

March 24, 2022
km/22-01542

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

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 concerns:

- SPCs are in many cases not up to date according to recent recognized research, empirical knowledge, and guidelines. Instead, they reflect knowledge at the time of approval. Some were approved decades ago. Therefore, dose and duration of treatment will, in many cases, be incorrect compared to recent knowledge and guidelines.
- We believe, that when forced to follow the SPCs, veterinarians will, in some cases, prescribe a less effective drug to treat the animal, because the exact indication must be mentioned in the SPC.
- If the SPC indicates a higher dose than required to treat the disease (and not an interval), this will increase the overall usage of antibiotics and may *increase* the risk of developing antimicrobial resistance in the long run.
- The work of harmonizing the SPC is still in its infancy, and we believe that it would be in line with the purpose of the Regulation if the SPCs had already been reviewed before Article 106 was implemented.

The Commission has [previously answered](#) that it is fully aware of the concerns raised by Denmark about the application of Article 106 (1), and pointed out, that Danish veterinarians could use mechanisms to ask for the review and possible update of SPCs.

According to us, this is not the solution to the problem:

- It is the marketing authorization holder who must apply for variation changes, and field data from veterinarians are not sufficient.
- If it is not profitable for the holder of the marketing authorization to do so, we fear it will leave veterinarians with even fewer veterinary products to resort to.
- Also, some of the issues are not due to side effects, but knowledge that a lower dose is sufficient to treat a specific disease.

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

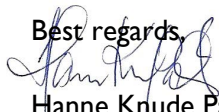
- I. In pig herds, where veterinarians in Denmark are subject to strict antibiotic reduction targets of a 2% decrease per year, adjusting to the SPCs will mean a significant *increase* in the prescribing of antibiotics - contrary to all political intentions. Today, several products are used for *fewer 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). This is *not* the same as prophylactic long-term treatment with low-dose antimicrobials.

2. 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.
3. Veterinarians working with horses are no longer 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.
4. Similar concerns are raised regarding pain management in several species, where indications, doses or administration intervals stated in the SPCs are insufficient. Treatment of lameness in horses is an example of this.
5. 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.

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

We therefore propose that the Commission postpone the implementation of Article 106 (1) until further discussions have taken place on the unforeseen and unfortunate consequences of the wording of Article 106 (1), and the intended harmonization of SPCs is at a stage where the desired effects and synergies have been achieved.

Best regards,



Hanne Knude Palshof
Chair, The Danish Veterinary Association

Contact:

Karin Melsen, DVM, Policy Advisor DVA.

km@ddd.dk