

EMA – Regulatory Science to 2025

Session I: Challenges and opportunities across the regulatory framework View from veterinarians

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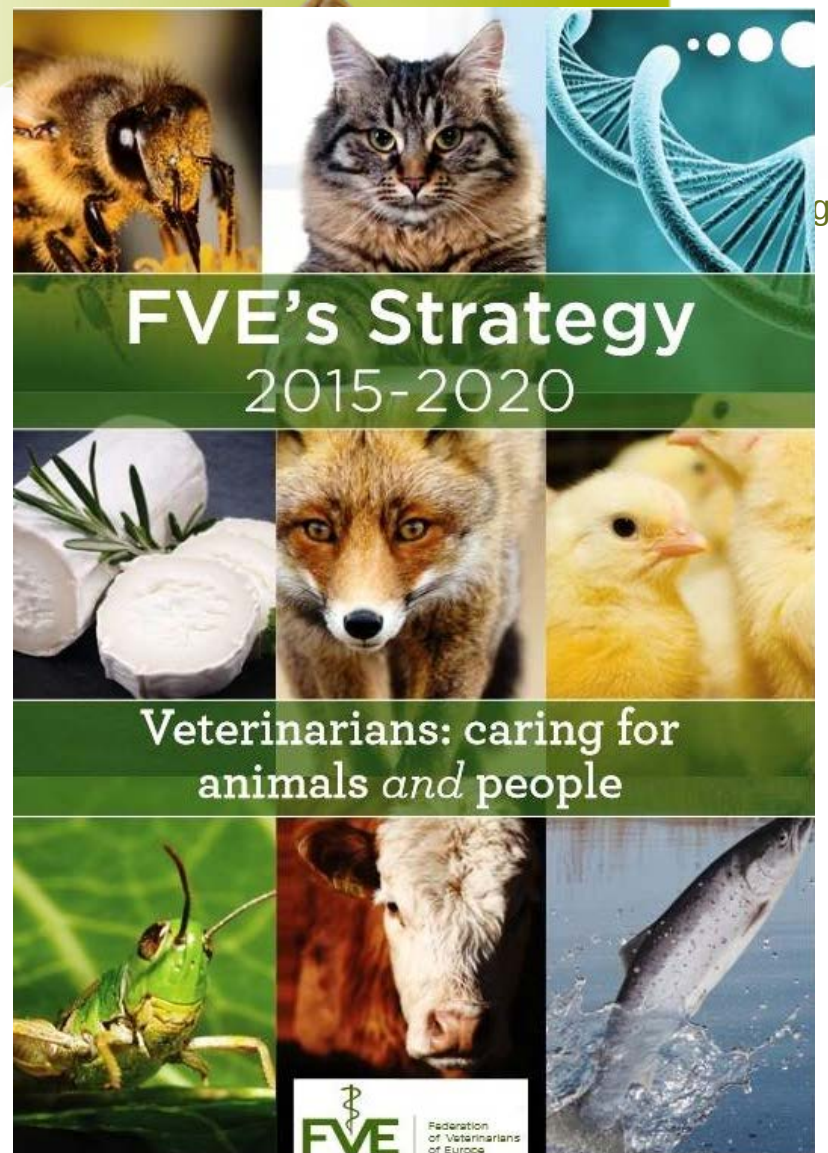


Federation of
Veterinarians of Europe



FVE's mission

The European veterinary profession, embodied by FVE, strives to **enhance animal health, animal welfare, public health and protect the environment** by promoting the veterinary profession.



48 national associations

39 European countries

The veterinary landscape is drastically changing



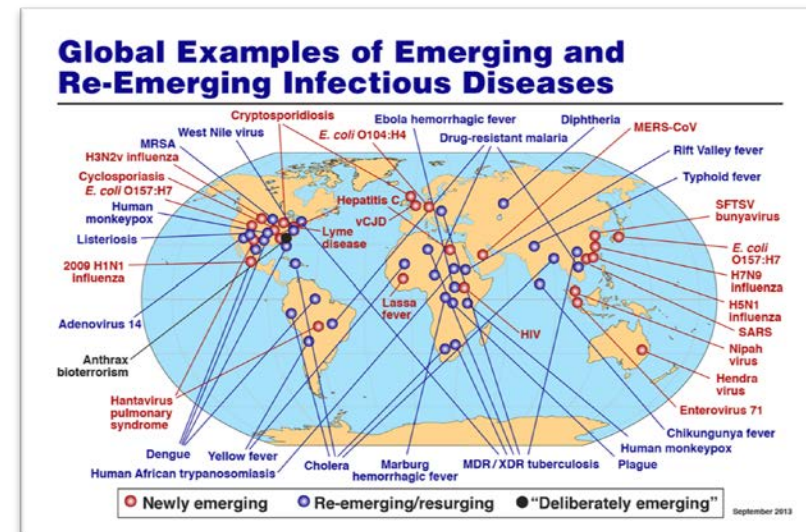
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Coorporatisation

Climate change and (re-) emerging diseases

PREVENTION
IS BETTER
THAN CURE



Challenges foreseen for Regulatory Science



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- How to merge world of regulators and veterinary practice?
- How to ensure animal and public health needs are satisfied, not just commercially interesting products developed?
- How to ensure regulation keeps pace with innovation and new technology?
- How to balance scientific evidence and societal pressure?



The world of regulators and veterinary practice needs solid collaboration



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- Veterinarians oath: *'prevent and relief animal suffering'*
- What if no effective product is available?
- SPC: recommendation or obligation? Professional judgement?



- ✓ Risk/benefit analysis
- ✓ Increased collaboration between practitioners, industry and legislators (example FishMedPlus)



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Commercially less attractive products can be developed

- Investment costs too high for industry to justify research certain products e.g. MUMS/limited markets
- Climate change leads to (re-)emerging diseases -) need to rapidly act



- Regularly monitor availability gaps
- Forecast emerging diseases
- True single market
- Retain strategy to address availability challenge (e.g. EMA MUMS policy, Availability task force, etc)
- Develop strong network with academia and research (e.g. JPI to address veterinary medicine gaps)
- Mimic human initiatives?

Regulation must keep up with innovation and new technology



- Big data and new technologies will impact future veterinary medicine (e.g. Biologicals, innovative medicines, pen-side diagnostics, AI, telemedicine, etc)



- Continue ADVENT, Innovation Task Force
- Continue collaboration with other regulatory authorities
- Ensure availability expertise
- Ensure societal understanding & acceptance new technology
- Ensure flexibility regulatory framework



Scientific evidence and societal pressure can be balanced by building public trust



- Anti-vaccine movement, fake news, dr. google, ...
- How to dispel myths like 'antibiotic use in animals is the highest contributor to AMR in people'



- Continue to ensure scientific excellence without being blind to societal needs
- Communication openly and promptly, ensure transparency to foster trust
- Engage further with civil society



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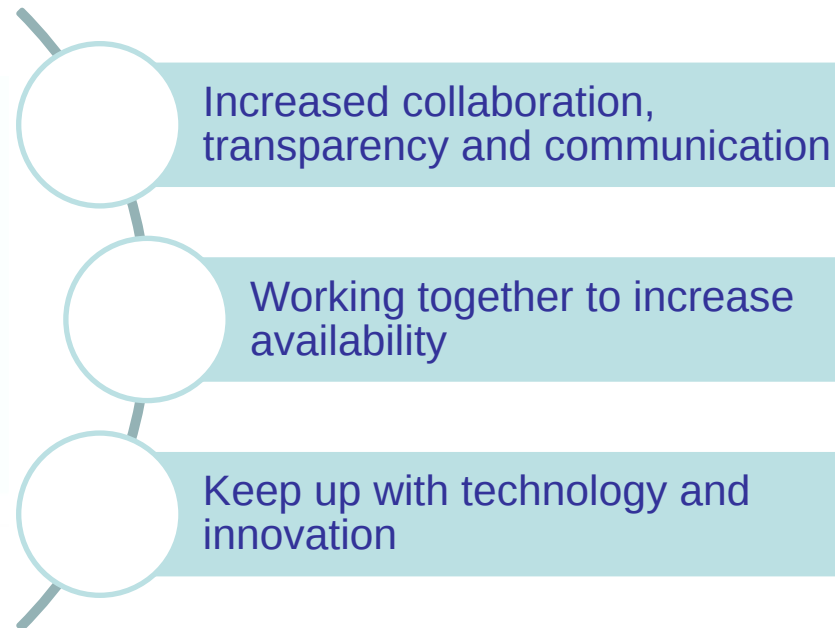
To foster **scientific excellence and societal trust** in the regulation of veterinary **medical products** ~~medicines~~ for the **benefit of animal and public health** while **facilitating and promoting innovation and access to (novel) medicinal products**.



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Do not fix, what ain't broken

Just tweak it to make it future proof....



And resources to do this....

THANK YOU !



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