EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Transform the regulatory framework for innovative veterinary medicines

Underlying actions

EMA's Regulatory Science Strategy to 2025 – Veterinary Stakeholder Workshop

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Transform the regulatory framework for innovative veterinary medicines

- Draft an annex to the new veterinary legislation that defines proportionate and future-proofed technical standards for novel veterinary therapies, particularly biologicals
- Develop standards for novel therapies and the promotion of new endpoints for the evaluation of efficacy
- Strengthen support to industry throughout the development lifecycle of novel therapies
- Contribute to, and share resources with, the human domain in the area of novel therapies, such as the approach to assessment of cell therapies, monoclonal antibodies, etc.
- Increase EU network capacity and capability in novel therapies drawing on knowledge and training from human experience.

High level concerns/recommendations

- Define future-proofed technical standards for novel veterinary therapies (particularly biologicals), as a flexible framework which enables innovation
- Promotion of new endpoints for the evaluation of efficacy to allow flexibility and harmonisation
- Support to industry throughout the development/authorisation of novel therapies (flexibility and fast outcome)
- Collaborate with the human domain in the area of novel therapies
- Increase EU network capacity and capability in novel therapies

Draft an annex to the new veterinary legislation that defines proportionate and future-proofed technical standards for novel veterinary therapies, particularly biologicals (1)

- Further support for the ongoing activities concerning innovative veterinary medicines in the new regulation is required in order to achieve the final adoption of the proposals. In addition, the development of accompanying guidelines should commence as soon as possible which requires re-activating the work of the working parties and possibly also alterations to their respective work plans.

- It will be necessary to ensure that the new regulatory environment is applied in a timely manner. To this end, priority to investments in new research for innovative drugs at national and European level should be provided through specific programs.

Draft an annex to the new veterinary legislation that defines proportionate and future-proofed technical standards for novel veterinary therapies, particularly biologicals (2)

- Rather than providing rigid standards that could ultimately block/delay innovation, the annex should provide a framework which is to be supplemented by guidance as appropriate. This guidance can propose proportionate technical standards, which in turn would be easier to update as the knowledge base increases and as such, would ensure that standards can and will be future-proofed.
- Besides the basic EU legislation (i.e. new Veterinary Medicines Regulation), to envisage for a side-by-side very flexible and rapid guideline system in place to allow quick reaction towards emerging and new technologies - so as not to depend on changes in the core regulations.

Draft an annex to the new veterinary legislation that defines proportionate and future-proofed technical standards for novel veterinary therapies, particularly biologicals (3)

- A sustainable regulatory system is not included; need to focus on improving what we have, not only on new challenges.

- Ensure communication, quick interaction and liaison with industry in order to develop and implement on a timely manner the required regulatory guidelines that would be required for novel therapies.

Develop standards for novel therapies and the promotion of new endpoints for the evaluation of efficacy

- Need for regulatory qualification of biomarkers by early engagement with biomarker developers.
- Avoid divergent standards, cooperation with standard setting organisations should be advanced e.g. European Pharmacopeia, WHO (h) and OIE (v).
- "That is the way to use 3 Rs principles".

Strengthen support to industry throughout the development lifecycle of novel therapies

- Scientific Advice, and even IFT, can be too structured – we need more flexible mechanisms for regulators to engage with industry in discussing innovation in all aspects.

- The administrative burden from scientific advice and the long pre- and post- meeting administrative procedures should be better addressed. Fast track licencing should also shorten the administrative time as well as the scientific assessment.

Contribute to, and share resources with, the human domain in the area of novel therapies, such as the approach to assessment of cell therapies, monoclonal antibodies, etc.

- Administrative and scientific preparedness for emerging health threats, GMOs and nanomedicines needs to be enhanced.

Increase EU network capacity and capability in novel therapies drawing on knowledge and training from human experience.

- The implementation of the RSS was described to be a network/NCA effort as the expertise and capacity of EMA for scientific assessment lies there.

- The RSS should not solely focus on innovation but also address challenges for the network; recommendations and actions related to NCA activities should be aligned with NCAs.

Other considerations received

- Collaboration with academia was found important for research and innovation in the regulatory framework.

- In many places there is reference to collaboration with academia; the strategy should not overlook that in many new scientific areas the experts lie within companies, particularly when considering the practical application of a new technology. Therefore the strategy should include more reference to finding ways to engage also with industry experts.

Other considerations received

- Every reference to novel therapies or novel VMPs should be expanded to "novel therapies and novel approaches to existing technologies"; this includes novel approaches to manufacturing both novel and more classical therapies, and novel approaches to clinical endpoints. A "novel" approach to benefit-risk assessment could also be required for certain novel therapies.

- The training of assessors and politicians is of high importance to increase acceptance of new products, techniques, non-animal tests of final batches etc.

Any questions?

Further information

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