Impact of future legislation on availability

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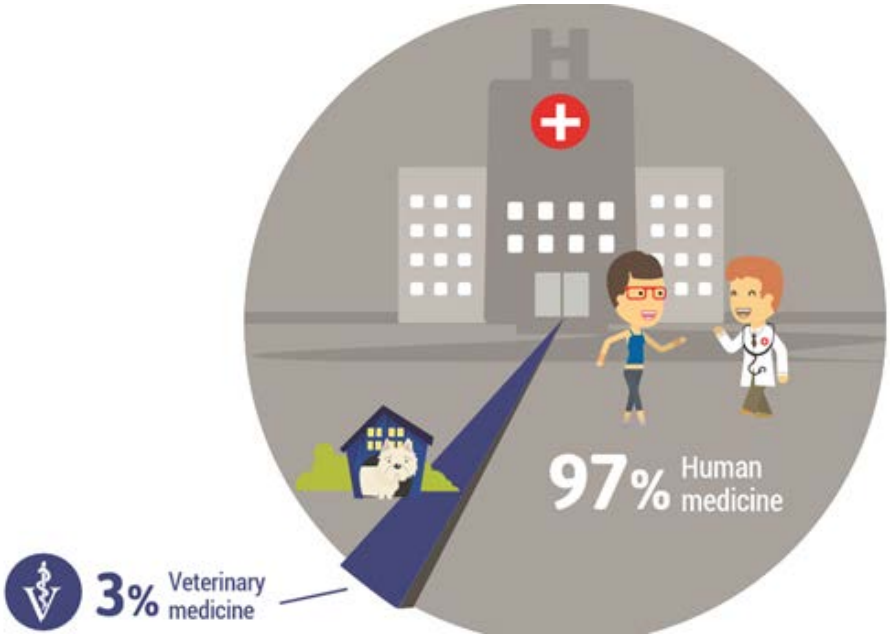
Veterinary Sector

- Need to develop medicines for a wide range of animals: specific veterinary products and different routes of administration



Current situation

- General agreement of the need to improve the availability of veterinary medicines in the EU:
  - The situation differs between Member States.
  - Particularly for “minor uses” & “minor species”
  - Less use of VMPs following the exceptional prescription system or off-label use
- ***FVE quote: “without a good range of medicines, veterinarians face great difficulties in solving animal health and welfare issues”.***
- Need to work also on the basis for alternatives therapies (new cellular therapy, etc.).
- Do we know the gaps/need in Europe? Some work have been done:

DISCONTOOLS

The database includes information relating to 52 significant diseases including key information and gaps identified along with the most important researchers across the globe.

Current situation

Spanish Medicines Agency – Committee for Availability of Veterinary Medicines

Identification & prioritisation of needs in the following species:

- Ovine & caprine
- Aquaculture
- Rabbits
- Horses
- Laying hens
- Honey bees
- Dogs & cats

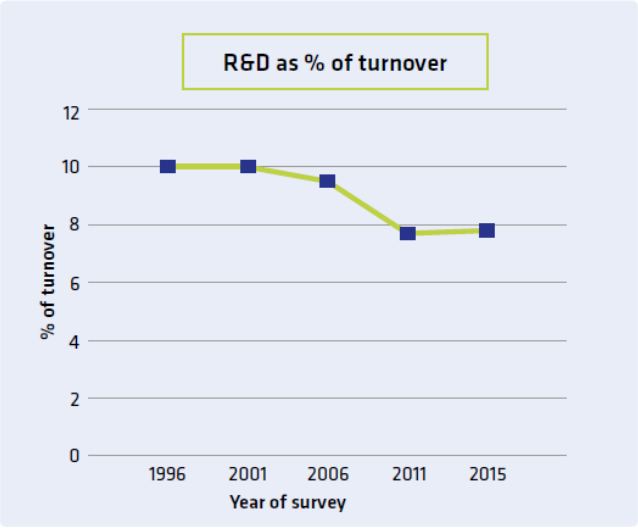
ACUICULTURA

1. Medicamentos de 1ª prioridad.
   - **a.** Antiparasitarios internos frente a: Uronema, Enterospora, Enteromyxum, Cryptosporidium, Myxozoos y Coccidios (pe. Monensina y Amprolio).
   - **b.** Antiparasitarios externos frente a Monogeneas (pe. praziquantel en formas farmacéuticas oral y para baño, mebendazol en formas farmacéuticas para el baño, etc.).
   - **c.** Antiparasitarios externos frente artrópodos (pe: deltametrina, azametifos, etc.).
   - **d.** Antimicrobianos (pe. flumequina, ácido oxolínico, sulfamidas combinadas con otros antibacterianos, neomicina, colistina, etc., en formas farmacéuticas orales y para el baño).
   - **e.** Anestésicos generales (pe. benzocaína, etc.).
   - **f.** Tranquilizantes (pe. isoeugenol, etc.).
   - **g.** Vacunas frente a *Phobacterium danselae*, subsp. *Piscida*.
   - **h.** Vacunas frente a *Listonella anguillarum* .
   - **i.** Vacunas frente a *Vibrio vulnificus*.
   - **j.** Vacunas frente a *Aeromonas hydrophila* y *Aeromonas salmonicida*.
   - **k.** Vacunas frente a Nodavirus.
   - **l.** Vacunas frente a *Pseudomona anguilliseptica*.
   - **m.** Vacuna frente a *Listonella anguillarum*.

Opportunity to improve availability of VMPs

Review of the veterinary medicines legislation in Europe.

- Importance of keeping the review on target
- Goal: Maintaining authorised veterinary medicines & Improving the development of new veterinary medicines



Drop in investment coincides with implementation of the 2004 legislation and negative influencers on investment (such as the 'global MA concept')

Source: Benchmarking survey 2015 IFAH Europe

Opportunity to improve availability of VMPs

Review of the veterinary medicines legislation in Europe.

- How?
  - Future-proof legislation
  - Science based balanced and proportionate benefit risk approach
  - Reducing administrative burden
  - Fostering innovation, driven by protection of technical documentation both in new and existing products
  - Ensuring flexibility for limited markets

Impact of future legislation on availability

- Harmonisation of SmPCs
- Protection of technical documentation
- Antibiotics and ERA
- Authorisation of VMPs, including pharmacovigilance
- Ensure reduced requirements for limited markets and exceptional circumstances
- Exceptional prescription (Cascade)
- EU product database

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Harmonisation of SmPCs

- Ensure that it has a positive effect on veterinary medicines availability
- Re-Assessment should only take place on the basis of serious risk to public health, animal health or the environment.
- Follow a pragmatic and feasible approach
- Option for Marketing Authorisation Holders to include the quality part (Part II) of the dossier.
- Mutual recognition for future changes of harmonised VMPs

Impact of future legislation on availability

Protection of technical documentation

- Measures to improve PTD and therefore new molecules and technologies by:
  - improving the length of the PTD
  - taking out formulation out of the GMA
- Measures to encourage and enable new developments (additional species, new indications, posology, route of administrations, etc.) for existing products
- 5 years protection for significant investments in data generated to improve or maintain an existing product
- Tremendous potential for new technologies and improvements to the veterinary market

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Antibiotics and ERA

- Encourage applying a science based, European wide, benefit-risk approach to tackling antimicrobial resistance and environmental assessments.

- Make sure it continues to apply at the product (not substance or class basis)

Restrictions on antibiotic use Increased requirements to address AMR Increased requirements to address environmental safety	→ Negatively impacts veterinary medicines availability

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Antibiotics and ERA

The impact of specific elements of regulations on the industry's ability to innovate

Top 4 challenges	RHS
1. Environmental risk assessments	-100%
2. Antimicrobial resistance requirements	-58%
3. Protection of technical documentation	-23%
4. Maximum residue limits data requirements	-23%

Source: RHS (relative helpfulness scores) – total percentage of companies regarding a procedure or requirement as helpful or very helpful minus the total regarding it

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Authorisation of VMPs, including pharmacovigilance

- Welcome the opening up of the centralised procedure
- Simplified rules for labelling and packaging → more multi-lingual labels → more product in the small markets
- To maintain the administrative subsequent recognition of MAs by other member states
- MAs with unlimited validity (no renewals)
- No sunset clause → will avoid loss of products that cannot be put on the market temporarily for various reasons
- Call for the reduction of unnecessary and disproportionate administrative burden hampering innovation
- Welcome the drive to modernise current approaches to pharmacovigilance
- Risk based variation procedures. Support the “positive” list for variations i.e. listing those that need assessment.

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Europe IFAH
Representing the European Animal Health Industry

Ensure reduced requirements for limited markets and exceptional circumstances

- Three parts of the dossier: quality, safety and efficacy
- 5 years validity
- Convert into an unlimited authorisation: use pharmacovigilance data
- Should be accompanied by a pragmatic and proportionate implementation and interpretation of the guidelines.
- Milk sheep, laying hens and salmon to be considered “limited markets”

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Representing the European Animal Health Industry

Exceptional prescription (Cascade)

- Necessary tool to allow vets, in exceptional circumstances and under their responsibility, to be able to treat animals in cases where there is a therapeutic gap and to avoid unnecessary suffering.
- The cascade order, however, should favour the use of authorised VMPs (quality, safety and efficacy assessed and approved) and not human medicines or products prepared extemporaneously.
- Ideally the improved PTD should stimulate the licensing of claims that are now off label use

EU product database

- Vets will be able to know the authorised products in the EU – this should help vets find products


Thanks for your attention!