WORKSHOP ON VETERINARY MEDICINES

Improving the availability of antimicrobials and their alternatives

New regulation on veterinary medicines: Opportunities and Challenges for the Animal Health Industry

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Veteterindustria is the Spanish Animal Health Industry Association

95 % animal health products market in Spain

Represents:

- Veterinary medicines: Pharma & Bio
- Additives and other zoosanitary products (diagnostics, hygiene, biocides, etc.).

Member of:

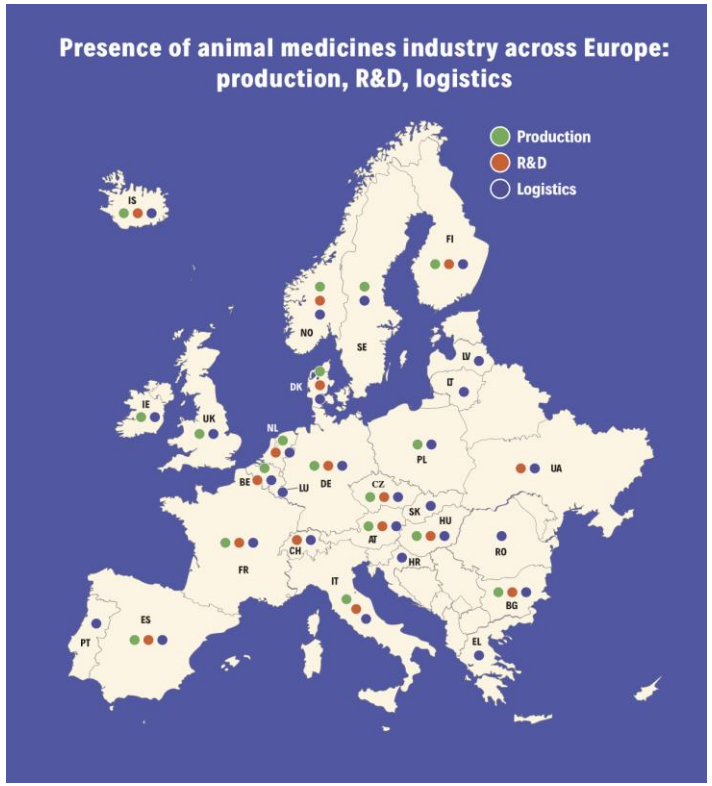
animalhealth europe

Health for Animals
global animal health association

feiQue Federación Empresarial de la Industria Química Española
Web de Formación

ASE BIO

CEOE
Empresas Españolas



Key figures

46 member companies
30 manufacturing sites in the whole country (8 immunological plants)
Average 6% turnover to R&D activities
12 R&D centers
Employment: 3,500 direct and 10,000 indirect
Market value: 1800 M€ (37% export)

Strategic Industry

Public Health

Animal Health & Welfare

Healthy and Sustainable Food

Protection of Environment

Regulation 2019/6 on veterinary medicines

Publication

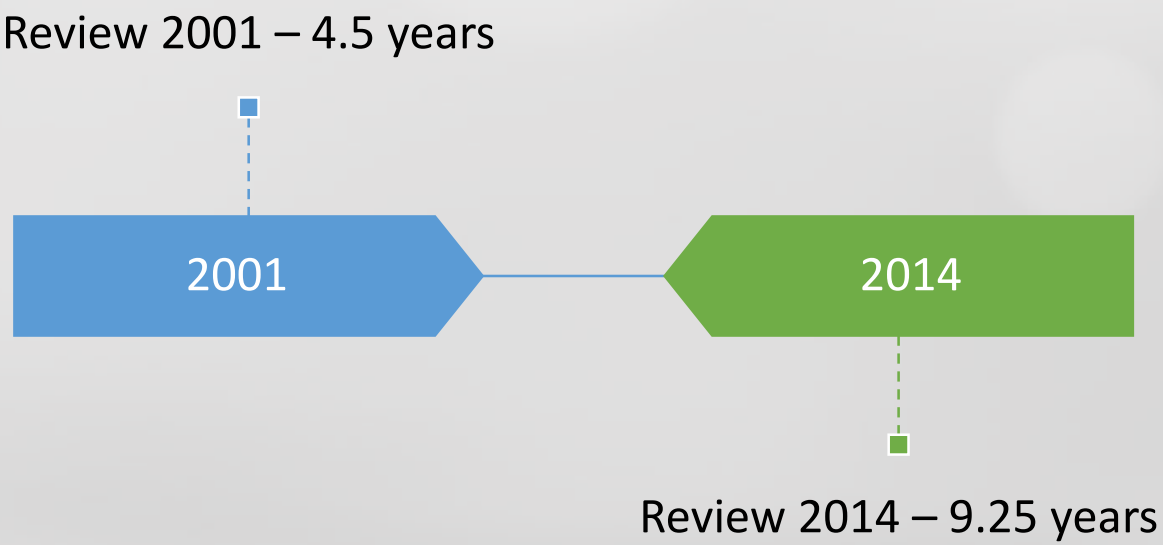
Jan. 2019

28 Jan. 2022

Applicable

Tremendous achievement

All involved must be congratulated



Are we meeting the original objectives?

- Increase availability of veterinary medicines
  - Reduce administrative burden
  - Stimulate competitiveness and innovation
  - Improve the functioning of the internal market
- Address the public health risk of Antimicrobial resistance


SANIDAD ANIMAL

Grupo de trabajo para mejorar la disponibilidad de medicamentos veterinarios y alternativas al uso de antimicrobianos

Es reconocido que en determinados casos y sobre todo para determinadas especies, las denominadas menores, existen muy pocas alternativas terapéuticas. Esto en general, tiene un impacto directo en el desarrollo de resistencias debido, por un lado, a que la falta de disponibilidad de alternativas al uso de antimicrobianos (AM) (por ejemplo, vacunas) no permite la prevención de infecciones, y por otro, que el reducido número de MV que contienen AM disponibles hace que se usen siempre las mismas moléculas, con el consiguiente riesgo de generar resistencias a estas.

Por tanto, para tratar de modificar esta situación se crea el denominado grupo de trabajo para mejorar la disponibilidad de medicamentos veterinarios y alternativas al uso de AM.

Además, muchos de los MV que están en el mercado necesitarán revisarse para adaptarse a la Nueva Legislación Veterinaria (NLV).

En este grupo se trabajará con los representantes de la AEMPS, Comité de disponibilidad, industria farmacéutica y los sectores, con el fin de promocionar y favorecer la disponibilidad de medicamentos veterinarios para todas las especies ganaderas de producción de alimentos y animales de compañía donde se produzca un vacío terapéutico y/o, por ser mercados reducidos, que no dispongan de medicamentos para tratar determinadas enfermedades.

Objetivos

- Fomentar el desarrollo y puesta en el mercado de nuevos MV o la disponibilidad de los ya existentes en otras especies.
- Actualizar los MV para adaptarse a la NLV.

Acciones para 2022-2024

- Establecer el grupo de trabajo con representantes de la AEMPS, Comité de Disponibilidad, industria, sectores y todos aquellos que se identifiquen como indispensables para el desarrollo del proyecto.
- Identificar por especies, teniendo en cuenta la información proporcionada por el comité de disponibilidad de la AEMPS y los datos de consumo y resistencias, aquellas herramientas terapéuticas más necesarias.
- Identificar el camino más factible para desarrollar dichas herramientas.

Plan Nacional Resistencia Antibióticos

Plan Nacional frente a la Resistencia a los Antibióticos 2022-2024

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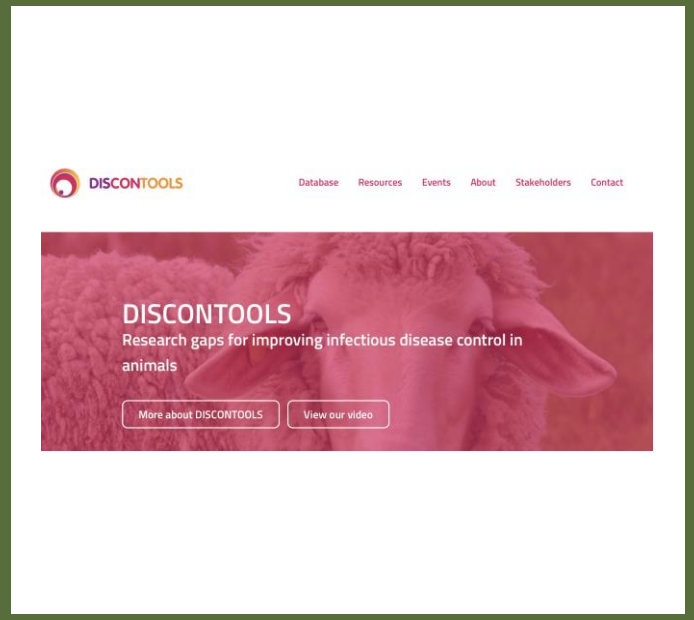
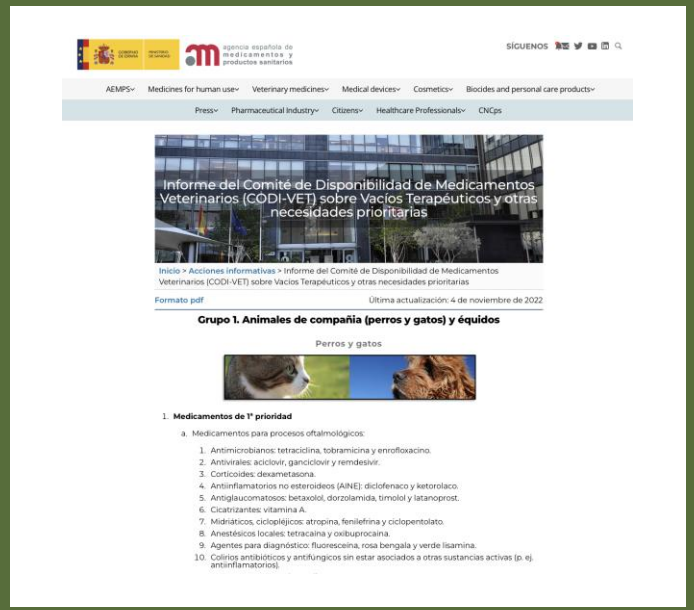




Do we know the gaps/needs in Europe?

Highlights on new developments

EMA 2019 - 2022

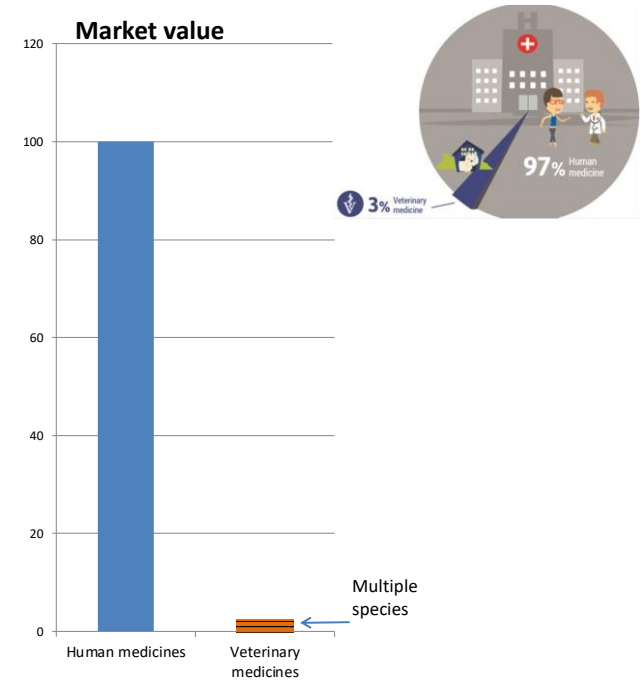
- 57 positive opinions, 25 new active substances
- Cats, horses, rabbits, sheep, rabbits, chickens, Pigs, dogs, ferret, cattle.
- Innovative medicines and vaccines
- New medicines that might help reduce the need for antimicrobials in animals
- New uses for existing medicines

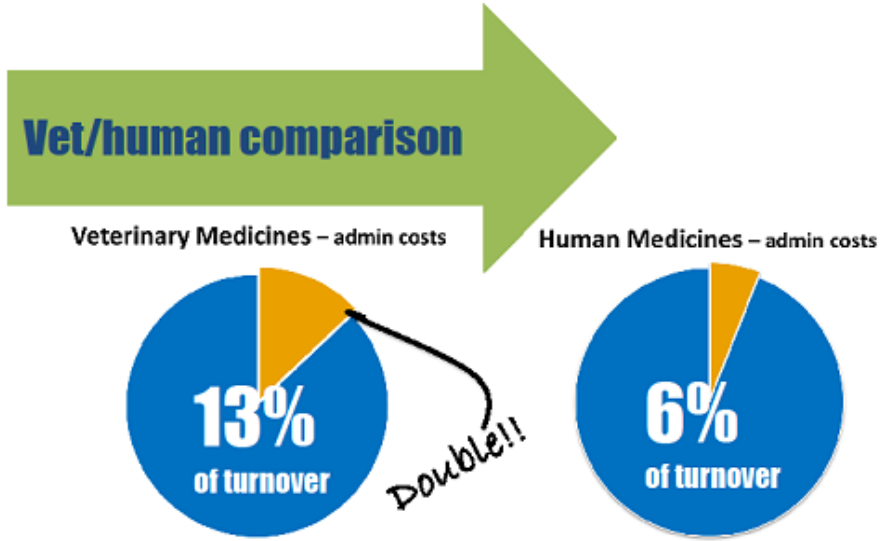
AEMPS (Spain) – 2019 - 2021

- There are 2,389 authorised veterinary medicines in Spain in 2021
- New medicines: 322 new authorisations in the period 2019-2021 (dogs, cats, pigs, bovine, sheep, hens, turkey, duck, horse, goat, bee, rabbits, ferret, ornamental birds, fish)
- Clinical trials: 93 during 2019-2021

Availability

- ✓ Need to develop medicines for a wide range of animals: specific veterinary products and different routes of administration
- ✓ Remember the original impact assessment–VMPs had double the admin burden experienced in human medicines sector





Regulation 2019/6

- Positive elements
  - Deletion of some elements within the marketing authorisation process (renewals, sunset clause)
  - Simplified rules for labelling and packaging
  - Pictograms and abbreviations in replacement of text
  - Marketing Authorisation unlimited validity
  - Legal definition for limited market (broader scope – milk sheep)
  - Cascade - allowed “out of stock” situations.
  - 4 years protection of technical documentation for innovations in existing products
  - Risk based approach on pharmacovigilance

New questions and challenges

- Challenge of implementing three new databases within three years: more resource intensive than expected.
- No data reduction for Quality (art. 23)
- Off-label use not allowed
- The hard definitions/requirements in the Reg 2019/6 could hinder innovation (no flexibility):
  - ‘antimicrobial’: if broad interpretation, AM restrictions will be applied to non antimicrobial VMPs
  - ‘new’ active substance: if too restrictive interpretation, Centralised Procedure becomes mandatory for VMPs. This may impact VMPs (such as some vaccines) intended for very limited geographic areas.

Some have been resolved

- Recent positive experiences of quick amendments:
    - Art 152(2) about deadline for compliance to new labelling requirements
    - Removal of GLP requirement for non-safety pre-clinical studies

The collaboration between the EMA, the national competent authorities and our industry has been very positive.

Challenges

E-leaflect

- Good example on national Spanish Legislation (AEMPS may authorise the substitution of paper for e-leaflect)

Harmonisation of SPCs

- Ensure it has a possitive effect on veterinary medicines availability
- Follow a pragmatic and feasible approach

Avoid Duplicate reporting and unnecessary admin burden

Implementation of Article 40.5 on additional protection of technical documentation

Increasing pressures on marketing authorisations

Titanium Dioxide potential ban of use

Substances restricted or banned under REACH: For instance, Triton-X and PFAS with impact on both products and manufacturing.

New packaging and waste legislation → additional labelling requirements

- Avoid over-regulation
- Maintain Benefit-risk concept
- Ensure harmonised labelling rules throughout the EU
- Involvement of Medicines Regulatory Agency from the first states is essential

EMA fees

New EMA Fee Proposed Regulation will increase fees by +/-50%:

- The appropriate funding of regulatory agencies is essential to the efficient regulatory control of veterinary medicinal products.
- The proposal represents in the region of a 50% (range 44% to 67%) increase in overall fees paid by a company in the VMP sector. This is not realistic for a small sector that represents just 3% of the human medicines market.
- Potential impact on R&D and availability
- There should be “no fee review” in the VMP sector until Regulation 2019/6 has been fully implemented and its objectives of reduced administrative burden and increased efficiencies delivered for the benefit of both regulators and the regulated industry.

Favorable environment for innovation with:

PREDICTABILITY

FLEXIBILITY

SCIENCE BASED DECISIONS

ALIGNMENT AND DIALOGUE AMONG STAKEHOLDERS

- Guidance: Value of having high-level technical guidance early enough, but cautious to not develop too detailed guidance too quickly – Balance to be found
- Informal interactions for Novel Therapies would be of help

We remain optimistic that, in the long-term, the new rules will deliver the promise of significant simplification, transparency and reduction of administrative burden to the benefit of animal Health

Antimicrobials

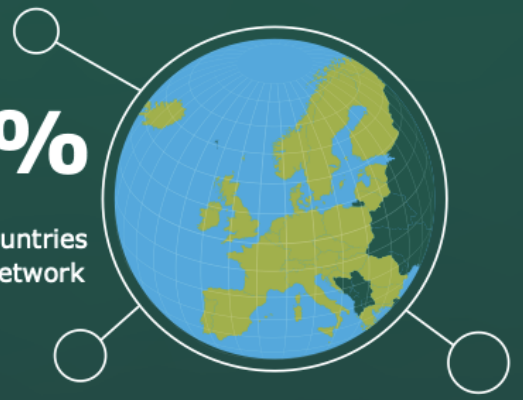
Increased requirements to address AMR in all stages (Authorisation, prescription and use, monitoring and surveillance, etc.)

Encourage applying a science based, european wide, benefit-risk approach

Good example is the decision on antibiotics reserved for human infection based on scientific grounds and following the “One Health” concept.

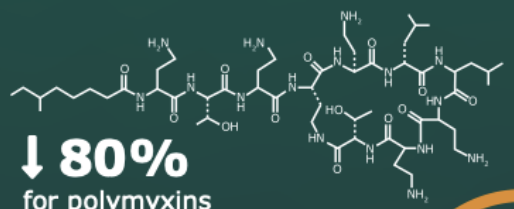
Europe is on the right track to fight antibiotic resistance...

2011-2021
Sales of antibiotics for veterinary use are declining

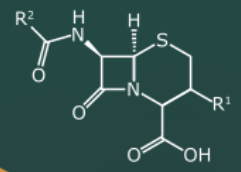


↓ 47%
overall sales in 25 of the 31 countries in the ESVAC network

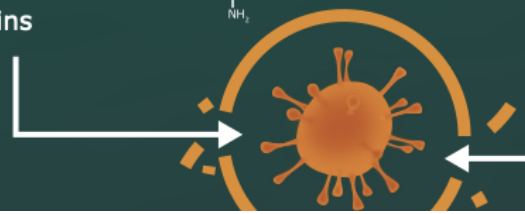
↓ 60%
in some countries



↓ 80%
for polymyxins



↓ 38%
for 3rd- and 4th-generation cephalosporins



- Sales and use data from animal and human health sectors can offer an indicator of trends in antibiotic use, it cannot measure whether AMR itself is rising or falling, and that’s what we really need to address.
- Sales/use reporting from all sectors must also be accompanied by AMR surveillance.

- Commitment from industry for the fight of AMR
  - Veterindustria supports the National Plan (objective is to reduce AMR and one Health approach)
- Objective should be to reduce the **need** for antibiotics
- Information and communication is essential nowadays
  - Further restrictions on use and prescription
  - Vets are key for the success of the implementation of this Regulation
  - Integral concept (biosecurity, vaccination, management, etc.)
  - Clear guidance and training courses to avoid any problems in the prescriptions – potential problems on animal Health and welfare
  - Allow advertising of immunological veterinary medicinal products to professional animal keepers in the UE (already allowed in Spain).

Plan Nacional
Resistencia
Antibióticos

Thanks for your attention!

Veterindustria

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