dose and duration** of treatment),
 - the **conditions of use** (e.g. **storage** conditions, shelf life, **withdrawal period**, **instructions for safe use** or instructions for **safe disposal** of waste)
 - any **precautions or warnings for safe use**, including possible contraindications.



Principles for marketing authorisation/ registration for veterinary medicines (2/5)

- Regulatory system needs to be established by governments for the authorisation and control of veterinary medicinal products.
 - Law or other legal act on procedure, principles, data requirements, control.
 - Guidance documents, which can be either in support of legislation or implemented by piece of legislation, dependant on structure of legislation in country
- The company that will bring the veterinary medicine on the market (also called sponsor or applicant) must submit an application to the responsible authority in the country concerned in order to obtain a marketing authorisation (or registration or licence)
- The application is accompanied by a package of data on the quality, safety and efficacy of the veterinary medicinal product. (This data package is often called 'dossier' or 'application').



Principles for marketing authorisation/ registration for veterinary medicines (3/5)

- The application needs to address also:
 - any **precautionary measures** e.g. when storing the product, administering it to animals, or disposing of waste of the medicine, together with an **indication of potential risks** that the product might pose to human and animal health and to the environment.
- Also to consider manufacturing standards (GMP)
- For medicines used in food-producing animals: information on the time when it is safe for the consumer to eat animal products (such as milk, meat or eggs) following treatment or the end of treatment period (“withdrawal period”).
- Also important to consider for medicines for food producing animals: maximum residue limits (MRLs)
 - Codex MRLs, MRLs of other countries.



Principles for marketing authorisation/ registration for veterinary medicines (4/5)

- Assessment of application and data submitted by responsible regulatory authority in country where product is intended to be marketed
- In general after initial assessment questions to applicant/sponsor arise
- Once all questions have been satisfactorily answered:
 - Risk - benefit assessment
 - no risks have been identified that would outweigh the efficacy and other benefits of the veterinary medicinal product
- the responsible authority can issue a marketing authorisation, with specific conditions of use (e.g. specific indications, animal species, withdrawal period), storage and waste disposal, as appropriate, for the specific product.



Principles for marketing authorisation/ registration for veterinary medicines (5/5)

- As the process of reviewing all scientific data requires a large amount of resources, countries may wish in some instances to rely on assessments already carried out for the same medicine by the authorities in other countries, at least for some parts of the dossier, e.g. the documentation regarding food safety (MRLs).
- Countries may also chose to work together and share work or accept mutually assessments.
- Decision of countries, what is most suitable for them.



Role of VICH guidelines in marketing authorisation application

- **VICH = International Cooperation on Harmonisation of Technical Requirements** for Registration of Veterinary Medicinal Products
- **Technical requirements** for registration (or marketing authorisation) = Data to be provided to the responsible authority for assessment and decision on application for registration
- Data on Quality, Safety (incl. residue data for food producing animals) and Efficacy
 - For both pharmaceuticals and vaccines
- Examples of data for a marketing authorisation for a pharmaceutical veterinary medicinal product is given in next slides
- Post authorisation: surveillance of safety of product through pharmacovigilance



Example of dossier requirements for pharmaceuticals (1/3)

Quality documentation (13 VICH GLs)

- Composition of the product
- Method of preparation: manufacturing method, in-process control tests and validation incl. batch analysis
- **Active substance(s)**: specifications, **impurities** in the starting material, suitability of the manufacturing method, stereoisomerism, where relevant and **stability**
- Excipients: specifications, suitability and safety data, where appropriate
- Packaging material (immediate packaging): specifications and suitability
- **Control tests on intermediate products**
- **Control tests on finished product**
- **Stability of the finished product**



Example of dossier requirements for pharmaceuticals (2/3)

Safety documentation (12 VICH GLs)

- Pharmacodynamics
- Pharmacokinetics
- Toxicology (Single dose toxicity, Repeated dose toxicity, Reproductive toxicity including teratogenicity, Genotoxicity, Carcinogenicity, other)
- Target animal safety
- Residue studies (Metabolism and residue kinetics, Pharmacokinetics, Depletion of residues, Analytical method)
- Safety of users
- Environmental impact assessment



Example of dossier requirements for pharmaceuticals (3/3)

Efficacy tests (11 VICH GLs + 1 in preparation)

Pre-clinical trials (might partly already be included in safety or residues data)

- Pharmacodynamic mechanisms underlying the therapeutic effect
- Pharmacokinetics
- Bioequivalence (if applicable)
- Dose determination
- Resistance development (antimicrobials, antiparasitics)

Results of clinical trials



Role of VICH guideline in marketing authorisation application (contd.)

- VICH guidelines describe harmonised study requirements
- Not complete dossier and layout harmonised, but most of key data requirements, i.e. what data are requested and how the study is to be conducted.
- If not harmonised, even small differences in requirements may lead to requesting a new study by authorising authority
 - Delay to marketing/having veterinary medicine available
 - Additional costs for drug development
 - Unnecessary repetition of studies in animals
- Once adopted, VICH guidelines replace existing national/regional guidelines (Commitment of VICH members)



Role of VICH guideline in marketing authorisation application (contd.)

- VICH guidelines do not prescribe assessment approach (exceptions: guidelines on environmental impact assessment, establishment of microbiological ADI)
- VICH does not discuss decisions on marketing authorisations



Conclusions (1)

- Regulatory system in place is pre-condition for marketing authorisation system for veterinary medicines – responsibility of countries
- VICH harmonises which data are required for a marketing authorisation and how studies are conducted, incl. pharmacovigilance data
- Harmonisation of requirements beneficial for bringing product on market/availability of medicines, reducing costs, reducing animal testing through acceptance of same studies by all countries which accept VICH guidelines
- VICH guidelines replace existing national/regional guidelines (Commitment of VICH members)



Conclusions (2)

- VICH does not provide guidance on assessment of studies (exceptions: ERA, microb. ADI)
- VICH does not discuss assessment or decisions on marketing authorisations

Assessment and decisions is responsibility of authorities in country where product will be marketed



Thank you for your attention!

