



State Scientific Research Control Institute of
Veterinary Medicinal Products and Feed Additives

National Agency of
Veterinary Medicinal Products and Feed Additives



**POSSIBLE REGULATORY OBSTACLES AND
PERSPECTIVES IN ADOPTING VICH GUIDELINES
IN VICH OUTREACH FORUM COUNTRIES/REGIONS
AND HOW TO OVERCOME THEM**

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Accepting VICH guidelines



GUIDELINES

Yes

May be

No

Adoption of VICH guidelines

- **VICH member countries/regions are obliged to use the VICH guidelines.**
- The use of the VICH guidelines **is not restricted** to the **VICH members and observers.**
- **Any country or regional organisation can use these guidelines** for the requirements for the authorisation of veterinary medicines in their country or region.

VICH guidelines

- All VICH guidelines are **publicly available** through the **VICH website**. They are also published on the websites of the regulatory authorities of the VICH members, observers and some VICH Outreach Forum members
- Document on implementation of VICH guidelines / how to use VICH guidelines has been developed and has been placed on VICH website (VICH/14/013)

Final and draft Guidelines available on the VICH public website

The screenshot shows the VICH public website (vichsec.org) with a navigation menu including CONSULTATIONS, ACTIVITIES, HOME, STRUCTURE, PROCESS, GUIDELINES, and MEMBERS. The GUIDELINES section is highlighted, and a search bar is visible. The main content area features a large 'GUIDELINES' heading and a list of categories: Pharmacovigilance, General, Comments at Step 4, Biologicals, Pharmaceuticals, Quality, Safety, Efficacy, Analytical validation, Impurities, Stability, and Specifications. A search box allows users to search guidelines by a dropdown menu (Choose one) and a 'Download full list' button. The Specifications section is expanded, showing two items: 'Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances + Decision Trees' (VICH GL39) and 'Decision Trees' (VICH GL39).

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6 VICH Public Conference, Cape Town, South Africa , 27-28 February 2019

Guidelines available on website SCIVP

scivp.lviv.ua

SCIVP | of veterinary medical products and feed additives

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Registration department

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Registration of veterinary medicinal products, feed additives

ATTENTION!
NEW REQUIREMENTS FOR COMPILATION OF THE REGISTRATION DOSSIER ON PREPARED FEEDS FOR NON-PRODUCTIVE ANIMALS.
NEW APPLICATION FORM FOR REGISTRATION [Download](#)
The attached file contains the order of 439 "Changes to the list of materials of the registration dossier concerning feeds for non-productive animals and the manner of its forming".

Regulation

- [The Law of Ukraine "On veterinary medicine"](#)
- [State Pharmacological Commission of Veterinary Medicine \(Article 61\) The Law of Ukraine "On veterinary medicine"](#)
- [Cabinet of Ministers of Ukraine Resolution N 1349, November, 21 2007 \(On approval of regulations on the state registration of veterinary medicinal products, feed additives, premixes and pet foods\)](#)
- [Order N 133.](#)
- [Registration scheme .](#)
- [Procedure of registration in SSRCI of Veterinary Medicinal Products and Feed Additives.](#)
- [Notes for Applicant.](#)
- [Sample of pet food package leaflet arrangement](#)
- [Sample of injection solution package leaflet arrangement](#)
- [International harmonisation and cooperation \(VICH\)](#)
- [International harmonisation and cooperation \(UA documents list\)](#)

- [List of veterinary medicinal products registered in Ukraine .](#)

- [State registration price list](#)

Home > Pharmacological Commission > Registration of veterinary medicinal products, feed additives

Latest News SCIVP
• Колектив ДНДКІ ветеринарних

News: Pharmacological Commission
• Засідання фармкомісії від

Attention! Dangerous products
• NR-07-02-2019

Registration of veterinary

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Implementation of VICH guidelines

There are different ways on how technical guidelines as the VICH guidelines can be implemented:

- Some countries use them **as separate technical guidelines** in support of legislation without making them part of legislation;
- Other countries implement them **as a regulation** or **part of legislation**.

It is the decision of the country or region and may depend on how the legislation in the country/region has been set up.

What types of documents are?



Law

Regulation

Order

Standard (DSTU, SOU)

Guidelines

Notice

Establishment SOU on base of VICH guidelines

SOU 85.2-37-406:2006 VETERINARY PRODUCTS. Analytical regulation.

SOU 85.2-37-407:2006 VETERINARY PRODUCTS. Requirement for registration dossier.

SOU 85.2-37-408:2006 VETERINARY PRODUCTS. Pharmacovigilance (general requirement).

SOU 01.25-37-390:2006 VETERINARY PRODUCTS. Laboratory animals for toxicological studies of VMP

SOU 85.20-37-391:2006 VETERINARY PRODUCTS. Methods for determining the safety.

SOU 85.2-37-399:2006 VETERINARY PRODUCTS. Technological regulations in veterinary medicine. Development, coordination, approval, registration.

SOU 85.2-37-741:2010. VETERINARY PRODUCTS. Methods of determining bacteriostatic and bactericidal concentrations of antimicrobial agents.

SOU 85.2-37-754:2012 Resistance of microorganisms to antimicrobial agents. Microbiological method for determining.

SOU 85.2-37-736:2011 VETERINARY PRODUCTS. Determine acute toxicity.

SOU 85.2-37-737:2011 VETERINARY PRODUCTS. Determining cumulative properties.

Establishment SSTU (DSTU) on base of VICH guidelines

DSTU. VMP. Determining sterility by direct seeding.

DSTU. Good Clinical Practice.

DSTU. Good Distribution Practice.

DSTU. VMP. Biolability.

DSTU. VMP. Bioequivalence.

DSTU. VMP. Good Manufacturing Practice (GMP).

All or selected VICH guidelines

- If a country/region considers implementing VICH guidelines, please bear in mind that it is **not necessary to implement all the guidelines as a package**, but a country/region may choose to implement **only selected guidelines**, e. g. the most needed or suitable guidelines, or may consider a stepwise implementation process.
- The VICH member countries/regions have the obligation to implement the VICH guidelines as adopted. **It is encouraged that also other countries using VICH guidelines would use them unchanged.**

Implementation of VICH guidelines in Ukraine

The Regulatory Authorities recommended following VICH guidelines to adopt them **without changes**.

- Quality
GL 1, GL 51
- Safety Antimicrobial
GL 36
- Efficacy antihelminthics
GL 14, GL 15, GL 16, GL 19, GL 20, GL 21
- Pharmacovigilance
GL 24, GL 29, GL 30, GL 35, GL 42

Guidelines available on website SCIVP



ветеринарних препаратів
та кормових добавок



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Міжнародне співробітництво та узгодження (VICH)



Нормативні документи:

- Міжнародне співробітництво та узгодження (гармонізація)
- Валідація аналітичних процедур: визначення та термінологія
- Ефективність антигельмінтних ветеринарних препаратів: Особливі рекомендації для кіз (для родини козячих)
- Ефективність антигельмінтних ветеринарних препаратів: Особливі рекомендації для коней (для родини конячих)
- Ефективність антигельмінтних ветеринарних препаратів: Особливі рекомендації для свиней (для родини свинячих)
- Ефективність антигельмінтних ветеринарних препаратів: Особливі рекомендації для собак (для родини собачих)
- Ефективність антигельмінтних ветеринарних препаратів: Особливі рекомендації для котів (для родини котячих)
- Ефективність антигельмінтних ветеринарних препаратів: Особливі рекомендації для птиці
- Ветеринарний фармакогляд Менеджмент повідомлень про побічні реакції VICH GL 24 (Жовтень, 2007 р.)
- Ветеринарний фармакогляд Менеджмент представлення регулярно оновлюваних звітів про побічні реакції (PSURs) VICH GL 29 (Червень, 2006 р. Імплементовано, червень 2007 р.)
- Ветеринарний фармакогляд: Контрольований список термінів
- Ветеринарний фармакогляд Електронні стандарти для передавання даних VICH GL 35 (Лютий, 2013 р.)
- Дослідження оцінки безпеки залишків ветеринарних препаратів у їжі людей: Загальні підходи до встановлення мікробіологічного щоденного допустимого прийому (ADI)
- Ветеринарний фармакогляд Елементи даних для представлення звітів про побічні реакції VICH GL 42 (Червень, 22, 2010 р.)
- Гармонізація критеріїв відмови тестування безпеки серії на цільових тваринах (TABST) для інактивованих вакцин для застосування у ветеринарії.

[Завантажити усі документи в одному архіві](#)



Головна > Фармкомісія > Реєстрація ветеринарних препаратів, кормових добавок

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Local conditions of VICH guidelines

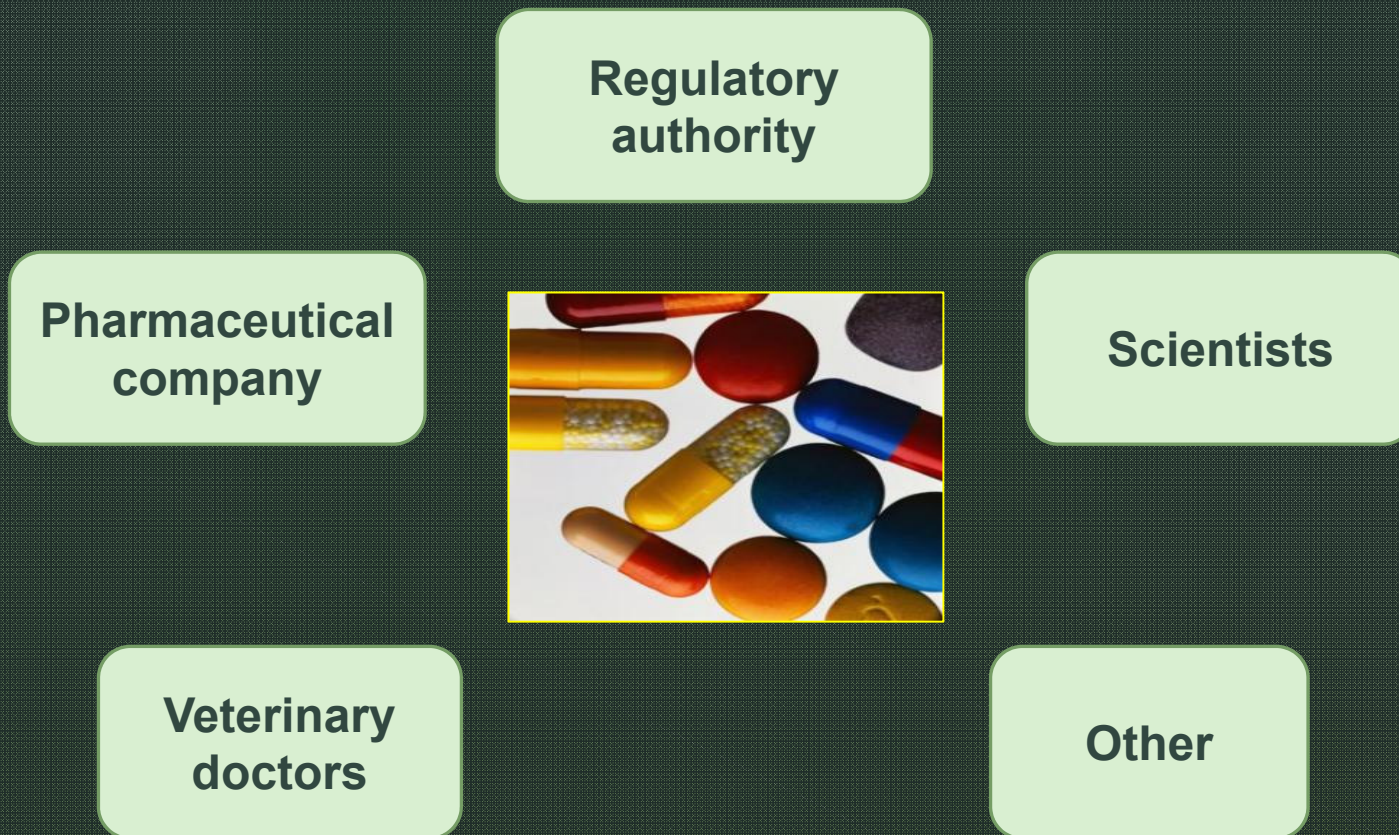
- However a country/region, which is not the VICH member, may apply the main part of a VICH guideline, without specific required details or some details, that are not suitable due **to the specificity of local conditions**, e. g. in respect to the specific animal diseases or animal species relevant for that country/region.

In such a case, a VICH guideline **can be implemented adapted, to the minimum extent necessary, to fit local conditions.**

The minimum changes of VICH guidelines

In the interest of promoting **harmonization of technical requirements** for the registration of veterinary medicinal products, VICH would **encourage the widest possible use of its guidelines, with the minimum changes only when absolutely necessary** to adapt the guidelines to local conditions.

Who is involved?



Collaboration with industry

**Creating National Agency
of VMP and FA
2013**

**Creating Association of manufacturer of VMP
UKRPROMSPILKA
2014**

**Creating Committee of VMP EBA
2016**

Dissemination knowledge about guidelines

Webs, books, journals, newspapers

Conference, seminar, training

Information about VICH guidelines

Preclinical trials of VMP (2006)

Clinical trials of VMP and FA (2013)

GL 9 GCP



Obstacles from Ukraine's point of view

- Translation
- Administrative obstacles
- Implementation
- Training
- *Mainly generics*



Conclusions

- ❖ Harmonization 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 cover most of the tests that are required for marketing authorization dossier, in particular for pharmaceuticals.
- ❖ Harmonised VICH guidelines help for scientific approach for assessments in different countries.
- ❖ Any country can use VICH guidelines if they wish.

Today and tomorrow of VICH guidelines

Benefits and challenges of integration of the use of VICH guidelines into the regulatory system for veterinary medicines is indisputable, because it's question of health, safety, times and money.



THANK YOU FOR YOUR ATTENTION !

