

Regulatory Convergence for Animal Health Products:

Objectives, approaches to implementation, and potential contributions from the OIE

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Chargé de mission

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5th Global Animal Health Conference and Workshop 2016

Improved Market Access for Authorised
Veterinary Medicines – The Asian Perspective

Organising Committee:

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GALVmed
Protecting Livestock – Improving Human Lives


INFHH


Health for Animals
global animal medicines association

DIA  **DEVELOP
INNOVATE
ADVANCE**



Regulatory Convergence for Animal Health Products: Objectives, approaches to implementation, and potential contributions from OIE

- ▶ What are the **aims and objectives** of regulatory convergence for animal health products?
- ▶ What are the **benefits**, and who potentially benefits?
- ▶ How widely is it supported by all stakeholders?
- ▶ What are some **potential approaches** to its implementation for regulation of animal health products in Asia and other regions?
- ▶ **How can the OIE contribute to convergence?**



Aims and Objectives

- ▶ To maintain healthy animals, we need timely access to high quality, safe, and efficacious animal health products.
- ▶ **Objectives:** Global **convergence** of regulations, technical standards, document requirements for animal health products to **streamline regulatory approval processes, without diminishing the overall regulatory controls** that are required to safeguard their quality, safety, and efficacy.



Convergence: Recent discussions

4th Global Animal Health Conference 2015

Theme: Regulatory Convergence

24-25 June 2015 in Dar Es Salaam, Tanzania

See conference report: HealthforAnimals website

**Press Release: Global Animal Health Conference
Addresses Regulatory Barriers 24/06/2015**

<http://healthforanimals.org/resources-and-events/resources/news/25-global-animal-health-conference-addresses-regulatory-barriers.html>

5th Global Animal Health Conference and Workshop 2016



WHO Regulatory Harmonisation

16th ICDRA Recommendations 2014

Regulators' role in access/availability (shortages etc.)

► *Recommendation for Member States:*

“Explore the possibilities to promote convergence and harmonization of regulatory processes, and use joint and collaborative assessments as appropriate (with neighbouring countries or between authorities with common interest in certain products), in order to facilitate registration of medical products and increase efficiency.”

Source:

WHO Drug Information Vol. 28, No. 3, 2014

Regulatory harmonization: 16th International Conference of Drug Regulatory Authorities (ICDRA) Plenary 5

http://www.who.int/medicines/publications/druginformation/WHO_DI_28-3_RegulatoryHarmonization.pdf



International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (**VICH**)

- ▶ The **VICH Guidelines** establish harmonised technical requirements for registration and post-registration oversight for animal health products.
- ▶ OIE participates as an associate member in the VICH process - disseminates the outcomes at a worldwide level.
- ▶ **VICH Outreach Forum:**
 - Provides a basis for wider international participation beyond the VICH member and observer regions and countries.
 - Currently includes 17 countries or regional organisations, and growing.
 - **Encourages reference to VICH guidelines in national systems of registration.**



Benefits of Convergence for Stakeholders

- ▶ **Facilitates incremental progress toward harmonisation** and avoidance of technical barriers to trade, to enhance availability of animal health products.
- ▶ Streamlines administrative processes – reduces workload; saves time and money for **both regulatory agencies and industry.**
- ▶ Enables **regulatory agencies** to redirect their attention toward other priority responsibilities.
- ▶ Can circumvent perceived obstacles to harmonisation through flexibility and adaptability.



Benefits of Convergence for Stakeholders, continued

- ▶ Minimizes regulatory burden (and costs) for **industry** (manufacturers and importers). Indirectly reduces costs of products for end users.
- ▶ Enhances timeliness of review and approval processes, which facilitates rapid access to new or improved animal health products for **end users** (veterinarians and animal owners).
- ▶ Builds capacity, enhances uniformity, and helps eliminate gaps in regulatory controls.
- ▶ Supports innovation through efficient regulatory systems



Potential advantages for national regulatory authorities (expediency and cost savings):

- ▶ Convergence helps reduce the investment required for developing and implementing science-based regulatory controls.
- ▶ Adopting common standards serves to streamline administrative procedures and minimize duplication, and can enable...
 - Adopting best practices, capacity building
 - Work-sharing, communications among counterparts
 - Delegation of lead responsibility for specific regulatory functions
 - Taking preceding regulatory decisions by counterparts in other agencies into consideration
 - Incorporation by reference



Incorporation by Reference

- ▶ **Regulations and policies** for manufacturing and testing of animal health products **could cite internationally accepted regulatory requirements and technical standards**, such as:
- *European Pharmacopoeia*
 - Good Manufacturing Practices (EMA, FDA, PIC/S)
 - United States Department of Agriculture *Title 9 Code of Federal Regulations (9 CFR)*
 - *VICH Guidelines*
 - *OIE Terrestrial Animal Health Code*
 - *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*



Convergence: Considering Other Decisions

- ▶ National regulatory agencies could clarify the **prerogative of their regulatory officials to take into consideration preceding approvals** or pertinent regulatory controls administered by counterparts in other countries, when reviewing and approving licensing submissions.



Documents to Authorise Communications between Regulators to Facilitate Product Reviews

- ▶ **Memorandum of Understanding** (MOU) for cooperation between **regulatory agencies** to authorize sharing confidential information and products that both regulate.
- ▶ **Alternatively**, if a MOU is not feasible, **a letter from the manufacturer** authorizing two national regulatory agencies to share confidential information and decision documents pertaining to a specific product or a group of products.
- ▶ Standardized templates could be developed for these.



Potential Contributions from the World Organisation for Animal Health (OIE) for Regulatory Convergence



Potential Contributions from the OIE

Question:

How can the OIE World Organisation for Animal Health most effectively contribute to global initiatives for convergence of regulatory oversight for animal health products?



OIE Perspectives

- ▶ The OIE recognizes the global importance of veterinary products* for animal health, animal productivity, food safety, and food security.
- ▶ Inadequate or inefficient regulatory oversight for animal health products, due to gaps in legislation, inefficiencies in registration procedures, or inappropriate distribution practices could adversely affect the availability or quality of animal health products, posing a threat to animal health, public health, and the environment.

* Veterinary products = veterinary drugs, vaccines, and diagnostic tests

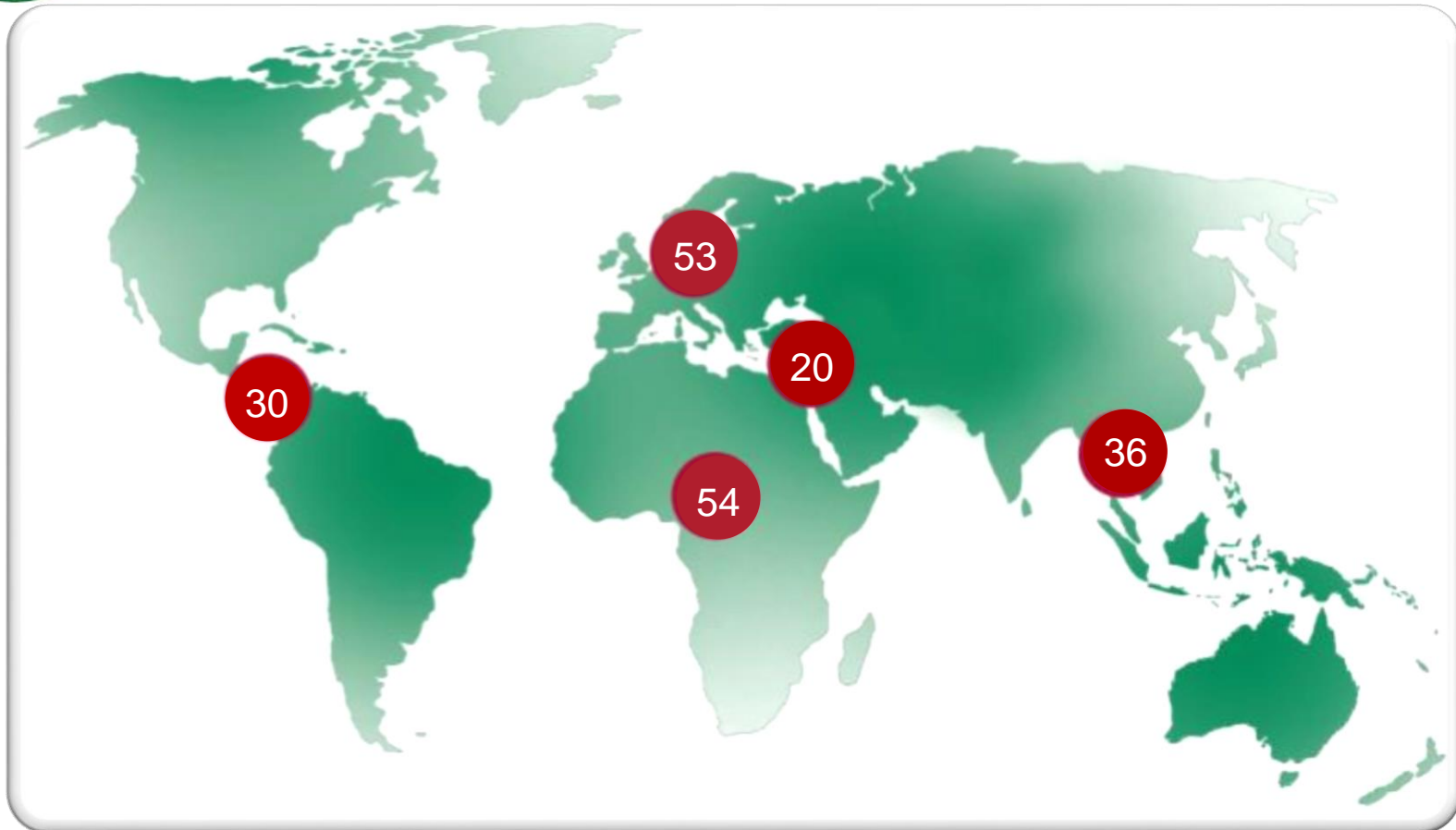


Potential Contributions from OIE

- ▶ OIE can contribute through its standard-setting role, its technical documentation, and its established networks:
 - OIE: - Delegates, Focal Points for Veterinary Products
 - Reference Centres, Reference Laboratories
 - Specialist Commissions, and *Ad Hoc* groups
 - Participation in government/industry harmonization fora, such as VICH Outreach Forum and CAMEVET.
 - Links with groups promoting regulatory convergence, harmonisation and capacity building funding and expertise)
 - e.g., Bill and Melinda Gates Foundation, GALVmed, STAR-IDAZ



OIE - 180 Member Countries including 36 in Asia, the Far East and Oceania



Africa 54 – Asia, the Far East and Oceania: **36** Member Countries

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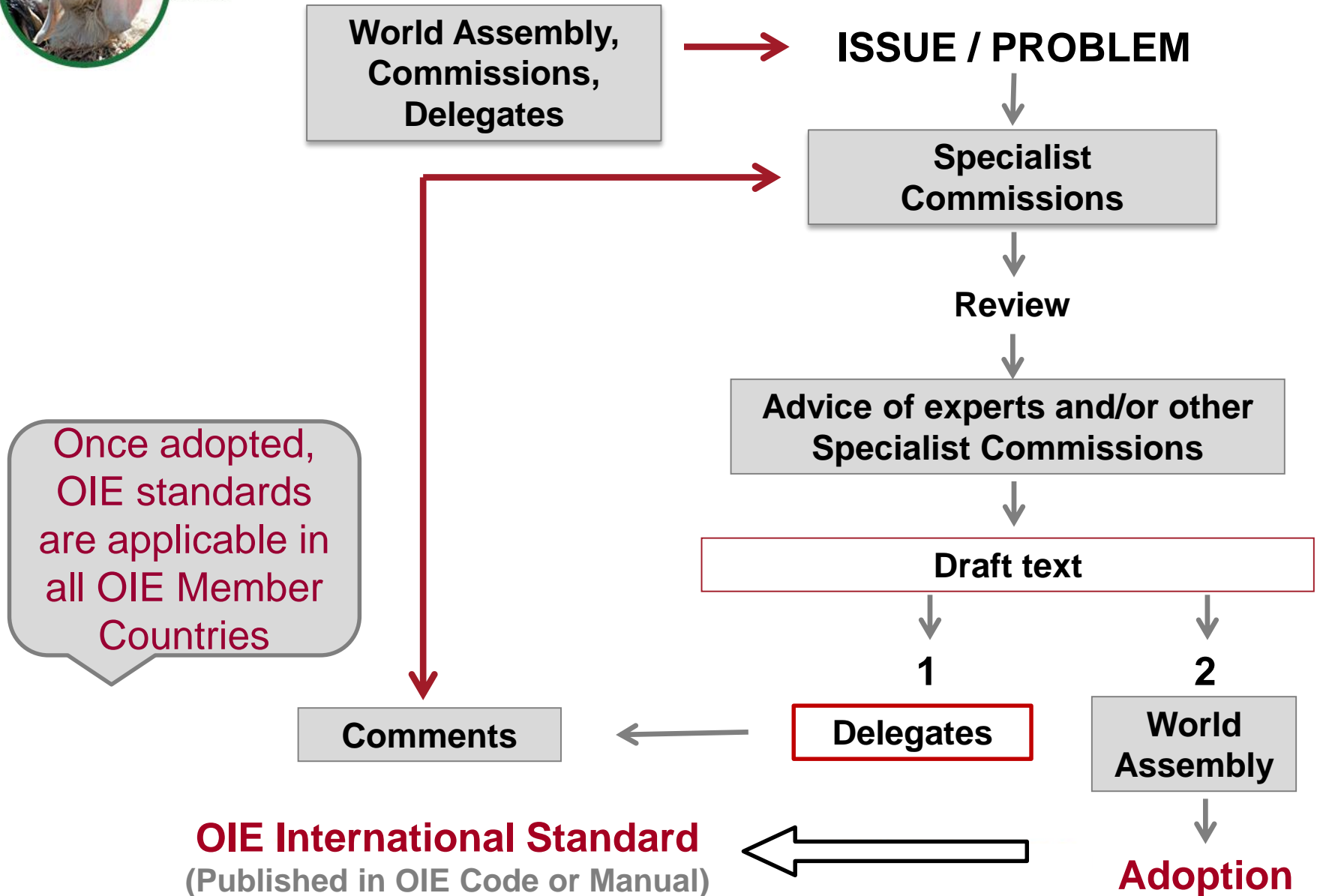


OIE – Standard Setting Role





OIE Standard Setting Process





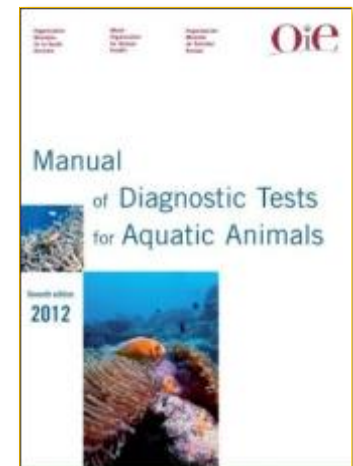
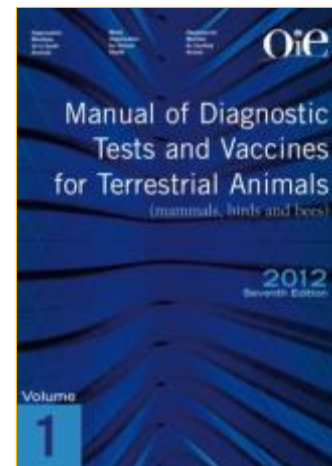
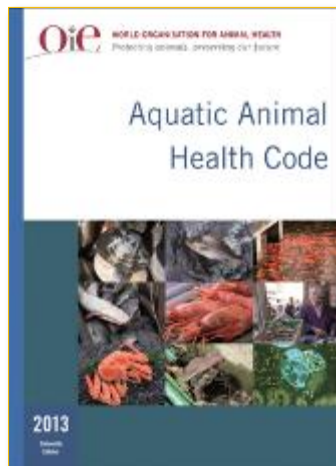
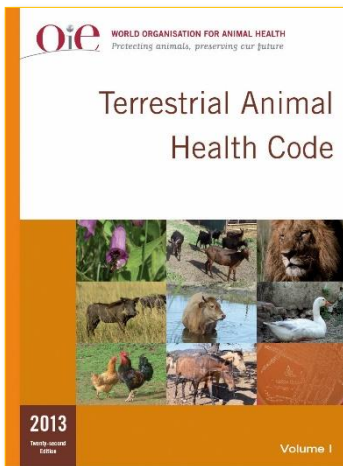
OIE – Standard Setting

CODES

- Terrestrial
- Aquatic

MANUALS

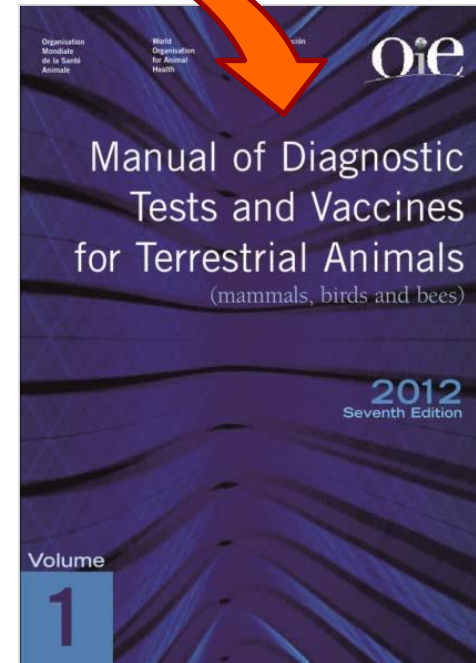
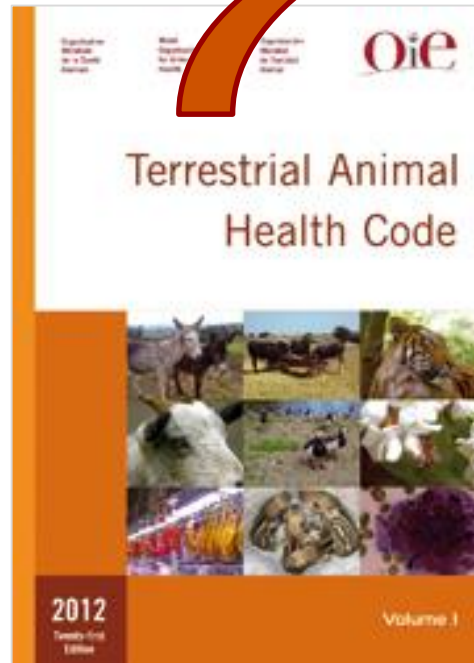
- Terrestrial
- Aquatic



Codes and Manuals available online (free) on the OIE website



Relationship between OIE Codes and *Manuals*



Where the ***Terrestrial Code*** requires that tests are carried out for international movement or recommends vaccination; the ***Terrestrial Manual*** provides recommended laboratory methods and, where applicable, sets vaccine standards.



OIE Terrestrial Animal Health Code.

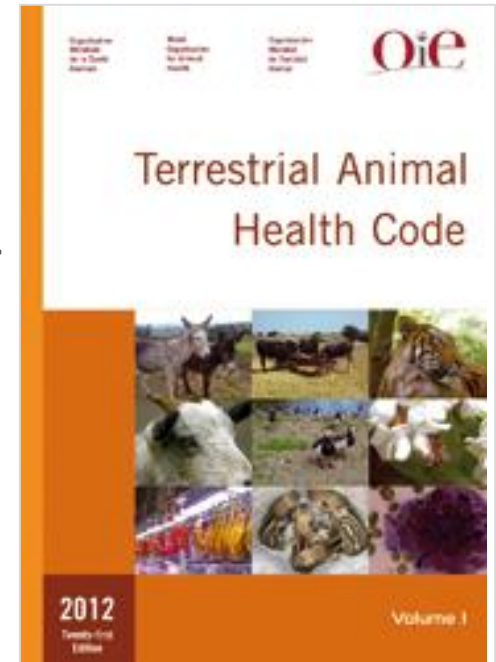
Chapter 3.4. **Veterinary Legislation**



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Article 3.4.11 Veterinary medicines and biologicals.

- ▶ **Veterinary legislation** should provide a basis for assuring the quality of veterinary medicines and biologicals and minimising the risk to human, animal and environmental health associated with their use.



Source: http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_vet_legislation.htm



Summary

- ▶ National regulatory agencies should **strive to adopt common technical standards and document requirements**.
- ▶ **‘Incorporation by reference’** could be a useful tool.
- ▶ To **streamline administrative processes and avoid duplication**, regulatory officials should take into consideration the preceding approvals and ongoing regulatory oversight in other jurisdictions when reviewing and approving licensing submissions.



Summary

- ▶ Global **convergence** of regulations, standards and requirements could **streamline regulatory approval processes to improve their availability, without diminishing the overall regulatory controls** that are required to safeguard their quality, safety, and efficacy.
- ▶ The OIE, can contribute to the successful adoption and implementation of global or regional convergence initiatives, through
 - its standard-setting role and international networks;
 - partnership with regional or international harmonization bodies, industry associations, and non-government organisations.



5th Global Animal Health Conference 2016: Improved Market Access for Authorised Veterinary Medicines. The Asian Perspective, New Delhi, India, 17 November 2016

**Thank you
for your attention**



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Appendix



Definition of Convergence

- ▶ **Convergence:** The **merging** of distinct technologies, industries, or devices into a unified whole. (Merriam-Webster)

Source: <http://www.merriam-webster.com/dictionary/convergence>



Working Definition: ‘Regulatory Convergence’ versus ‘Regulatory Harmonisation’

Adapted from US FDA Center for Biologics and Research (FDA CBER)

- ▶ **“Regulatory convergence** represents a process whereby the regulatory requirements across countries or regions become more similar or ‘aligned’ over time

through gradual adoption of internationally recognized technical guidance documents, standards and scientific principles, common or similar practices and procedures,

or adoption of regulatory mechanisms that might be specific to a local legal context but that align with shared principles to achieve a common public health goal.”

Source:

<http://www.fda.gov/BiologicsBloodVaccines/InternationalActivities/ucm271079.htm>



HealthforAnimals

Meeting Report: Innovation in Animal Health

- ▶ *“**Regulatory streamlining** is also required for vaccine technology. This barrier can be linked to broader inefficiency and a lack of transparency in government procurement of vaccines. However, regulatory barriers can often be overcome rapidly in times of emergency.”*
- ▶ *“There is **potential for coopetition** in the area of vaccine technology.”*

Source: HealthforAnimals Roundtable Meeting 22 Sept 2015

http://www.worldvet.org/uploads/news/docs/healthforanimals_report_2015_innovation_in_animal_health.pdf



HealthforAnimals

Meeting Report: Innovation in Animal Health

- ▶ “**Vaccine banks** are hugely important and merit a greater allocation of funding. Vaccine banks can hold ready-to-use, formulated vaccines, and/or antigen components, to be formulated into vaccines as needed.”
- ▶ “The World Organisation for Animal Health (OIE) has developed a new concept that creates virtual rolling stocks: suppliers produce the vaccines only when needed, or they remain with the suppliers at their own risk and are renewed on a rolling basis under **terms and conditions** contractually defined with the OIE.”

Source:

http://www.worldvet.org/uploads/news/docs/healthforanimals_report_2015_innovation_in_animal_health.pdf



Options for Implementing Convergence:

Convergence:

- Can be implemented in **many forms** - unilaterally, bilaterally, multilaterally (regions or sectors), or globally.
- Can be applied at **any stage**, regardless of the current level of “harmonisation” or official recognition of equivalence among partners.
- Activities **can be prioritized/targeted** to focus on key elements (sectors, products, or trading partners).
- **Specific convergence measures be implemented on their own, or as a component of broader harmonisation initiatives.**



Incorporation by Reference

- ▶ National regulatory agencies could adopt common international standards for animal health products, through various convergence pathways, including incorporation of international standards by referencing them in national regulations and policies, where applicable (**‘incorporation by reference’**).
- ▶ Technical standards, such as those outlined in the OIE ***Terrestrial Animal Health Code*** and ***Terrestrial Animal Health Manual***, **VICH Guidelines**, or regional harmonization documents could serve as a baseline reference for advancing international convergence initiatives.



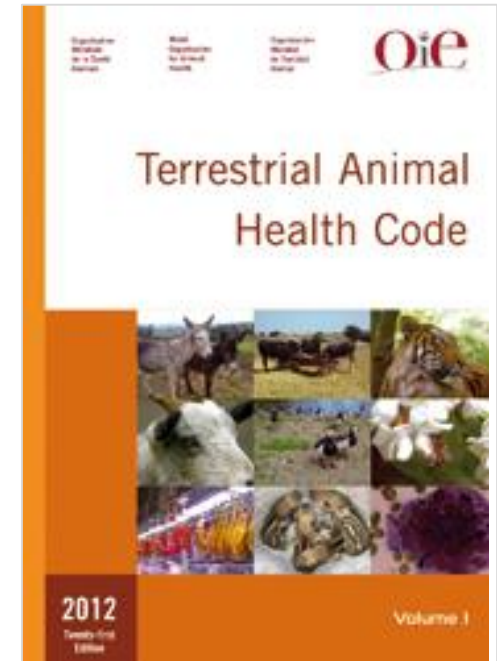
OIE Codes and Manuals

- ▶ Terrestrial Animal Health Code = “**Terrestrial Code**”
- ▶ Aquatic Animal Health Code = “**Aquatic Code**”
- ▶ Manual of Diagnostic Tests and Vaccines for Terrestrial Animals = “**Terrestrial Manual**”
- ▶ Manual of Diagnostic Tests for Aquatic Animals = “**Aquatic Manual**”



OIE Terrestrial Animal Health Code: Chapter 6.9. **Responsible and prudent use of antimicrobial agents in veterinary medicine**

- ▶ Outlines the responsibilities of the competent authority (regulatory agency) and veterinary pharmaceutical industry regarding the marketing authorisation for veterinary medicinal products containing **antimicrobial agents**.



Source: http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_antibio_use.htm



OIE Terrestrial Manual

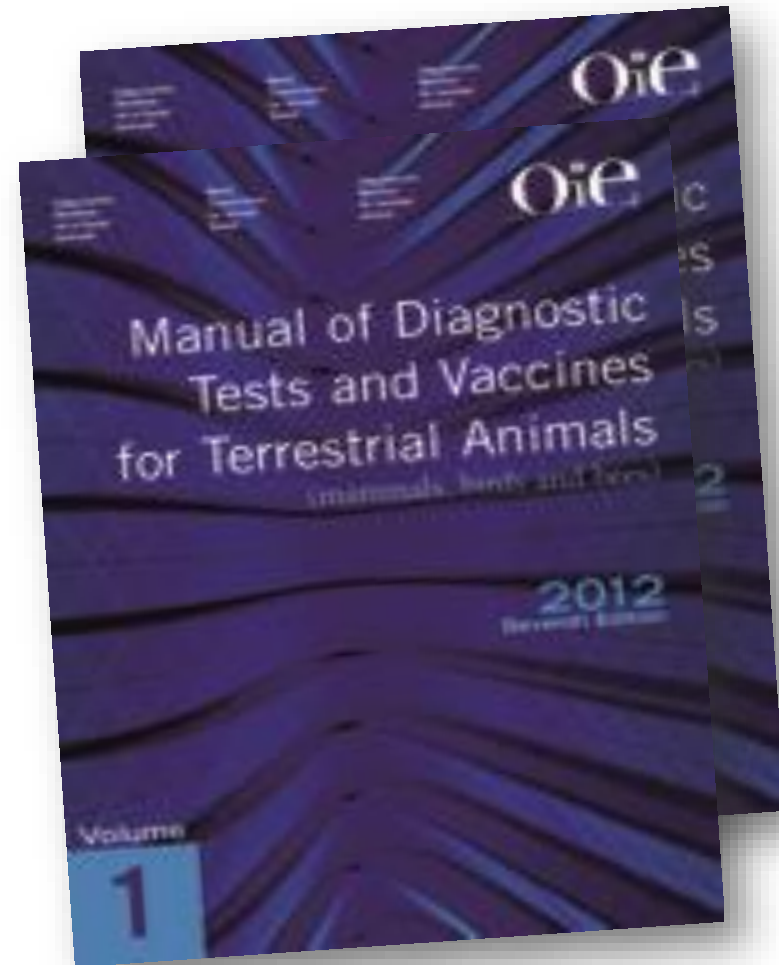
Terrestrial Manual: Divided into two volumes, parts 1-4.

Vol. I **Part 1** General Standards

Vol. II **Part 2** OIE Listed Diseases and Other Diseases of Importance

Part 3 Specific Recommendations

Part 4 OIE Reference Experts and Disease Index





Terrestrial Manual – Part 1

Part 1

General Standards

Section 1.1

Introductory Chapters

Chapter 1.1.1

Management of veterinary diagnostic laboratories (May 2015)

Chapter 1.1.2

Collection, submission and storage of diagnostic specimens (May 2013)

Chapter 1.1.3

Transport of specimens of animal origin (May 2013)

Chapter 1.1.4

Biosafety and biosecurity: Standard for managing biological risk in the veterinary laboratory and animal facilities (May 2015)

Chapter 1.1.5

Quality management in veterinary testing laboratories (May 2012)

Chapter 1.1.6

Principles and methods of validation of diagnostic assays for infectious diseases (May 2013)

Chapter 1.1.7

Standards for high throughput sequencing, bioinformatics and computational genomics (May 2016)

Chapter 1.1.8

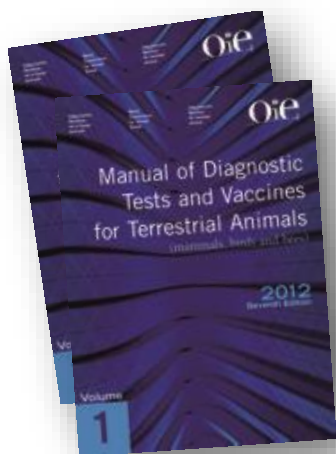
Principles of veterinary vaccine production (Updated: May 2015)

Chapter 1.1.9

Tests of biological materials for sterility and freedom from contamination (May 2008, To be updated in 2017)

Chapter 1.1.10

Vaccine banks (New: May 2016)





Terrestrial Manual – **Part 2** Listed Diseases and Other Diseases of Importance

Structure of the Chapters on specific diseases:

- Summary
- A. Introduction
- B. Diagnostic techniques
- **C. Requirements for vaccines and diagnostic biologicals**
- References

Terrestrial Manual – Part 3



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Part 3

Specific Recommendations

Chapter 3.1

Laboratory methodologies for **bacterial antimicrobial susceptibility testing** (May 2012)

Chapter 3.2

Biotechnology in the diagnosis of infectious diseases (May 2012)

Chapter 3.3

The application of **biotechnology** to the development of **veterinary vaccines** (May 2010)

Chapter 3.4

The **role of official bodies in the international regulation of veterinary biologicals** (May 2008)

Chapter 3.5

Managing biorisk: examples of aligning risk management strategies with assessed biorisks (May 2014)

Section 3.6

Recommendations for validation of diagnostic tests (May 2014)

Section 3.7

Recommendations for the manufacture of vaccines

Chapter 3.7.1

Minimum requirements for the **organisation and management** of a vaccine manufacturing facility (**New:** May 2016)

Chapter 3.7.2

Minimum requirements for the **production and quality control** of vaccines (**New:** May 2016)

Chapter 3.7.3

Minimum requirements for **aseptic production** in vaccine manufacture (**New:** May 2016)

Part 4

OIE Reference Experts and Disease Index

List of OIE Reference Laboratories
Alphabetical list of diseases

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