

European Commission
Directorate- General for Health and Food Safety
Att: Director for food and feed safety, innovation
Dr Sabine Jülicher

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Dear Dr Jülicher,

The Danish Agriculture & Food Council (DAFC) and The Danish Veterinary Association (DVA) welcomes the new Regulation (EU) 2019/6 on veterinary medicinal products (VMP) and the new Regulation (EU) 2019/4 on medicated feed (MF), that will take effect from 28th of January 2022. The new regulatory framework contains several important elements, and both DAFC and DVA fully support the ambition of harmonized and responsible use of veterinary medicinal products in the European Union.

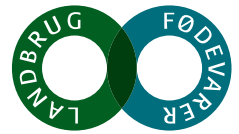
DAFC and DVA are aware that the European Commission as part of the implementation of the new regulation is in the process of adopting delegated and implementing acts. One of these delegated acts will establish rules on appropriate measures to ensure the effective and safe use of veterinary medical products authorised and prescribed for oral administration according to article 106 (6) in the VMP.

Responsible use of veterinary medicine, with an emphasis on antimicrobials, have been a top priority among shifting Danish governments, DAFC, and DVA for more than a decade. The close collaboration between authorities, industry, and veterinarians means that the Danish agriculture and food sector have significantly reduced the use of antimicrobials and are amongst the lowest users in Europe. This has also been acknowledged by the European Commission, who concluded in the last fact finding mission in Denmark on prudent use of antimicrobials in animals, that: *“Various aspects of the comprehensive measures put in place in Denmark aimed at encouraging the prudent use of antimicrobials in animals and tackling the broader issue of antimicrobial resistance could serve as an illustration of potential good practices to other Member States”*¹.

Oral administration through water in case of pig farms or on-farm mixing with feed in case of aquaculture have been important tools in Denmark to ensure a targeted, and in effect, low and prudent use of especially antimicrobials where treatment of individual animals is not effective. On pig farms administration of antibiotics through the water pipe systems allows for a targeted treatment of animals down to the individual pen. A similarly targeted treatment of pigs through medicated feed is not possible as feeding systems typically will consist of only one feeding pipe supplying a whole section or barn resulting in unnecessary treatment of animals in pens not affected by a disease outbreak.

We strongly support a responsible use of oral medication. However, DAFC and DVA are concerned if the delegated act becomes too restrictive and leads to a situation where medicated feed will be favoured over the administration through drinking water or on-farm mixing. As illustrated by the above example it will not be possible to ensure a similar targeted and low use of antimicrobials

¹ Final report of a fact-finding mission carried out in Denmark from 01 February to 05 February 2016 in order to gather information on the prudent use of antimicrobials in animals. DG (Sante) 2016-8882-MR



when using medicated feed. A shift away from oral administration toward medicated feed can potentially lead to an increase in the use of antimicrobials compromising the overall ambition of the European Commission to reduce antimicrobials and AMR. DAFC and DVA would like to stress the importance that the Commission considers both the practical reality on farm level, and differences when treating different species of animals. In our perspective this is a key component to be able to support the objective of a reduced and overall prudent use of antimicrobials in farm animals in the EU. It would be very unfortunate if the veterinarians are forced to follow procedures that lead to a less targeted treatment of animals and results in an otherwise unnecessary increased use of antimicrobials.

In Denmark medicated feed is solely used in situations, where medical remediation is the only option for treatment of diseases in the herd. This is also in line with the EMA categorisation of antibiotics in the EU of December 12, 2019 (EMA/CVMP/CHMP682198/2017)², where EMA gives scientific advice on the impact on public health and animal health of the use of antibiotics in animals. In this categorization EMA gives a suggested listing of routes of administration and formulation. We would like to highlight that EMA in this categorization have ranked oral group medication (metaphylaxis) above group medication via feed/premixes.

DAFC and DVA would be very pleased if we could be granted a meeting and get the opportunity to present our view and practical experiences. Oral medication is an important tool to secure a prudent use of antimicrobials, and we hope that the Commission will look favourably on developing legislation that supports all Member States in their efforts to promote a prudent use of antimicrobials.

Sincerely

A handwritten signature in blue ink, appearing to read 'Hanne Knude Palshøj'.

Hanne Knude Palshøj
President, Danish Veterinary Association

A handwritten signature in blue ink, appearing to read 'Flemming Nør-Pedersen'.

Flemming Nør-Pedersen
Executive Director

² Categorisation of antibiotics in the European Union - EMA/CVMP/CHMP/682198/2017
(https://www.ema.europa.eu/en/documents/report/categorisation-antibiotics-european-union-answer-request-european-commission-updating-scientific_en.pdf)