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VICH 6

The Importance of Global Regulatory Convergence

Dr. Alexander Boettner, MSD Animal Health
On behalf of HealthforAnimals
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MSD Animal Health

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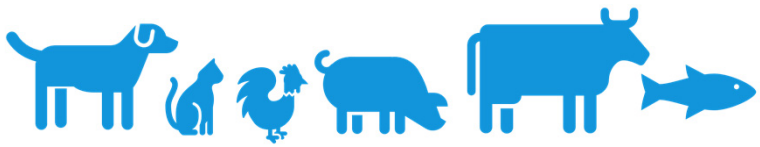

Our Network

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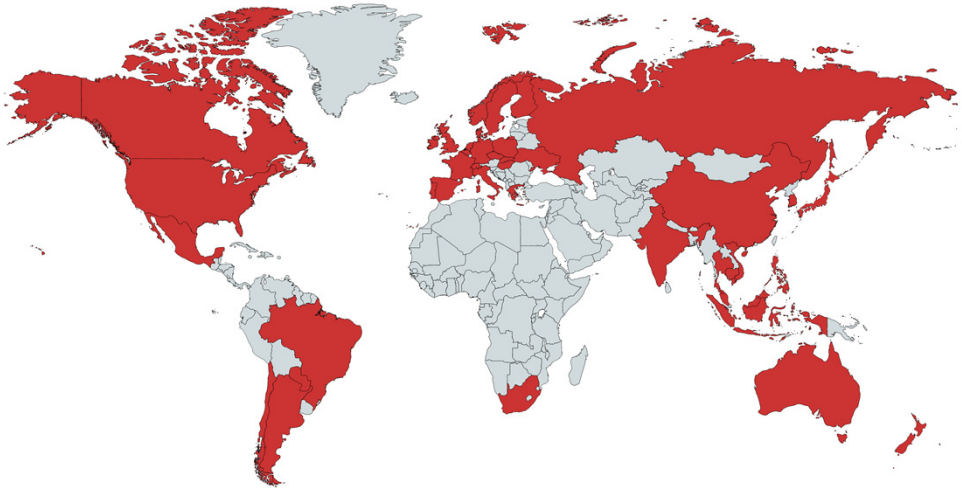
28 Regional & National Associations
Working in **40 countries**



Nine Largest Animal Health Companies
Working in **140+ countries**

zoetis

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Boehringer Ingelheim

Elanco

Ceva

vetoquinol
ACHIEVE MORE TOGETHER

BAYER

Virbac

Phibro
ANIMAL HEALTH CORPORATION

Global Industry Environment

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- Highly regulated industry
- Socio-economic and political aspects have high impact, tendency to increase! (AMR, animal production & welfare, social media, environment, climate change)
- Economics of animal production are the major driver in livestock
- Pet owner growing expectations and health demands (oncology, geriatrics)
- Small market size, highly fragmented (multiple species) and cost sensitive (livestock production)
- Global development projects vs. Differing country/regions requirements

What is Regulatory Convergence

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- Aggregation,
- Collection,
- Grouping,
- Assembly,
- Concurrence,
- Merging,

of all regulatory aspects into a structured framework (legal documents and systems)

which operates by standard procedures and

follows scientific, ethical and administrative requirements.

What is Regulatory Convergence ctd.

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- Harmonised regulatory systems including databases (e.g. PV)
- Harmonised regulatory requirements (VICH)
- Global dossiers
- Uniform gateways for global data rooms
- Standard regulatory procedures (Good Regulatory Practice)
- Predictability (e.g. review and approval timelines, market access)
- Science-based assessments and decisions
- Transparency

What would be the benefits

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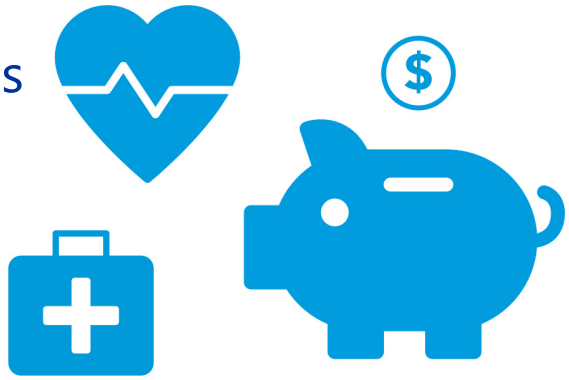
- Efficient regulatory operations
- Safe and effective veterinary medicines of high quality
- Globally available veterinary medicines
- Improves animal health and welfare
- Facilitates productive, sustainable and efficient ways to grow food
- It avoids added costs (e.g. repetition of studies and waste of regulatory resources)
- It facilitates novel therapies and new science (needs proactive flexibility from, and communications between regulators)
- It potentially makes secondary markets viable



Industry Projects & Initiatives

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- Initiated Global Regulatory Vision (supported by a 10-point plan)
- Organised Global Animal Health Conferences and workshops
- Supports VICH workshops, OIE focal point training, CAMEVET, ASEAN workshops, etc.
- Created global resource site www.vetmed.world
- Partnerships (OIE, World Bank, Bill & Melinda Gates Foundation, GALVmed, Regulatory agencies)
- Provides materials / brochures / guidance (e.g. illegal and counterfeit medicines report, the essentials of Pharmacovigilance, promotes harmonised bar coding – 2D data matrix system)

Industry Global Vision for Regulation 2025

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

10-point plan:

1. Science based decisions (no differentiation for local/global companies)
2. Predictable timeframes – max 24 months new products, max 12 months 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
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

Find the Vision and 10 point plan here: https://www.healthforanimals.org/resources-and-events/resources/publications/158:vision-for-regulation-of-veterinary-medicines-across-the-world.html

Global Conferences & Workshops

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Vetmed.world

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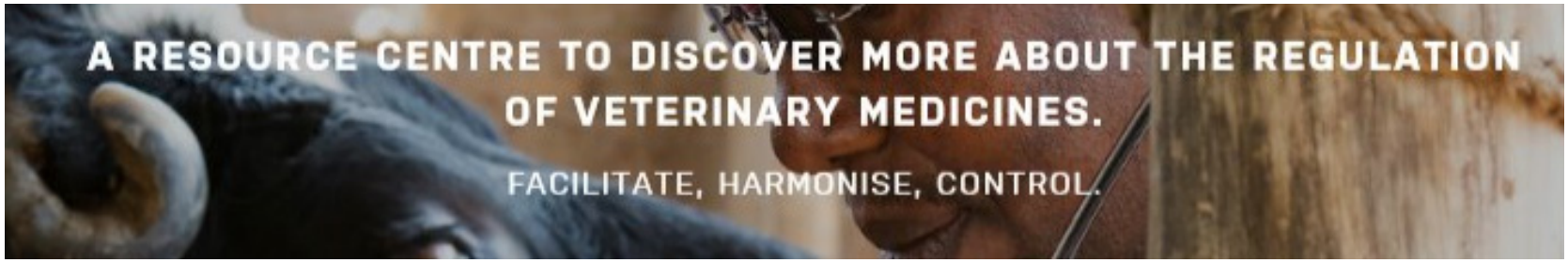
HARMONISING VETERINARY MEDICINES REGISTRATION



GUIDELINES * VIDEOS * TRAININGS * BEST PRACTICES * TEMPLATES * SEARCHABLE

https://vetmed.world/

Importance of Partnerships

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- Partner with other credible reputable organisations
- Non-profit, NGOs or governments
  - OIE
  - World Bank
  - Bill & Melinda Gates Foundation
  - GALVmed
  - Regulatory agencies

Surveys

Conferences
Workshops

Training events

Regional
initiatives

World Bank, OECD

- **Global Benchmarking points to big differences between regions**

- **Significant trade cost of regulatory divergence (OECD 2017)**

Materials, Brochures & Guidance

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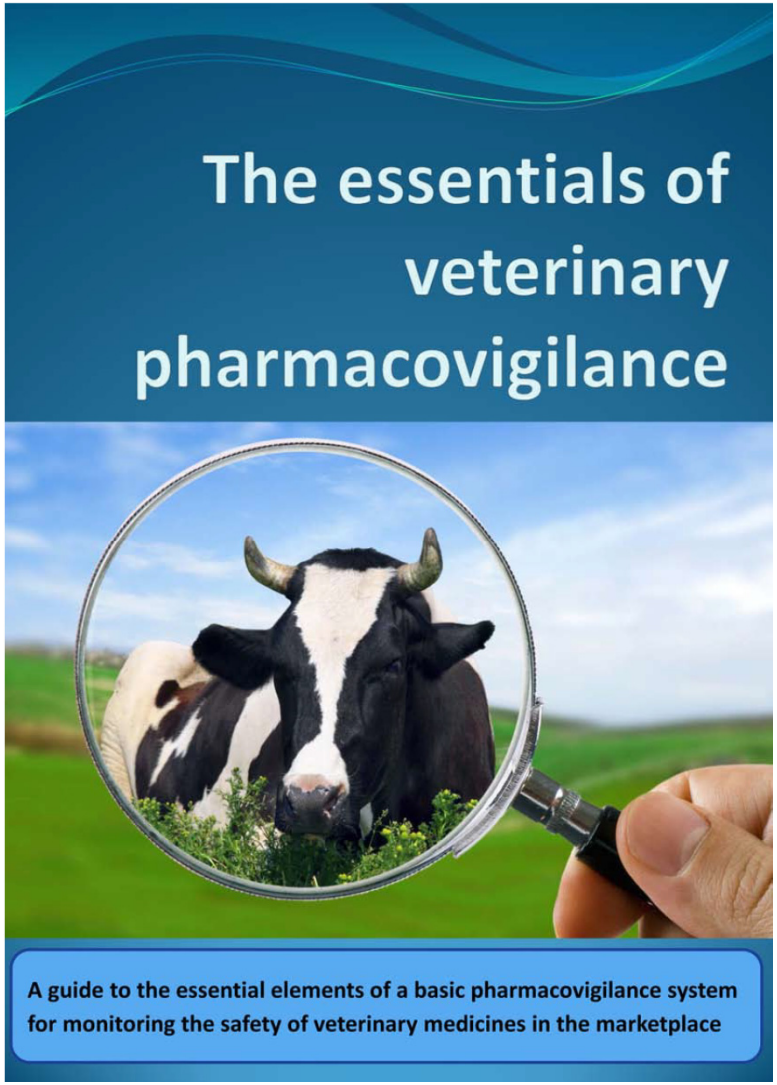
Example – Illegal medicines

- Identifying the problem
- Proposing solutions



Short- to mid-term objectives

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- Global, harmonized pharmacovigilance system and inspection criteria
- Harmonised inspection systems, e.g. more vet agency involvement in PIC/S and a special workgroup (PIC/S Vet)
- More VICH guidelines
- Regulatory authority network and work-sharing
- Joint assessments and mutual recognition standards
- Regulatory expert network, centres of excellence
- More communication, outreach, co-operation and exchange between key stakeholders
- Manufacturing possible anywhere in world to same set of standards
- Good Regulatory Practices

Long-term objectives

- Globally harmonised requirements
- Globally harmonised dossier formats
- Global electronic gateways and data rooms
- Global electronic access to dossiers

Our vision is to have globally acceptable and mutually recognisable marketing authorisations.

Our Challenges

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- Countries are increasing their regulatory requirements
- Reluctance of authorities to change
- Regional and global politics (trade barriers & tariffs)
- Rapid responses and decisions required (emerging diseases) in a traditionally slow moving, highly regulated environment

- Contradictory national requirements preventing regulatory convergence

Conclusions

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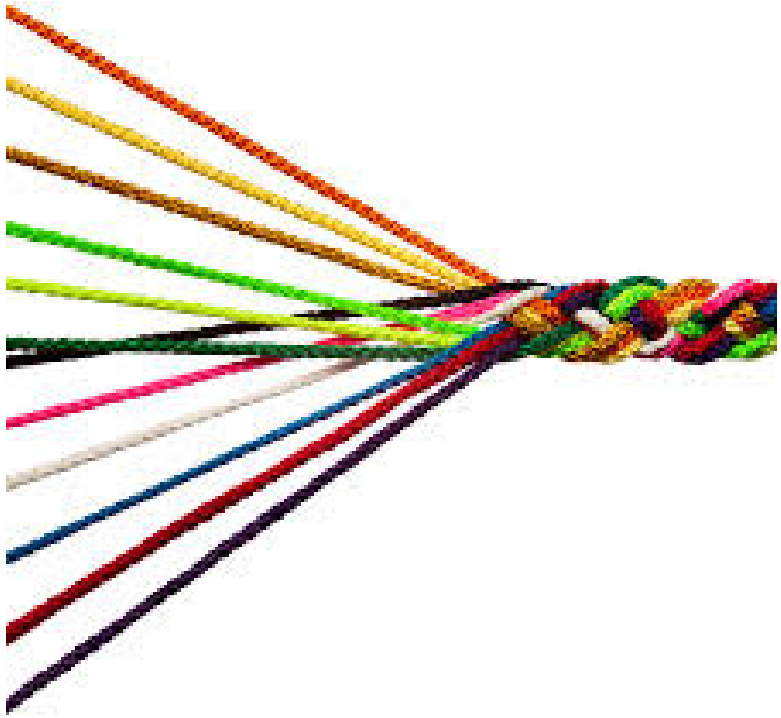
- The exercise is worth the effort
- We have a long way ahead of us
- We need to set realistic goals and have a stepwise approach in the direction of the ultimate goal
- VICH is an important part of the process



Thank you