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Animal Health: how to leverage synergies between human and animal health

4th AMR Conference, Basel, 25 August 2020

Current status of and challenges for antimicrobial VMP development

Dr. Klaus Hellmann
Founder & CEO of Klifovet AG

KLIFOVET

26.08.2020

Content

- Antimicrobials used as VMP?
  - Definitions in veterinary legislation
  - Restrictions and control of use (MRL, FPA, CA, cascade …
- CVMP strategy on antimicrobials 2021-2025
- EC: categorization of antimicrobials for future use
- Incentives to promote the development of new AMs for veterinary use: data protection and risks
- Limitations of the development of AM VMPs
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- Synergies between human and animal health?

Antimicrobials in Veterinary Medicine

- Traditionally, beyond antiparastics the most important class of medicines for animals
- Gone from 25% to 15% of VMPs sold worldwide in the last 10 years, some countries reduced by >50 %
- Currently, no true incentives to develop new antimicrobials: risk to high to fail (politically)
- However, new Regulation 2019/6, coming into effect on 22JAN2022, may be the start of a change to improvement
- Transfer of AMR from animals to humans: exists, but less relevant than thought
- Relevant restrictions existing: how to de-risk?

Antimicrobials are the most highly regulated class with highest requirements: **Highest risk to fail, not scientifically, but politically!**

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Important definitions in AM as VMPs* (Regulation (EU) 2019/6)

Term	Definitions (Art. 4)
Antimicrobial	means any substance with a **direct action on micro-organisms used for treatment or prevention of infections or infectious diseases**, including antibiotics, antivirals, antifungals and anti-protozoals;
Antibiotic	means any substance with a **direct action on bacteria** that is **used for treatment or prevention of infections or infectious diseases**;
Antimicrobial resistance	means the **ability of micro-organisms to survive or to grow in the presence of a concentration of an antimicrobial agent** which is usually sufficient to inhibit or kill micro-organisms of the same species;
Prophylaxis	means the **administration of a medicinal product** to an animal or group of animals before clinical signs of a disease, in order to **prevent the occurrence of disease or infection**;
Metaphylaxis	means the **administration of a medicinal product** to a group of animals **after a diagnosis of clinical disease** in part of the group has been established, with the aim of **treating the clinically sick animals and controlling the spread of the disease to animals in close contact** and at risk and which may already be subclinically infected;

* All antimicrobials are prescription only Veterinary Medicinal Products (VMPs) (Art. 105)

Restrictions for use, as defined in Regulation (EU) 2019/6

Art. 107	Use of Antimicrobial Veterinary Medicinal Products (AVMPs)
1.	AVMPs shall **not be applied routinely nor used to compensate for poor hygiene**, inadequate animal husbandry or lack of care or to compensate for poor farm management.
2.	AVMPs shall **not be used** in animals for the purpose of **promoting growth nor to increase yield**.
3.	shall **not be used for prophylaxis** other than in exceptional cases, for the administration to an **individual animal or a restricted number of animals** when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe: limited to individuals.
4.	shall be **used for metaphylaxis only when the risk of spread of an infection** or of an infectious disease in the group of animals is high and where **no other appropriate alternatives** are available. Member states to provide guidance …
5.	Medicinal products which contain the designated antimicrobials referred to in Article 37(5) shall not be used in accordance with Articles 112, 113 and 114.
7.	**Member State may further restrict** or prohibit the use of certain antimicrobials in animals on its territory

Art. 37 (5): limited use of certain AM in Vet Med due to commission implementing act

Restrictions for use, as defined in Regulation (EU) 2019/6

Art. 107	Use of Antimicrobial Medicinal Products (AVMPs)
6.	The Commission may, by implementing act, … **establish a list of antimicrobials** which
(a)	shall not be used in accordance with Articles 112, 113 and 114; or
(b)	shall only be used in accordance with Articles 112, 113 and 114 subject to certain conditions
	When adopting those implementing acts, the Commission shall take account of the following criteria:
(a)	**risks to animal or public health** if the antimicrobial is used in accordance with Art 112 to 114;
(b)	risk for animal or public health in case of development of **antimicrobial resistance**;
(c)	**availability** of other treatments **for animals**;
(d)	**availability** of other antimicrobial treatments **for humans**;
(e)	**impact on aquaculture and farming** if the animal affected by the condition receives no treatment.
7.	**Member State may further restrict** or prohibit the use of certain antimicrobials in animals on its territory

Art. 112, 113 and 114: Use of VMPs outside the terms of the SPC in pets, aquatic and food producing animals

Use in Food Producing Animals

- A **Maximum Residue Level** (MRL, safe to be consumed by consumers) must be established according to Regulation 470/2009
- A **withdrawal period** must be fixed for the use in each food producing species for the relevant target tissue (meat, eggs, milk, honey)
- Art. 107 (2) shall apply to **operators in third countries**: shall not use the designated antimicrobials if imported to EU
- AVMPs shall **not be distributed for promotional purposes** as samples or in any other presentation.
- **AVMPs previously registered** and containing AM reserved for treatment in humans, may **loose their registration**:
  - Art. 37 (5): The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans.

Commission appears to understand, that this may cause long-term problems: initiatives to encourage new activities

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 June 2020
EMA/CVMP/179874/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP strategy on antimicrobials 2021-2025

Draft

Adopted by CVMP for release for consultation	18 June 2020
Start of public consultation	1 July 2020
End of consultation (deadline for comments)	30 September 2020

Comments should be provided using this template. The completed comments form should be sent to Vet-Guidelines@ema.europa.eu

CVMP strategy on antimicrobials 2021-2025

An 'antimicrobial' is defined in Regulation (EU) 2019/6 as 'any substance with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and anti-protozoals'.

2. Summary

Aim 1: To provide opinions for the **authorisation of effective antimicrobial veterinary medicinal products** ensuring that the necessary **risk management measures** are applied so that products can be used safely and sustainably.

Actions: CVMP will update its existing guidance documents in line with the definitions relating to antimicrobial use provided in the new veterinary medicines legislation and will review the indications for antimicrobial medicines authorised via centralised procedure for prophylactic/preventive use.

Aim 2: To consider and advise on the **risk to public health** that could arise from the use of antimicrobials in animals, and to balance this against the need to protect animal health. To provide advice in a One Health context, considering the interaction between humans, animals and the environment as sources of antimicrobial resistance genes.

Actions: The AMEG's categorisation will be reviewed as required to take account of evolving patterns of AMR and antibiotic usage in human and veterinary medicine.

AMEG: Antimicrobial Advice Ad hoc Expert Group of CVMP and CHMP (EMA)

CVMP strategy on antimicrobials 2021-2025

Aim 3: To **maintain the effectiveness of antimicrobial substances that are already authorised** in veterinary medicinal products by monitoring and analysing their **sales and usage**, encouraging surveillance for changes in susceptibility of target pathogens and zoonotic bacteria, and subsequently **reviewing the authorisation** of substances and/or products, especially when there is evidence that there may be a related change in the benefit-risk of the authorisation.

Actions: CVMP will provide support to ESVAC in its preparations to receive data on sales and use of antimicrobials by animal species and will provide appropriate governance over the ESVAC and JIACRA reports. Recommendations will be taken forwards on dose review and adjustment for established antibiotic products.

Aim 4: To encourage the **development of new and existing antimicrobial veterinary medicinal products.** To encourage the development of **alternatives to antimicrobials.**

Actions: The CVMP will provide regulatory and scientific advice on the development of new and existing antimicrobial medicinal products and will progress options for the regulatory framework for alternatives to antimicrobials.

ESVAC: European Surveillance of Veterinary Antimicrobial Consumption
JIACRA: Joint inter-agency antimicrobial consumption and resistance analysis: Collaboration between ECDC, EFSA and EMA

CVMP strategy on antimicrobials 2021-2025

Aim 5: To support the **responsible use** of antimicrobials both in accordance with Marketing Authorisations and under the **cascade**.

Actions: Scientific advice will be provided on the implementation of the new legislation pertaining to restrictions on the use of antimicrobials under the cascade. A reflection will be made on use and availability of diagnostic tests to improve the responsible use of antimicrobials.

Aim 6: Recognising that **AMR is a global problem** affecting both animal and human health, to work in partnership with the European Commission and its agencies, competent authorities in the Member States, international regulatory bodies, human and animal health organisations and the pharmaceutical and livestock industries to provide science led guidance on the responsible use of antimicrobials in animals.

Actions: CVMP will continue its engagement with its diverse stakeholders and to collaborate with colleagues in EU agencies and international regulatory bodies in developing guidance and advice on antimicrobial-related issues.

https://www.ema.europa.eu/en/documents/scientific-guideline/cvmp-strategy-antimicrobials-2021-2025_en.pdf

Aim 4: encourage development of AM VMPs and foster …

CVMP's proposed actions:

The CVMP will provide regulatory guidance through the **Innovations Task Force** and the **ADVENT group**, and **scientific advice including Preliminary Risk Profiling** on request from marketing authorisation applicants on the development of new antimicrobial products and alternatives to antimicrobials for the treatment of microbial infections.

In addition, CVMP will provide advice on the circumstances and type of data that could support **demonstration of a reduction in AMR** and hence a variation to the terms of the marketing authorisation that would benefit from an additional **4 years' data protection** (Article 40(5)).

The CVMP will **collaborate with other EU Agencies** (EFSA, ECHA) on the **classification and regulation of alternatives to antimicrobials (ATAm)**. Further guidance will be developed on **data requirements and** potential **claims for ATAm,** and how demonstrated treatment benefits should be factored into the benefit/risk assessment for veterinary medicines. CVMP will promote **international cooperation** and exchange of information with other regulatory regions to assist the global development and alignment of the approach to authorisation of ATAm.

The CVMP will continue to take into consideration **data requirements for limited markets** when reviewing marketing authorisation applications for designated products and will consider if the related guidance can be revised to improve the availability of antimicrobials for minor uses and minor species.

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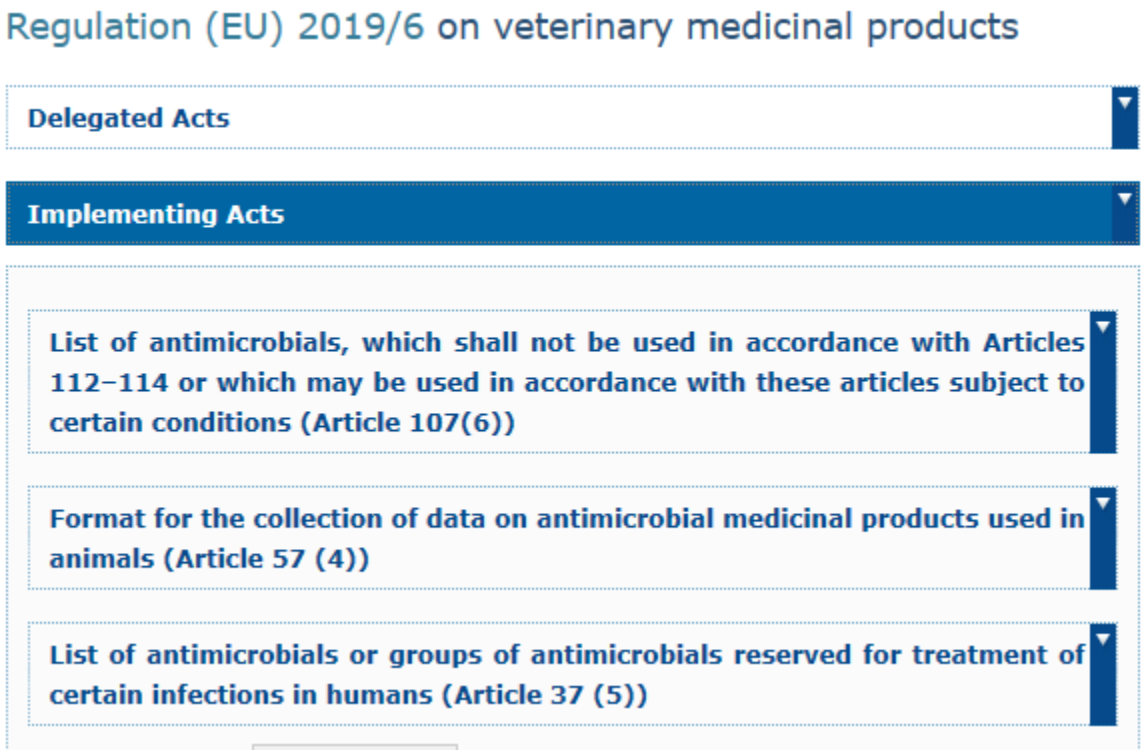
EC categorisation and rules on use of AM in animals

Regulation (EU) 2019/6 on veterinary medicinal products

Delegated Acts

- Rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed, such as mixing of water for drinking with a veterinary medicinal product or as manual mixing of a veterinary medicinal product into feed and administered by the animal keeper to food-producing animals (Article 106 (6))
- Criteria for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of those antimicrobials (Article 37 (4))
- Requirements for the collection of data on antimicrobial medicinal products used in animals (Article 57 (3))
- Amendments to Annex II (Article 146 (2))

EC categorisation and rules on use of AM in animals



https://ec.europa.eu/food/animals/health/veterinary-medicines-and-medicated-feed/imp-regs-2019_en

Regulation (EU) 2019/6

Art. 107	Use of Antimicrobial Veterinary Medicinal Products (AVMPs)
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Incentives during product development for marketing authorisations for VMPs

- Horizont Europe 2021-2027
- Innovation Task Force
- Scientific Advice
  - EMA
  - NCA
- SME incentives
- Special incentives for MUMS/limited markets, if for food producing species and no product for that indication available
- Data Protection

Definition of Major Species

Directive EC 2001/82 as amended	Regulation EC 2019/06 Def. 29
Cattle	Cattle
Sheep	Sheep for meat production
Pigs	Pigs
Chicken (incl. laying hens)	Chicken
Salmon	
Dogs	Dogs
Cats	Cats

Future benefit: salmon

Definition of Limited Market (MUMS)

Directive EC 2001/82	Reguation EC 2019/09 Def. 29
Minor Species (=Non Major Species) or	Non Major Species or
Minor Use:	VMPs for the treatment or prevention of diseases
◀ Low prevalence/ incidence	◀ that occur infrequently or
◀ Limited geographic spread	◀ in limited geographic areas

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Comparison of Protection Periods

Data protection	Directive 2001/82 as amended	Regulation 2019/9, effective for submissions from 28JAN2019, Art. 39
Additional data for existing products	---	Reduction of **antimicrobial**/-parasitic resistance or improvement of benefit/risk: **4 years**
New product, 1 species	10 years	Major species: **10 years** **Minor species 14 years** (incl. salmon and dairy sheep)
Additional species	+ 1 year (only food-producing species)	+ 1 year per major species + 4 years per minor species
Fish and bees	13 years	Fish 14 years Bees 18 years
Antimicrobials	As other products	New active substance: **14 years**
Max. protection period	13 years (10 +3x1 year)	**18 years**
MRL	3 years, if any	**New species,** together with safety and residues tests and pre-clinical studies and clinical trials **: 5 years**

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Limitations: per Regulation and Guidelines

- Regulation (EU) 2019/6, as above
- VICH guidelines
  - Target animal safety (VICH GL43)
  - Good Clinical Practices (VICH GL9)

- EMA/CVMP guideline
  - Pharmacokinetics
  - Efficacy of antimicrobials
  - Fixed combination products
  - Statistical principles for veterinary clinical trials
  - Palatability

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SCIENCE MEDICINES HEALTH

21 January 2016
EMA/CVMP/627/2001-Rev.1
Committee for Medicinal Products for Veterinary Use (CVMP)

Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances

Draft agreed by CVMP Efficacy Working Party (EWP) and Antimicrobials Working Party (AWP)	February 2013
Adopted by CVMP for release for consultation	16 May 2013
Start of first public consultation	29 May 2013
End of consultation (deadline for comments)	30 November 2013
Focus group meeting with interested parties	9 December 2013
Revised draft agreed by EWP	26 November 2014
Revised draft agreed by AWP	20 January 2015
Adopted by CVMP for release for second consultation	12 February 2015
Start of second public consultation[1]	24 February 2015
End of consultation (deadline for comments)	31 May 2015
Revised draft agreed by EWP and AWP	2 December 2015
Revised draft adopted by CVMP	21 January 2016
Date for coming into effect	1 August 2016

The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Veterinary Use

EMEA/CVMP/133/99-FINAL

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

GUIDELINES FOR THE CONDUCT OF PHARMACOKINETIC STUDIES IN TARGET ANIMAL SPECIES

APPROVAL BY CVMP FOR RELEASE FOR CONSULTATION	18 MARCH 1999
TRANSMISSION TO INTERESTED PARTIES	19 MARCH 1999
DEADLINE FOR COMMENTS	19 SEPTEMBER 1999
DISCUSSION IN EFFICACY WORKING PARTY	7 FEBRUARY 2000
ADOPTION BY CVMP	8 MARCH 2000
DATE OF COMING INTO EFFECT	8 SEPTEMBER 2000

SPC guideline: limitations

- The intended use of the product should be clearly worded in the indication, i.e. the clinical disease/signs to be treated
- The target bacterial species shall be listed for each target animal species and for each indication for use.
- Antimicrobial products should only be used when bacteria are susceptible to the antimicrobial substance and, where feasible, in line with susceptibility testing
- "Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target bacteria at farm level, or at local/regional level."
- "Use of the product should be in accordance with official, national and regional antimicrobial policies."
- "The <product name/antimicrobial> should not be used routinely as part of herd health programmes."

https://www.ema.europa.eu/en/glossary/cvmp

Demonstration of efficacy guideline

- Pharmacology, mode of action,
- MICs, MBC and kinetics, resistance incl. co- and cross-resistance, synergy or antagonism and other in-vitro susceptibility studies
- PK studies, potentially PK/PD to justify dose and dosing interval, in each species per administrations route and for each pathogen
- Dose confirmation studies in each species and for each pathogen
- Clinical field studies in each species and for each pathogen, multicentric in all species
- Specific approach in case of claim for “resistant bacteria”
- Special considerations for a “metaphylaxis” as well as “preventive” claims

https://www.ema.europa.eu/en/documents/scientific-guideline/final-guideline-demonstration-efficacy-veterinary-medicinal-products-containing-antimicrobial_en.pdf

Other limitations

- Use in humans
- Categorization for human use: critical?
- New data coming up
  - Latest example: Colistin / Polymyxin B
    - Long time not relevant for humans due to nephrotoxicological effects
    - Now considered critical for treatment of multiresistant gram-negative pathogens
    - Long time extended veterinary use for “local” treatment of gram-negative pathogens
- Situation may change any time for a “new” active ingredient
- Risk to high compared to RoI

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SCIENCE MEDICINES HEALTH

10 October 2019
EMA/CVMP/461776/2017
Committee for Medicinal Products for Veterinary Use

CVMP Reflection paper on promoting the authorisation of alternatives to antimicrobials in the EU

Draft

Adopted by CVMP for release for consultation	10 October 2019
Start of public consultation	18 October 2019
End of consultation (deadline for comments)	30 April 2020

Comments should be provided using this template. The completed comments form should be sent to vet-guidelines@ema.europa.eu

Keywords	Alternatives to antimicrobials, authorisation, gap analysis, measures, veterinary medicinal products

https://www.ema.europa.eu/en/documents/scientific-guideline/cvmp-reflection-paper-promoting-authorisation-alternatives-antimicrobials-eu_en.pdf

Alternatives to Antimicrobials

- The use of ATAm represents one way in which to reduce the use of antimicrobials, particularly antibiotics, in veterinary medicine. This reflection paper therefore explores ways by which to ensure that the EU is encouraging the authorisation of ATAm.

Working definition of CVMP for an ATAm:

- 'a veterinary medicinal product the use of which provides an alternative approach to the use of antimicrobials in animals or that reduces the need for their use'.

- "In practice, the **increased uptake of vaccination** represents one of the most practical ways in which the use of antimicrobials in general and in particular the use of antibiotics can be reduced, both now and in the future. "
- Some of the alternatives themselves fall within the definition of an antimicrobial

Examples of ATAms*

- Vaccines
- Antibodies
- Immunomodulators
- Bacteriophages (wild-type, engineered)
- Lysins
- Antimicrobial peptides (e.g. bacteriocins, host-defence peptides)
- CRISPR-Cas9-based products
- Probiotic and live organisms (e.g. probiotics, predatory bacteria, competitive exclusion)
- Prebiotics - Symbiotics - Postbiotics
- Interferons
- Phytochemicals - Herbals/Botanicals
- Organic acids
- Biocides
- Teat sealants

*Classification of ATAm products as veterinary medicinal products, feed additives, biocides, etc. will depend on their presentation, intended use and claims made for the product.

Proposed actions to promote ATAm (acc. to CVMP)

- Definition for ATAm: **should include vaccination** as vaccines have a major potential for reducing use of antimicrobials in animal husbandry
- Provide clarity to applicants on the **classification of borderline products**
- Explore how the new veterinary regulation (NVR) provides framework for authorisation of appropriate ATAm as veterinary medicines and reflect on need for **additional guidance**
- Generate additional guidance specifically intended to clarify **requirements for ATAm**. Specific examples are given in the rows below
  - Benefit:risk of ATAm, if reducing use of AM
  - How can this be reflected in SPC?
- Internationally aligned requirements are needed to **promote global development** programmes for ATAm: in context of TATFAR
- Companies seek early 'upstream' advice to reduce risk related to development of ATAm: ITF meetings
- Support EMA and NCA **incentives to SMEs** working in the area of ATAm
- **Financial or other incentives** to authorization of ATAm
- Create a **platform for communication** and dialogue between industry and regulators

Define more specific regulatory requirements

- for bacteriophages
- for novel biologically active molecules that kill bacteria but are not classic pharmaceutical antibiotics (e.g. lysins, peptides, lysozymes and other enzymes),
- for non-specific immuno-stimulants
- for gene editing technology presented as medicinal products (e.g. CRISPR-Cas9)
- for herbals, phytochemicals and other non-biological active substances presented as alternatives to antimicrobials
- for MRLs for products mentioned above, if for food producing animals

But also

- Develop objective targets to monitor success of measures to promote ATAm

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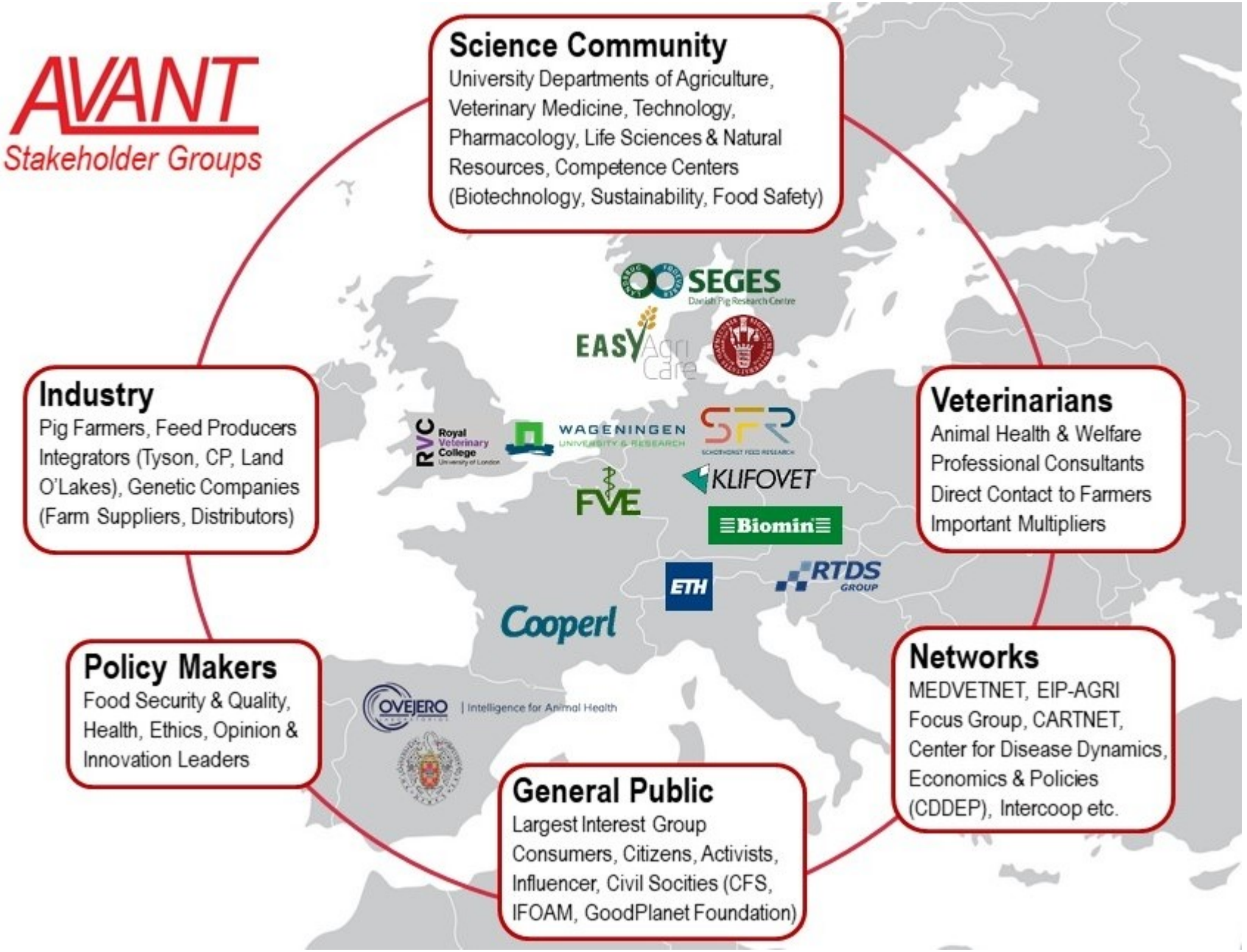
AVANT Stakeholder Groups



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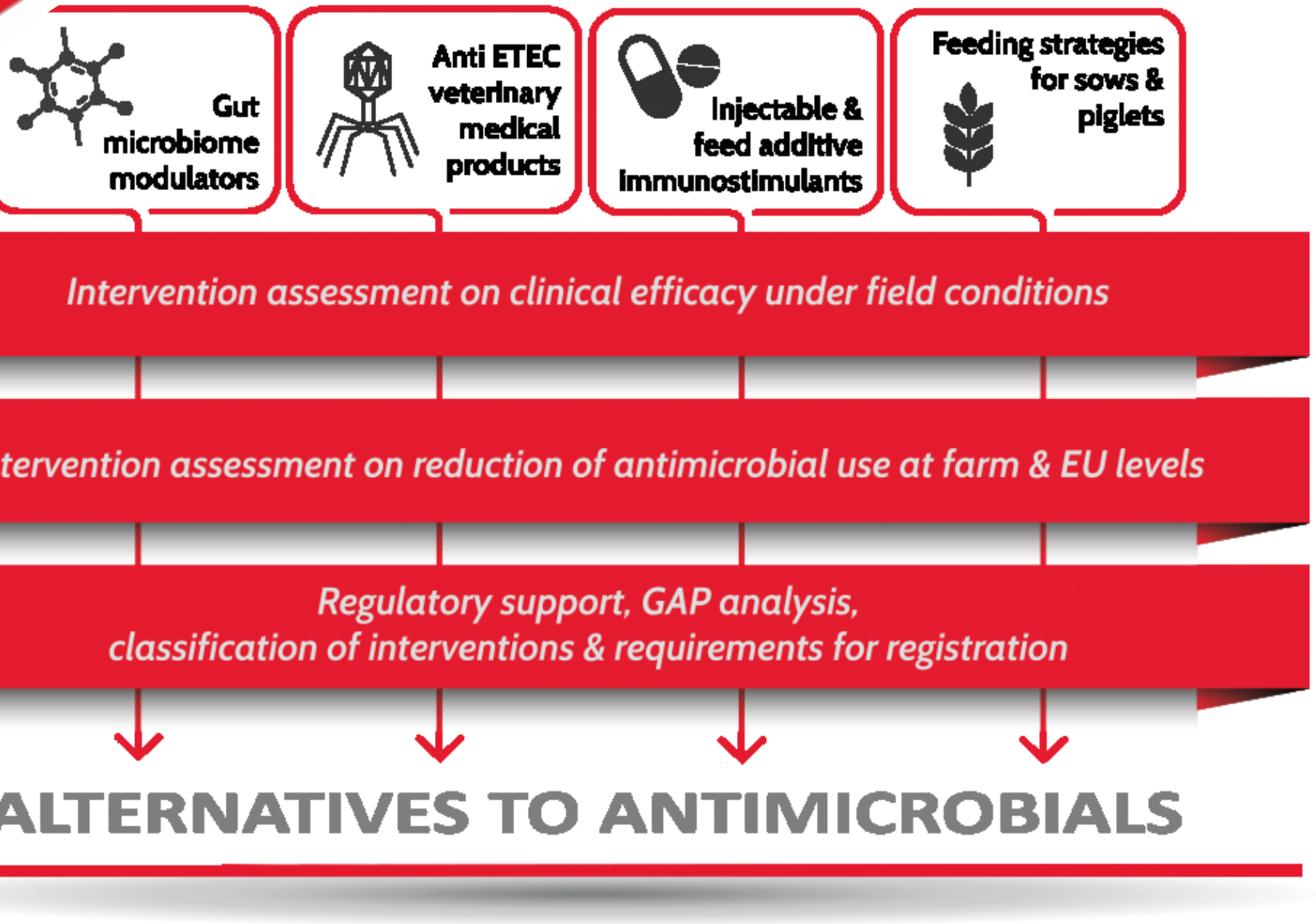
AVANT



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Synergies within One Health

- Traditionally, lots of synergies
  - Most active ingredients first licensed in Human Health before developed for animals
- Based on current view on antimicrobial resistance, development of new AVMPs very challenging
- As use of critically important actives limited to humans, development of new actives within AVMP very risky, thus unlikely
- Any development highly risky, as political decision poses permanent risk
- Recommend to de-risk any new development with EC/EMA/CVMP
- Potential use of animal studies as pre-clinical studies for HMPs?
- In other therapeutic areas: synergies on both sides possible
  - Technology transfer from human medicine to veterinary medicine: frequently applied in many areas
  - Technology transfer from veterinary medicine to human medicine: seldom
  - Use of pre-clinical studies in mammals seldom used, but would de-risk human medicine development significantly in a variety of indications (naturally occurring diseases)
  - Humans are just one species of mammals: there is a difference, but not a big one!
  - Zoonosis

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Summary

- Use of antimicrobials in animals highly restrictive
- No development of novel antimicrobials for 10 years, no pipeline
- Still in process to develop more clarity on future options
- Currently, risk to fail politically too high as compared to RoI
- Alternatives to Antimicrobials appear more attractive (e.g. AVANT)
- Synergies between human and animal health for the development of new antimicrobials appear limited in current political situation: rather in pets than in Food Producing Animals (unless destroyed)
- However, both sides can learn a lot from each other

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Q & A

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