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Trends in regional and global regulatory convergence

MEVMAS Conference , 7 February 2022

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Regulatory convergence / harmonization

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Regulatory convergence/harmonization is the convergence of all regulatory aspects - initial registration, variations, pharmacovigilance, etc.

Ultimate goal: single package of studies, single dossier format, common approval outcome and common management following authorization
Realistic goal: stepwise but continuous movement in that direction

Regulatory convergence / harmonization

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Converged regulatory regimes = benefits for authorities, sponsors, users:

- Improved predictability
- Cross learning between authorities
- Efficient resource use for all
- Enhanced compliance
- Better access to smaller markets
- Reduce average time to market
- Better availability of innovative products

Vision and core elements

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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 animal health products for as many as possible.

Core elements of an efficient regulatory system

1. authorization decisions are science-based
2. no differentiation between local and other manufacturers
3. predictable regulatory timeframes
4. ability to locate manufacturing anywhere operating to a single set of standards
5. fair return on investment for innovation
6. more countries/regions co-operating on core assessment of the same product
7. regulatory frameworks which can manage innovative products/new technologies
8. ability for companies to undertake global product developments
9. single system of pharmacovigilance for the same product

NOTE: 6-9 benefit from cooperation and coordination with others.

healthforanimals-global-regulatory-vision.pdf

Five trends in regulatory convergence

Trend 1
Continued success of global initiatives

Trend 2
Increasingly active regional initiatives

Trend 3
Different models for different regions

Trend 4
More resource/interest for harmonization

Trend 5
Increasing support from veterinarians

Trend 1: Continued success of global initiatives

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International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

- since 1995, harmonize technical requirements for data necessary for marketing authorisation of veterinary medicinal products
  - Core: EU, USA, Japan: governments + industry
  - Observers: Australia, New Zealand, Canada, South Africa
  - Outreach Forum: 25+ countries

- produced 59 Guidances: legal requirement to apply by core members

- 2019 assessment: global interest to apply VICH guidelines (full or in-part)

- Outreach Forum open to all countries, all documents publicly accessible

Trend 1: Continued success of global initiatives

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OIE actions

- promoting convergence, supportive of VICH
- develops global standards for veterinary products
- trains 100s national focal points re veterinary products

FAO vaccine prequalification

- for FAST diseases (FMD+similar transboundary animal diseases) initially
- list of vaccines which have met requirements (not a regulatory process)
- procedure in place by 2023

Trend 2: Increasingly active regional initiatives

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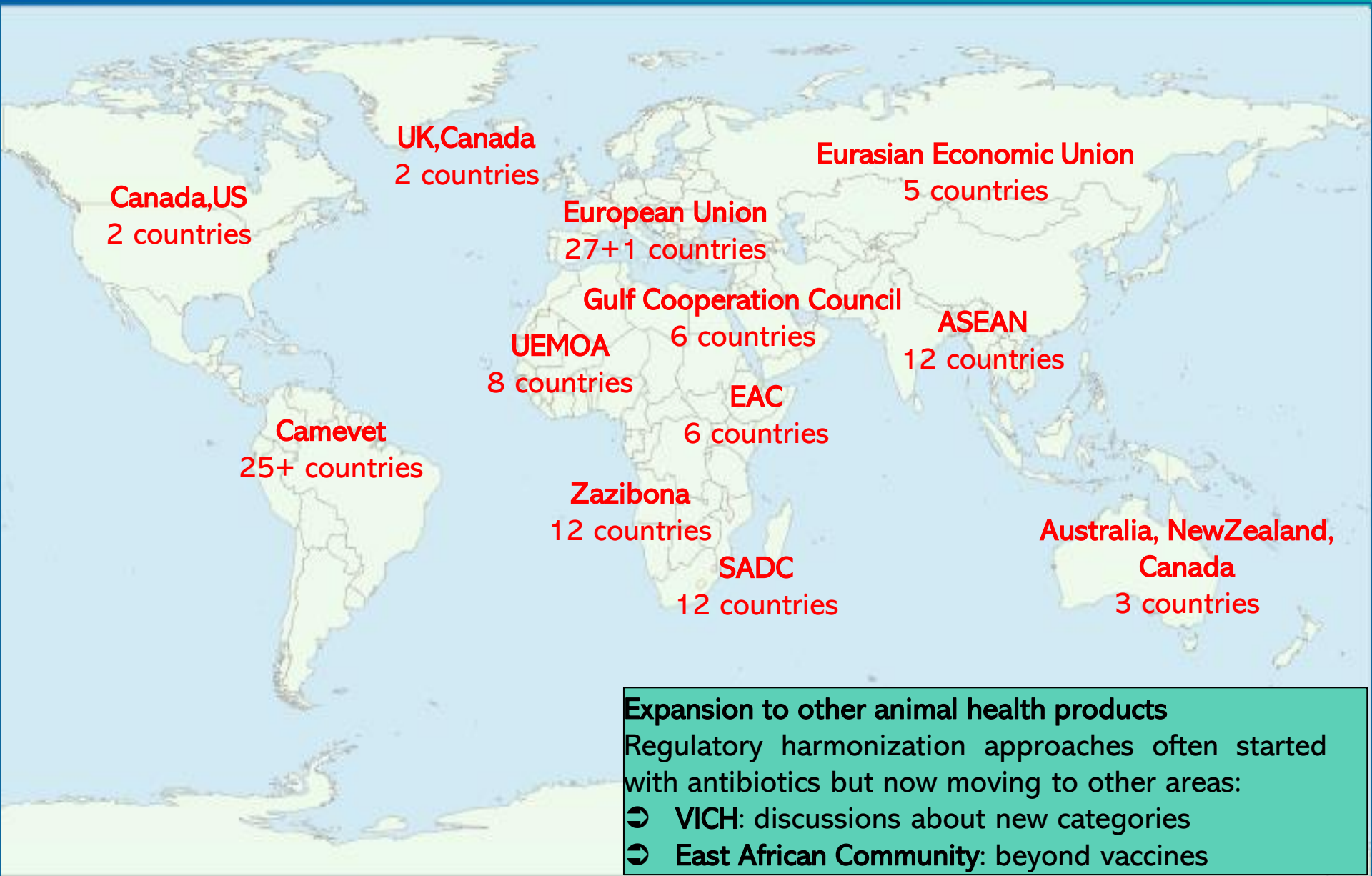

Expansion to other animal health products

Regulatory harmonization approaches often started with antibiotics but now moving to other areas:

- **VICH**: discussions about new categories
- **East African Community**: beyond vaccines

Trend 2: Increasingly active regional initiatives

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Lessons learned: what is needed to make mutual recognition work?

1. Common set of technical registration requirements

2. Registration Procedure: defined and common understanding of how MRP or central coordination will be applied

3. Political will & legal framework to operate: existing supranational body/ organization/forum & national laws to be adapted

4. Implementation: need for coordinated, practical, hands-on, step-by-step guidance

Interest from many regions for regional common dossier structure or a global dossier structure.

Trend 3: Different models work for different regions

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Centralized systems

- Where one central authority manages + approves authorization for multiple countries
- EU (1995), UEMOA (2009) – results in a single authorisation for the region

Mutual recognition

- Where multiple countries cooperate to mutually perform an authorization process
- Results in a set of aligned national authorisations
- EAC (2016) and ASEAN, Zazibona, SADC, EAEU are building

Formal regulatory cooperation

- Close cooperation agreements between regulatory departments
- Based on written agreements, VICH guidances often used
- US+Canada; Australia+New Zealand+Canada; United Kingdom+Canada

NEW: UK VMD led initiatives

- SSA - single online submission portal and application form
- Recognizes value of regional approaches
- BMGF support

Trend 4: More interest + resources for harmonization

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Increasing number of initiatives in most regions

- VICH meetings and trainings – several per year
- UEMOA workshop - January 2022
- EAC workshops – 2 in 2021
- UK VMD African Regional Conferences – 4 in 2022

Increasing support from donors/others

- BMGF actively supporting regulatory harmonization for many years
- GALVmed dedicated efforts
- UK VMD efforts for SSA
- World Bank/OECD supportive

Increasing engagement by companies

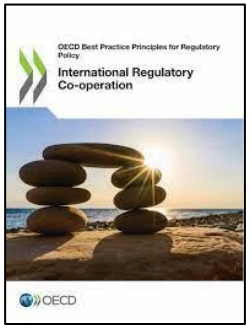
- Many major companies increasing product availability in more harmonized regions
- Most major companies are engaged in harmonization and convergence projects
- Global industry and national federations supportive and engaged

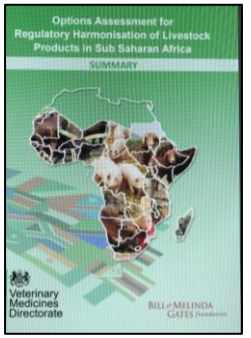
Increasingly learnings from other efforts accessible

vetmed.world
HARMONISING VETERINARY MEDICINES REGISTRATION

VICH

SMArt Safe Medicines for Animals through regulatory training





Trend 5: Increasing support from vet community

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Strongly supports regulatory harmonization

Representing public sector veterinarians

"….the approval process is duplicated in various regions and/or countries…. presents an unnecessary regulatory hurdle that undermines broader availability of licensed veterinary medicines ….Regulatory convergence & harmonization between regions and/or countries should be explored and enacted…."

WSAVA Global Veterinary Community

WORLD VETERINARY ASSOCIATION

Federation of European Companion Animal Veterinary Associations
Commonwealth Veterinary Association
Federación Iberoamericana de Asociaciones Veterinarias de Animales de Compañía
Federation of Asian Small Animal Veterinary Associations
Federation of Veterinarians of Europe
Fédération des Associations Francophones Vétérinaires pour Animaux de Compagnie
Caribbean Veterinary Medical
Federation of Asian Veterinary Association

Represents 1+ million private sector veterinarians

Action for Animal Health

Call on governments: *"...support the international harmonisation of regulatory approaches to veterinary medicines…"*

Represents global coalition of animal health NGOs

Links and resources

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VICH: harmonising technical requirements for veterinary product registration
https://www.vichsec.org/en/

VetMed.world (Harmonized veterinary medicine registration: examples + good practices)
https://vetmed.world/

OECD Regulatory cooperation best practices
https://www.oecd.org/gov/regulatory-policy/international-regulatory-cooperation-best-practice-principles.pdf

VMD: Options assessment for regulatory harmonization of livestock products
VMDhttps://www.vmd.defra.gov.uk/online/SSA/SSA_Options_Assessment_-_Summary_Report.pdf

SMART (Safe medicine for animals through regulatory training)
https://smart-org.uk/