From: [redacted]
To: SANTE VETERINARY MEDICINES
Subject: Re: New Veterinary Medicines legislation targeted stakeholder consultation
Date: 03 July 2020 16:28:34

Dear Ms Zamora.

Please find below the contribution from Copa and Cogeca to this consultation process.

As far as we understand, the main problem regarding the implementation of the new Regulation will be how the availability of the old antimicrobials with their not-updated Summary of Product's Characteristics (SPCs), for instance the family of tetracyclines, would be allowed.

For us it would be essential and very important to have those veterinary medicines available for use without a new demand for new SPCs being required for them. If those antimicrobials cannot be used until new SPCs arrive, there is a risk that veterinarians would end prescribing large-spectrum antibiotics instead of other more suitable options. This would not be good either for AMR situation or for the public image of animal husbandry.

Many thanks for taking our comments into consideration.

Best regards,

[redacted]

Policy Advisor

Plant Health & Phytosanitary Questions
Animal Health & Welfare
Risk Management & Insurance

Copa-Cogeca

From: SANTE-VETERINARY-MEDICINES@ec.europa.eu [mailto:SANTE-VETERINARY-MEDICINES@ec.europa.eu]

Sent: 12 June 2020 16:13
To: SANTE-VETERINARY-MEDICINES@ec.europa.eu
Subject: New Veterinary Medicines legislation targeted stakeholder consultation

Dear Madam, Dear Sir,

The new Regulation (EU) 2019/6 on veterinary medicinal products, published on 7 January 2019, will become applicable in January 2022.

As part of its implementation, the new Regulation requires the European Commission to adopt delegated and implementing acts.

These include:

1) Implementing act on Good Pharmacovigilance Practice;
2) Implementing act Pharmacovigilance System Master File

The Commission asked the European Medicines Agency (EMA) for its recommendations on

the above-mentioned acts.
Please kindly note that the EMA scientific recommendations have now been published on the Commission's dedicated webpage:
https://ec.europa.eu/food/animals/health/veterinary-medicines-and-medicated-feed/imp-regs-2019_en

Implementation of Regulation (EU) 2019/6 on veterinary medicinal products and Regulation (EU) 2019/4 on medicated feed | Food Safety

ec.europa.eu

Implementation of Regulation (EU) 2019/6 on veterinary medicinal products and Regulation (EU) 2019/4 on medicated feed

We would like to kindly ask you for your views and comments as regards the EMA recommendations, as your comments will provide valuable information to the Commission.
Please note that the deadline for submitting written comments is Friday, 3 July 2020.
Should you have any further questions please do not hesitate to contact us at SANTE-VETERINARY-MEDICINES@ec.europa.eu.
Kind regards,
Eva Zamora Escribano
Head of Unit
DG SANTE E5
Animal nutrition, veterinary medicines