From: Jenny Ivarsson
Sent: den 27 september 2022 09:56
To: 'Adam Estrup'
Cc: Roxane Feller
Subject: Sv: Forespørgsel om møde vedr. PFAS (perflouralkylstoffer)

Dear Adam,
Thank you for your e-mail.
During the last two years, the five countries have put much effort in gathering information on the tonnages, emissions, functionality, alternatives and economic impacts of potential restrictions of PFASs. This information was received in two consultation rounds and in addition several studies by external consultants were performed. In the restriction dossier (including Annexes) the information will be presented and based on this one or more restriction options will be proposed. At this stage we are quite busy with the preparation of the restriction dossier and cannot prioritize meetings with stakeholders.

Please also note that submission of the dossier to the European Chemicals Agency (ECHA) is foreseen in January 2023 and will be followed by a 6 months consultation period where you will have the possibility to comment on the proposal and provide relevant input. After the two scientific committees (RAC and SEAC) have formulated their opinions, the dossier will be handed over to the European Commission and a policy decision will be taken. More information on the restriction procedure can be found on ECHA's webpage:
Restriction process - ECHA (europa.eu)

Best regards,
Jenny

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How we treat your personal data

Från: Adam Estrup <[redacted]@vinordic.org>
Skickat: den 23 september 2022 09:52
Till: Jenny Ivarsson <[redacted]@kemi.se>
Kopia: Roxane Feller <[redacted]@animalhealtheurope.eu>
Ämne: Forespørgsel om møde vedr. PFAS (perflouralkylstoffer)

Kære Jenny Ivarsson!
Denne henvendelse på vegne af AnimalhealthEurope og Veterinary Industry Nordic.
AnimalhealthEurope (https://animalhealtheurope.eu) er den Bruxelles-baserede interesseorganisation for den veterinære del af lægemiddelindustrien og vi hos Veterinary Industry Nordic den nordiske pendant.
Vi er stærkt bekymrede for, at de aktuelle overvejelser vedr. et totalforbud mod anvendelse af perflouralkylstoffer vil få sundhedsmæssige konsekvenser for både dyr og mennesker. Vi redegør for vores bekymringer nedenfor, herunder også, hvordan et sådant forbud efter vores opfattelse vil være i strid med de grundlæggende principper for EU-lovgivning.
I den forbindelse vil anmode vi om et møde – meget gerne *in person* – med jer og på dette forelægge og uddybe disse bekymringer.

Et møde vil have deltagelse af Roxane Feller (generalsekretær for AnimalhealthEurope), Jaume Colomer (Senior Technical Manager, AnimalhealthEurope) og undertegnede.
Vi har retter samme henvendelse til myndighederne i Danmark og Norge.
Ser frem til at høre fra jer.
Mange venlige hilsner

Adam Estrup
Chief Executive Officer

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Uddybning

With the new and very recent Veterinary Regulation 2019/6, which came into effect on 28 January 2022, the European Institutions have further finetuned the standards for development, authorisation, manufacturing, and use of Veterinary Medicinal Products (VMPs) for the years/decades to come. The Regulation ensures high protection of human health, animal health and the environment while at the same time aiming to address compelling issues such as the reduction of administrative burden and increasing the availability of VMPs in the Union.

However, in practice, some EU environmental legislations threaten to potentially overlap and conflict with legislation for veterinary medicines. This is in particular the case for:

The REACH Regulation (Reg 1907/2006). Various initiatives under this Regulation are already impacting VMPs either during their manufacture or in their composition, or are imposing labelling requirements which are in direct conflict with the rules in Reg 2019/6:

- Examples include restrictions on aprotic solvents NMP, DMF and DMAc; rules on labelling and reporting of microplastics in medicinal formulations.
- The recently launched proposal for restriction of per- and polyfluoro alkyl substances (PFAS) which, given its broad definition of PFAS, threatens a ban on specific VMPs or renders their manufacture impossible as there are no alternatives. E.g., this could eliminate all inhalation anaesthetics currently used in both human and veterinary medicine, and it could cause significant treatment gaps in other areas with implications for animal health but also for public health as some of the conditions that are treated by these medicines (e.g., fleas and ticks, and the diseases they carry) can impact human health if the animals are left insufficiently treated, or even untreated.

Human and veterinary medicinal products are regulated by weighing their benefits with the potential risks that might be associated with them and where this balance is positive, the medicines receive a marketing authorisation. This principle which governs the provisions of Regulation 2019/6 is in contrast to the principle of regulating based on the hazard alone, which is at the core of EU environmental legislation. By default, this basic difference in governing principles will ultimately result in serious availability issues with

both human and veterinary medicines if the “one substance, one assessment” proposal would be pursued in a non-discriminatory way.

This area of environmental legislation not only causes legal conflicts with regulation 2019/6 but also risks resulting in dual and even conflicting legislation for VMPs which is unacceptable under the basic principles of EU Law.

This situation already causes uncertainty for companies, and we know from experience that the lack of predictability of our legal environment will rapidly result in a decrease in investment and with that of innovation for the EU Medicine sector.