

The Veterinary Medicines Regulation: A New Toolbox For Veterinarians In The Fight Against AMR

Nancy De Briyne, FVE Executive Director VMP Regulation Event, 20 June 2022

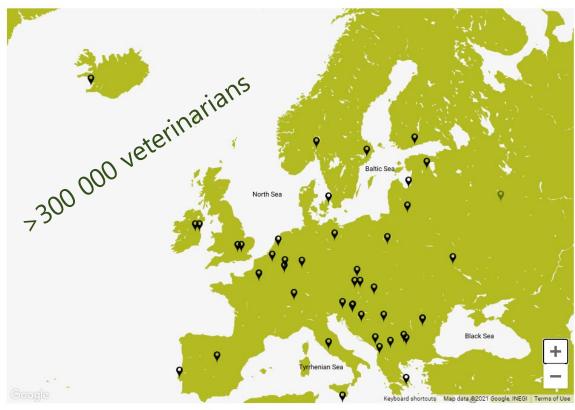






The FVE Network





Federation of Veterinarians of Europe

- 46 national associations
- 38 European countries
- 4 Sections

- UEVP (*Practitioners*)
- UEVH (Hygienists Public Health Officers)
- EASVO (Veterinary State Officers)
- EVERI (Education, Research, Industry)

FVE's mission

The European veterinary profession, embodied by FVE, **enhances animal health, animal welfare, public health and protect the environment** by promoting the veterinary profession.



Together with its members, FVE supports veterinarians in delivering their professional responsibilities to the best possible standards and ensures that veterinary expertise is recognised and valued by society.

Veterinarians know, care and contribute











European Commission

efsa.









BIVSA

Veterinary organisations





European **Institutions**



International Organisations











Timeline EU Medicines legislation revision: 2019/6



All FVE position papers on www.fve.org

Aims new legislation:

- Address the public health risk of antimicrobial resistance (AMR)
- Increase availability of veterinary medicinal products; and Improve the functioning of the internal market
- Reduce administrative burden
- Stimulate competitiveness and innovation

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New Reg provides excellent tools to fight AMR

- Veterinary profession has & is further committed to fight AMR by a scientific One Health approach → Regulation follows this
- Even animals who are kept in the best conditions can become sick, and animals deserve treatment too



· VETERINARIANS KNOW, CARE AND CONTRIBUTE ·











Reg provides extensive toolbox to fight AMR e.g.











Veterinary
antimicrobials = on
prescription +
quantity/amount
prescription

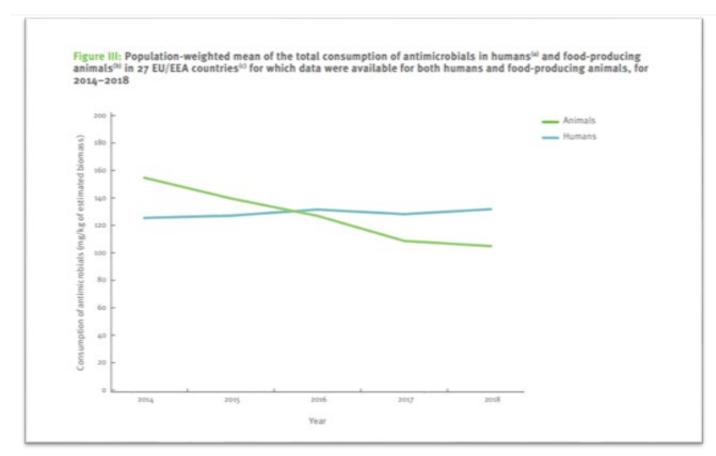
esvac collection of Use Data per Species

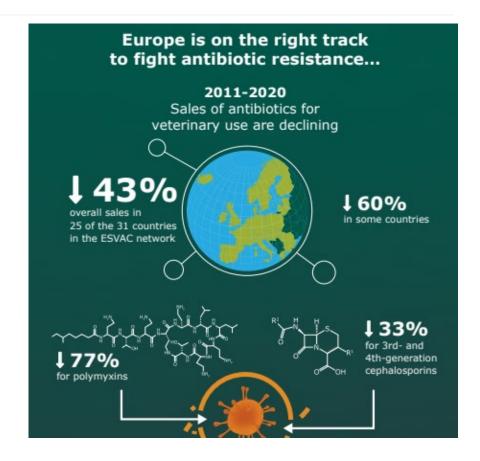
Routine prophylactic & metaphylactic use will not be allowed anymore List of reserved antimicrobials for human use only

Import rules







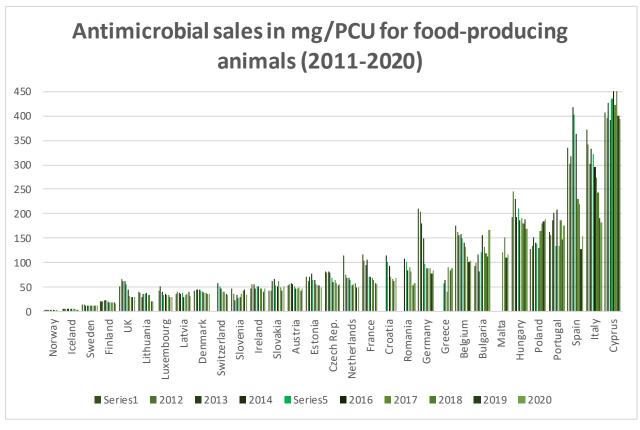






- F2F goal: EU sales of antimicrobials for animals minus 50% by 2030
- Reduce gap between MSs
- Enhance 'One Health Approach'





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New regulation has potential to increase availability



Veterinary medicines = many species/sub-species → needs flexibility



Increased flexibility of prescription cascade



Stimulate innovation incl. new medicines



Union Product Database & easier import of medicines from other EU MSs; prescriptions valid throughout the EU



Extension centralized authorization procedure





We need to ensure that this potential is used to increase availability

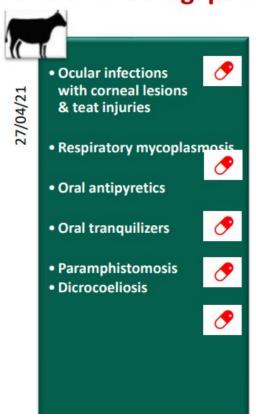
- Huge concerns that veterinarians are no longer able to deviate from the dose and duration in the SPC (Art 106.1).
- Shortages, supply problems, lack of incentives for investment, national restrictions, more stringent regulatory requirements, etc all influence availability.
- Important for regulators to use flexibility (risk-benefit)
- Important to monitor availability e.g. ANSES example



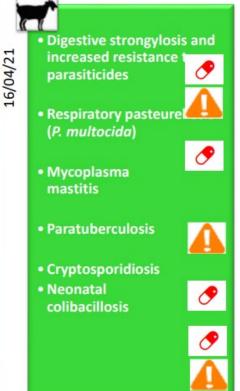




3 to 5 MAJOR gaps in producing animal sectors







Mapping done together with profession

https://www.reseaufrancais-santeanimale.net/lerfsa/cartographie-desgaps-therapeutiques/







4TH EMA FVE WEBINAR ON NEW VETERINARY MEDICINAL PRODUCTS REGULATION

27 JUNE 2022 11:30-13:00 CET

SPECIAL FOCUS:
UNION PRODUCT DATABASE BENEFITS, FUNCTIONALITIES AND
UPCOMING IMPROVEMENTS

TARGET AUDIENCE:
VETERINARIANS, ANIMAL HEALTH PRACTITIONERS,
COMPETENT AUTHORITIES

REGISTRATION OPEN



FVE infographic: explaining the new Regulation



European law on veterinary medicines: what's new?



he EU has officially adopted new legislation on veterinary medicines*. It will be applicable in all EU countries from 28 January 2022.

FVE has actively contributed to the drafting of the Regulations, allowing the new legislation to strengthen the position of the veterinarian.

The rules are more transparent and easier to implement, helping the profession in safeguarding animal health, animal welfare and public health, including combating antimicrobial resistance.

What will change in veterinary practice?





Veterinary prescriptions can only be issued by veterinary surgeons (exceptions apply). The prescription will be valid throughout the EU. The quantity prescribed should be limited to

Ben 12793 Att. ES.

the treatment.



The prescription cascade will become more flexible. Importing veterinary medicines from another EU country will become easier.

Third country medicines can also be used under certain conditions. Restrictions may apply to antibiotics.

Seq. (274) 41, 112-115



A central EU database of all authorised veterinary medicines will be set up, easily accessible by all veterinarians.

Pharmacovigitance data, recording adverse events, will become accessible to all veterinarians. The reporting will become more user-friendly.

Bog 20795 Att 55, 56, 74.



Online sales are only allowed for medicines not requiring a veterinary prescription. Individual Member States can overrule this, but only on their own territory.

Legal online pharmacies must be monitored and certified with a common EU logo.

Bog 20793 Att. 106



To combat antimicrobial resistance, use of certain important antibiotics can be restricted or prohibited in animals. The European Commission is expected to draw up a list. Preventive antibiotic use is only permitted in exceptional

circumstances, Restrictions also apply to metaphylactic use. Box MYSSER IS, MT



On-farm monitoring systems of antibiotic use and national surveillance of antibiotic use become mandatory.

Advertising veterinary prescription medicines in the lay press will be forbidden, although Member States can allow vaccine adverts for farmers.

Bog Brigs av 17,138



Medicated feeds require a veterinary prescription, can only be prescribed for two weeks and cannot contain more than one antimicrobial substance.

Preventive antibiotic use is not allowed, metaphylactic use only under certain conditions.

deg, MYSS Art. 186, 109, deg, MYSS Art. 16



Imported animals and

animal products from outside the EU need to conform to the ban on growth-promoting antimicrobials and the ban on antibiotics reserved for human use.

Reg. MPREAR III

* Regulation (ER) 2009 6 constraining mediciones impor/play at complete lists implicating directive 1809/456, hope from the complete into 1909/46 on medicated freed: https://doi.or.no.ip.com/discom/

Continuation of the close collaboration

 Example of nice collaboration of regulators, industry and stakeholders

Ensures legislation which is effective and applicable.

Let's continue this!

THANK YOU!



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WHERE WE ARE

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