



EMA Regulatory Science Strategy Challenges and Opportunities across the European Regulatory Framework

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Agenda

- Environment
- Challenges
- Opportunities
- Conclusions

The Environment

Regulatory environment in the EU

- Highly regulated framework
- More progress needed for risk based assessments
- Well functioning but resource constraints, opportunities of NVR must be utilised!
- Dialogue is key and should be expanded

Major influencers & challenges:

- Socio-economic and political aspects have high impact, tendency to increase!
(AMR, animal production & welfare, social media, environment, climate change)

Major driver:

- Economics of animal production (livestock)
- Common agriculture policy
- Pet owner growing expectations and health demands (oncology, geriatrics)

Major constraint on innovation:

- Small market size, highly fragmented (multiple spp) and cost sensitive (agri)
- Political/public attitudes towards new technologies (risk aversion)
- Global development projects vs. differing country/regions requirements

The Challenges

- Modern production systems, socio-economic factors and environmental aspects will continue to be a major driver of changes in livestock production
- More complex animal health needs are likely to evolve from there (e.g. antimicrobial alternatives, herd health optimization, adaption to climate change, food safety)
- Emerging diseases require rapid responses (vaccines, novel therapies)
- Non proportionate regulatory constraints can halt new product developments (e.g. REACH, MRLs and excipients, ERA requirements)
- Regulatory uncertainty for new technologies/innovative product developments
- Political attitudes and public acceptance towards new technologies (risk aversion)

The Opportunities

- High regulatory standards should be maintained but have to become more „suitably adapted“
 - Risk benefit vs. „worst-case“
 - Consistent application of benefit-risk assessment
 - Regulatory opportunities for new technologies (early dialogue, requirements)
 - Adjust requirements to needs (e.g. sterility test for oral vaccines, monoclonal antibodies)
 - Enable more tailored, regulatory provisions (e.g. proof of clinical efficacy)
- Dialogue and co-ordinated exchange
 - Efficient and timely co-ordinated advice with regulatory authorities
 - More expert networking including industry expertise, global expert panels etc.
 - New technologies, avoid the need for future regulatory convergence, alignment from the start

The Opportunities (ctd.)

- Regulatory science will advance and will require new disciplines
 - Epidemiology
 - Databases and information technology experts
 - Risk assessor vs. hazard assessor
 - Modelling tools (in-vitro / in silico vs. in-vivo models)
- Vaccine readiness and availability
 - Pre-approved versatile production platforms
 - Accelerated regulatory approval processes (e.g. multi-strain dossiers, antigen master files)
 - More pragmatic approach (field efficacy only when needed, serology as surrogate of efficacy, efficacy at “herd” level)

The Opportunities (ctd.)

- PPHOVA / SmPC harmonisation
 - Utilize existing knowledge and act pragmatically
 - More expertise needed (modelling tools)
- Conditional licensing / limited markets and exceptional circumstances
- Annex II of the new veterinary regulation
 - Fit for purpose
 - Provisions required for new technologies and the „unknown“
 - Opportunity should not be missed despite various constraints
- Utilize high EMA reputation and international profile for
 - Regulatory convergence
 - Reduction of administrative burden
 - Coordinated exchange



Conclusions

- Regulatory science strategy initiative is an excellent starting point to shape the future regulatory environment
- Today workshop must be a start for further exchanges; more work needs to be done before finalisation
- High, science based regulatory standards should foster innovation and medicines availability
- Major challenges and opportunities ahead
- Challenges can become opportunities and vice versa!

Thank You

