Association of Veterinary Consultants

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# EMA Regulatory Science to 2025 Public Consultation Veterinary Stakeholders Workshop: Session 2

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- **Transform the regulatory framework for innovative veterinary medicines**
- **Reinforce and further embed 3Rs**
- **Facilitate implementation of novel manufacturing models**

# Transform the regulatory framework for innovative VMPs

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- "Reliable" Guidance to 'novel therapy veterinary medicinal product' as defined in the New Regulation:
  - (a) a VMP specifically designed for gene therapy, regenerative medicine, tissue engineering, blood product therapy, phage therapy;
  - (b) a veterinary medicinal product issued from nanotechnologies; or
  - (c) any other therapy which is considered as a nascent field in veterinary medicine;
- Keep flexibility for the unknown as far as possible; apply the principles, but keep flexible; provide binding (for authorities) guidance where possible
- Assure consistency and predictability of CVMP and EC decisions
- Support new concepts: medicated feed for pets, new claims (incl. non-medicinal claims on top of medicinal), platform technologies for vaccines

# Reinforce and further embed 3Rs

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- **Full support for „pre-clinical“ work:** why still tox testing for VMP, when data already available to Competent Authorities (Actives used also as Human Med, biocide, CropProt)
- **Fully supported for batch release tests:** replace by GMP compliant in-vitro tests
- **Concerned:** Misvalue of the benefits of „Clinical Studies“ in new Reg.
  - New regulation states, that clinical field studies should use **minimum** number of animals as possible
  - However, purpose is to show „representative“efficacy and safety in EU
  - Although **clinical field studies** are outside the sope of Directive 2010/63, Increasing challenge to get test permits as NCA apply Directive 2010/63 in many cases, as soon as neg. controlled, multiple blood samples, certain „new“ claims, pain involved: cannot test for „serious pain“, as no ethical approval!)
  - Should we rather have a minimum number of animals to be tested in the field to assure representative efficacy (and safety) evaluation?

# Facilitate implementation of novel manufacturing models

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- Learn and accept from other sides (e.g. Human Med Products)
- Be open for new approaches to be translated into GMP: production of APIs in new environments (e.g. larvae; mammals; technological developments like printers, batch control?)
- As we cannot foresee the future, need to provide flexibility while adhering to the principles