To: FVE

February 9, 2022
km/22-00413

Concerns regarding Regulations on Veterinary Medicines (EC 2019/6)

The Danish Veterinary Association (DVA) would like to thank FVE for the hard work in relation to the implementation of regulation 2019/6 and for closely monitoring all implementing and delegated acts. We would also like to thank FVE for the opportunity to provide input on the challenges that we are experiencing in Denmark.

The DVA would like to express our concerns regarding several significant issues in the ongoing implementation of Regulation EC 2019/6. Especially concerning the fact that veterinarians must follow the SPCs exactly as written (art.106).

Article 106
Article 106.1 of the Regulation requires veterinarians to prescribe medicinal products in accordance with the Summary of Product Characteristics (SPC), and thus the veterinarian must strictly follow the listed indication, dose, and duration.

Our concern is that SPCs in many cases are not up to date according to recent recognized research, empirical knowledge, and guidelines. Instead, they reflect given knowledge at the time of approval regarding indication and treatment protocol. At this time, the primary goal was product approval and pharmaceutical companies sought data support from well-educated specialists – the veterinarians – to qualify its use beyond the marketing authorization.

We believe, that when forced to follow the SPCs, which were approved decades ago, and with a far too narrow list of indications, veterinarians will, in some cases, prescribe a less effective drug to treat the animal, because the exact indication must be mentioned in the SPC. Just as dose and duration of treatment will, in many cases, be incorrect compared to recent knowledge and guidelines. If the SPC indicates a higher dose than required to treat the disease, this will increase the overall usage of antibiotics and may *increase* the risk of developing antimicrobial resistance in the long run.

We would like to substantiate our claims with the following examples:

- In pig herds, where veterinarians in Denmark are subject to strict antibiotic reduction targets of a 2% decrease per year, adjusting to the SPCs will mean a significant *increase* in the prescribing of antibiotics - contrary to all political intentions. Today, based on recent research, several products are used for fewer days and sometimes in smaller doses than listed in the SPC. This is supported by the Danish Veterinary Council - (reference can be obtained upon request - in Danish). Furthermore, some infections are possible to treat with narrow spectrum antibiotics *if* a higher dose is used. The regulation will force veterinarians to use more broad-spectrum antibiotics, again increasing the risk of resistance.

- Veterinarians working with horses will no longer be able to treat certain infections effectively – e.g., joint infections - where higher doses or multiple administrations are needed, despite not being listed as an option in the SPC. Similar concerns are raised regarding pain

Den Danske Dyrlægeforening | Danish Veterinary Association | Codanhus | Gl. Kongevej 60, 9. sal | DK-1850 Frederiksberg C | Tlf: +45 3871 0888
E-mail: ddd@ddd.dk | www.ddd.dk

management in several species, where indications, doses or administration intervals stated in the SPCs are insufficient.

- For lower urinary tract infections in dog and cats, guidelines tell us to end treatment, when clinical symptoms resolve – a principle adopted from human medicine and proven in several scientific studies. According to the regulation, the veterinarian consequently must choose an antibiotic based on which SPC holds the right indication and not based on recent research and guidelines. Therefore, veterinarians will have to treat the animal with a broad-spectrum antibiotic for a longer period instead of the narrow spectrum one used today for as long as needed.

- In addition, we have learned that veterinarians may no longer terminate initiated treatment of mastitis in cattle despite laboratory analysis show no signs of bacterial infection.

The DVA finds it concerning, that the regulations are depriving veterinarians of the right to deviate from the SPCs based on current scientific knowledge and guidelines, and that the regulation disregards veterinarians' competencies in pharmacology, animal pathology and physiology.

Article 112-114

Veterinarians in Denmark are aware of the benefits of the new rules regarding the use of medicinal product outside the terms of the marketing authorisation (cascade), and the idea of a Union Product Database is good, but unfortunately, it is still incomplete. Given the incompleteness of the database, veterinarians find it difficult to search the database and to understand SPCs in foreign languages. Furthermore, when prescribing according to these rules, veterinarians must apply (the Danish Medicines Agency) for permission to use a product from another member state, before prescribing an easily accessible human medicinal product with the same active substance. This unnecessarily prolongs the time until the animal can be treated. There is also still a lack of an overview of how veterinarians should ensure immunological products for the treatment of e.g., allergies.

We recognize the significant work already done by FVE on this matter. With this letter, the DVA wishes to draw FVEs attention to our concerns and the impact on animal welfare and risk of increased development of antibiotic resistance – not only in Denmark, but also in other countries that interpret the regulations in the same manner as Denmark.

Kind regards,

Hanne Knude Palshof
Chair, The Danish Veterinary Association

Den Danske Dyrlægeforening | Danish Veterinary Association | Codanhus | Gl. Kongevej 60, 9. sal | DK-1850 Frederiksberg C | Tlf: +45 3871 0888
E-mail: ddd@ddd.dk | **www.ddd.dk**