The challenges of a universal PFAS ban

Impacts on animal health and welfare, research and innovation, as well as manufacturing capabilities in the EU

The animal health industry shares concerns about the environmental impact of PFAS[1]. However, PFAS is a broad non-specific term which does not inform whether a compound is harmful, and not all PFAS present the same risks[2] to the environment or health. **Although the use of PFAS in the animal health sector is low, their specific applications are essential for continued availability of veterinary medicines.**

The animal health industry welcomes the proposed derogation for PFAS Active Pharmaceutical Ingredients (APIs). However, **additional derogations are needed for PFAS used in:**

- Precursor chemicals and equipment for manufacturing and supply chains
- Substances for scientific research, development, and quality control
- Packaging of veterinary medicines and devices

We will endeavour to ensure substitution, but valid alternatives need to be approved, supply guaranteed, and sufficient time accorded for regulatory approval, to avoid disruptions in animal care.

PFAS are present throughout R&D, manufacturing, packaging, and administration of veterinary medicines.

R&D	Manufacturing	Packaging & Distribution	Administration
Laboratory Equipment, Instruments, Piping	**Chemicals** APIs, Starting materials, Intermediates, Process materials	**Production equipment** Pipes, Gaskets, Caps, Valves, Injectors, Degassers, Filters, Refrigerants, Lubricants	**Packaging** Stoppers, Blisters	**Storage & transport** Plastics, Coatings, Refrigerants	**Administration** Medicines delivery devices, Diagnostics






KEEP IN MIND

- Not all PFAS substances present **the same human health and environmental risk.**
- Veterinary medicines are highly regulated and only receive marketing authorisation when they pass thorough quality, safety and efficacy assessments, and socio-economic and benefit-risk analysis. Restrictions on uses of substances which do **not pose a risk is not in line with the principles of REACH.**
- The scope of the EU Restriction deviates from other jurisdictions. This broad-brush approach impacts animal patients and their owners globally and puts EU-based companies and associated manufacturing at a **major competitive disadvantage.**
- Without appropriate derogations, there will be **insuffcient time** to identify suitable alternatives and further develop waste treatment technology and analytical methods.
- Veterinary medicines production in Europe will be impacted by **a shortage of key raw materials** if suppliers cannot produce or import into the EEA.

With a universal ban for PFAS, access to medicines will be impacted for:

300,000
Veterinarians[3]

91 million
Households that have pets[4]

3.3 million
Farms with animals[5]

Additional PFAS derogations would ensure uninterrupted access to key veterinary medicines, including vaccines

Our recommendations

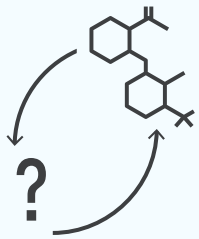
Keep the proposed derogation for APIs classed as PFAS, and also:

- Provide derogations for manufacturing and packaging until suitable alternative solutions are agreed, qualified and approved
- Develop partnerships throughout supply chains and distribution channels to better manage emissions
- Ensure global health authorities expedite approvals of suitable alternatives

The animal health industry supports substitution in the manufacturing process

However, replacing PFAS–containing materials in a highly regulated sector like veterinary medicines is challenging:

- In most cases **no alternatives are currently available**;
- Any alternatives must be analysed and assessed for their functionality and safety, and consistent supply.
- When a viable and scalable alternative is identified, **implementation will require time and collaboration** amongst different stakeholders in the value chain, including regulatory authorities.



Fluoropolymers[6] are highly resistant to heat, chemicals, and degradation. Potential replacements providing the same benefits will be hard to find and may also be persistent in the environment.

Appropriate derogations will be critical to ensure continued supply of veterinary medicines.

Without an exemption for APIs and further derogations for veterinary medicines manufacturing and packaging processes, Europe's strategic autonomy will be impacted

50,000
People working in the veterinary medicines sector[7]

120+
Manufacturing plants across Europe[7]

27%
Of global sales of veterinary medicines, **2nd largest** market in the world[8]

€7.9 billion
In veterinary medicines sales in 2023[8]

The animal health industry relies on PFAS–containing substances and materials for the safe manufacturing, distribution and use of **veterinary** medicines, including vaccines.

Access to veterinary medicines is a prerequisite for animal health, for animal welfare, and for our shared One Health.

1. The PFAS (per- and polyfluoroalkyl substances) Ban or Restriction, which was created by five national authorities (Germany, the Netherlands, Sweden, Norway and Denmark) is currently being assessed by ECHA (European Chemicals Agency).
2. Certain PFAS have been identified as environmental pollutants, resulting in protective measures e.g., drinking water standards. This substance group, includes short and long chain fluorosurfactants or telomers.
3. https://fve.org/cms/wp-content/uploads/FVE-Survey-2023-updated-13-Dec-23.pdf
4. https://europeanpetfood.org/about/statistics/
5. https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Farms_and_farmland_in_the_European_Union_-_statistics#Farms_in_2020
6. "Fluoropolymers" represent a distinct subset of fluorinated polymers, based on a carbon–only polymer backbone with F atoms directly attached to it, e.g. polytetrafluoroethylene (PTFE); though some fluoropolymers also have Cl or O directly attached to the backbone. [Buck et al (2011) Perfluoroalkyl and polyfluoroalkylsubstances in the Environment: Terminology, Classification and Origins]
7. AnimalhealthEurope membership
8. CEESA