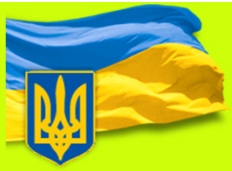

State Scientific Research Control Institute of
Veterinary Medicinal Products and Feed Additives

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

Yes

May be

No

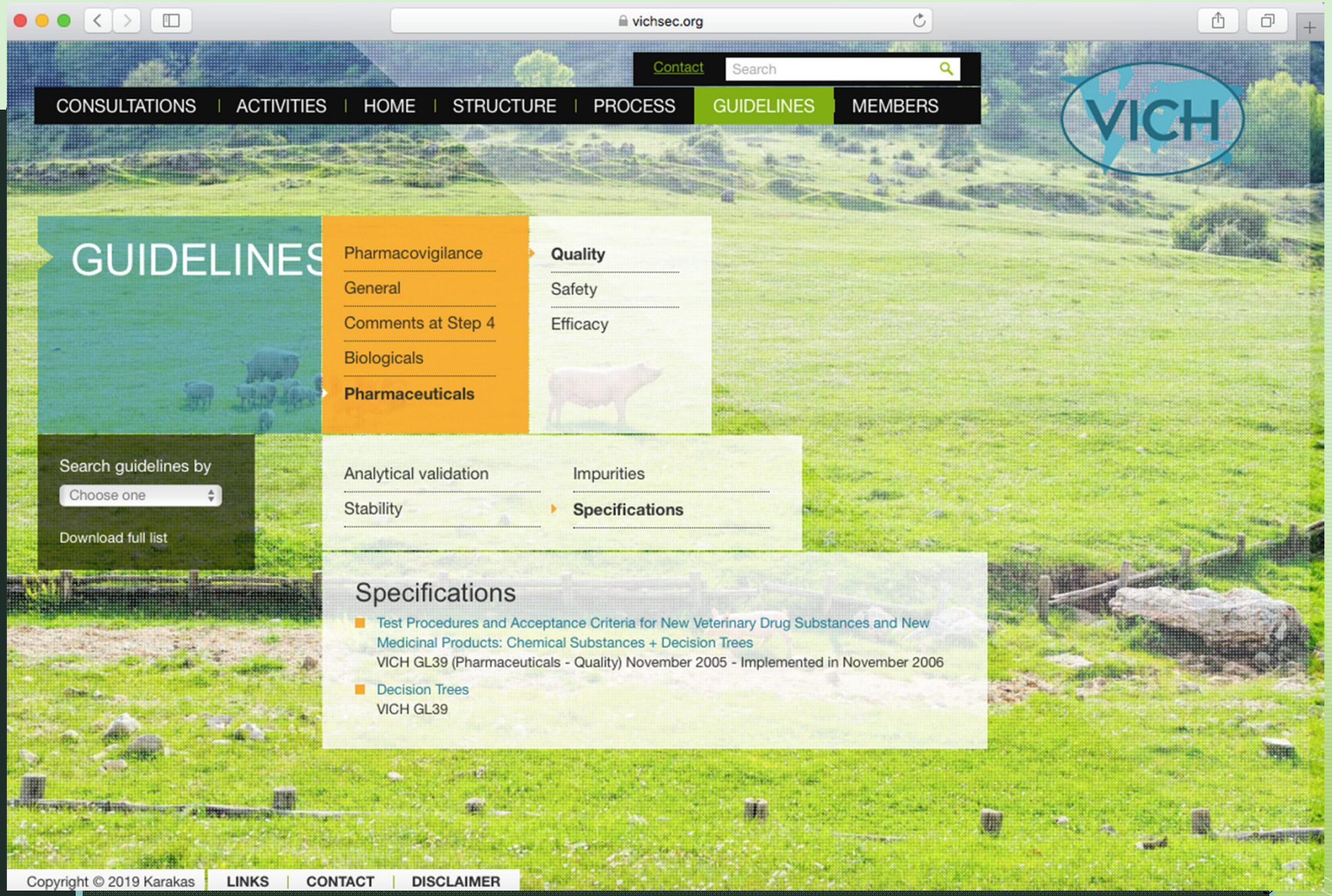
Adoption of VICH guidelines

- 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



Guidelines available on website SCIVP

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

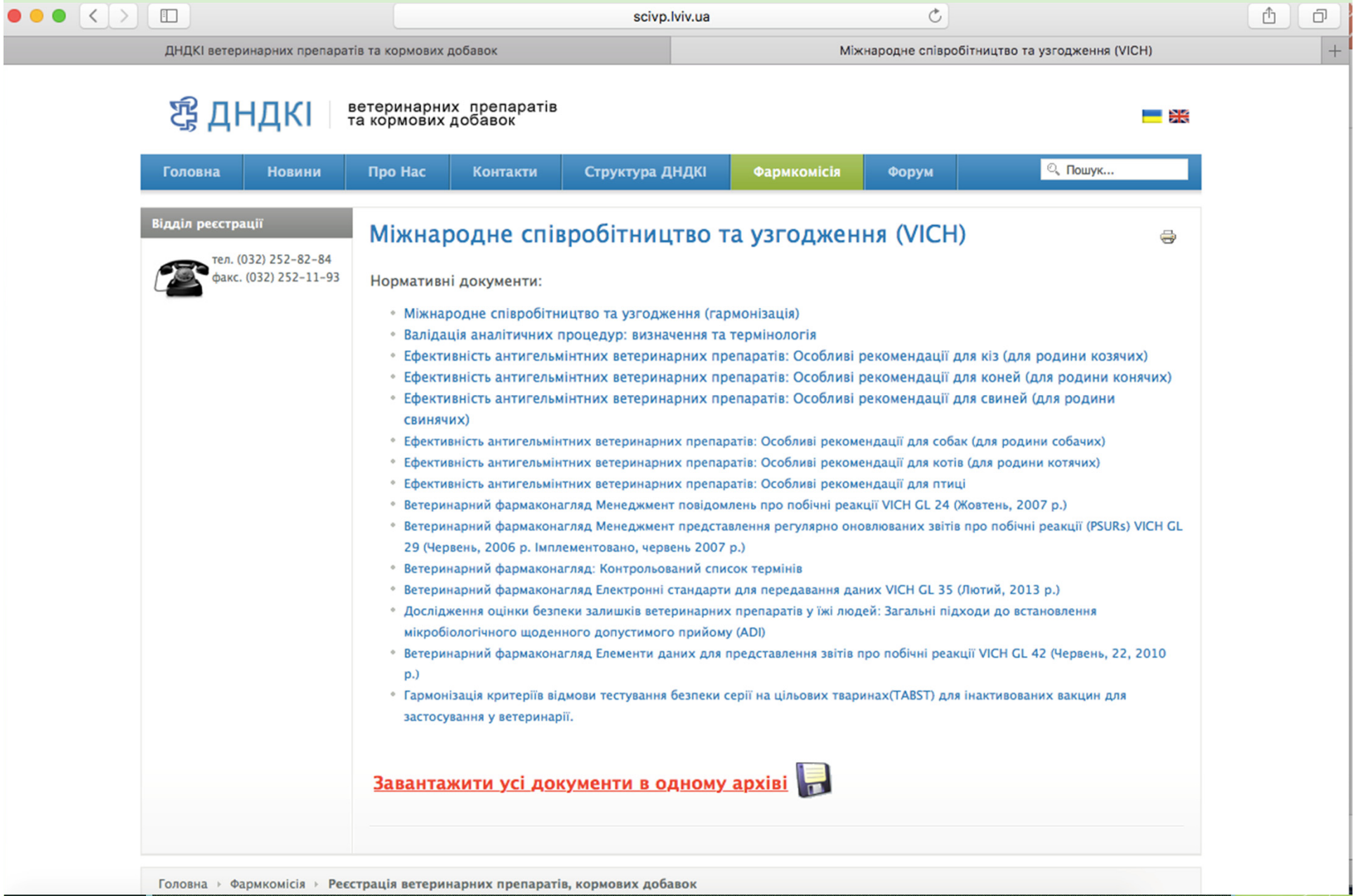
- If a country/region considers implementing VICH guidelines, please bear in mind that it is **not necessary to implement all the guidelines as a package**, but a country/region may choose to implement only selected guidelines, e. g. the most needed or suitable guidelines, or may consider a stepwise 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



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?

Regulatory authority

Pharmaceutical company

Scientists

Veterinary doctors

Other

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 !

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