

Brussels, 18 January 2021
(Sent by email)

Re: Continued provision of animal health products in Europe to be severely jeopardised
as of 28 January 2022

Dear President Von der Leyen,

On behalf of the animal health industry in Europe (AnimalhealthEurope, Access VetMed), and the veterinary profession (FVE), we would like to draw your attention to a very serious concern regarding the upcoming application of the EU Regulation 2019/6 on veterinary medicines on 28 January 2022.

It has been brought to our knowledge that the interpretation of an article (152(2)) within the new regulation, will mean that new batches of currently approved veterinary products used for treating or preventing disease in animals (e.g. vaccines, pain medication, antibiotics, etc.) would no longer be released to the entire EU market as of the date of application.

With this letter we ask if you, as European Commission President, would be willing to find a solution that does justice to the intention of the regulation and find a workable solution in order to continue to protect animal health and welfare, and avoid a total standstill of the industry and the consequential serious impact on the veterinary profession, that of livestock farmers, and other animal owners due to impending shortages?

To explain in short:

Following a number of exchanges with DG SANTE concerning the interpretation of an article on the “transitional provisions” (article 152(2)) of Regulation 2019/6, we believe there is reason to understand that the continued provision of new batches of veterinary medicines will be jeopardised.

Until now, it has been our understanding, and the interpretation of the European and national medicines regulatory agencies, that article 152(2) allowed a 5-year transition period to adapt packaging and labelling of existing marketed products until 29 January 2027. The transition period is justified due to the immense workload involved for industry and the regulatory authorities, and because the required changes are largely of format and not content, so that the benefit-risk assessment of the products will not change. This interpretation was made available to business operators by means of a series of publications on the EMA’s website (Sept. 2021), the CMDv website and websites of several national medicines agencies, with guidance on the application of Regulation 2019/06 as of 28 January 2022.

From our exchanges with DG SANTE, the most recent Commission interpretation being put forward as a ‘not-legally-binding opinion’ implies that all products must immediately comply

with the new packaging and labelling rules after the date of applicability on 28 January 2022. As this is not in line with previous communication nor with the definition in the Regulation of ‘placing on the market’, and therefore impossible to achieve within the notice given, this implies that the release of any new batches of all veterinary medicines into the supply chain would stop on this date.

This means that within a few weeks after the application of the new Veterinary Medicines Regulation there will be a complete shortage of all veterinary medicines in the EU Market that would continue for several years.

We believe that large-scale shortages of veterinary medicines is neither the intention of the Commission nor that of the co-legislators.

We remain certain that the consequential severe negative impact on animal health and welfare and public health (due to lack of appropriate medication and increased risk of the use of human medicines by veterinarians without a validated dose or withdrawal period), the environment (tonnes of veterinary medicines and packaging would need to be destroyed), the biosecurity threat and economic impact to agriculture and aquaculture sectors is well-understood.

We therefore seek your urgent action on this important matter in the days to come, as the entry into force of the new legislation EU 2019/6 is imminent.

Thank you for your prompt consideration.

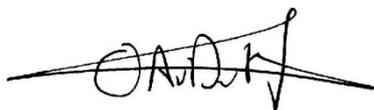
Hans Dittrich
President, AnimalhealthEurope



Dolores Cainzos
President, AccessVetMed



Rens van Dobbenburgh
President, Federation of Veterinarians of Europe



Cc:
European Commission Vice-President, Frans Timmermans
European Commissioner for Health and Food Safety, Stella Kyriakides