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OIE role in the VICH, VICH Guidelines

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Innovation Week in Veterinary Services

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electronic conference



WORLD ORGANISATION FOR ANIMAL HEALTH *Protecting animals, preserving our future*

Summary

- OIE in brief
- Link between the OIE and VICH
- OIE Cooperation with VICH
- What does the OIE see as the main benefit of the VICH for OIE Member Countries?
- VICH Guidelines
- Future expectations
- Conclusion



THE OIE IN BRIEF

World Organisation for Animal Health

The World Organisation for Animal Health (OIE) in brief

- An Intergovernmental Organisation
- Formed in **1924** as the *Office International des Epizooties* (OIE)
- Mandate to Improve Animal Health, Welfare and Veterinary Public Health
- **Sets international standards recognised by the WTO**

264
Reference Laboratories

182
Member Countries

75
Partner organisations

For each Member Country:

- **1** National Delegate to the OIE
- **8** National Focal Points on specific subject matter, *including one on Veterinary Products including AMR*

Headquarters in Paris
158 staff

13 Regional offices
74 staff

182 Members in 2022





Link between the OIE and VICH

Link between the OIE and VICH

What is the VICH?

VICH is a trilateral (EU-Japan-USA) programme aimed at harmonised technical requirements for veterinary product registration. Its full title is the International Cooperation on Harmonisation of Technical Requirements for Veterinary Medicinal Products

Who is involved?

Full Members: EU, Japan USA

Observers: Australia, Canada, South Africa, New Zealand and the UK

VICH Outreach Forum:

Argentina, Brazil, China (Peop. Rep. of), India, Korea (Rep. of), Mexico, **Morocco**, Nigeria, Russia, **Saudi Arabia**, Chinese Taipei, Tanzania, Thailand, Uganda, Ukraine and Zimbabwe. 14 Countries and 3 Organisations

Link between the OIE and VICH

What is the VICH Outreach Forum (VOF)?

The VICH Outreach Forum is a VICH initiative whose main objectives are to:

- provide a basis for wider international harmonisation of registration requirements
- improve information exchange
- raise awareness of VICH and VICH guidelines with non-VICH countries/regions

<https://www.vichsec.org/en/about/vich-outreach-forum/what-is-vich-outreach-forum.html>

Link between the OIE and VICH

- The OIE, **as an associate member** of VICH, has the opportunity to take part in the discussions of the Steering Committee meetings
- The OIE does not take part in any formal decision-making on topics or guidelines, nor does it sign-off on any VICH draft/final guidelines
- As an associate member to support and disseminate the VICH meetings outcome at a worldwide level



OIE Cooperation with VICH

OIE Cooperation with VICH

- The OIE provides support to VICH and encourages OIE Member Countries to take into consideration the VICH guidelines when developing and implementing guidelines and standards for veterinary medicinal products. OIE also encourages OIE Member Countries to join the VICH Outreach Forum
- The OIE gives regular updates to VOF Member Countries about their activities after each meeting by sending a summary letter
- The OIE Collaborating Centre (ANSES-France) chairs the VICH Outreach Forum (VOF) meetings, taking into account the needs of VOF Countries (for example by proposing subjects for the agenda)

OIE Cooperation with VICH

- The OIE participates in the **consultation phase, circulating draft VICH guidelines** to all Member Countries' Delegates and Focal Points for Veterinary Products and encourages them to provide comments
- VICH was included into the OIE training seminars for OIE National Focal Points for Veterinary Products from the beginning
- The OIE provides updates to the Biological Standards Commission on the relevant VICH Guidelines to achieve harmonisation between OIE Standards and the relevant VICH Guidelines (GL) as much as possible

OIE Cooperation with VICH

Why is this cooperation being pivotal?

- The OIE considers the international harmonisation of technical requirements for pre- and post-marketing authorisation of veterinary medicines to be a necessity for **animal health, public health, environmental protection**, and **facilitation of international trade**
- The World Trade Organization considers the standards, guidelines and recommendations of the OIE to be the reference for trade in animals and animal products
- VICH Guidelines can be very valuable tools to achieve these aims



- What does the OIE see as the benefit of VICH for OIE Member Countries

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Main benefits for OIE Member Countries include:

- VICH Member Countries
- Observer Countries
- VICH Outreach Forum Member Countries
- Non VICH Member Countries

To facilitate international trade, with increased **availability** of quality-assured, safe and efficacious veterinary medicinal products (VMPs), taking into account the **need for a harmonised regulatory environment**

What does the OIE see as the benefit of VICH for OIE Member Countries

Main benefits for OIE Member Countries include:

VICH Guidelines:

Solid base for harmonisation of the registration/authorisation of VMPs with appropriate legislation

Better registration or recognition increases availability of VMPs

Facilitate international trade and ensure food security

What does the OIE see as the main benefit of VICH for OIE Member Countries

VICH Guidelines and their implementation contribute to high standards of veterinary medicinal products, which in turn promotes global animal health, animal welfare and public health

To contribute to the “One Health approach” by decreasing antimicrobial resistance and to protect the environment

What does the OIE see as the main benefit of VICH for OIE Member Countries

VICH Priorities Phase 5 : 2021-2025 document VICH/19/017

“The desire to foster effective cooperation with the OIE, particularly with regard to the OIE’s strategic focus on promoting good governance of veterinary medicinal products which provides the framework within which OIE member countries can apply the technical requirements established in VICH guidelines. In this context, the OIE strategy refers to VICH as the reference body regarding the technical requirements for registration of veterinary medicinal products and related scientific aspects”

“Foster the already close collaboration with OIE as a pre-requisite to successful implementation of the wider objective of international harmonisation. **VICH will support the strategic activities of OIE that are targeted at good governance of veterinary medicinal products in OIE member countries**”

<https://vichsec.org/en/library/organisational-documents-priorities-strategy-and-charter.html>

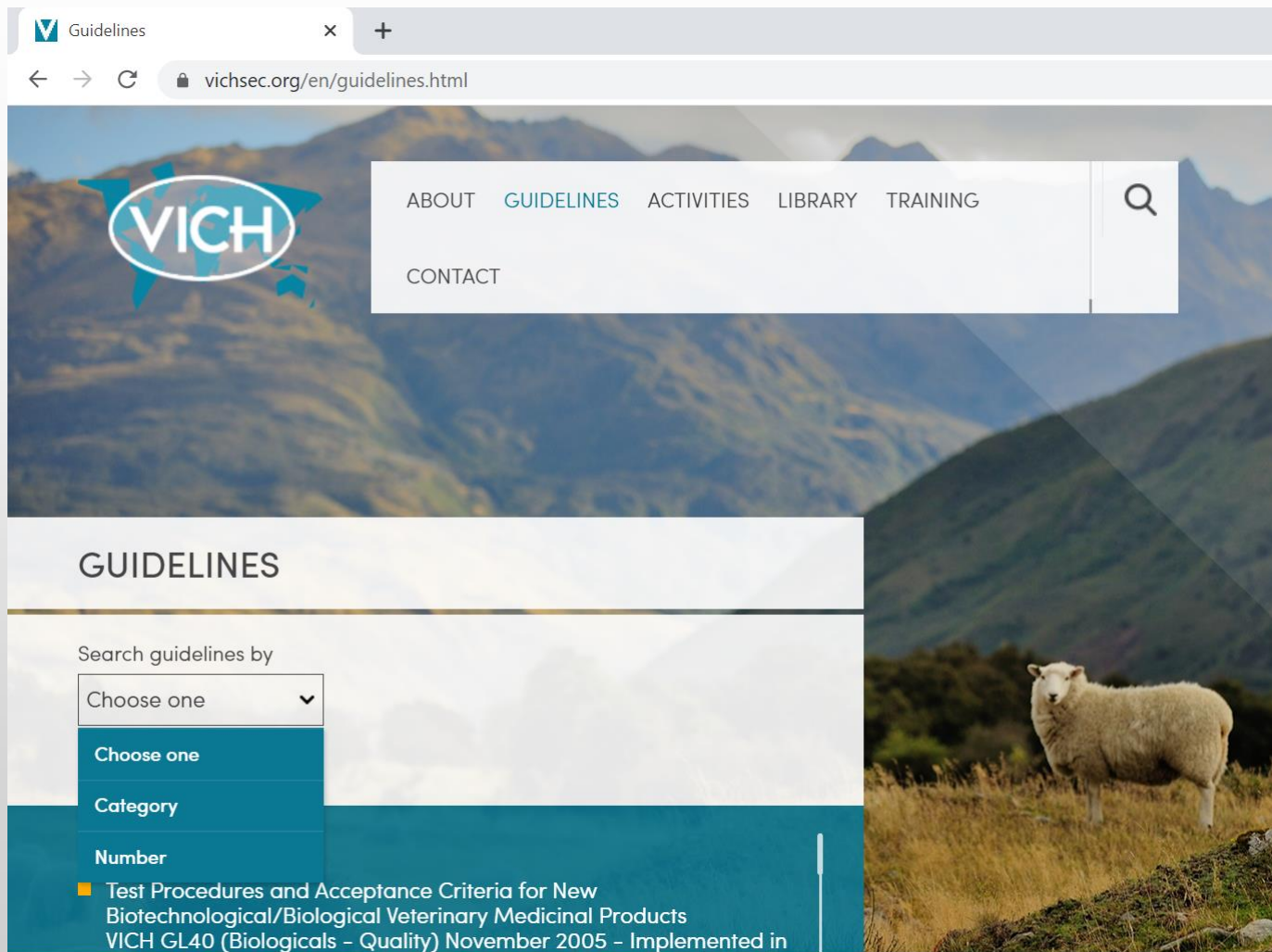


■ VICH Guidelines

VICH Guidelines by category

Category		GL numbers
Pharmaceuticals	Quality	1, 2, 3(R), 4, 5, 8, 10(R), 11(R), 17, 18(R), 39, 40, 45, 51, 58
	Efficacy	7, 12, 13, 14, 15, 16, 19, 20, 21
	Bioequivalence	52
	Environmental Safety	6, 38
	Metabolism and Residue	46, 47, 48(R), 49(R), 56, 57
	Toxicology	22, 23(R), 28(R), 31, 32, 33(R), 37, 54
	Target Animal Safety	43
	Antimicrobial Safety	27, 36(R)
Biologicals	Quality	34, 25, 26
	Target Animal Safety	41, 44, 50(R), 55, 59
General	Good Clinical Practice	9
	Pharmacovigilance	24, 29, 30, 35, 42
	Electronic File Format	53

VICH Guidelines

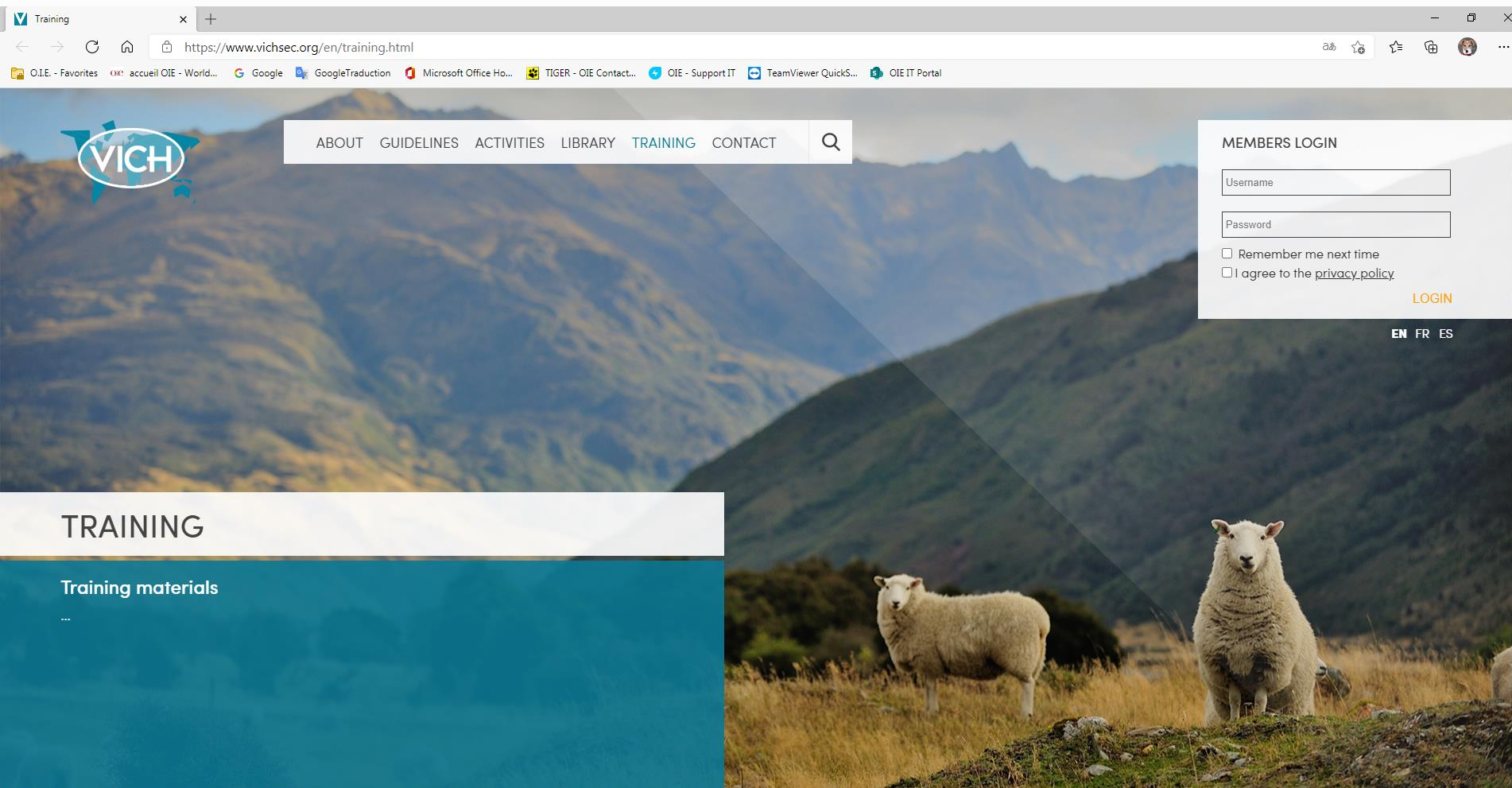


<https://www.vichsec.org/en/guidelines.html>

VICH Guidelines

- VICH Guidelines
 - VICH has developed and adopted 59 guidelines
 - Several draft guidelines are under development
- Increasing implementation in other countries and regions represented in the VICH Outreach Forum

VICH Guidelines

A screenshot of a web browser displaying the VICH Guidelines Training page. The browser's address bar shows the URL https://www.vichsec.org/en/training.html. The page features a large background image of a mountain range with two sheep in the foreground. The VICH logo is in the top left. A navigation menu at the top includes links for ABOUT, GUIDELINES, ACTIVITIES, LIBRARY, TRAINING (highlighted), and CONTACT, along with a search icon. On the right, there is a 'MEMBERS LOGIN' section with fields for Username and Password, checkboxes for 'Remember me next time' and 'I agree to the privacy policy', and a LOGIN button. Below the navigation menu, a 'TRAINING' section is visible with a link to 'Training materials'. At the bottom right of the page, there are language links for EN, FR, and ES.

Training

https://www.vichsec.org/en/training.html

O.I.E. - Favorites OIE - accueil OIE - World... Google GoogleTraduction Microsoft Office Ho... TIGER - OIE Contact... OIE - Support IT TeamViewer QuickS... OIE IT Portal

VICH

ABOUT GUIDELINES ACTIVITIES LIBRARY **TRAINING** CONTACT

MEMBERS LOGIN

Username

Password

☐ Remember me next time

☐ I agree to the [privacy policy](#)

LOGIN

EN FR ES

TRAINING

Training materials

<https://www.vichsec.org/en/training.html>



- Future expectations

Future Expectations

- More OIE Member Countries taking into consideration the relevant VICH guidelines when **developing and implementing national systems registration** for veterinary medicinal products
- The future guidelines might take into consideration the **wider needs** worldwide
- **Raise awareness** of the VICH guidelines and their implementation
- More OIE Member Countries' legislation to **support** a solid regulatory system, which would serve as a base for a **harmonised/convergent regulatory authorisation/registration system for veterinary medicinal products**



■ Conclusion

Conclusion (1)

- **There is a call** to join the VICH Outreach Forum and to benefit from the existing **VICH Guidelines** in order to achieve wider harmonisation, or just simply take into consideration in their national or multinational/regional registration system for authorising veterinary medicines
- With solid legislation of registration/authorisation for veterinary medicines, and consequently a well-established regulatory system, by taking into account the existing VICH Guidelines (GL), OIE Member Countries can achieve quality assured, safe and efficacious veterinary products worldwide.

<https://vichsec.org/en/about/vich-outreach-forum/what-is-vich-outreach-forum.html>

Conclusion (2)

- This could lead to the **elimination of falsified and substandard products** from the market concerning veterinary medicinal products from both animal and public health points of view
- Acceleration of veterinary medicinal product development, **facilitation of innovation**

Questions

- Are you using the VICH GLs during the assessment of the dossiers of the Veterinary Medicinal Products ?
- What would be your recommendations to the VICH, VICH Outreach Forum for the future ?



WORLD ORGANISATION FOR ANIMAL HEALTH
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