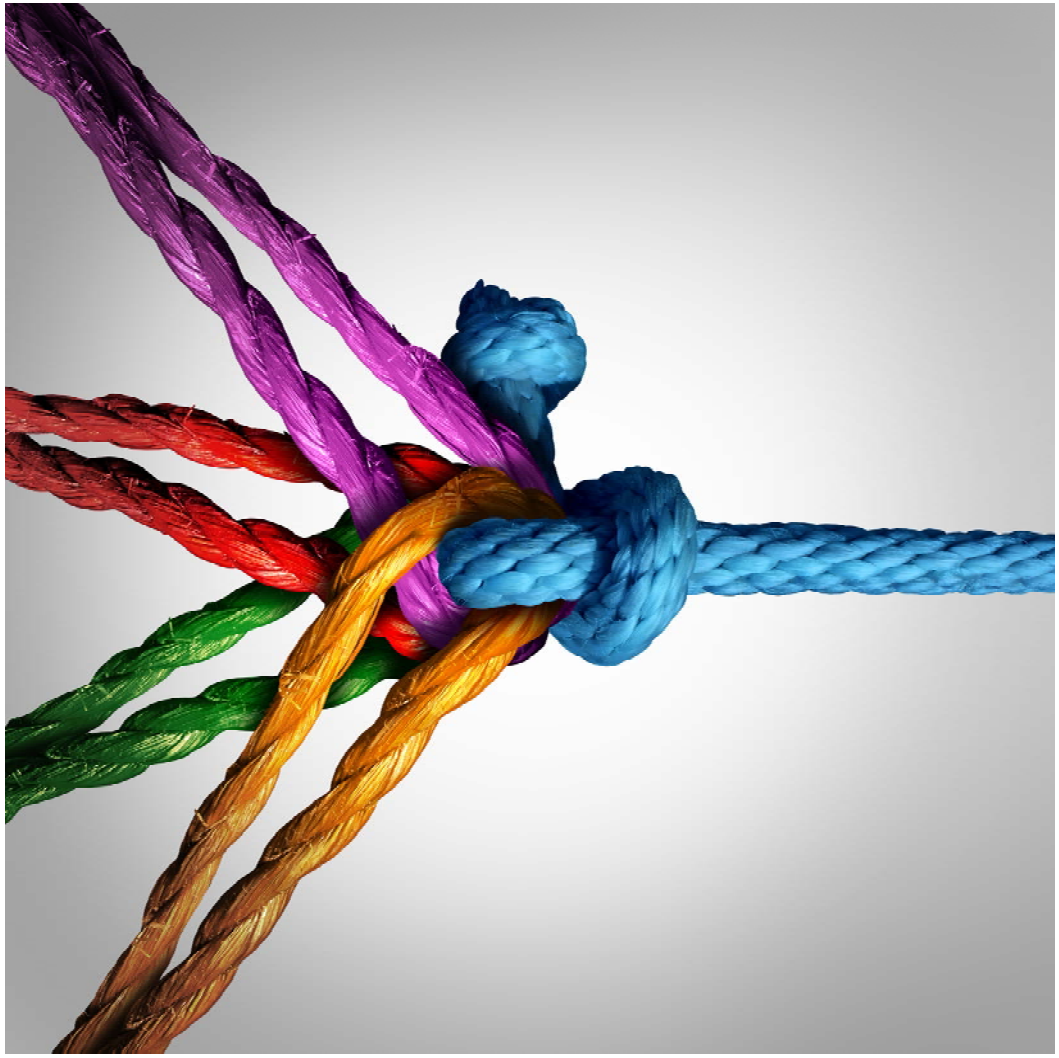
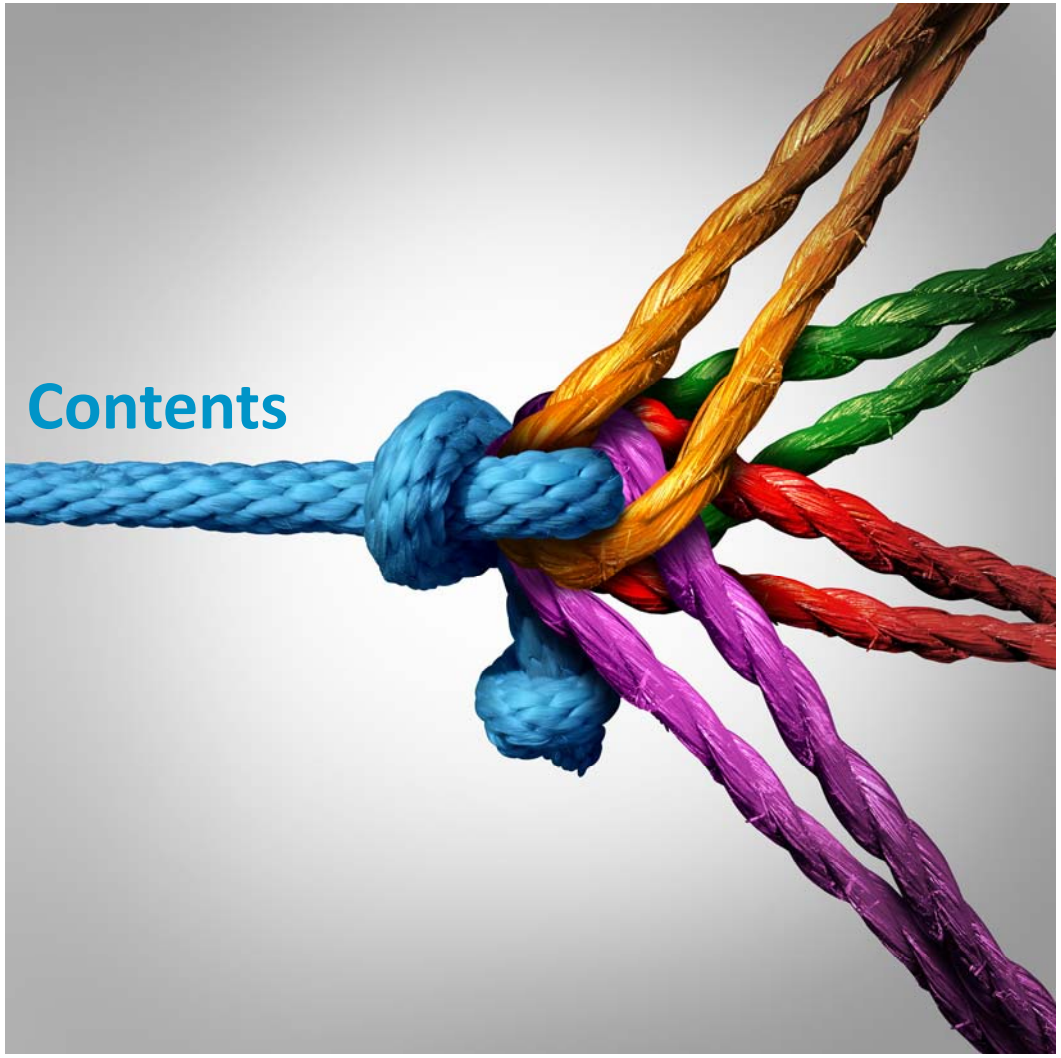


Regulatory Convergence

Regulatory Strategy Team
HealthforAnimals

Addis Ababa, July 2019

Health for Animals
global animal medicines association



Regulatory Convergence
1. Why is it important?

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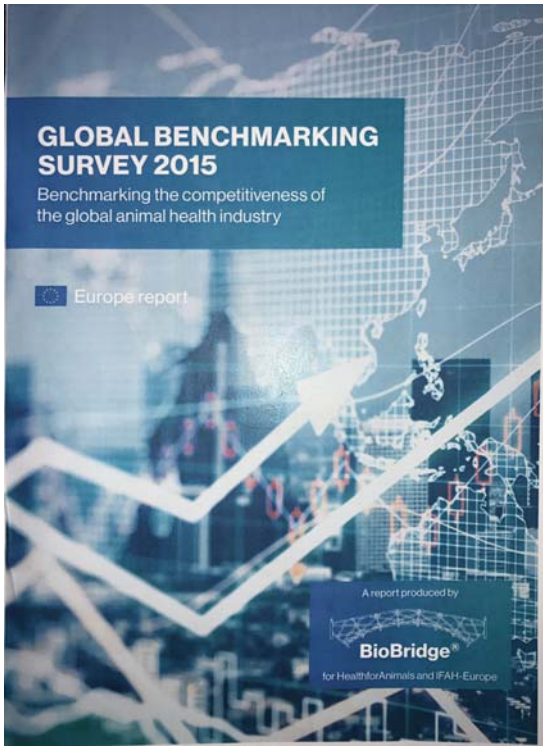
Global Benchmarking Survey report 2015

- significant regulatory differences between countries or regions,

e.g.

- maturity of the regulatory framework,
- different types of application procedures,
- change management,
- post-authorisation safety surveillance,
- transparency of the Authorities and
- resources available



Regulatory Convergence
1. Why is it important and what is it?

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What is it?

- Not just using international guidelines (VICH) and standards
- Convergence of all aspects of regulatory systems
    - Legislative framework,
    - Authorisations
    - Variations,
    - Testing
    - Pharmacovigilance,
    - etcetera…

Regulatory Convergence
1. Why is it important and what is it?

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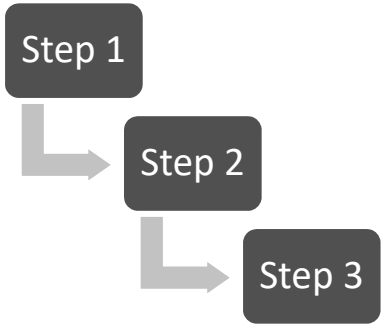
What is the ultimate goal?

- Long term goal?
  - A single global regulatory system
    - single set of studies,
    - single dossier format,
    - common approval outcome
    - common management following authorisation
- Realistic approach required
  - step-by-step,
  - regional and/or country by country
  - Challenges are plenty



Regulatory Convergence
1. Why is it important?

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Challenges:

- **Authorities**
  - Tendency to ramp up requirements
  - Cherry pick requirements from e.g. USA, Japan or EU
    - but not always compatible
  - Risk of re-inventing the wheel
  - “Mature” Authorities reluctance to change
- **Industry continues to consolidate: mergers and acquisitions**
  - Increasing pressure on R&D funding
  - Increasing global approach
  - Increasing threshold of market entry

Regulatory Convergence
1. Why is it important?

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Consequences of lack of convergence

- Adds costs
  - Adds costs:
    - Repetition of studies
    - Slows market entry
- Soaks up regulatory resources
  - From authorities ànd companies
  - Causes
    - Delayed access to medicines
    - Less animal welfare

Regulatory Convergence
1. Why is it important?

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Benefits of regulatory convergence

- Bring efficiencies and avoid wastage
  - Less duplication and repetition
- Allow more new product developments
  - Less resources per project
- Allow more new registrations
  - Same dossier valid in more markets
  - Avoid focus just on major markets
    - Countries
    - Species and indications
- Avoid well-established products removed from markets
  - Less “specific” or “special” requirements for specific markets

Regulatory Convergence
2. Vision

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global animal medicines association

Vision for Regulation of Veterinary Medicines across the World

Vision for 2025: Efficient regulatory systems that result in harmonized, science-based decisions in predictable timeframes, resulting in the wide availability of safe and effective veterinary medicines.

Background – Current Situation

The 2015 Global Benchmarking Report provides a good basis for considering the future needs for the regulatory system for veterinary medicines; this includes, but is not limited to the countries and regions covered by the benchmarking report.

The report reveals significant differences between countries or regions, for example in terms of maturity of the regulatory framework, the different types of application procedures available, the different ways in

Regulatory Convergence
2. Vision

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Industry Global Vision for Regulation 2025

The 10 point plan:

1. Science based decisions
   - no differentiation for local/global companies
2. Predictable transparent timeframes for registration
   - max 24 months new products,
   - max 12 months for significant changes,
   - accelerated pathways for needed products
3. Efficient Regulation – reduced administrative burden
4. More co-operation/recognition of assessments of other country Authorities
5. Innovation – fair returns on investment

Regulatory Convergence
2. Vision

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Industry Global Vision for Regulation 2025

The 10 point plan cont.:

6. Enabling for highly innovative products
7. Global developments support all registrations
8. Manufacture possible anywhere in world to same set of standards
9. Companies able to operate a single pharmacovigilance system
10. Rules on use of medicines require veterinary registered products to be considered first

Regulatory Convergence
3. Main tools

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1. **A Project Team** – **RST** + several task forces
2. **Problem definition - mapping**
   - HealthforAnimals Global Benchmarking Study
     - 7 regions, repeated every 4 years
   - World Bank Survey - report January 2017
     - Enabling the Business of Agriculture / Livestock
     - mapping regulatory systems in 62 countries
   - Regulatory intelligence network, reports from the field

3. **Global Regulatory Vision** (with 10 Point Plan)

Regulatory Convergence
3. Main tools

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Partnerships

- Team up with other credible reputable organisations
- Non-profit, NGOs or governments
  - OIE
  - World Bank
  - Bill & Melinda Gates Foundation
  - GALVmed
  - Regulatory agencies
    - European Medicines Agency and national EU agencies
    - US FDA
    - JMAFF

Conferences

Workshops

Training events

Regional initiatives

Regulatory Convergence
4. Projects

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In partnership with other organisations

- Harmonisation of technical standards – VICH and CODEX

- Global Animal Health Conferenc
  - Dar es Salaam 2015
  - New Delhi 2016
- Workshops o
  - VIC 2015
  , New Delhi, 2016
  ractice, Nairobi, 2017

Authorities are strongly encouraged to participate in such conferences and to join VICH Outreach.

Regulatory Convergence
4. Projects

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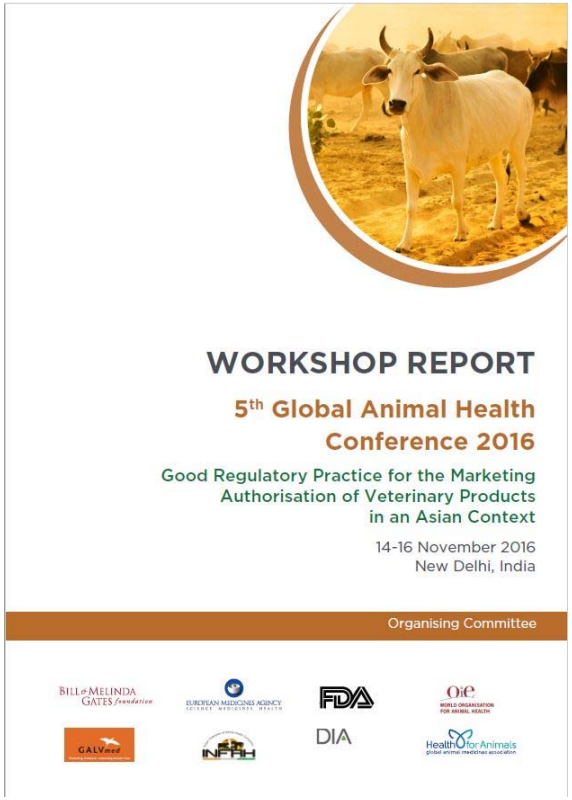
Global Animal Health Conferences & Workshops



Regulatory Convergence
4. Projects: vetmed.world

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global animal medicines association

- www.vetmed.world.com
  - Bringing together all kinds of (global) regulatory resources
    - Training
    - Guidelines
    - Templates and examples
    - Good Practices
  - Intended to be an easy accessible reference / library
  - For consultation by authorities ànd companies

  - You can always propose a “missing link”!

Regulatory Convergence
4. Projects: vetmed.world

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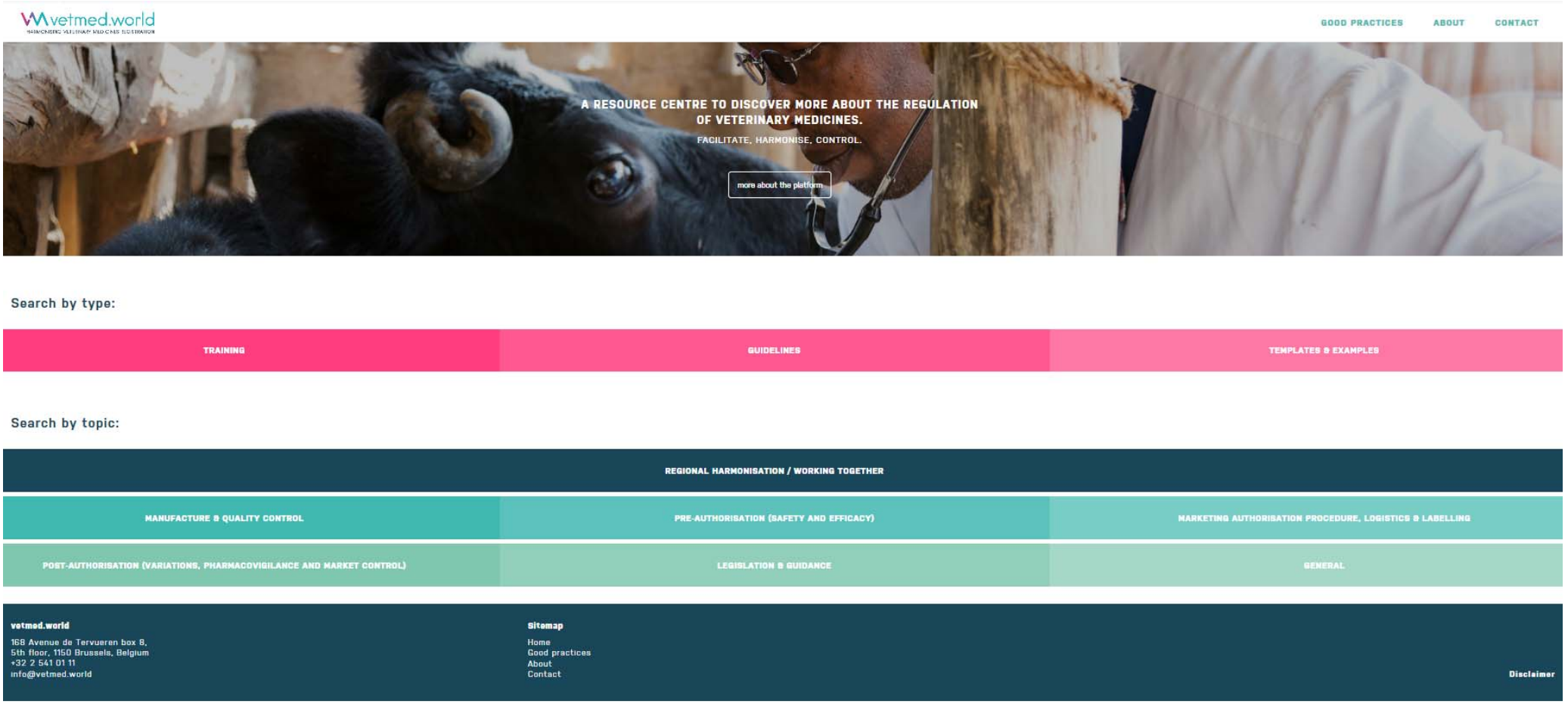
global animal medicines association



Regulatory Convergence
4. Projects: vetmed.world

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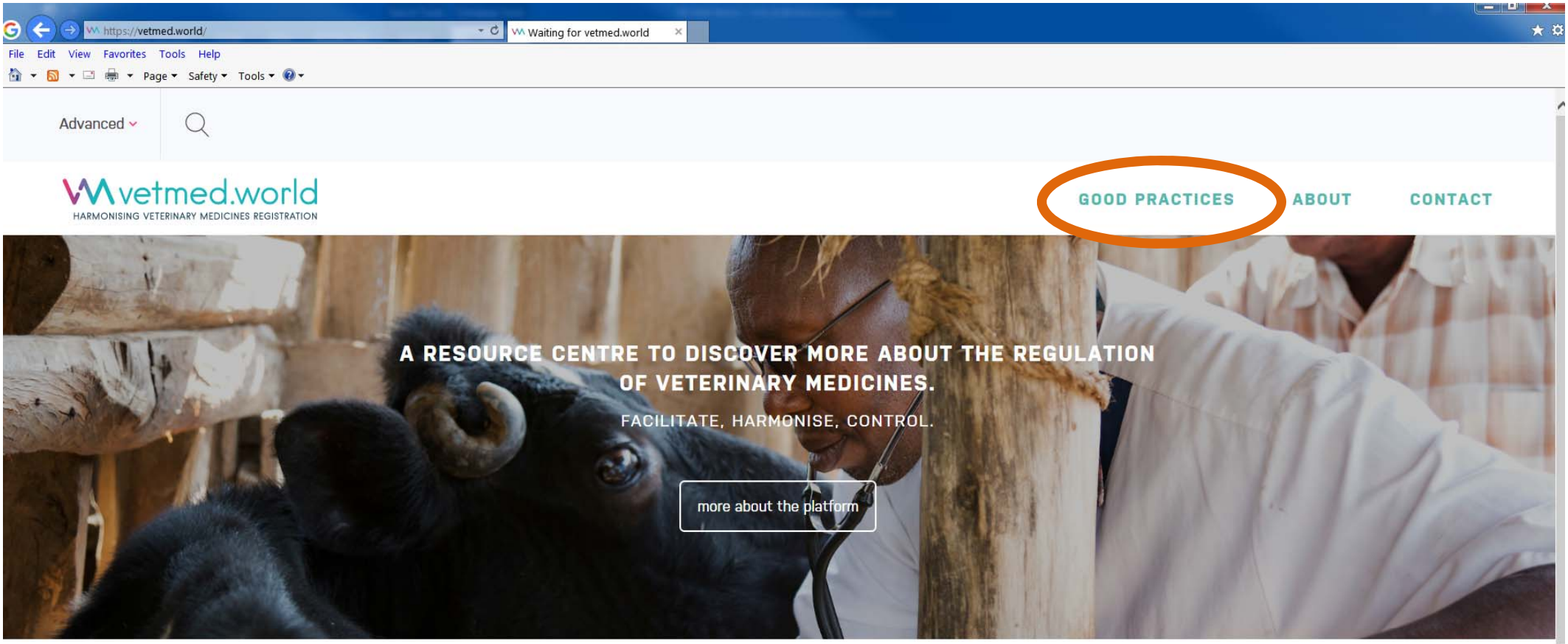

Search by type:

TRAINING | GUIDELINES | TEMPLATES & EXAMPLES

Regulatory Convergence Projects
vetmed.world-good practices

Health for Animals
global animal medicines association

vetmed.world
HARMONISING VETERINARY MEDICINES REGISTRATION

GOOD PRACTICES ABOUT CONTACT

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Regulatory Convergence Projects
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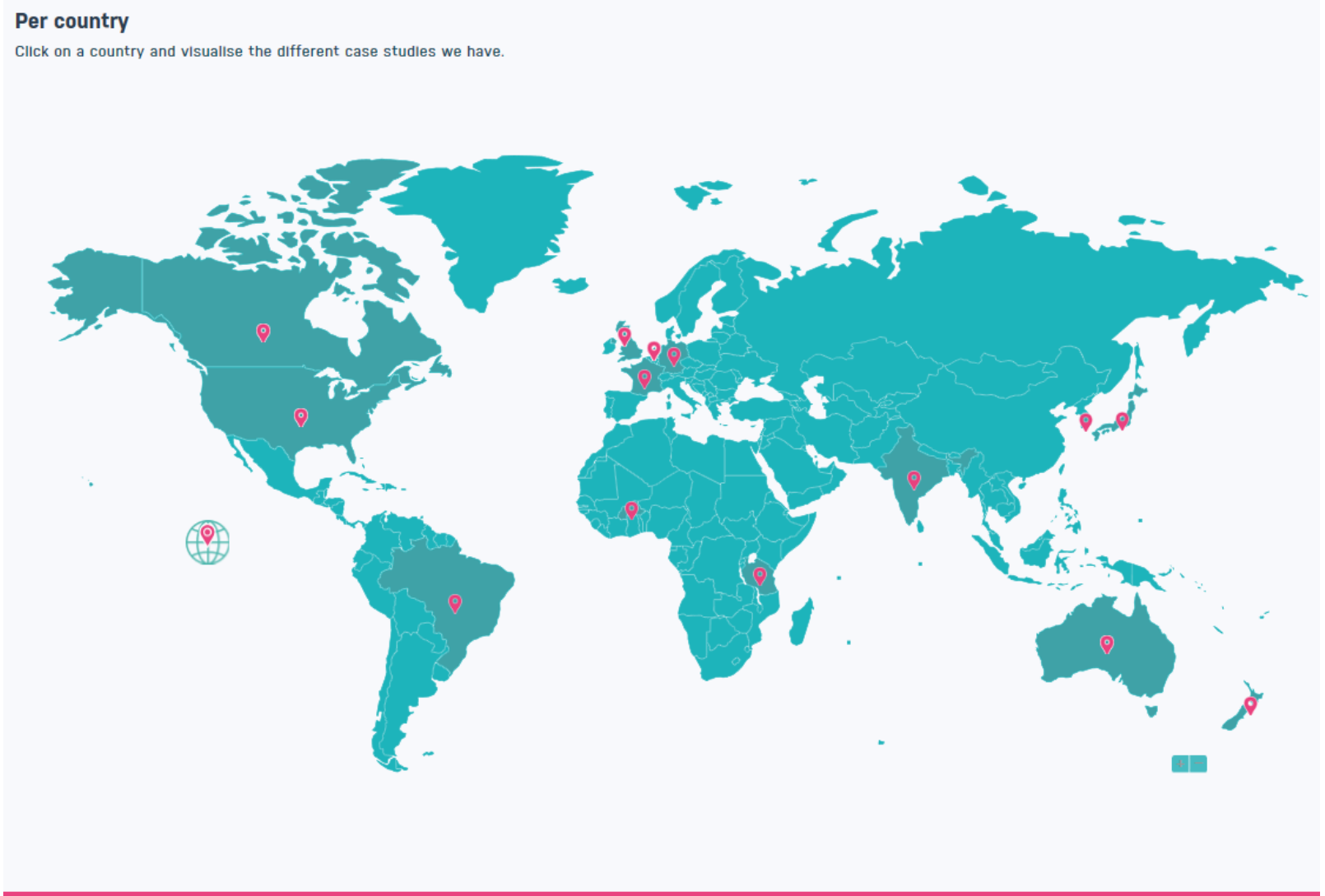


Regulatory Convergence
4. Projects: vetmed.world-training

Health for Animals
global animal medicines association

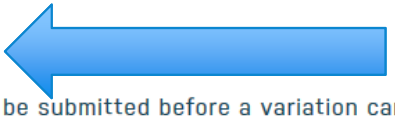
Training course on dossier assessment for veterinary vaccine applications

Presentations

This training course on dossier assessment for veterinary vaccine applications was organised in the EAC in 2017.
The course comprises of 10 presentations, a template for dossier assessment and the EAC application form:

Read more

Guidelines on Variations to a registered pharmaceutical product in Uganda



This Guideline is intended to provide guidance to applicants on the conditions to be fulfilled and the type of documentation to be submitted before a variation can be approved by National Drug Authority of Uganda

Read more

EudraLex –Volume 5- Pharmaceutical legislation for medicinal products for veterinary use

EU guidelines

EudraLex contains the EU legislation for medicinal products for human and veterinary use. It also contains a number of guidelines covering all topics associated with good practice in regulating medicines for human and veterinary use.

Read more

CVM guidance for Industry

USA guidelines

The FDA's Centre for Veterinary Medicine (CVM) develops and issues guidelines for applicants from the pharmaceutical industry.

Read more

USDA Biologics Regulations and Guidance

Immunologicals, USA guidelines

Regulatory Convergence
4. Projects: vetmed.world-training

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TRAINING
Presentations

PRACTICAL INFORMATION
Date: 28/05/2018

Topics:
Marketing authorisation procedure
logistics & labelling
Pre-Authorisation (Safety and Efficacy)

Back to resources page

Training course on dossier assessment for veterinary vaccine applications

This training course on dossier assessment for veterinary vaccine applications was organised in the EAC in 2017.
The course comprises of 10 presentations, a template for dossier assessment and the EAC application form:

- Background to harmonised registration in EAC
- Template for Dossier Assessment presentation
- Template for Dossier Assessment document
- Application Form - presentation
- EAC APPLICATION FORM - document
- Stucture of a Registration Dossier
- Summary of Product Characteristics
- Labelling and Package Leaflet
- QUALITY
- SAFETY
- EFFICACY
- Introduction to EAC MRP

Regulatory Convergence
4. Projects: vetmed.world-templates

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Templates & examples

On this page you will find some examples or templates of documents, forms and other useful items. If you are looking for examples or templates of one specific topic, please use the dropdown menu.

Show:
☐ EU ☐ Templates ☐ Examples ☐ EAC ☐ SADC

Filter by:
Topics

EU Product Information Templates: Summary of Product Characteristics and Labelling
EU, Templates

In the EU, Templates for SPCs and labelling are available as PDFs and Worddocs for applicants to complete.

Read more

EU Electronic Application Forms
EU, Templates

Forms are available for electronic submissions.

Read more

EU Validation checklist for initial Marketing Authorisation Application – immunologicals (applicable to submissions under Art. 12(3) of Directive 2001/82)
EU, Templates, Examples

This document is the validation check list used by the European Medicines Agency for immunological products.

Read more

EAC Templates for Draft Summary of Product Characteristics and Packaging for Immunological Veterinary Products
Templates, EAC

For countries in the East African Community, the regulatory authorities have adopted harmonised requirements for registering veterinary immunoligicals. The headings to be followed for the different sections of the summary of product characteristics (SPC) and product

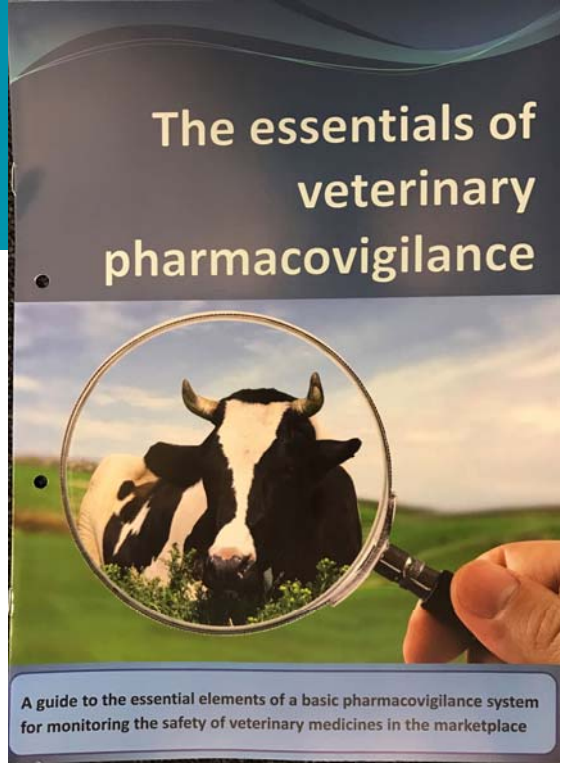
Read more

EAC Harmonised Application Form for the Registration of Immunological Veterinary Products
Templates, EAC

This harmonised application form is for use in National or Mutual Recognition procedures in the East African Community for the registration of veterinary immunological products

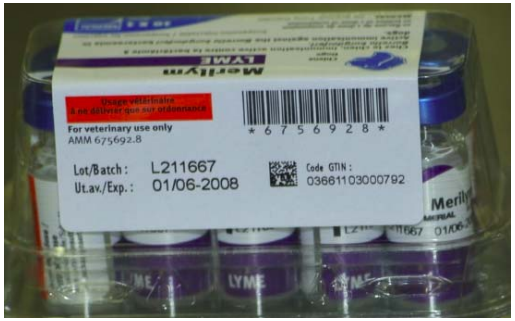
Read more

Regulatory Convergence Projects



HealthforAnimals Regulatory Strategy Team

- Benchmarking Survey
- Good Regulatory Practices resource at www.vetmed.world.com
- Data protection / data exclusivity communication toolkit
  - Ensure the confidentiality of submitted data: Best Practice Guide (for Authorities) on data confidentiality and data security
- The Essentials of Pharmacovigilance brochure
- Harmonised dossier content - regional templates
- Industry harmonised approach to labelling
  - 2-D data matrix



Regulatory Convergence Projects:
How can (you)/(this) help (you)?

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HealthforAnimals Regulatory Strategy Team

- Benchmarking Survey

  Where do you want to be in the benchmark?

- Good Regulatory Practices resource at www.vetmed.world.com

  What can we pick up from other agencies?

- Data protection / data exclusivity communication toolkit

  Essential for all innovation and therefore for all companies, innovator and/or generic

  - Ensure the confidentiality of subm
    (for Authorities) on data confidentiality and data security

- The Essentials of Pharmacovigila

  Will you introduce PV?
  Do you want to enhance the basic requirements?

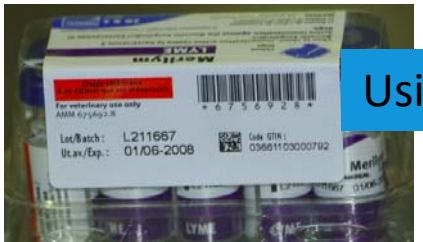
- Harmonised dossier content - regional templates

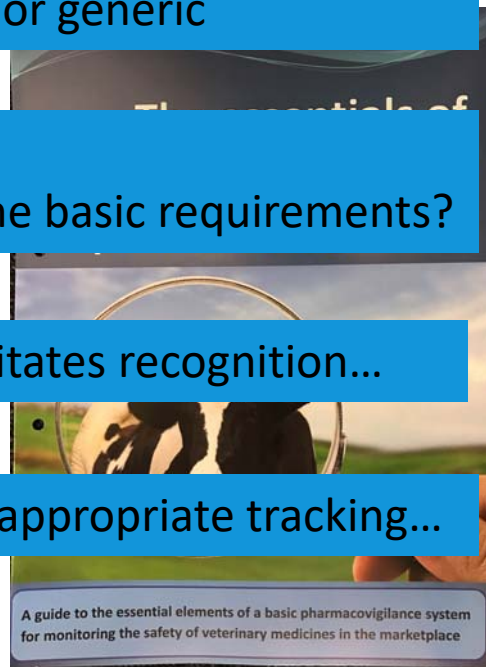
  Adhering to templates facilitates recognition…

- Industry harmonised approach t

  Using a global solution for appropriate tracking…

  - 2-D data matrix





Regulatory Convergence Summary

Health for Animals
global animal medicines association

- Problem Definition
- A vision and a 10 point action plan
- How are we contributing further…
  - Helping to map the current global regulatory situation
  - Partnerships and VICH
    - Harmonizing guidelines
    - Conferences, workshops, …
  - Toolkits
    - Data protection and data exclusivity
    - Pharmacoviglance
    - Harmonised dossier content
    - Harmonised identification via 2D Data Matrix
  - VetMed.world website
    - Collecting global regulatory resources
    - Including examples of “Good Regulatory Practice”

End

Thank you