FVE
Federation
of Veterinarians
of Europe

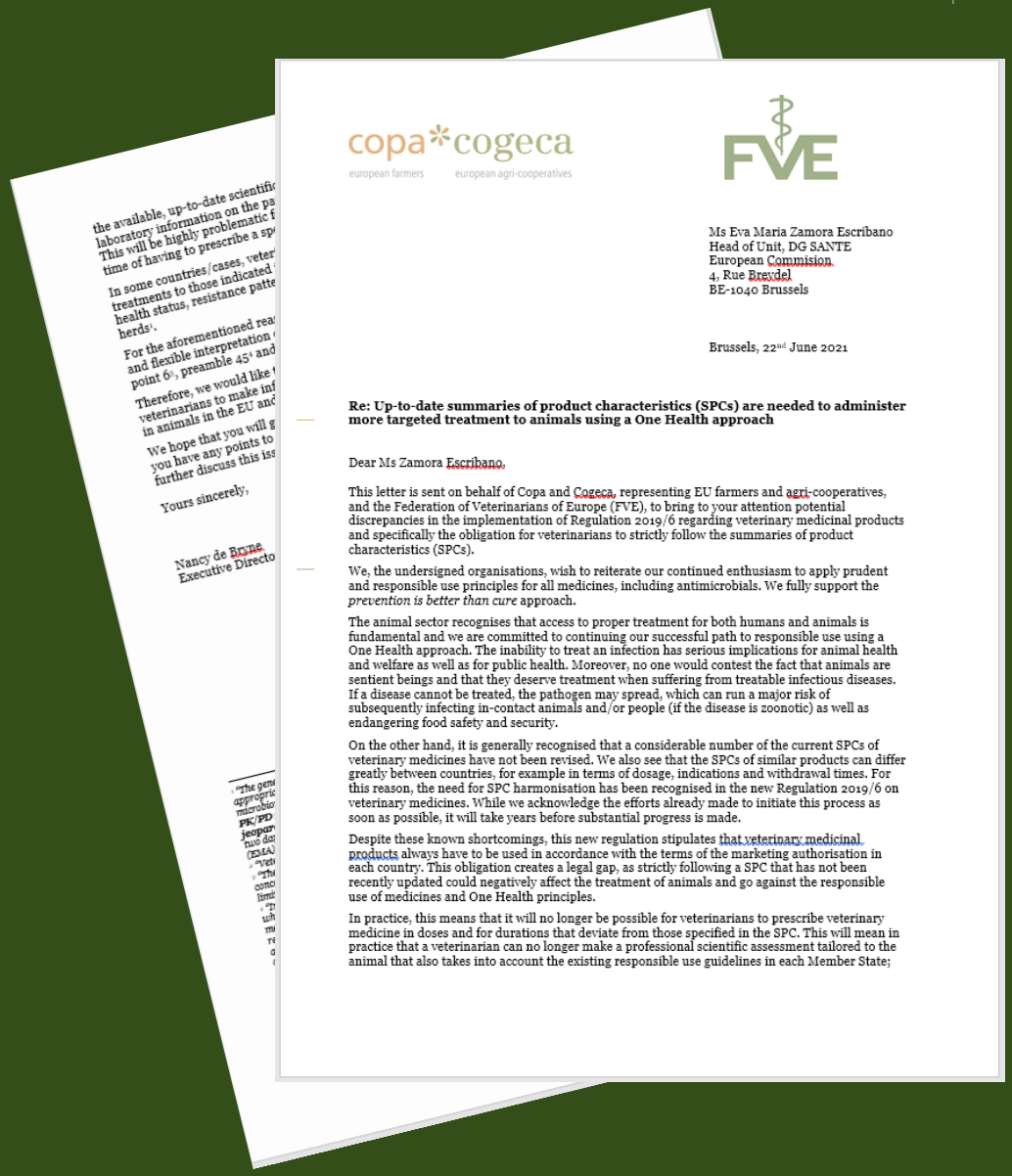
Article 106(1) of Regulation (EU) 2019/6

From legal interpretation to practical implementation

Problem statement

- Considerable number of current SPCs have not been revised
- SPCs of similar products greatly differ per country
- It will take time before SPCs for all products are finally harmonized

Legal gap!



copa cogeca
european farmers european agri-cooperatives

Ms Eva Maria Zamora Escribano
Head of Unit, DG SANTE
European Commision
4, Rue Breydel
BE-1040 Brussels

Brussels, 22nd June 2021

Re: Up-to-date summaries of product characteristics (SPCs) are needed to administer more targeted treatment to animals using a One Health approach

Dear Ms Zamora Escribano,

This letter is sent on behalf of Copa and Cogeca, representing EU farmers and agri-cooperatives, and the Federation of Veterinarians of Europe (FVE), to bring to your attention potential discrepancies in the implementation of Regulation 2019/6 regarding veterinary medicinal products and specifically the obligation for veterinarians to strictly follow the summaries of product characteristics (SPCs).

We, the undersigned organisations, wish to reiterate our continued enthusiasm to apply prudent and responsible use principles for all medicines, including antimicrobials. We fully support the *prevention is better than cure* approach.

The animal sector recognises that access to proper treatment for both humans and animals is fundamental and we are committed to continuing our successful path to responsible use using a One Health approach. The inability to treat an infection has serious implications for animal health and welfare as well as for public health. Moreover, no one would contest the fact that animals are sentient beings and that they deserve treatment when suffering from treatable infectious diseases. If a disease cannot be treated, the pathogen may spread, which can run a major risk of subsequently infecting in-contact animals and/or people (if the disease is zoonotic) as well as endangering food safety and security.

On the other hand, it is generally recognised that a considerable number of the current SPCs of veterinary medicines have not been revised. We also see that the SPCs of similar products can differ greatly between countries, for example in terms of dosage, indications and withdrawal times. For this reason, the need for SPC harmonisation has been recognised in the new Regulation 2019/6 on veterinary medicines. While we acknowledge the efforts already made to initiate this process as soon as possible, it will take years before substantial progress is made.

Despite these known shortcomings, this new regulation stipulates that veterinary medicinal products always have to be used in accordance with the terms of the marketing authorisation in each country. This obligation creates a legal gap, as strictly following a SPC that has not been recently updated could negatively affect the treatment of animals and go against the responsible use of medicines and One Health principles.

In practice, this means that it will no longer be possible for veterinarians to prescribe veterinary medicine in doses and for durations that deviate from those specified in the SPC. This will mean in practice that a veterinarian can no longer make a professional scientific assessment tailored to the animal that also takes into account the existing responsible use guidelines in each Member State;

Arguments in support of the need for special attention on legal interpretation of Article 106(1)

Lack of flexibility

- could negatively affect the treatment of animals
- goes against the responsible use of medicines
- goes against One Health principles
- disregards the professional ability of veterinarians to make a scientific assessment of the health condition of the animal(s) under their care
- creates dilemmas and ethical issues for the veterinarian
- goes against scientific literature and in some cases responsible use guidelines

FVE and Copa-Cogeca (European Farmers Organisation) wrote to the European Commission

Answer European Commission: A different dosage or duration of treatment is not allowed!

A Member of the European Parliament asked a similar question and received a similar reply

European Parliament

BG ES CS DA DE ET EL EN FR GA HR IT LV LT HU MT NL PL PT RO SK SL FI SV

Parliamentary questions

39k 9k

2 February 2022

E-000452/ WORD

Question for written answer E-000452/2022
to the Commission
Rule 138
Pernille Weiss (PPE)

Answer in writing

Subject: Regulation (EU) 2019/6 on veterinary medicinal products and the obligation to comply with information on dosage

Among other objectives, Regulation (EU) 2019/6 on veterinary medicinal products aims to ensure the prudent use of antimicrobials in order to address issues of antimicrobial resistance. This is of great importance to animal and human health in the EU.

Article 106(1) of the regulation states that 'Veterinary medicinal products shall be used in accordance with the terms of the marketing authorisation'. According to Article 36(1) such terms relate to the 'summary of the product characteristics', which must contain clinical information about the 'administration route and dosage' (Article 35(1)(c)(ix)).

1. Does the Commission support the interpretation that veterinarians may not use a lower dosage than what is described in the summary of the product characteristics, even when it is advisable for the sake of the health of the animal being treated?

2. If it does support this, can the Commission clarify how such an interpretation can be considered consistent with the objective of ensuring the prudent use of antimicrobials?

3. What flexibility, if any, do the Member States' authorities have to allow a lower dosage than that stipulated in the summary of the product characteristics when their experience shows it to be advisable in practice?

Whereas

- CMDv is already working on SPC harmonization for similar products
- This process will take long
- Veterinarians are ethically and professionally responsible and accountable for the treatment of each animal under their care [*dosage and duration is often related to the condition of the respective animal; the resistance level (MIC) identified; clinical efficacy of previously applied treatment in the herd, etc.*]
- There is no tool for notification of different protocols [*pharmacovigilance system is not the proper tool*]
- Lack of clear interpretation will lead to different implementation practices in the different Member States

*Urge policy-makers to work together and take a **common** approach that **trust veterinarians** as a highly educated profession able to make informed and professional decisions in line with the principles on responsible use of medicines in animals in the EU and a true application of the One Health concept*

Reflections on the way forward: potential short-time solutions

Not ideal:

- SPC Harmonisation: will take long / not really solve the problem
- Dose optimization: will take long, will be difficult/ will not tackle the duration or withdrawal periods
- Companies revise SPC's: too administratively burdensome /could lead to products disappearing from market
- Countries taking individual approaches to solve this problem: eg. non-enforcement, allowing national guidelines to prevail over the SPC, etc., ***but*** this will breach Art 106(1) and will put veterinarians in a difficult liability situation

Better approach:

- EC to revise art 106 by replacing '*shall*' by '*should*' or ending the sentence with some defined exceptions (e.g. based on recognised prescription guidelines)
- Allow to change dosage and/or duration under the cascade regime based upon

Reflections on the way forward

Medium-long term solutions:

- Work with EMA/NCA's to move towards a ***more future-proof SPC*** which can last for the whole life-time of a product, counter-acting the current trend of always going more prescriptive.

Thank you for your attention