WildFish.

The problem of veterinary medicines in the aquatic environment

---

Contents:

Acknowledgements

WildFish would like to convey its sincere thanks to the following for their expert comments on and contributions to this report:

Professor Dave Goulson, Professor of Biology, University of Sussex

Ms Amanda Boag, FRCVS

Dr. Rose Perkins, BVSc PhD MRCVS, Veterinary Surgeon and Associate Researcher, University of Sussex

Dr. Calum Ramage, University of Nottingham

Executive summary

Veterinary medicines (“vet meds”) play a central role in ensuring animal health and food production.

However, their use in intensive farming, aquaculture, and in domestic pet care, has raised environmental concerns, particularly for the aquatic environment and ecosystems.

This report examines the pathways through which vet meds enter aquatic environments in the UK, the gaps in monitoring, the impacts on ecosystems, the lack of use data, as well as failures in authorisation and regulation of vet meds and the prevention of environmental harm.

The report makes recommendations for improvements, including to the underlying law as applied in Great Britain, to address the harms being caused.

1. Veterinary medicines in the UK

1.1 Vet meds are used to treat or prevent disease in animals raised for food production, equines and companion animals (pets).

1.2 The National Office of Animal Health, the trade association representing 97% of the UK animal health industry, reports around £745 million in annual UK sales of authorised vet meds.

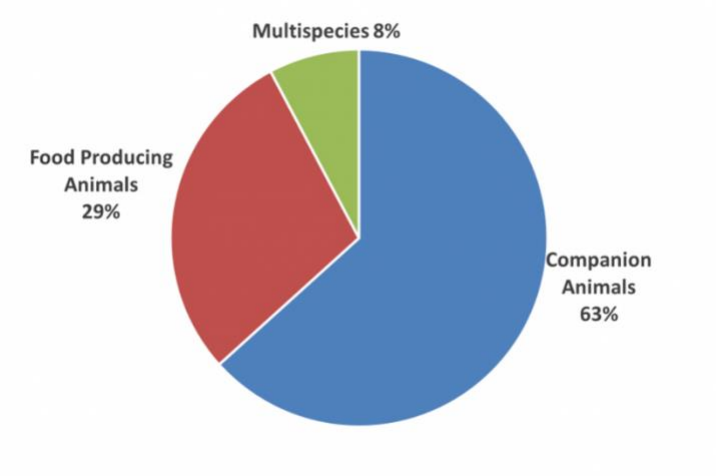
1.3 The term 'vet meds' covers a range of products including –

- ectoparasiticides (preventing and treating external parasites such as mites, ticks, fleas, lice and flies);
- endoparasiticides (preventing and treating internal parasites such as worms and flukes);
- antimicrobials (antibiotics used in bacterial infection);
- vaccines;
- other vet meds (anti-inflammatories, painkillers, and other specific therapeutants).[1]

1.4 The active substances ('actives') in vet meds are often also used as 'actives' in plant protection products (PPPs) (i.e. herbicides, insecticides and fungicides used in agriculture) as well as in biocides (for example, wood preservatives, rodenticides or products for dealing with cockroach infestations of properties). However, these three categories - PPPs, biocides and vet meds - are controlled and regulated under different legal regimes.

[1] See https://www.noah.co.uk/about/industry-facts-and-figures/

1.5 In the 1980s, around 70% of vet meds were used in farm livestock. Now over 60% of vet med sales, by value, are for companion animal (pets) use.[2]



UK veterinary market sales by species - 12 months to end Q3 2022 (source: NOAH)[3]

1.6 Many vet meds for treating or preventing infestation of both livestock and companion animals are aimed at controlling parasites (worms, ticks, fleas etc). For example, the most frequently used vet med active ingredients in the UK are fipronil and imidacloprid, largely used against fleas and ticks[4] and available 'over-the-counter' so without prescription.

1.7 All authorised vet meds are listed on the Veterinary Medicines Directorate's (VMD) Product Database[5] although many underlying regulatory documents are still to be found on the European Medicines Agency (EMA) Product Database.[6]

[2] See Industry Facts and Figures | NOAH (National Office of Animal Health)

[3] See Industry Facts and Figures | NOAH (National Office of Animal Health)

[4] Wells, C. and Collins, C.M.T. (2022) A rapid evidence assessment of the potential risk to the environment presented by active ingredients in the UK's most commonly sold companion animal parasiticides. Environ Sci Pollut Res 29.

[5] See Product Information Database - Home

[6] See Union Product Database | European Medicines Agency (EMA)

2. Veterinary medicines in the aquatic environment – pathways

2.1 Vet meds can and do enter the aquatic environment through:

- run-off from land, from livestock or pet faeces, or after manure spreading in agriculture, including from equines;
- discharge of effluent from livestock rearing (including intensive livestock units);
- discharges of wastewater from domestic sewerage systems and surface water drains;
- direct contamination from treated animals (both livestock and pets) entering waters.

2.2 Discharges of vet meds from aquaculture directly into the marine environment, as part of the normal mode of operation of marine fish farms, particularly Scottish salmon farms, are also very significant. However, these are outside the scope of this report– see Salmon Farming | Salmon Farming Crisis | Wildfish for further information.

2.3 A review of the environmental impacts and risks associated with vet meds conducted twenty years ago by the Environment Agency concluded that:

> *"the main routes of entry to the terrestrial environment are from the use of veterinary medicines in intensively reared livestock, via the application of slurry and manure to land, and by the use of veterinary medicines in pasture-reared animals where pharmaceutical residues are excreted directly into the environment. Veterinary medicines applied to land via spreading of slurry may also enter the aquatic environment indirectly via surface runoff or leaching to groundwater. It is likely that topical treatments have*

greater potential to be released to the environment than treatments administered orally or by injection".[7]

2.4 That review also suggested that inputs of vet meds from pet treatments were likely to be minimal in comparison to inputs of vet meds used in intensively-reared livestock - a view that has changed completely in recent years (see below).

2.5 Significant inputs from the use of vet meds now occur through washing of pets (with subsequent discharge via surface water drains or sewage treatment systems), direct entry of treated pets into watercourses and through deposition of faeces[8].

3. Veterinary medicines in the aquatic environment – monitoring

3.1 When considering contamination of the aquatic environment, the 2004 review conducted by the Environment Agency also concluded that:

"monitoring studies demonstrate that veterinary medicines do enter the environment, with sheep dip chemicals, antibiotics, sealice treatments, and anthelmintics being measured in soils, groundwater, surface waters, sediment, or biota. Maximum concentrations vary across chemical classes, with very high concentrations being reported for the sheep dip chemicals".

[7] Boxall AB, Fogg LA, Blackwell PA, Kay P, Pemberton EJ, Croxford A (2004) Veterinary medicines in the environment. Rev Environ Contam Toxicol. 2004;180:1-91.

[8] For example, specific warnings on the use on chewable tablets for dogs, for the treatment of fleas - *"Special precautions for the protection of the environment: The active substance is mostly excreted in the faeces (poo) and may be toxic to non-target organisms. In order to avoid contamination of the environment, ensure that dog faeces are bagged up and disposed of safely".*

3.2 Typically, regulatory or surveillance monitoring for vet meds in the aquatic environment is routinely 'lumped in' with monitoring efforts for pesticides generally.

3.3 Although in 2012, the Environment Agency stated that it "*routinely monitors pesticide concentrations in rivers*"[9], monitoring of vet meds in the water environment in the UK is still not yet routine, and is characterised by a lack of consistent monitoring, a point brought up repeatedly across academic papers. What datasets do exist are often fragmented, or only at local/regional scales.

3.4 In England, the Environment Agency's water quality archive[10] holds any available data on vet med residues. Samples are taken at sampling points around England and can be from coastal or estuarine waters, rivers, lakes, ponds, canals or groundwaters. Any available vet meds monitoring data is included, but there is not currently a wealth of data.

3.5 Similarly, data for Wales is held on the Natural Resources Wales (NRW) water quality archive.[11]

3.6 In Scotland, there is almost no vet meds data available for freshwater, although in 2024, the Scottish Environment Protection Agency (SEPA) unveiled a new method to detect chemicals in water environment (which could include vet meds) to allow it to conduct large-scale analysis of diverse chemical compounds, including pesticides, pharmaceuticals, and vet meds[12]. In contrast, the widespread use of vet meds in Scottish salmon farming to combat sea lice infestation – and the modelled discharge of residues – is publicly reported[13].

---

[9] Environment Agency (2012) Observatory Monitoring Framework - Indicator factsheet - Pesticides in Water"

[10] See https://environment.data.gov.uk/water-quality/view/landing

[11] See NRW Water Quality Archive | DataMapWales.

[12] See https://beta.sepa.scot/news/2024/sepa-unveil-new-method-to-detect-chemicals-in-water-environment/

[13] See Scotland's Aquaculture | Home

3.7 Addressing this 'monitoring gap' in national monitoring for pesticides generally (including vet meds) in English rivers, researchers noted that:

> *"between 2000 and 2023, fewer than 50 samples were collected for pesticide residue analysis from the majority of riverine monitoring sites (see Figure 1) and no riverine sites in the Southwest, Southeast, and Thames regions had more than 50 samples collected in total for pesticide residue analysis. In contrast, the Midland and Anglian regions of England received more comprehensive sampling efforts, with samples collected every year over the 24-year period and with some riverine sites having more than 800 samples collected for pesticide residue analysis (See online supplementary material Figure S4). For the Northwest, Southwest, Southeast, and Thames regions, riverine samples for pesticide analysis were collected from 2015 onwards only and for the Thames region for the year 2020 only"*[14].

3.8 The Grantham Institute of Imperial College London reported in 2023 that:

> *"In recent years, there have been substantial improvements in the technology available for monitoring chemicals in the environment, meaning the detection of harmful chemicals such as pesticides has become increasingly common. Even so, only a fraction of the UK's waters are routinely tested for these chemicals; and in many cases, only a small subset of potential pesticides are quantified, so much of this sampling is still relatively ad hoc and often done by non-regulatory bodies".*[15]

[14] Poyntz-Wright IP, Tyler CR (2025) Mind the gap-national pesticide monitoring data needs for invertebrate effects assessments in English rivers. Environ Toxicol Chem. 2025 Mar 1;44(3):637-642

[15] See Are urban areas hotspots for pollution from pet parasiticides? | Grantham Institute – Climate Change and the Environment | Imperial College London

3.9 The position for vet meds is perhaps worse that for pesticides regulated as plant protection products (PPPs) (i.e. herbicides, insecticides and fungicides) or as biocides. Focussing particularly on parasiticides, which contain the same 'actives' pesticide compounds, the Grantham Institute highlighted the general paucity of monitoring data:

> *"Improvements in laboratory testing allow chemicals to be detected at ever-lower concentrations, yet there are still notable blind spots in the UK's formal monitoring programmes. The lack of coordinated spatiotemporal monitoring has resulted in patchy datasets that limit our ability to capture potential impacts on species. In the best available monitoring dataset for England, imidacloprid[16] has been tested in 88% of the Environment Agency's liquid chromatography mass spectrometry (LC-MS) sampling sites…*
>
> *However, if we only consider sites regularly tested for imidacloprid, this figure would be even lower, as testing is not consistently carried out across all sampling sites. "Furthermore, the dataset's geographic coverage falls short of complete representation, as parasiticides such as imidacloprid are not tested in all river catchments in England. This is partly because there are no formal requirements for organisations such as the EA to monitor all these chemicals routinely under current regulations. For chemicals introduced as veterinary parasiticides more recently (e.g., afoxolaner, selamectin, and fluralaner), environmental data are even more scarce – <u>with most monitoring schemes ignoring them completely</u>.*
> *Though parasiticides are used in small individual doses, they are now used so frequently on so many animals (i.e., in large aggregate volumes) that we consider it imperative to develop our understanding of their characteristics and effects".*

[16] Imidacloprid is authorised for use in flea and tick treatments of companion pets.

3.10 The Institute also highlighted the need for improved monitoring of vet meds, reporting that the current environmental monitoring program is not systematically tracking vet med residues in water:

> *"We recommend that future research should "stratify and increase the spatial extent of long-term monitoring of parasiticides in UK water bodies and coverage of the full spectrum of likely sources, entry points, and pathways of parasiticides entering the environment" and "assess the severity and geographic extent of contamination of freshwater ecosystems and impacts, especially at the higher community and ecosystem levels of biological organisation".*

3.11 This lack of monitoring makes it highly likely that there are unquantified environmental impacts from vet med residues occurring in aquatic systems in the UK:

> *"It is also now well recognized that various pesticides used in veterinary medicines for livestock care, including anti-helminthics such as ivermectin and doramectin (Environment Agency, 2006), and in pet care, for example, imidacloprid and fipronil, used for flea treatments (Perkins et al., 2021) and are highly toxic to invertebrates, are entering waterways, thus posing a potential threat riverine invertebrates, but these compounds <u>have rarely been detected/monitored as part of the UK National Monitoring Programme (WIMS)</u>"*[17]*.*

3.12 The same researchers further concluded in 2025 that:

> *"in our analysis of the UK's 24-year national chemical monitoring program (WIMS database; years 2000 to 2023), we show that of the*

[17] Poyntz-Wright IP, Tyler CR (2025) Mind the gap-national pesticide monitoring data needs for invertebrate effects assessments in English rivers. Environ Toxicol Chem. 2025 Mar 1;44(3):637-642.

nine pesticides that pose the greatest likely threat to UK freshwater invertebrates based on concentrations measured in British rivers exceeding the lowest effect concentrations (ECs) in laboratory-based toxicity tests, seven pesticides have exceeded the ECs across England between the years 2000 and 2023".

3.13 Of those seven pesticides, chlorpyrifos, once used in vet meds, is now banned in the UK. Cypermethrin is still authorised for use as a vet med in horses, sheep and cattle. Deltamethrin is still authorised for use as a vet med in dogs, sheep and cattle. Fenitrothion, parathion and malathion were also once used as vet meds.

3.14 Vet meds are a clear risk to aquatic environments and ecosystems. Most recently, UK Water Industry Research (UKWIR) concluded that:

"For quantifying input concentrations and loads, reliable monitoring data are needed, but there still is a lack of data and information for many substances. The main reasons being:

- *most chemicals are not included in national routine monitoring programs,*
- *often very low environmental concentrations and low concentrations in wastewater (effluent),*
- *the need for sensitive analytical methods: low limits of detection (LoD) and quantification (LoQ)."*[18]

3.15 Clearly therefore, monitoring in the aquatic environment is not sufficient and resources are required to improve overall monitoring for vet med residues.

[18] .J. Gardner, S.D.W. Comber, B. Ellor (2022) Summary of data from the UKWIR chemical investigations programme and a comparison of data from the past ten years' monitoring of effluent quality, Science of The Total Environment, Volume 832, 2022.

4. Evidence of harm

4.1 Although vet meds are appearing in the very limited monitoring data available, over years, vet meds used in intensive farming, aquaculture, and domestic pet care have raised environmental concerns, particularly for the aquatic environment and impacts on aquatic ecosystems.

4.2 The review conducted for the Environment Agency in England and Wales in 2004 concluded that: *"because of historic, measurable impacts in the environment, a number of groups of veterinary medicines (i.e. sheep dip chemicals, fish farm medicines and anthelmintics) are known to be of environmental concern. However, the environmental fate, behaviour and effects of other veterinary medicines and their potential environmental impacts are less well understood".*[19]

4.3 There is still a serious issue with 'actives' used in vet meds, particularly in relation to the decline in insect populations in the wild. It is unsurprising, given their designed toxicity to the nervous systems of insects and other invertebrate parasites of livestock and pets, that many vet meds are a particular risk for aquatic invertebrates, including insects.

4.4 A third of global aquatic insect species are threatened with extinction[20]. UK insect populations are not spared[21]. A large number of international scientists recently issued a concerned statement together with a plan for the conservation of insects and recovery of insect populations. They made it clear that "*there is now a strong scientific consensus that the*

[19] Environment Agency (2002) Review of Veterinary Medicines in the Environment
R&D Technical Report P6-012/8/TR A B A Boxall, L Fogg, P A Blackwell, P Kay and E J Pemberton
Research Contractor: Cranfield Centre for EcoChemistry R&D Technical Report P6-012/8/TR

[20] See Global insect declines: 33% of aquatic species threatened with extinction | The Freshwater Blog

[21] See The Silent Killer of UK Rivers: new study shows English rivers exhibiting increased chemical stress and declining invertebrate diversity - Buglife latest news

decline of insects, other arthropods and biodiversity as a whole, is a very real and serious threat that society must urgently address".[22]

4.5 This has relevance for the control of vet meds which often have potent toxicity for insects and other invertebrates. In the aquatic environment, vet meds show differing degrees of toxicity to aquatic organisms, including aquatic invertebrates.

4.6 Therefore, the impact of vet meds in rivers and lakes in the UK, on invertebrate populations and on the general ecology of water bodies, and the role that vet meds may be playing in the decline in insect populations generally warrants urgent attention.

4.7 Further, impacts are not limited to invertebrates, with fish reported as bioaccumulating active ingredients including those used in vet meds in English rivers[23].

4.8 This general threat has been recognised by the establishment in 2023 of the UK Pharmaceuticals in the Environment (PiE) cross-government group, said to be working to reduce the impacts of pharmaceuticals (including vet meds) in the environment[24], although the work of the Group has yet to lead to any recognisable decisive action, having only begun to consider fipronil and imidacloprid to date (see below), with the Group reported as recently as February 2025 merely to "*have aspirations to broaden the scope beyond fipronil and imidacloprid".*[25]

4.9 There are key examples of harm caused, over recent years, by vet meds used in:

---

[22] Harvey, J.A., Heinen, R., Armbrecht, I. *et al.* (2020) International scientists formulate a roadmap for insect conservation and recovery. Nat Ecol Evol 4, 174–176 (2020).

[23] Calum I. Ramage, Raquel Alfama Lopes dos Santos, Lisa Yon, Matthew F. Johnson, Christopher H. Vane (2025) Widespread pesticide pollution in two English river catchments of contrasting land-use: from sediments to fish Environmental Pollution, Volume 375, 2025.

[24] See New Pharmaceuticals in the Environment cross-government group - GOV.UK

[25] PiE Group Meeting Bulletin Update 12 February 2025

- treatments for ectoparasites in sheep (sheep dip)
- other agricultural parasiticides
- cat and dog flea and tick treatments
- equine treatments.

Sheep dip

4.10 Sheep dip has been used to protect sheep from infestation by external parasites such as sheep scab mites, flies, ticks and lice, and have been used since the 19th century.

4.11Sheep dip is regulated as a vet med.

4.12 A range of different chemicals have been used over the years. Initially, arsenical compounds were used, to be replaced by organochlorines such as lindane. Dieldrin, another organochlorine once used in 'sheep dip', had a notorious impact on natural ecosystems[26].

4.13 More modern sheep dip formulations containing organophosphates or synthetic pyrethroids have been widely used in UK and their spreading onto land has been identified as the most practical disposal method for 'used' dip although the release into the wider environment of active ingredients has always been problematic.[27]. Pyrethroid sheep dips were implicated in invertebrate population declines in water bodies in sheep-rearing areas of the UK[28].

[26] Kabasenche, W.P., Skinner, M.K. (2014) DDT, epigenetic harm, and transgenerational environmental justice. Environ. Health 13, 62.
[27] Tatiana K. Boucard, Charles McNeill, Richard D. Bardgett, Christopher D. Paynter, Kirk T. Semple (2008) The impact of synthetic pyrethroid and organophosphate sheep dip formulations on microbial activity in soil. Environmental Pollution, Volume 153, Issue 1, 2008, pp207-214.
[28] See Sheep dips poison river life | New Scientist

4.14 Referring to monitoring data gathered between 1998 and 2007, in a reference to synthetic pyrethroid sheep dips, the Environment Agency noted in 2012 that *"certain pesticides such as pyrethroid insecticides can also have devastating effects on aquatic fauna"*[29].

4.15 In 2006, a decade-long campaign led by the Anglers' Conservation Association (now Fish Legal), Buglife and WildFish (then called the Salmon & Trout Association) led to the decision by the VMD to suspend the sale of cypermethrin sheep dip in the UK after evidence showed that cypermethrin has caused catastrophic damage to invertebrate life of river systems in sheep-rearing areas throughout the country.

4.16 That suspension followed a three-year long battle between the ACA and the VMD over the publication of the ecological risk assessments (ERAs) provided to the VMD by the sheep dip manufacturers, which ended when the VMD capitulated and published the ERAs shortly before appeals were to be heard at the Information Tribunal[30].

4.17 Guidance in the form of codes of practice have existed for years as to how to use sheep dip with less environmental impact, thought adherence to such codes is uncertain, as is the efficacy of what those codes recommend[31].

4.18 In 2025, NRW announced an intention to phase out the decades-old practice of allowing farms to spread diluted waste sheep dip to land, requiring farms to employ a registered waste carrier to dispose of their waste dip "*in a suitable waste facility*"[32].

---

[29] Environment Agency (2012) Observatory Monitoring Framework - Indicator factsheet - Pesticides in Water

[30] See https://ico.org.uk/media2/migrated/decision-notices/500612/FER_0137609.pdf

[31] See Sheep dip: groundwater protection code - GOV.UK

[32] See Farms' Natural Resources Wales sheep dip disposal ban for rivers - BBC News

4.19 However, the fate of used sheep dip, and residues from treated animals reaching the aquatic environment, remains a serious concern wherever there is significant sheep rearing.

Other parasiticides used in agriculture

4.20 There are many other examples of vet meds causing harm to aquatic ecosystems. Attention has focussed on the use of endoparasiticides used in agricultural livestock, particularly those that have residual activity in livestock faeces.

4.21 Ivermectin, which is authorised for use in a wide range of products for horses, sheep, pigs and cattle, is well known to show toxicity to aquatic invertebrates, fish, and algae, affecting reproduction, growth, and behaviour. Freshwater species such as *Daphnia magna* have been found to be particularly sensitive to ivermectin[33].

4.22 Typical warnings on ivermectin-containing vet meds for use in agriculture cover the disposal of packaging –

"Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate Container disposal: EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used container. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements".[34]

- but do not mention the risks from residues in faeces or manures.

[33] Bruce A. Halley, William J. A. VandenHeuvel, and Peter G. Wislocki (1993) Environmental Effects of the Usage of Avermectins in Livestock *Veterinary Parasitology* 48, no. 1 (1 June 1993): 109-125

[34] See, for example, Summary of Product Characteristics for IVOMEC (injectable ivermectin for sheep and cattle), at SPC_139538.PDF

4.23 While legislation such as the Reduction and Prevention of Agricultural Diffuse Pollution (England) Regulations 2018 or the Water Resources (Control of Agricultural Pollution) (Wales) Regulations 2021, and agricultural guidance issued by the Scottish Government all suggest that manures, potentially containing ivermectin residues (or indeed other vet meds), should not be stored within 10m of any surface water and 30m if the land is sloping[35], these measures may be insufficient to prevent ivermectin residues reaching vulnerable water bodies.

4.24 Although it is hoped that rapid photodegradation of ivermectin when placed outdoors in summer can mitigate these risks, with a half-life of 14 days or less, in winter, the half-life of ivermectin can be as long as 217 days, further when stored as a muck heap in which only the top layer of faeces is in contact with sunlight at the surface, limiting the extent of photodegradation[36].

4.25 Recent reviews have suggested that ivermectin *"represents a risk to aquatic invertebrates and their predators, which deserves further studies, especially in the context of their bioaccumulation and biomagnification through the aquatic and terrestrial trophic webs"*[37]. As well as direct acute or chronic toxicity to certain species, disruption of aquatic ecosystems can lead to long-term ecological imbalances.

4.26 Fenbendazole, sold as Fenben or Panacur, is a broad-spectrum anthelmintic drug. It is used to treat parasites and worms such as tapeworms, hookworms, roundworms, and whipworms in farm animals

[35] DEFRA, 'Storing Organic Manures in Nitrate Vulnerable Zones', 12 October 2023, at https://www.gov.uk/guidance/storing-organic-manures-in-nitrate-vulnerable-zones

[36] Callum J. Haseler, Julia L. Shrubb, Hannah G. D. Davies, David I. Rendle, Polly C. Rathbone, Timothy S. Mair (2023) Environmental impacts of equine parasiticide treatment Equine Veterinary Education: Volume 36, Issue 7, Pages: 381-392

[37] Camila Jazmín Lorente, Leticia Mesa, Luciana Montalto, María Florencia Gutiérrez, María Victoria Miró, Adrián Lifschitz (2023) Ivermectin bioaccumulation and transfer through developmental stages in Culex pipiens (Diptera: Culicidae), Chemosphere, Volume 322, 2023.

and pets. It is authorised for the treatment of endoparasites in cats, dogs, pigs, sheep, chickens, pheasants and cattle. Introduced in 1974, it is available over the counter in many countries which has resulted in a larger contamination of the environment and possible negative effects on biota.

4.27 Toxicity to fenbendazole has been found in a number of aquatic organisms, with the crustacean, *D. magna*, typically used in ecotoxicological assessments, appearing particularly sensitive[38]. As the presence of the fenbendazole in the environment has been confirmed in concentrations in the range of few nanogram per litre up to microgram per litre, researchers consider that toxicity to *D. magna* at the levels of microgram per litre might influence these organisms in the environment, suggesting that "*further investigation should be taken into consideration concerning chronic tests in longer period of time*"[39].

4.28 By 2015, fenbendazole had been classified as emerging environmental contaminants for almost 15 years[40].

4.29 Generally, anthelmintic residues have been found at 8% of groundwater sites and 28% of surface water sites in the Republic of Ireland. It is likely that similar rates of detection would be found in livestock producing areas of the UK. Higher levels are identified in February/March and August/September, coinciding with periods of increased use of anthelmintics in livestock[41].

---

[38] Marta Wagil et al.(2015) Toxicity of Anthelmintic Drugs (Fenbendazole and Flubendazole) to Aquatic Organisms, *Environmental Science and Pollution Research* 22, no. 4 (1 February 2015): 2566–73.
[39] Wagil, M., Białk-Bielińska, A., Puckowski, A. *et al.* (2015) Toxicity of anthelmintic drugs (fenbendazole and flubendazole) to aquatic organisms. *Environ Sci Pollut Res* 22, 2566–2573 (2015).
[40] Wagil, M., Białk-Bielińska, A., Puckowski, A. *et al. (2015)* Toxicity of anthelmintic drugs (fenbendazole and flubendazole) to aquatic organisms. *Environ Sci Pollut Res* 22, 2566–2573 (2015).
[41] D. Mooney, K.G. Richards, M. Danaher, J. Grant, L. Gill, P.-E. Mellander, C.E. Coxon (2021) An analysis of the spatio-temporal occurrence of anthelmintic veterinary drug residues in groundwater, Science of The Total Environment, Volume 769, 2021.

Cat and dog flea and tick treatments

4.30 More recently, concern has focussed on the neonicotinoid imidacloprid, and on fipronil both used as vet meds for the treatment of ectoparasites in cat and dogs[42].

4.31 The use of fipronil as a PPP was banned for all but limited use in greenhouses.[43]

4.32 Fipronil has also been banned for use as a biocide[44], BASF has announced that its insecticide products, Goliath Gel and Formidor, was withdrawn, with the last sales in March 2024[45]. The phaseout comes as a result of a European-wide withdrawal of the active substance fipronil under the European Biocidal Products Regulation (Reg. EU 528/2012).

4.33 However, fipronil is still used as an over-the-counter prophylactic (preventative) treatment for fleas by very many dog and cat owners in

---

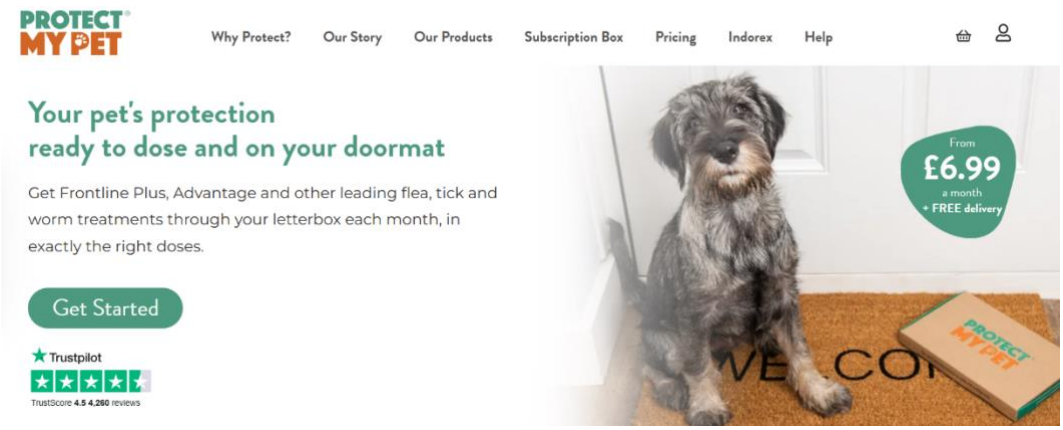
[42] Anthe, M. et al (2020) Development of an aquatic exposure assessment model for Imidacloprid in sewage treatment plant discharges arising from use of veterinary medicinal products. *Environmental Sciences Europe*, 32, no. 147 (2020) and Perkins, R., Whitehead, M. and Goulson, G. (2021) Dead in the water: comment on "Development of an aquatic exposure assessment model for imidacloprid in sewage treatment plant discharges arising from use of veterinary medicinal products". *Environmental Sciences Europe*, 33, no. 88 (2021)

[43] Implementing regulation - 781/2013 - EN - EUR-Lex

[44] Biocides are governed by a separate legal framework (both in the EU and the UK). Biocides are used to protect people and animals, preserve goods, stop pests like insects or rodents and control viruses, bacteria and fungi. Common examples are disinfectants, wood preservatives and insect repellents.

[45] See BASF to phaseout Goliath Gel and Formidor in 2024 | Pest Magazine

the UK and is advertised for such regular and routine use by suppliers, for example:



4.34 Fipronil has variable toxicity to non-insects, with widely varying levels of toxicity reported in animals within the same taxonomic group. It is reported to bioaccumulate in fish and can be toxic to gallinaceous birds[46]. Fipronil is highly toxic to bees, both via contact and ingestion, and its agricultural use is thought to have been responsible for the reduction in honey bees in the 1990s[47]. The half-life of fipronil in the environment is variable, but it degrades into compounds which are more toxic than the parent compound[48].

4.35 In 2013, the European Food Safety Agency (EFSA) assessed the risks to bees from fipronil use as a plant protection product (the use in agriculture as an insecticide).[49]

[46] Colin CD Tingle et al.(2003) Fipronil: Environmental Fate, Ecotoxicology, and Human Health Concerns *Reviews of Environmental Contamination and Toxicology: Continuation of Residue Reviews*, 2003, 1–66.
[47] Philippa J. Holder et al. (2018) Fipronil Pesticide as a Suspect in Historical Mass Mortalities of Honey Bees, *Proceedings of the National Academy of Sciences* 115, no. 51 (2018): 13033–38.
[48] Haseler, Callum & Shrubb, Julia & Davies, Hannah & Rendle, David & Rathbone, Polly & Mair, Tim. (2023). Environmental impacts of equine parasiticide treatment.
[49] Peer review of the pesticide risk assessment for bees for the active substance fipronil | EFSA

4.36 However, according to the VMD, there are 148 authorised vet med products containing fipronil and/or imidacloprid (see below), either alone or in combination with other actives[50].

4.37 Imidacloprid has also been banned for non-vet med uses. However, by weight, imidacloprid is one of the best-selling veterinary parasiticides in the UK.

4.38 Immediately before the ban on crop use, a combined total of over 4000kg was used for agriculture and sold for veterinary use in a single year in the UK.

4.39 After the chemical was fully banned for all outdoor use in 2018, this dropped markedly, but over 2500 kg was still being sold in the following year, all of which was destined for the domestic pet market as a parasiticide.

4.40 This represents a vast number of non-agricultural doses in circulation, given the estimated 25 million cats and dogs across the UK. Altogether, it is unsurprising that concerns have been raised regarding parasiticides as a potential source of seemingly 'hidden' water pollution in the UK[51].

4.41 Fipronil has been found in 99% and imidacloprid in 66% of river samples[52]. It has been demonstrated that small animal pets may make a major contribution to this contamination through several routes such as dogs swimming in rivers or owners washing their hands after

[50] Response to FOI request to VMD by WildFish April to June 2025

[51] Preston-Allen et al. (2023) 'Are Urban Areas Hotspots for Pollution from Pet Parasiticides'. Briefing Note No 15.

[52] Rosemary Perkins, Martin Whitehead, Wayne Civil, Dave Goulson (2021) Potential role of veterinary flea products in widespread pesticide contamination of English rivers, Science of The Total Environment, Volume 755, Part 1, 2021.

application of topical treatments, washing pet bedding or the pets themselves.

4.42 Samples taken from in English waterways between 2016 and 2018 showed detectable fipronil in 98.6% of the 3861 samples tested. The mean concentration of fipronil was over 5 times the chronic toxicity limit, while the mean concentration of the persistent metabolite, fipronil sulfone, was over 38 times the chronic toxicity limit, indicating a high environmental risk to aquatic ecosystems. In this study, the highest levels were detected downstream of wastewater treatment works, suggesting washing of treated pets and pet bedding may well be a source of contamination, in addition to direct entry into waterways through swimming[53] [54].

4.43 The overall pollution levels in English rivers indicate that fipronil, imidacloprid and toxic breakdown products pose a high risk to aquatic ecosystems.

.

[53] Rosemary Perkins (2020) Are Pet Parasite Products Harming the Environment More than We Think?, *The Veterinary Record* 187, no. 5 (2020): 197–197.
[54] Perkins et al (2025) Swimming emissions from dogs treated with spot-on fipronil or imidacloprid: assessing the environmental risk. VetRecord, April 2025.

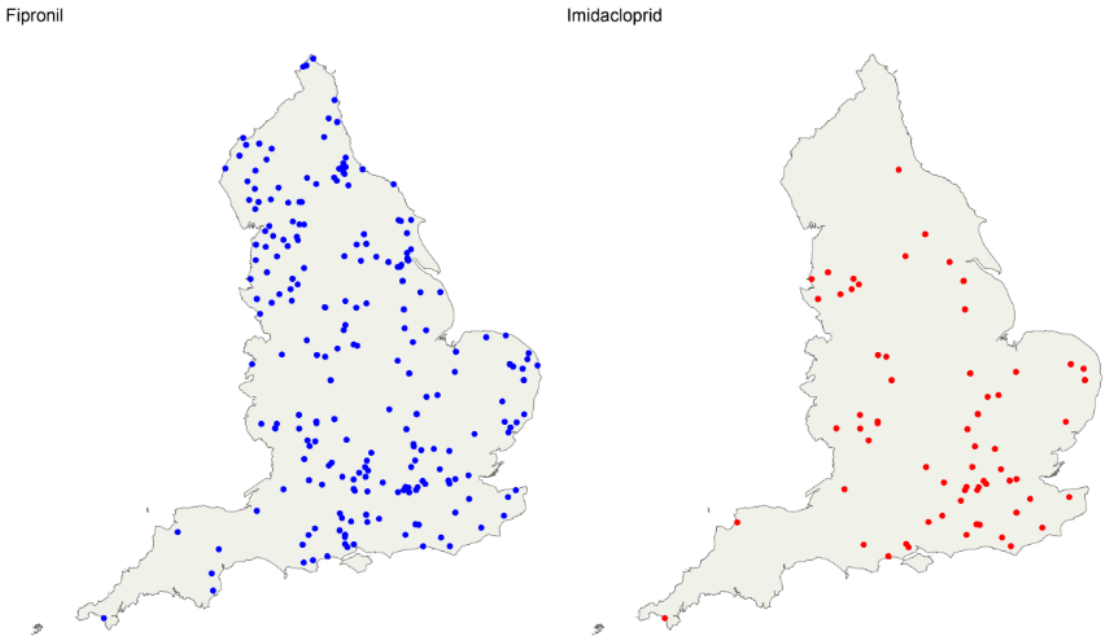


Figure 1: Distribution of fipronil (blue) and imidacloprid (red) at potentially harmful concentrations in rivers across England. The points are sites in English rivers at which fipronil and imidacloprid were detected in excess of their respective freshwater predicted no-effect concentration (PNEC) values from liquid chromatography mass spectrometry (LC-MS) analysis between 2016-2022 (7). The PNEC in fresh water for fipronil is 0.77 ng/L and 13 ng/L for imidacloprid (9). Between 2016 and 2021, 121 and 64 out of 284 total sites sampled had concentrations of fipronil and imidacloprid exceeding their respective PNEC values.

Reproduced from "Pet treatments could be harming freshwater life" Freshwater Biological Association, February 2024, FBA Info Note 2.

4.44 In 2025, the Environment Agency reported that concentrations of fipronil in water samples had not changed much over recent years, but that the frequency of its detection as part of routine sampling had declined slightly from 99.9% of all samples in 2014 to 89% in 2024. However, the Agency is reported as stating that fipronil was still being found very frequently and at concentrations above the predicted no effect concentration - *"it's incredible how toxic these substances are"* (referring to fipronil) and "*nothing comes close to fipronil*"[55].

4.45 UK Water Industry Research (UKWIR) has shown that, for fipronil and imidacloprid, Predicted No Effect Concentrations (PNEC) values are regularly breached in UK watercourses including downstream of sewage treatment works, with researchers concluding that *"although*

[55] See Vet Record 29 March – 12 April 2025 page 251

these substances are no longer licenced for use in agriculture they can be found in products for household use as pet flea treatments. The observed PNEC exceedances suggest further consideration should be given to policies around the use of these substances".[56]

4.46 In November 2023, WildFish, along with many other eNGOs, had called for a ban on the continued use in vet meds for cats and dogs of active substances already banned or not otherwise permitted for use on agricultural crops (as plant protection products), and that active substances deemed to be too harmful to be used on agricultural crops should be automatically banned from appearing within vet meds[57].

4.47 As at June 2025, the widespread, routine prophylactic use of fipronil and imidacloprid containing vet meds continues, the VMD seemingly relying only on alterations in warning leaflets supplied with products as its chosen method of reducing the risk to the aquatic environment. It is an open question the extent to which warning leaflets are read and acted upon by users.

Vet meds used for equines

4.48 As of 2023 there were an estimated 850,000 horses in the UK [58]. Approximately 1.1 million equine anthelmintic doses for horses were sold in the UK in 2018. This is currently the latest known published information on the sale of equine ectoparasiticide treatments.[59]

---

[56] UKWIR (2023) The National Chemical Investigations Programme 2020 to 2022 Volume 5 Monitoring of substances of emerging concern. Report ref No 22/EQ/01/26

[57] WildFish et al (2023) *Preventing pesticides in veterinary medicines for dogs and cats from damaging the environment*. Open letter to UK Govt. November 2023 Pesticides_veterinary_medicines_openletter_FINAL_2023.pdf

[58] BEA, 'State of Nation Report 2023' (British Equestrian Association, 2023), https://www.britishequestrian.org.uk/assets/EXTRA_Docs/Short%20State%20of%20the%20Nation.pdf

[59] David Rendle et al.(2019) Equine De-Worming: A Consensus on Current Best Practice, *UK-Vet Equine* 3, no. Sup1 (2019): 1–14.

Summary of the ecotoxic effects of commonly used parasiticide drugs in horses (reproduced from Haseler et al (2024):[60]

Drug name	**Route of excretion**	**Principal metabolite**	**Duration of excretion**	**Toxicity**
Moxidectin	Faeces	Unmetabolised moxidectin	>75 days	Less toxic to invertebrates than ivermectin (freshwater animals) (fish) Dung-degrading invertebrates
Ivermectin	Faeces	Unmetabolised ivermectin	>40 days	Freshwater animals Fish Dogs
Pyrantel	Faeces	Unknown	Unknown	Unknown
Fenbendazole	Faeces	Fenbendazole sulfoxide (oxfendazole)	4–5 days	Freshwater animals Fungi
Doramectin	Faeces	Unmetabolised doramectin	>60 days	Dung-degrading invertebrates Freshwater animals Fish
Praziquantel	Faeces	Unknown	Unknown	Unknown (low toxicity)

[60] Callum J. Haseler et al. (2024) Environmental Impacts of Equine Parasiticide Treatment: The UK Perspective *Equine Veterinary Education* 36, no. 7 (2024): 381–92.

4.49 Fipronil is not authorised for use in equines, but it has been reported as being used topically as an off-label treatment for chorioptic mange (leg mange) under what is known as the 'cascade', under which vet meds authorised for other treatments, or in other countries, or ultimately not authorised at all, may be prescribed by vets where no other suitable treatment exists.

4.50 The use of fipronil in equines is concerning but largely unquantified, as is any threat from this use to the aquatic environment: "*The environmental impact of fipronil use in horses is difficult to quantify given the lack of data on equine ectoparasiticide sales and use. However, given its toxicity for bees and other insects, as well as the relatively high volumes needed to treat the equine limbs, its use in horses is likely to have a significant environmental cost. If possible, the use of fipronil in horses should be avoided. If there is no other appropriate option, it would be prudent to take measures to minimise contamination to both the immediate environment as well as contamination of water sources*[61]."

4.51 The researchers conclude that "*while there are limited data on the environmental impact of administering equine parasiticide drugs, evidence from other species indicates significant negative ecological effects".*

4.52 The use of vet meds in equines may therefore be a significant concern in catchments with large equine populations.

[61] Haseler et Haseler, Callum & Shrubb, Julia & Davies, Hannah & Rendle, David & Rathbone, Polly & Mair, Tim. (2023). Environmental impacts of equine parasiticide treatment.

5. Authorisation and use of veterinary medicines

5.1 Prior to Brexit, the authorisation of vet meds was governed by a regime set at a European level, primarily by EU Regulation 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use.

5.2 Post-Brexit, in Great Britain, the Veterinary Medicines Regulations 2013 (S.I. 2013/2033, as amended, now set out the legislative regime for vet meds and medicated feed[62] and govern the manufacture, authorisation, marketing, distribution, and use of vet meds.

5.3 The 2013 Regulations are drawn under the power in section 10 of the Medicines and Medical Devices Act 2021:

"Power to make regulations about veterinary medicines -
(1)The appropriate authority may by regulations make provision specified in sections 11 and 12 amending or supplementing the Veterinary Medicines Regulations 2013 (S.I. 2013/2033).
(2)In making regulations under subsection (1), the appropriate authority's overarching objective must be to promote one or more of the following—
(a)the health and welfare of animals;
(b)the health and safety of the public;
(c)the protection of the environment".

5.4 The power to make regulations need not always be used to "*promote the protection of the environment".*

5.5 However, the regulatory framework is very largely still based upon the European system that applied at Brexit but assimilated into UK law, but

[62] While, the VMR as originally made extended to the UK, since Brexit, EU law on veterinary medicines and medicated feed continues to apply in respect of Northern Ireland.

that Great Britain and Northern Ireland now operate under separate regimes, with vet meds in NI still effectively under EU regulatory control. This report deals only with the legal regime as it applies in England, Wales and Scotland (i.e. GB).

5.6 The 2013 Regulations have faced several criticisms and challenges over the years, both pre- and post-Brexit, including inconsistent enforcement by the VMD, concerns about illegal online sales of vet meds escaping regulation, unregulated imports and grey-market products. The 2013 Regulations also have a somewhat limited focus on companion animals (pets), with regulations historically leaning toward vet meds used in agricultural livestock and food-producing animals. There has also been insufficient provision in the 2013 Regulations related to the environmental impact of vet meds, including residues in water and soil, and impact on non-target biota.

5.7 A Post Implementation Review (PIR) of the 2013 Regulations, published in August 2023, examines the objectives of the Regulations and states:

"*The policy objective of the VMR is to ensure that veterinary medicines are safe to animals, the person administering or handling the medicine or the treated animal, the environment and, in the case of medicines for food producing animals, the consumer of produce from treated animals"*[63].

5.8 The PIR then demonstrates a degree of complacency including a statement that

"*from the evidence collated, it is apparent that the policy objectives were successfully achieved*", but it is perhaps noteworthy that the

[63] Post Implementation Review of the Veterinary Medicines Regulations 2013. Report of Post Implementation Review (PIR) by the Veterinary Medicines Directorate (VMD)
Date: 09 August 2023 ukia_20230170_en.pdf

conclusion of the PIR is that "*overall, the PIR shows that the Regulations when updated in 2013 were indeed fit-for-purpose. The adjustments made to the existing powers of enforcement when the VMR came into force are very much relevant and still fit-for-purpose in the protection of animal health and welfare".*

5.9 The PIR notably does not conclude that the regulations are 'fit for purpose' for the protection of the environment.

5.10 As to how the system is supposed to operate, before a company can market a vet med product, it must first apply for a marketing authorisation. Each application must be accompanied, says the VMD, by supporting scientific data to be assessed "*against statutory criteria for quality, safety and efficacy. This assessment process evaluates the benefits of the product and takes account of any potential risks to the environment, to animals, to people who administer the medicine and, for farmed species, to those who may consume produce from treated animals*"[64].

5.11 For existing vet meds already authorised at a European level, at Brexit, these vet meds were 'grandfathered' into authorisation in Great Britain, per Schedule 1A of the 2013 Regulations - Converted EU marketing authorisations.

5.12 The key to the authorisation of vet meds is the so-called 'risk-benefit balance'. As the VMD puts it "*one of the significant factors taken into account, during independent assessment by the regulator, is balancing the benefits of using a veterinary medicinal product for animal health and welfare reasons, and for the benefits to human health, when*

[64] See Ectoparasiticide Veterinary Medicinal Products Containing Fipronil, Imidacloprid, and Permethrin - GOV.UK

weighed against the risks, including risks to the environment. Products will only be authorised where the benefits of use outweigh the risks"[65].

5.13 In Northern Ireland, "*the "risk-benefit balance" means an evaluation of the positive therapeutic effects of the veterinary medicinal product in relation to— (a) any risk to human or animal health relating to the quality, safety or efficacy of the veterinary medicinal product; or (b) any risk of undesirable effects on the environment".*

5.14 Note that in GB, since Brexit, reference is made to the benefit-risk balance (somewhat oddly the words simply being reversed for GB) and now *" 'benefit-risk balance' means in relation to a veterinary medicinal product, an evaluation of the positive effects of the veterinary medicinal product in relation to the following risks relating to the use of that product— (a) any risk to human or animal health relating to the quality, safety or efficacy of the veterinary medicinal product; (b) any risk of undesirable effects on the environment; or (c) any risk relating to the development of resistance".*

5.15 Contrast this benefit-risk balance approach (for vet meds) with the authorisation process for plant protection products (herbicides, insecticides and fungicides) which is carried out under assimilated Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market etc.

5.16 Often the active substances for vet meds and PPPs are, in fact, the same chemicals (eg neonicotinoids, pyrethroids, organophosphates etc).

5.17 Article 4(2)(b) of 1107/2009 requires that PPP residues "*shall not have any unacceptable effect on the environment".*

[65] See Ectoparasiticide Veterinary Medicinal Products Containing Fipronil, Imidacloprid, and Permethrin - GOV.UK

5.18 Article 4(3) further requires that *"a plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:...*

(e) it shall have no unacceptable effects on the environment, having particular regard to the following considerations where the scientific methods accepted in accordance with paragraph 8 to assess such effects are available:

(i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation;

(ii) its impact on non-target species, including on the ongoing behaviour of those species;

(iii) its impact on biodiversity and the ecosystem".

5.19 So, while for plant protection products, there must be "*no unacceptable effects on the environment*" when the same chemicals are authorised as vet meds it is all a question of the "*benefit-risk balance*", implying that unacceptable effects on the environment may still be tolerated if the benefits (the positive effects of the vet med on animal welfare, food production etc) are considered to outweigh those effects.

5.20 Per paragraph 22(c) of Schedule 1 of the 2013 Regulations, the VMD, acting for the Secretary of State, when considering an application for a

marketing authorisation "*must reach a conclusion in relation to the benefit-risk balance of granting a marketing authorisation*".

5.21 Pursuant to paragraph 24, the VMD must refuse to grant a marketing authorisation if the benefit-risk balance of the veterinary medicinal product is "*unfavourable*".

5.22 However, a vet med can be authorised even if it has a risk of undesirable effects on the environment if the Secretary of State, in the form of the VMD, considers that the benefit-risk balance is still favourable. In other words, if there is more to be 'gained' in terms of animal health and the interests of, for example, the livestock industry (the positive effects of the veterinary medicinal product) than lost in terms of damage to the environment, a vet med can still be authorised.

5.23 The VMD makes its assessment on the basis of a dossier of information supplied to it by the manufacturer seeking authorisation. While the VMD can ask for further information, the dossier is the work of the applicant, and it is upon that basis that the VMD generally assesses an application and then, if agreeable, grants an authorisation.

5.24 As to what is in a dossier supplied by an applicant for authorisation, and how the assessment process should work, the UK, like the EU follows the guidelines issued by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products, known simply as "VICH".

5.25 While international trade and harmonisation in the authorisation of vet meds is well established nevertheless it always remains possible for the UK, post-Brexit, to tighten the regulation of vet meds, certainly within GB, in order to better protect the environment.

5.26 Members include the EU, the USA and Japan. VICH describes itself as *"an ongoing programme to harmonise technical requirements for marketing authorizations for veterinary medicinal products*", and while much of the emphasis of the VICH relates to the efficacy and safety of the product in terms of the treated animal, VICH recommends that applications "*should also address any precautionary measures to be taken when storing the veterinary medicinal product, administering it to animals, disposing of waste of the medicine together with an indication of potential risks that the product might pose to human and animal health and to the environment".*

5.27 The VICH recommends a two-phase approach to the assessment of environmental impact for potential vet meds. Phase I involves an exclusionary assessment based on the potential for environmental exposure from the intended use:

"In Phase I, the investigator shall assess the potential extent of exposure of the environment to the product, its active substances and other ingredients, taking into account:

- *The target species, and the proposed pattern of use*
- *Characteristics of the constituents of the VMP*
- *The method of administration*

In Phase I several exemptions from further testing are incorporated. When these exemptions do not apply, and trigger values are exceeded, one enters Phase II."[66]

5.28 One of the key failings of the VICH approach is that "*it is assumed that VMPs with limited use and limited environmental exposure will have limited environmental effects and thus stop in Phase I*"[67].

[66] See Guideline on environmental impact assessment for VMPs in support of the VICH GL6 and GL38

[67] VICH GL6 (Ecotoxicity Phase I) June 2000 Environmental Impact Assessment (EIAs) for Veterinary Medicinal Products (VMPs) - Phase I Microsoft Word - Gl06_st7.doc

5.29 In effect, only food-producing animal vet meds receive a more detailed Phase II ecotoxicological assessment[68]:

"The aim of the guidance provided in Phase II (and in Phase I) is to assess the potential for VMPs to affect non-target species in the environment, including both aquatic and terrestrial species. It is not possible to evaluate the effects of VMPs on every species in the environment that may be exposed to the VMP following its administration to the target species. The taxonomic levels tested are intended to serve as surrogates or indicators for the range of species present in the environment. Impacts of greatest potential concern are usually those at community and ecosystem function levels, with the aim being to protect most species. However, there may be a need to distinguish between local and landscape effects. There may be some instances where the impact of a VMP at a single location may be of significant concern, for example, for endangered species or a species with key ecosystem functions. These issues should be handled by risk management at that specific location, which may even include restriction or prohibition of use of the product of concern in that specific local area. Additionally, issues associated with cumulative impact of some VMPs may be appropriate at a landscape level. These types of issues cannot be harmonized but need to be considered as part of the EIA and if recommended, addressed by each region/local area".

5.30 In short, if a vet med is not used on food-producing animals in large quantities, it is exempt from detailed ecotoxicological assessment.

5.31 Worryingly, this includes all vet meds used on pets, as they end at Phase I, as *"non-food animals are not intensively reared products. Also, products used on these animals are usually individual treatments. Approval of the VMPs for use in non-food animals is likely to be*

[68] VICH GL38 (Ecotoxicity Phase II) October 2004 Environmental Impact Assessment for Veterinary Medicinal Products Phase II Guidance VICH Environmental Impact Assessments for VMPs, Phase II Draft Guidance, July 2003

associated with fewer environmental concerns than approval of the VMPs in food producing animals simply because there is less total amount of the product used".

5.32 The VICH does suggest that "*some VMPs that might otherwise stop in Phase I may require additional environmental information to assess particular concerns associated with their activity and use".*

5.33 The VMD also suggests that[69] "*if environmental exposure is thought to be high, an in-depth 'Phase II' risk assessment is performed to further evaluate risks to the environment. The findings from this assessment are factored into the decision whether to approve a veterinary medicinal product"*.

5.34 However, in the case of imidacloprid or fipronil used in GB for cat and dog flea treatments - given the number of dogs and cats in GB and the propensity to treat prophylactically on the basis of aggressive marketing - it is clearly nonsensical that full Phase II ecotoxicological assessments are not expressly required prior to authorisation of such products.

5.35 Whatever 'depth' of ecotoxicological assessment is required, eventually the Secretary of State (in the form of the VMD) will issue a market authorisation if the benefit-risk balance is favourable.

5.36 There is an appeal mechanism for those applicants for a marketing authorisation aggrieved by a decision of the Secretary of State (in the guise of VMD) not to grant authorisation, in the first instance to be made to the Veterinary Products Committee (VPC), a committee of Secretary of State-appointed "*professional people who are eminent in their field, and any lay members as the Secretary of State sees fit"* (Regulation 28 of the 2013 Regulations).

[69] See VMD Connect 14/04/2025

5.37 As to the balance of expertise on the VPC, of the current 18 members of the VPC, there are 9 vets, 2 pharmacists or Suitably Qualified Persons, 2 pharmacologists, 1 parasitologist,1 epidemiologist, 1 farmer, 1 toxicologist (with declared interests in the vet med industry) and only 1 environmental scientist, again with declared vet med industry interests.

5.38 Note, that since Brexit, all vet meds, once authorised in GB, are authorised indefinitely. That is the effect of paragraphs 32 of Part 3 of Schedule 1 to the 2013 Regulations, as amended in 2024. In Northern Ireland, vet meds authorisations are only valid initially for 5 years and still subject to renewal thereafter on the basis of a re-evaluation of the risk-benefit balance.

5.39 All marketing authorisations place vet meds into a number of categories, under which differing rules apply for sale and use[70].

- POM-V: Prescription Only Medicine – Veterinarian. These vet med products are only to be supplied under prescription by a veterinary surgeon.
- POM-VPS: Prescription-Only Medicine – Veterinarian, Pharmacist, Suitably Qualified Person (SQP). These vet meds used for food-producing animals (including horses), must be prescribed by any a vet, pharmacist or an appropriately qualified person.
- NFA-VPS: Non-Food Animal Medicine. These vet meds, for companion animals, may be supplied by any vet, pharmacist or suitably qualified person, but do not require a prescription.
- AVM-GSL: Authorised vet med – general sales list. There are no legal restrictions for the retail supply of these 'over the counter' vet meds.

[70] See https://www.gov.uk/guidance/marketing-authorisations-for-veterinary-medicines

5.40 Note that all vet meds for food-producing animals need to be prescribed, according to their legal category (so are POM-V or POM-VPS).

5.41 However, many widely used vet meds for pets are classified as AVM-GSL, meaning they are available 'over the counter' or on the Internet without any prescription or professional oversight. Ease of access can lead to widespread inappropriate use of vet meds, as is the case with the unnecessary prophylactic use of, for example, flea and tick treatments for cats and dogs containing fipronil or imidacloprid. Note also that per Regulation 9(7) of the 2013 Regulations, *"there are no restrictions on the importation of an authorised veterinary medicinal product in category AVM-GSL".*

5.42 However, even if there is a Phase II assessment of a vet med proposed for authorisation, the data supplied to support the Phase II assessment, and the performance of the Phase II assessment itself, is provided by the applicant for authorisation (or by consultancies employed by the applicant for that purpose). It would be surprising if Phase II assessments did not 'lean' towards providing the VMD or other regulators with the 'ammunition' required to grant an authorisation. There is little or no submission of independent data into the process, nor performance of primary ecotoxicological work independent of the manufacturers.

5.43 Phase II assessment may also lack comprehensive environmental fate and toxicity data and do not routinely address cumulative effects, ecotoxicity with other vet meds or pesticide residues that may be present in the aquatic environment, or long-term persistence in sediments or in the aquatic environment of such residues.

5.44 Overall, Phase II assessments fail to give a true evaluation of likely real-world effects and criticism of the ecotoxicological assessment

procedures conducted pre-authorisation for pesticides and veterinary medicines is not new.

5.45 For example, the European Academies Science Advisory Council wrote in 2025[71] recently to the European Food Safety Agency suggesting the development of a new environmental risk assessment processes for non-target arthropods, stating:

"In our previous work, we pointed to the failure of the pesticide approval system to identify the broader system effects of neonicotinoids, which eventually led to their withdrawal. That these failures continue can be shown by the similar trajectory of substitutes such as sulfoxaflor that was also approved, only to be later withdrawn when its negative side effects were seen in field use.

These cases have, as you have recognized, sparked many calls to update the pre-approval process. We need better evaluations of real-world effects. This change can prevent approvals that harm the environment and waste industry resources. Companies lose their investment when new pesticides are later withdrawn. An improved ERA should spot negative impacts before approval".

5.46 EASAC also suggested that assessments should:

- select test species that represent organisms of a range of sensitivity;
- recognise the importance of testing not just short-term exposure but also cumulative and long-term impacts;
- recognise that current testing based on one substance fails to account for the potential for combined (additive or interactive) toxic effects in mixtures and exposure to different pesticides and co-formulants;

[71] See Letter_from_EASAC_arthropods_February_2025.pdf

- ensure that 'cocktail' exposure should be considered in assessments.

5.47 EASAC also questioned the general assumption of the potential for recovery of depleted populations from surrounding 'reservoirs' of non-target species, suggesting that *"this may be a false assumption - not only because such reservoirs simply do not exist for many intensive agricultural landscapes, but because the decline in arthropods has been shown to be widespread and extending to protected areas".*

5.48 Professor Ian Boyd, one-time Chief Scientific Adviser at the UK Department for Environment, Food and Rural Affairs summed up the problems with the assessment process, in this case of neonicotinoids, also authorised over the years as vet meds:

"The results of lab studies were quite clear, but they did little more than confirm that neonicotinoid insecticides were poisonous to insects. Thus, much of the direct evidence produced did not help with making a policy decision. Similar criticisms could be levelled at the regulatory studies used to support the licencing of neonicotinoids as pesticides. These studies were not open to scrutiny, and I was never given access to them. The drive to avoid multiple jeopardy and to protect commercial confidentiality does nothing to promote transparency and trust in the regulatory system. Possibly as a result of this, I also saw that the agri-chemical and farming industries appeared to misunderstand the duty they have to promote transparency in how they supply and use pesticides. Too often, it seemed that, to them, the function of regulation was to protect their business interests rather than to deliver public goods"[72]*.*

That desire of regulatory systems to protect the business interests of the producers of pesticides, including vet meds, rather than to deliver public

[72] Boyd IL (2018) An inside view on pesticide policy. Nature Ecology and Evolution.

goods, runs through much of the regulatory approach to vet meds in the UK.

5.49 Professor Boyd also addressed the problems with assessment of pesticides generally, many authorised over the years as vet meds:

"Since the introduction of organochlorines, like DDT and dieldrin, in the 1940s, successive classes of chemical pesticides have been licensed for agricultural use and then been withdrawn from use as unexpected environmental or health impacts have appeared. This is now a familiar cycle, and neonicotinoids are the current incarnation of this pattern.

As chief scientific adviser to the United Kingdom's Department of Food, Environment and Rural Affairs (DEFRA), I have observed aspects of the neonicotinoid story that are instructional for future pesticide management and for the science-policy interface in general. New pesticides are typically licenced for use based on guidance written on the label of the container. This guidance is constructed from efficacy and safety testing conducted in specific circumstances, but which cannot simulate all the conditions encountered by users.

As demand for a new pesticide increases, growers develop farming systems and business structures that rely on it. But as unanticipated impacts and pest resistance begin to appear, community opposition to the pesticide grows, chemical companies scramble to develop 'less harmful' variants, and governments struggle to balance their obligations to food production and environmental responsibility. As the evidence base against the pesticide grows, governments withdraw licences for use ..."[73]

[73] Boyd IL (2018) An inside view on pesticide policy. Nature Ecology and Evolution.

5.50 On the ecotoxicological assessment methods employed in considering whether or not to grant a marketing authorisation, Professor Boyd says:

"Standard environmental toxicity tests used to license pesticides are performed on particular test species and have limited predictive power when chemicals are used widely. Diffuse environmental effects that arise from ecosystem connectivity at a landscape scale are hard to measure but may still be appreciable. There is a low level of trust in current toxicology testing regimes because they are unable to encompass the full range of toxic effects that could emerge when used at scale"

and that

"The current assumption underlying pesticide regulation — that chemicals that pass a battery of tests in the laboratory or in field trials are environmentally benign when they are used at industrial scales — is false. Future regulation to deal with this issue may have to vary regionally because of differing cost benefit analyses, but the effects of dosing whole landscapes with chemicals have been largely ignored by regulatory systems". [74]

5.51 In 2022, WildFish, together with other eNGOs, published a report "*Chemical Pollution - The Silent Killer of UK Rivers",* incorporating evidence from WildFish's citizen science invertebrate monitoring programme. That report called for steps to be taken to "*improve gaps in the risk assessment for chemicals before they are approved"*[75].

[74] Alice M. Milner, Ian L. Boyd (2017) Toward pesticidovigilance. Science 357,1232-1234 (2017)

[75] New study shows English rivers exhibiting increased chemical stress and declining invertebrate diversity | Wildfish

5.52 This echoed both the Freshwater Biological Association's conclusion that it is *"important to ensure that appropriate regulatory protocols are developed and implemented for the next generation of parasiticides that come to market, especially if we are to avoid simply repeating the mistakes of the past but with a new suite of chemicals…"*[76] and Professor Boyd that "*better regulation is needed to control how pesticides are used and affect the environment at a landscape scale".* [77]

5.53 It is clear therefore that there are many serious problems with the authorisation of vet meds in GB.

5.54 To address the concerns raised above - and generally to strengthen the process of authorisation for vet meds – the Annex to this Report sets out proposed amendments to the 2013 Regulations.

5.55 These amendments are designed collectively to ensure that the authorisation process, particularly the benefit-risk assessment process, takes into account the direct or indirect risks to the environment arising from the use of any particular vet meds, including considering in-combination adverse effects with other vet med products, plant protection products or biocides (nothing that the active ingredients can be common to all of these categories of regulated products).

5.56 Specifically, the amendments in the Annex to this Report, dealing with the authorisation process, address –

- the benefit-risk balance, requiring that the benefit-risk balance should always be considered unfavourable if there are or are

[76] Pet treatments could be harming freshwater life" Freshwater Biological Association, February 2024, FBA Info Note 2.
[77] Alice M. Milner, Ian L. Boyd (2017) Toward pesticidovigilance. Science 357,1232-1234 (2017)

expected to be greater than negligible direct or indirect risks to the environment arising from the use over vet meds;

- the balance of expertise on the Veterinary Products Committee and transparency relating to the proceeds of the VPC particularly when it deals with appeals against refusals to grant marketing authorisations;

- the information required in an application for marketing authorisation, requiring technical documentation demonstrating the direct or indirect risks to the environment arising from the use of the product and an evaluation of the most up-to-date scientific knowledge relevant to those risks (this also applying to other types of applications for marketing authorisations, such as bibliographic applications, applications for marketing authorisations for new combinations of active substances, applications for generic veterinary medicinal products, and the marketing of products authorised in another country);

- that for "over the counter" vet meds for pets, where there is likely to be widespread use, for example in domestic dog or cat populations, vet meds must go through the Phase II assessment processes (currently not required under the VICH guidelines on harmonisation);

- transparency and publication of information, to remove the requirement that commercially confidential information cannot be published in notices granting marketing authorisations, summaries of the product characteristics, or in the VMD assessment reports that go alongside authorisations, where that information relates to information on emissions as

defined in Regulation 12(9) of the Environmental Information Regulations 2004;

- the updating of vet med assessment reports whenever new information that relates to direct or indirect risks to the environment arising from the use of the product becomes available; and

- that records to be kept by marketing authorisation holders, now that marketing authorisations persist indefinitely post-Brexit, need also to be kept indefinitely while the product remains on the market.

6. Post-authorisation regulatory control

6.1 Once authorised, the use of vet meds needs to be monitored and any suspected or actual environmental impacts investigated. As Professor Boyd has noted with assessment of pesticides generally - many authorised as vet meds – unexpected problems and issues can and do arise post-authorisation:

"Since the introduction of organochlorines, like DDT and dieldrin, in the 1940s, successive classes of chemical pesticides have been licensed for agricultural use and then been withdrawn from use as unexpected environmental or health impacts have appeared. This is now a familiar cycle and neonicotinoids are the current incarnation of this pattern".

6.2 There is a long history of active ingredients used in pesticides and in vet meds causing unanticipated or unexpected environmental impacts particularly where there is widespread use.

6.3 However, in relation to post authorisation regulatory control, which is supposed to pick up and deal with such unexpected impacts, this

predominantly consists of the VMD analysing adverse event reports that are received by it and consideration of whether the 'benefit-risk balance' has become unfavourable[78]:

"Once a product has been granted a marketing authorisation it is then subject to post marketing surveillance. The Marketing Authorisation Holder has a legal responsibility to report to the VMD any reports of adverse events it receives relating to the use of the product on the animal, any adverse events experienced by those administering the product to the animal or animal owners, any adverse events to the environment and also whether there is a lack of efficacy. Furthermore, we encourage adverse event reporting directly from veterinary surgeons and also from the owners of animals and the general public".

6.4 The VMD states that: *"The VMD's pharmacovigilance team continuously monitor all authorised veterinary medicinal products for adverse events by analysing reports received. In light of this information, and the possible signals being detected, the VMD has the power to request changes to how the product is used, and this can also include suspension or revocation of the marketing authorisation."*[79].

6.5 However, there is little *proactive* post-authorisation monitoring. The system rests largely on reporting of adverse events to the regulator, which are recorded, but to which the regulator may or may not then react.

6.6 It is clear that the VMD adverse event reporting system tends to focus predominantly on acute adverse reactions in the treated animals, and not on chronic or wider ecological harm being caused.

6.7 For example, on fipronil and imidacloprid, the VMD reports:

---

[78] VMD (2024) The VMD expands evidence base with latest research on pathways of flea and tick treatments https://www.vmdconnect.uk/the-environment

[79] Ectoparasiticide Veterinary Medicinal Products Containing Fipronil, Imidacloprid, and Permethrin - GOV.UK 17th November 2023

"Based on the data we have received, when considering reported adverse events in humans when compared against the volumes of the products sold, the incidence of adverse events to humans are calculated as:

Active	*Incidence Rate*
Fipronil sprays (cats and dogs)	*1 adverse event per 10,000 doses administered.*
Fipronil spot-on (cats, dogs)	*<1 adverse event per 10,000 doses administered*
Imidacloprid spot-on (dogs, cats, ferrets)	*<1 adverse event per 10,000 doses administered.*
Imidacloprid collars for dogs	*<1 adverse event per 10,000 doses administered.*

It is important that reports of suspected adverse events are reported to the VMD so that we can continue to monitor the situation for signals that may emerge". [80]

6.8 The VMD fails to mention any wider environmental risk from the use of fipronil or imidacloprid in its adverse reporting. That is perhaps not that surprising as even where ecotoxicologically significant concentrations of those active ingredients are appearing in rivers, it is difficult to conceive of a situation in which a member of the public or a veterinary surgeon would be aware sufficiently of the damage being caused to invertebrate populations in the aquatic environment to make a formal adverse event report to the VMD.

6.9 Further, there are currently no legal requirements to report an adverse event in the environment and all reports are submitted on a voluntary

[80] VMD (2024) The VMD expands evidence base with latest research on pathways of flea and tick treatments https://www.vmdconnect.uk/the-environment

basis. As academics suggest "*pharmacovigilance on the scale that is required for medicines does not exist to assess the effects of pesticides in the environment*"[81].That includes for vet meds:

> *"there is no equivalent to the Yellow Card, EudraVigilance, or VigiBase systems to monitor the environmental effects of pesticides during normal use. There is also no estimate of the number of incidents that go unreported and that are therefore not investigated. Monitoring and preventing misuse, accidents, and unintended effects of pesticides requires investment in organizational design for information collection and processing, which is absent in most countries. The United Kingdom has one of the most developed regulatory and monitoring systems for pesticides. Yet, it has no systematic monitoring of pesticide residues in the environment… There is no consideration of safe pesticide limits at landscape scales"[82].*

6.10 Nevertheless, the VMD continues to rely on self-reporting by users of vet meds stating that "*it is important that reports of suspected adverse events are reported to the VMD so that we can continue to monitor the situation for signals that may emerge*".[83]

6.11In response to an FOI request for information on adverse events generally during the 2021/22 financial year, the VMD confirmed to WildFish that they had received 9,133 cases of adverse events, 9,010 of which related to animal adverse events, which included suspected lack of efficacy cases, environmental cases and residue incidents.

[81] Alice M. Milner, Ian L. Boyd (2017) Toward pesticidovigilance. Science 357,1232-1234 (2017)

[82] Alice M. Milner, Ian L. Boyd (2017) Toward pesticidovigilance. Science 357,1232-1234 (2017)

[83] See Ectoparasiticide Veterinary Medicinal Products Containing Fipronil, Imidacloprid, and Permethrin - GOV.UK

6.12 When asked for clarification as to how many of the 9,010 cases were environmental cases, the VMD confirmed that **only three** were environmental cases:

"During the time period, 01 Apr 2021 to 31 Mar 2022, we received a total of 3 reports that were classified as adverse environmental events. An adverse environmental event means an event where a non-target organism, population or ecosystem is adversely affected as a result of exposure to a VMP, its active substances or its metabolites present in soil, water or animal remains.

The 3 reports, all originating from Scottish Agricultural Science Agency, contained the following information:

a) *Involved a fox, which was reported to be circling and fitting in a field. It did not respond when captured and was then euthanised. GC-MSMS analyses determined: Stomach content material 0.474 mg/kg Diazinon.*

b) *Involved a raven, found dead in woodland. GC-MSMS analyses determined: Liver tissue 0.074 mg/kg Diazinon, Oesophageal contents 0.430 mg/kg Diazinon.*

c) *Involved a red kite, found dead. GC-MSMS Analyses determined: Liver tissue 4 mg/kg Diazinon, Stomach content material 500 mg/kg Diazinon".*

6.13 In other words, only three environmental adverse events were reported, all from Scotland, and all three strongly associated with the deliberate criminal poisoning of wildlife.

6.14 It is noteworthy that there were no adverse environmental reports involving fipronil or imidacloprid, despite ongoing public concerns, which illustrates how the system fails to react to obvious concerns. That seems to be also true of the VMD's formal regulatory response.

CASE STUDY

The regulatory response to the fipronil and imidacloprid issue

There is increasing concern over fipronil and imidacloprid vet med residues in UK rivers causing unwanted environmental impact, especially on aquatic ecosystems in the UK. These vet meds can wash off treated pets and enter drains, rivers, and water bodies. Studies in the UK have found detectable levels of imidacloprid and fipronil in urban waterways, likely from domestic pet treatments rather than agricultural sources. Imidacloprid is highly toxic to aquatic invertebrates, such as insects and crustaceans. Fipronil is also highly toxic to fish and aquatic invertebrates.

Even at very low concentrations, these chemicals can disrupt ecosystems by affecting the base of the aquatic food chain. These compounds are persistent and bioaccumulative, meaning they can remain in water or sediment for long periods and build up in the environment.

So, what has been the regulatory response?

The most obvious response appears to have been the establishment of an expert group to examine the issue of pharmaceutical and vet med residues in water, the Pharmaceuticals in the Environment (PiE) Group, chaired independently of Government and *"provid[ing] a platform for discussion and knowledge exchange relating to pharmaceuticals in the environment. The aim is to develop a co-ordinated strategy to reduce the impacts of pharmaceuticals on the environment".*[84]

That cross-government group[85] was formed in April 2023 *"to enable discussion and knowledge exchange relating to pharmaceuticals in the*

[84] Ectoparasiticide Veterinary Medicinal Products Containing Fipronil, Imidacloprid, and Permethrin - GOV.UK

[85] Membership of the Pharmaceuticals in the Environment Group: Veterinary Medicines Directorate (VMD),Veterinary Products Committee (VPC), Environment Agency (EA), Health and Safety Executive (HSE), Department of Environment, Food and Rural Affairs (Defra), Medicines and Healthcare products Regulatory Agency (MHRA), Natural Resources Wales/Welsh Government (NRW/WG), Northern Ireland Environment Agency/Department of Agriculture, Environment and Rural Affairs (NIEA/DAERA), Scottish Environment Protection Agency (SEPA), Joint Nature Conservation Committee (JNCC), NHS Highland

environment from human veterinary and where there is a crossover agricultural and non agricultural sources"[86].

The group met a second time in June 2023 and convened a third time in October 2023 *"to continue discussions regarding levels of imidacloprid and fipronil in UK surface waters" and will then "engage with stakeholders to identify opportunities to fill evidence gaps… create a road map, including allocated ownership of activities. The process mapping exercise will also help to inform future strategy for other substances of concern".*[87]

The group has met 6 times since it was constituted in 2023[88].

Progress has been slow.

As the Veterinary Products Committee reported *"the slow progress made delivering results has led to some criticism. However, new data published indicates that areas of rivers downstream of water used by companion animals conclusively show a large increase in pesticides and it seems clear that veterinary medicines are the source. This is despite all the correct environmental assessments and regulatory measures being carried out for the products. Dialogue is ongoing with industry representatives and a workshop will be held in June to discuss all the components and find ways of resolving problems while being mindful of benefit : risk arguments".*[89]

The most recent public announcement made in July 2025[90] reports that the PiE Group has, after over 2 years of work, only just "*set out a roadmap of activities to address the levels of fipronil and imidacloprid detected in UK waterways*".

However, that roadmap does not anticipate any immediate regulatory actions, with those to be considered over the long term. The PiE prefers to

[86] New Pharmaceuticals in the Environment cross-government group - GOV.UK

[87] Pharmaceuticals in the Environment Group agrees next steps - GOV.UK

[88] https://www.gov.uk/government/publications/vmd-foieir-requests-april-2025/eir-information-on-pharmaceuticals-in-the-environment-pie-group-ati1058

[89] 2974136-v1-VPC_February_2025_Minutes_for_Gov_uk.pdf

[90] Cross-government Pharmaceuticals in the Environment Group Roadmap - GOV.UK

rely on short term communication and education messaging to users of pet topical parasiticides, while continuing to gather further evidence over the medium term.

Faced with this regulatory failure, WildFish asked for information on the **formal regulatory response** to the fipronil and imidacloprid vet med concerns.

The response of the VMD has not been encouraging:

Anyone who holds a marketing authorisation is required (paragraph 28 Schedule 1 of the 2013 Regulations) to immediately inform the VMD of any new information that might adversely affect the benefit risk balance of a vet med. There are a number of other duties on authorisation holders.

This would seem to be an obvious case of where the VMD might expect to receive such information.

The VMD only provided information from 17th May 2024, arguing that any of the requested information covering 2000-2024 was in "*legacy databases*" [91] and that retrieving it would make the request "*exceed the appropriate limit, which currently stands at £600".* That matter is being appealed to the Information Commissioner on be basis that the alleged time it would take the VMD to provide regulatory information covering the period 2020 to 2024, a total of 4,700 hours, clearly an absurd figure, the VMD suggesting that it would take the equivalent of a dedicated full-time member of its staff, doing absolutely no other work whatsoever, 125 working weeks (based on a 37.5 hour working week), or roughly 3 years, to provide the information,

However, in response to the WildFish request for *"all instances of the Secretary of State being informed, pursuant to paragraph 28(1) of Schedule 1 of any new information that might adversely affect the benefit-risk balance of the veterinary medicinal product",* the VMD confirmed that there have been no benefit-risk reports received from market authorisation

[91] FOI response to WildFish VMD 7th April 2025.

holders that include new information that might adversely affect the risk balance for AVM-GSL products authorised in GB and containing fipronil and/or imidacloprid.

That calls into question whether authorisation holders are complying with their obligations under the 2013 Regulations to report to the VMD on such matters. It is not clear whether any reports have been made subsequent to the discovery of widespread and high levels of fipronil and imidacloprid in English rivers as such reports are presumably in the VMD's *"legacy databases"* and are inaccessible.

Similarly, when asked for "*all instances of the Secretary of State being notified under the signal management process, of a new risk or a change in the benefit-risk balance of a veterinary medicinal product pursuant to paragraph 56A(3) of Schedule 1 (with details of any application then submitted pursuant to paragraph 56A(4)*)", the VMD replied that "*there have been no signal notifications or benefit-risk reports received that include new information that might adversely affect the risk balance for AVM-GSL products authorised in GB and containing fipronil and/or imidacloprid*".

When asked for "*all instances of the Secretary of State being provided with information relevant to detecting a change to the benefit-risk balance of a veterinary medicinal product pursuant to paragraph 56B(d) of Schedule 1*", the VMD replied that "*there has been no information provided to the Secretary of State by a qualified person (pharmacovigilance) relevant to detecting a change to the benefit-risk balance for any AVM-GSL product authorised in GB and containing fipronil and/or imidacloprid as pursuant to paragraph 56B(d) of Schedule 1. This excludes adverse event reports*".

Further, in relation to pharmacovigilance, when asked for "*all instances of the Secretary of State being informed of actions taken* [by a marketing authorisation holder] *pursuant to paragraphs 56(11) and (12) of Schedule 1 in respect of a risk posed to the environment from the use of the product*", the VMD confirmed that "*no action(s) pursuant to paragraphs 56(11) and (12) of Schedule 1 have been taken in respect of a risk posed to the*

environment from the use of any GB authorised AVM-GSL product containing fipronil and/or imidacloprid".

When asked for "*all reports made under paragraph 57(3) in respect of suspected occurrence(s) of an adverse environmental event, and supplies of information made under paragraph 57(4) of Schedule 1, together with all requirements then placed on the marketing authorisation holder imposed under paragraph 57(4A) of Schedule 1*", the VMD replied that "*no reports made under paragraph 57(3) in respect of suspected occurrence(s) of an adverse environmental event relating to any AVM-GSL product authorised in GB and containing fipronil and/or imidacloprid have been received*".

In short, there have been no concerns or actions reported to the VMD by the marketing authorisation holders, despite legal duties to do so.

However, nor does it appear the VMD has been proactive here.

When asked for *"all instances of the Secretary of State requiring data pursuant to paragraph 28(3) of Schedule 1, together with any data then received",* the VMD confirmed that they "*have not requested the Marketing Authorisation holders to provide additional data relating to the benefit-risk balance for GB authorised AVM-GSL products containing fipronil and/or imidacloprid*".

The VMD also confirmed that no action had been taken on account of pharmacovigilance by the Secretary of State pursuant to paragraph 61 of Schedule 1 in respect of any GB authorised AVM-GSL product containing fipronil and/or imidacloprid.

Unsurprisingly perhaps, when asked for "*details of all action(s) taken pursuant to paragraph 38(1), (2) and (3) of Schedule 1, including but not limited to (a) any consideration as may have been given to the benefit-risk balance of a veterinary medicine; and /or (b) any decision to suspend, require an application for variation of, or revoke an authorisation*", the VMD stated that "*no action(s) pursuant to paragraph*

38(1), (2) and (3) of Schedule 1 have been taken on in relation to a GB authorised AVM-GSL product containing fipronil and/or imidacloprid".

In any event authorisation holders are supposed to submit annual benefit-risk reports, but the VMD stated that the requested "*annual benefit-risk reports submitted under paragraph 59 of Schedule 1*" were "*commercially sensitive data and therefore, will not be released*".

The same reason – commercial sensitivity – was given to a request for sales data as an approximation of how much of these vet meds are being used in the UK. When asked for "*details of any request by the Secretary of State made to the marketing authorisation holder to provide data relating to the volume of sales of the veterinary medicinal product by the holder, pursuant to paragraph 31(3) of Schedule 1, and any such data held*", the VMD declined to provide sales data saying that "*information held pursuant to paragraph 31(3) of Schedule 1 is commercially sensitive data and therefore, will not be released*".

Subject to what might yet be released following referral of the information request to the Information Commissioner's Office, the answers given by the VMD appear to indicate that no regulatory action has been taken under the 2013 Regulations in response to the high level of fipronil and imidacloprid being found in English rivers in all likelihood as a result of the use of those vet meds in cat and dog flea and tick treatments.

That calls into question whether the VMD is properly performing its statutory functions in respect of the environment and preventing harm from the use of these vet meds, particularly to the aquatic environment.

6.15 It is therefore amply clear that post-authorisation regulatory control of vet meds is proving to be inadequate.

6.16 To address the concerns over the process of post-authorisation monitoring of vet meds, amendments to the 2013 Regulations are included in the Annex on:

- the need for a duty on all marketing authorisation holder to notify the Secretary of State of any new information on direct or indirect risks to the environment arising from the use of a vet med;

- the publication of any such information received by the Secretary of State;

- the suspension or revocation of a marketing authorisation where the Secretary of State becomes satisfied that there are greater than negligible direct or indirect risks to the environment arising from the use of a vet med;

- a duty on marketing authorisation holders in respect of pharmacovigilance particularly in relation to the direct or indirect risks to the environment arising from the use of a vet med;

- a duty on qualified persons dealing with pharmacovigilance for the same;

- a duty to provide to the Secretary of State the most up-to-date scientific knowledge relevant to direct or indirect risks to the environment rising from the use of vet med;

- the definition of an adverse event to include direct or indirect risks to the environment arising from the use of a vet med;

- the ability of the Secretary of State to require a marketing authorisation holder to undertake studies on direct or indirect risks to the environment;

- the publication of annual benefit risks reports (that are already required from all marketing authorisation holders) to include new information on direct or indirect risks to the environment arising from the use of the product;

- a requirement that commercially confidential information must not be deleted from published material if that information relates to emissions as per Regulation 12(9) of the Environmental Information Regulations 2004;

- the updating of vet med assessment reports whenever new information that relates to direct or indirect risks to the environment arising from the use of the product becomes available; and

- that records to be kept by marketing authorisation holders, now that marketing authorisations persist indefinitely post-Brexit, need also to be kept indefinitely while the product remains on the market.

7. The use data gap for vet meds

7.1 There is a particular issue with the use data gap – knowing how much of which vet meds are used where and when.

7.2 When the VMD grants marketing authorisations, it points out that these companies "*may or may not market their product dependent on the*

commercial decisions of those companies"[92]. The VMD's Product Information Database provides details of all vet meds authorised in the UK[93].

7.3 However, *"there is currently no requirement under the Veterinary Medicines Regulations for veterinary surgeons to declare their prescribing or use of veterinary medicines"*[94] although "*product sales data are submitted for the purpose of pharmacovigilance periodically, at intervals of 6 months to 3 years, depending on how long the product has been on the market. This is provided aggregated for the UK and not regionally…".*

7.4 Although the VMD is at pains to point out that *"sales data is not a reliable substitute for usage data as there will be a proportion of products not used and disposed of, or in storage waiting to be used which can be up to the end of their shelf life",* there is a significant gap in the data sets available – both to conservation and to academics - which means identification of the sources of the vet med compounds being found in watercourses is hampered and sudden increases in overall use of a vet med of active ingredient, which might warrant re-evaluation of the benefit-risk balance of a vet meds, can be missed.

7.5 Contrast that with the position for Plant Protection Products (pesticides) where professional users' records can be accessed pursuant to Article 67 of the relevant assimilated European Regulation.

7.6 To illustrate the issue here, in February 2024, WildFish made a request for information concerning vet meds used in a particular catchment of the Welsh Dee to the east of Wrexham in order to try and find out what use

[92] FOI response VMD to WildFish 27 March 2024

[93] Check if an animal medicine is licensed - GOV.UK

[94] FOI response VMD to WildFish 27 March 2024

data was available to enable WildFish scientists to try to identify which vet meds are most likely to have been used in the catchment.

7.7 The WildFish SmartRivers invertebrate sampling project, which uses profiling of the full range of aquatic invertebrate species to give an assessment of water quality in UK watercourses, had suggested a significant impact of chemicals in the sub-catchment using the biometric system SPEAR (SPEcies At Risk), a metric weighted towards the detection of pesticide 'actives' impacting invertebrate communities[95].

7.8 However. the VMD confirmed that it does "*not undertake routine environmental testing, and therefore have no records of chemical analyses undertaken in relation to the sites requested*" and that it does "*not hold any national or regional veterinary medicine usage information".*

7.9 In response to a request for clarification on whether or not the VMD has any sales data available, the VMD then added that "*we would be unable to provide you with sales data for individual products, however, it may be that we could comply with a request about specified active substances, within the appropriate limits, although we cannot guarantee that this will be the case*".

7.10 So, the VMD cannot provide use data at any sort of geographical scale that would enable any academics or researchers to identify what quantities of vet meds are sold or used in locations where residues are being detected in rivers.

7.11 On this obvious data gap, Professor Ian Boyd, one-time Chief Scientific Adviser at the UK Department for Environment, Food and Rural Affairs

[95] SmartRivers data on a number of rivers (the Hampshire Avon, the Wensum) have suggested impacts from pesticides (including vet medicines) on invertebrate populations

said in 2018, of neonicotinoids, such as imidacloprid, then used in agriculture:

"If they were so pervasive and widespread then what were their indirect, diffuse effects on insect and soil invertebrate faunas? We had no idea. My advice became that neonicotinoids were probably being used on scales outside the scope of their licence. Even if every individual farmer was using neonicotinoids according to the regulations, those regulations did not account for how many farmers were using them or how often they were being used"[96].

7.12 It appears that similarly, Professor Boyd's concerns would continue today to apply to vet meds incorporating neonicotinoids, or indeed any other active ingredient. The vet med use data gap is very large indeed.

7.13 This is a data gap that could easily be plugged by regulation. Section 11 of the Medicines and Medical Devices Act 2021, under which the 2013 Regulations are drawn, expressly provides that those regulations may make provision about:
"(j) notification and reporting requirements in relation to veterinary medicines (or things purporting to be veterinary medicines) that have been placed on the market".

In other words, the VMR could be amended to provide for record keeping and publication of vet meds use data, by geographical area such as postcode district, at least for those vet meds used under prescription.

7.14 For any vet meds that are prescription only, or are incorporated into feeds, it would be entirely reasonable to require the relevant persons to provide information on prescription or supply to the VMD, for collation and publication.

[96] Boyd , I L 2018 , ' An inside view on pesticide policy ' , Nature Ecology and Evolution .

7.15 For ‘over the counter’ sales to ordinary members of the public, sales data could be required from retailers. While the VMD points out that “*sales data is not a reliable substitute for usage data as there will be a proportion of products not used and disposed of, or in storage waiting to be used which can be up to the end of their shelf life”*, the public does not often buy vet meds not intending to use them.

7.16 Overall, it is not unreasonable to require that vets, the holders of marketing authorisations for vet meds and retailers all have to provide use/sales data broken down by geographical area, whether the vet meds concerned are prescription-only or ‘over the counter’. This is particularly true for pet vet meds sold in regular prophylactic ‘pet plan’ subscriptions. It is reasonable to suppose that, as a general rule, customers would not be paying for regular subscriptions and not using the products.

7.17 That data would then enable researchers and academics to assess which vet meds, that are turning up in the rivers, are being used for what purposes and by which group of vet med users (farmers or pet owners), thereby better informing how the more ‘problematic’ vet meds can be controlled, or which active ingredients need to be substituted for less persistent and toxic alternatives.

7.18 In order therefore to address the concerns over the data gap amendments to the 2013 Regulations are also including in the Annex to address relevant duties in relation to

- the collection of prescription data and sales data for over-the-counter vet meds; and

- the reporting and publication of vet med sales and use data for vet meds

8. Conclusions

8.1 Vet meds are used widely in GB to control disease, infection and infestation in food-producing animals, companion animals (dog and cats) and equines. The market in GB for veterinary medicines is significant.

8.2 The active substances in veterinary medicines are often the same as those used in plant protection products (herbicides, insecticides and fungicides) as well as in biocides such as wood preservatives, rodenticides or other such products. However, these three categories are authorised and controlled under three different regulatory regimes.

8.3 Residues of veterinary medicines can and do enter the aquatic environment, for example in run-off from agricultural and the built environment, discharges of effluent from livestock production, discharges from wastewater and sewerage systems and from direct contamination when treated animals enter watercourses.

8.4 While there has been concern for decades over the likely impacts of vet med residues on the aquatic ecosystems in rivers and lakes in GB, the monitoring of vet meds across GB in the aquatic environment is very poor, with little data available. Many academics and eNGOs have recommended markedly increasing monitoring of the wider environment for vet med residues.

8.5 There is nonetheless significant evidence of harm to the aquatic environment and aquatic ecosystems caused by vet meds, particularly those with activity against insects or other invertebrates. Examples include the use of sheep dip, other agricultural parasiticides, cat and dog flea and tick treatments for companion animals and the general use of veterinary medicines in equines.

8.6 Recent concerns have focused on the use of fipronil and imidacloprid in cat and dog flea treatments available over-the-counter and being marketed inappropriately for prophylactic treatment of companion animals.

8.7 The authorisation and use of vet meds in GB is largely based on assimilated EU law transposed into the Veterinary Medicines Regulations 2013, as amended. However, the 2013 Regulations have been criticised for their focus upon food-producing as opposed to companion animals and a lack of focus on the control of vet med impacts on the wider environment.

8.8 The procedures put in place under 2013 Regulations concentrate on the health and welfare of the treated animal, treatment efficacy, food safety in relation to residues in food-producing animals and the safety of persons administering vet meds, but with almost no focus on the protection of the wider environment from vet med residues. As a result, the VMD as regulator has tended to focus on the efficacy of vet meds and the safety for food-producing animals, over the impact on the wider environment.

8.9 Post-Brexit amendments to the 2013 Regulations have altered the position for vet meds in GB so that, once authorised, authorisation is indefinite. There is no longer regular review of authorised vet meds in GB.

8.10 The adherence to VICH guidelines means that there is insufficient ecological risk assessment prior to authorisation of vet meds to be used on companion animals, despite the widespread use of such products on the millions of cats and dogs in GB.

8.11 Even where more detailed (Phase II) assessments are conducted they do not consider sufficiently cumulative effects, ecotoxicity with other vet

med or pesticide residues present in the aquatic environment, or long-term persistence of residues in sediments, water or the biota. There is almost no consideration of the potential for the 'cocktail effect' in real world situations where ecosystems are exposed to a range of vet meds, pesticides, pharmaceuticals and other chemicals.

8.12 Post-authorisation regulatory control and monitoring is also inadequate, based upon a system of voluntary reporting of adverse events, largely focuses on safety for the treated animal and efficacy, rather than on any impact on the wider environment. There is an almost complete absence of reports relating to wider environmental effects, but this is erroneously taken by regulators to indicate that no such effects exist. However, there is almost no proactive environmental monitoring conducted by or for the VMD. The case of fipronil and imidacloprid cat and dog flea treatments, with concentrations at ecotoxicologically significant levels being found in British rivers, illustrates that the adverse reactions reporting system is not fit for purpose.

8.13 There is a particular problem with the lack of use or sales data for vet meds, meaning the eNGO, scientific and research communities cannot easily identify where vet meds may be an issue for aquatic ecosystems. This contrasts badly with the position for plant protection products, for which professional users' records are accessible under the relevant assimilated EU Regulation and pursuant to the Environmental Information Regulations 2004.

9. Recommendations

9.1 The legal framework for the authorisation and post-authorisation monitoring of vet meds needs amending to ensure that it protects the environment, particularly the aquatic environment, from vet med residues reaching ecotoxicologically significant concentrations (either alone or in combination with over chemicals).

9.2 Greater consideration needs to be given to the direct and indirect risks to the environment from the authorisation and use of vet meds.

9.3 Specifically, greater consideration must be given by applicants for, and holders of marketing authorisations, and by regulators, to the most up-to-date evidence and research, including that conducted by third parties such as universities, concerning the direct or indirect risks to the environment caused by vet meds.

9.4 The effect of vet med residues on ecosystems needs to be viewed in the context of the potential for in-combination effects (with other chemicals, particularly those products regulated as plant protection products or as biocides which often contain the same 'actives' as products authorised as vet meds).

9.5 Greater priority given to adverse effects on the environment, at least equivalent to the priority currently given to adverse effects in terms of efficacy of vet meds or on the health and welfare of the treated animals.

9.6 Specifically, there needs to be vastly improved monitoring of the aquatic environment for vet med residues.

9.7 Both the VMD's functions under the 2013 Regulations, and those on marketing authorisation applicants and holders, need to be adjusted to ensure proper weight is given to the need to protect the wider environment from harm caused by the use of vet meds.

9.8 There needs to be a balance of expertise on the VPC to ensure protect the wider environment from harm caused by the use of vet meds.

9.9 The duty on all marketing authorisation holders to provide any new information to the VMD that affects the benefit-risk balance of any vet med must be clarified to include information on the potential for direct or indirect environmental impacts from use, to include a duty to include information published by third parties, academics, regulators, Universities and similar. Similarly, there needs to be a clear duty on marketing authorisation holders to update annual benefit-risk reports with any such information on the potential for direct or indirect environmental impacts from use.

9.10 No vet med should be authorised if there are expected to be greater than negligible direct or indirect environmental impacts.

9.11 There needs to be a clear duty on the Secretary of State (in the form of the VMD) to vary, modify or revoke existing marketing authorisations if evidence comes to light of a greater than negligible direct or environment or indirect environmental impact from the use of any vet med.

9.12 To address the particular failings in the environmental assessment of vet meds used on pets, all vet meds that are potentially or actually used for a large number of companion animals should be subject to a detailed ecological risk assessment prior to authorisation. Further, if a vet med becomes, or is likely to become widely used after authorisation, without such a detailed assessment having been performed, then it need to be the duty of the VMD to suspend the marketing authorisation pending such assessment.

9.13 All authorisations for vet meds should require the recording and publication of use and sales data for vet meds including date and location of use/sale, dose and frequency of use. This would assist academics, NGOs and the wider public in reducing impacts of vet meds.

9.14 The regulatory functions of both the VMD and the VPC need to be fully transparent, with timely publication of all information supporting applications for authorisation and any post-authorisation regulatory activity. Similarly, any further submissions made by the holders of, or applicants for marketing authorisations should be published.

9.15 No information or data should be redacted or deleted prior to publication, if the information to be redacted relates to information on emissions, in alignment with Regulation 12(9) of the Environmental Information Regulations 2004.

9.16 Appropriate amendments to the 2013 Regulations are proposed in the Annex.

Annex: Proposed amendments to the Veterinary Medicines Regulations 2013 (as they apply in GB)

Amendments appear in bold and underlined.

PART 1

Introduction

Definition of "veterinary medicinal product", interpretation and scope

2. – ...

(2) In these Regulations—

"direct or indirect risks to the environment arising from use of the product" means any risks, whether realised or not, of any adverse effect on any element of the environment (water, soil, air, biota) as a result of exposure to a veterinary medicinal product, its active substance(s) or metabolite(s), to include in-combination adverse effects with other veterinary medicinal products, Plant Protection Products and Biocides, their active substance(s) or metabolite(s);

…

"adverse environmental event" means an event where a non-target organism, population or ecosystem is adversely affected as a result of exposure to a veterinary medicinal product, its active substances or its metabolites present in soil, water or animal remains, **including in-combination adverse effects with other veterinary medicinal products, Plant Protection Products and Biocides, their active substance(s) or metabolite(s**;

…

"benefit-risk balance" means, in relation to a veterinary medicinal product, an evaluation of the positive effects of the veterinary medicinal product in relation to the following risks relating to the use of that product—

(a) any risk to human or animal health relating to the quality, safety or efficacy of the veterinary medicinal product; or

(b) any risk relating to the development of resistance;

provided always that the "benefit-risk balance" shall be unfavourable (negative) if there are or are expected to be greater than negligible direct or indirect risks to the environment arising from use of the product;

…

"Biocides" means any products authorised under the Great Britain Biocidal Products Regulation (assimilated Regulation (EU) No 528/2012 of the European Parliament and of the Council) of 22 May 2012 concerning the making available on the market and use of biocidal products;

…

"Plant Protection Products" means any products regulated under assimilated Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

…

"pharmacovigilance" means the science and activities relating to the detection, assessment, understanding and prevention of suspected adverse events, **direct or indirect risks to the environment arising from use of the product,** or any other problem related to a medicinal product;

PART 3

[new Regulation]

Records

Annual reporting of sales and usage data in relation to veterinary medicine

(17A)

(1) Any person mentioned in paragraph (2) must record information in paragraph (3) relating to any supply of a veterinary medicine belonging to the following categories -

(a) Prescription Only Medicine–Veterinarian (POM-V);

(b) Prescription Only Medicine–Veterinarian, Pharmacist, Suitably Qualified Person (POM-VPS); and

(c) Non-Food Animal–Veterinarian, Pharmacist, Suitably Qualified Person (NFA-VPS).

(2) The persons are—

(a) a veterinarian;

(b) a pharmacist;

(c) a suitably qualified person.

(3) The information to be recorded is –

(a) the location of the intended use by postcode district;

(b) the name of the product;

(c) the amount of active substance supplied;

(d) the date of intended use or administration of the product; and

(e) the breed or species of animals to be treated.

(4) Any keeper of food-producing animals must record the information in paragraph (5) relating to any use of feed containing a veterinary medicine

(5) The information to be recorded is –

(a) the location of the intended use of the feed by postcode district;

(b) the name of the veterinary medicine(s);

(c) the amount of active substance;
(d) the date of intended use or administration of the feed; and
(e) the breed or species of animals to be treated.

(6) Any person mentioned in paragraph (7) must record information in paragraph (8) relating to the sale of a veterinary medicine belonging to the category of Authorised Veterinary Medicine– General Sales List (abbreviated to AVM-GSL).

(7) The persons are—
(a) the holder of a manufacturing authorisation;
(b) the holder of a marketing authorisation;
(c) the holder of a wholesale dealer's authorisation;
(d) a retailer.

(8) The information to be recorded is –
(a) the location of the sale to users by postcode district;
(b) the name of the product;
(c) the amount of active substance sold; and
(d) the breed or species of animals to be treated.

(9) The information recorded under paragraphs (1) (4) and (6) above must be provided to the Veterinary Medicines Directorate each year by 31st January in the year following the year to which the information relates and in such format as the Secretary of State shall by order prescribe.

(10) It is an offence to fail to provide the information under paragraph (9) and Regulation 44 (Penalties) applies.

(11) The information provided under paragraph (9) shall be published online by the Veterinary Medicines Directorate by 30 June in the year following the year to which the information relates.

PART 5

Miscellaneous provisions, enforcement and offences

The Veterinary Products Committee

28.—(1) There shall continue to be a Veterinary Products Committee.

(2) The Secretary of State may appoint members of the Committee from professional people who are eminent in their field, and any lay members as the Secretary of State sees fit, **provided always that the Committee shall have a balance of members with interests in -**
(a) the efficacy and pharmacology of veterinary medicines;
(b) animal welfare;
(c) ecotoxicology;
(d) the protection of habitats and species;
(e) veterinary medicine users; and
(f) veterinary medicine authorisation holders.

(3) The function of the Committee is to provide scientific advice on any aspect of veterinary medicinal products asked for by the Secretary of State which shall **include advise on the direct or indirect risks to the environment arising from use of those products** and to carry out any functions specified in these Regulations.

(4) The Secretary of State may pay members of the Committee such amounts as the Secretary of State may decide.

(5) The Secretary of State may consult the Committee at any time

Veterinary Products Committee appeals procedure

29.

(1) The following procedure applies when any person receives a notification from the Secretary of State informing that person (the appellant) of a right to an appeal to the Veterinary Products Committee.

(2) The appellant must inform the Secretary of State of an intention to appeal within 28 days of the notification which is the subject of the appeal.

(3) The appeal **shall be in writing**

(4A) Any appeal documents and any representations made by the Secretary of State shall be immediately published online by the Secretary of State;

(4) The appellant may not present to the Committee any new data not available to the Secretary of State at the time of the original decision.

(5) The Committee must consider the appeal and any representations made by the Secretary of State, and report its findings in writing to the Secretary of State together with its recommendations.

(6) The Secretary of State must send a copy of the report to the appellant on request **and at the same time publish the report online**

(7) The Secretary of State must consider the report and then form a provisional decision.

(8) The Secretary of State must then notify the provisional decision to the appellant, together with the reasons for it **and at the same time publish such decision and reasons online.**

SCHEDULE 1

Marketing authorisations in Great Britain

PART 1

Application for a marketing authorisation

1. An application under these Regulations for a marketing authorisation for a veterinary medicinal product must be made to the Secretary of State.

Information with the application: general

2.—(1) An application must include the matters mentioned in sub-paragraph (2) and—

(a)where the veterinary medicinal product is an antimicrobial, the matters mentioned in sub-paragraph (4);

(b)subject to sub-paragraph (6), where the product is to be administered to a food-producing animal and is a product containing pharmacologically active substances that are not permitted under Regulation (EC) No 470/2009 of the European Parliament and of the Council, the matter mentioned in sub-paragraph (5);

(c)where the product contains or consists of genetically modified organisms, the matters mentioned in sub-paragraph (7).

(2) For the purposes of sub-paragraph (1) the matters are—

(a)the name of the person who will hold the marketing authorisation and that person's address or registered place of business;

(b)the name and the address or registered place of business of—

(i)the manufacturer of the finished product;

(ii)any importer of the finished product;

(iii)the manufacturer of any active substances involved at each stage of the manufacture;

(c)the name and address of the sites where—

(i)each stage of the manufacture is carried out;

(ii)any imported products are held; or

(iii)any control or batch release is carried out;

(d)the nature of the marketing authorisation being applied for, and the provisions in Part 2 of Schedule 1 which are relevant to the application;

(e)in relation to the veterinary medicinal product—

(i)the name and the ATCvet code;

(ii)a description of the active substances within the product and, if applicable, a description of any diluent;

(iii)the strength of the product, or, in the case of an immunological veterinary medicinal product or a biological veterinary medicinal product that is not immunological, the biological activity, potency or titre;

(iv)the pharmaceutical form of the product;

(v)the route of administration;

(vi)a description of the target species;

(f)a document showing that the manufacturer is authorised to produce veterinary medicinal products or a certificate of good manufacturing practice issued by the Secretary of State or equivalent certification issued by an authority recognised by the Secretary of State for that purpose, together with a description of the manufacturing process for the active substances and finished product which falls within scope of that authorisation or certificate;

(g)the reference number and a summary of the pharmacovigilance system master file in relation to the product and, where appropriate, the risk management plan that the applicant will put in place;

(h)the proposed summary of product characteristics;

(i)a description of the final presentation, the packaging and labelling of the product;

(j)the proposed text of the information to be included on the immediate packaging, the outer packaging and the information leaflet accompanying the product;

(k)details of any country where—

(i)a marketing authorisation has been granted or revoked in relation to the product;

(ii)a marketing authorisation has been submitted or refused;

(l)a summary of product characteristics included in the terms of any marketing authorisation granted by another country;

(m)technical documentation demonstrating the quality, safety and efficacy of the product, **and the direct or indirect risks to the environment arising from use of the product**;

(n)a report (a "critical expert report") on the quality, safety and efficacy of the product **and the direct or indirect risks to the environment arising from use of the product**.

(3) For the purposes of sub-paragraph (2)(n), each critical expert report must—

(a)be prepared with regard to the state of scientific knowledge at the time of the application;

(b)include an evaluation of each test and trial referred to in the application, addressing all aspects relevant to quality, safety and efficacy, with detailed results and precise bibliographic references (including copies of the referenced material);

(bb) include an evaluation of the most-up-to-date scientific knowledge relevant to direct or indirect risks to the environment arising from use of the product with precise bibliographic references (including copies of the referenced material);

(c)where technical documentation within sub-paragraph (2)(m) is referenced, include precise cross-references;

(d)be signed and dated by the author, and include details of the author's educational background, training and occupational experience, and the author's professional relationship with the applicant.

(4) For the purposes of sub-paragraph (1)(a), the matters are—

(a)information on direct or indirect risks to public or animal health or to the environment arising from use of the antimicrobial product in animals;

(b)information about the methods of mitigating the development of antimicrobial resistance as a result of the use of the product.

(5) For the purposes of sub-paragraph (1)(b), the matter is a document certifying that a valid application for the establishment of maximum residue levels has been submitted to the Secretary of State.

(6) Sub-paragraph (1)(b) does not apply in respect of a veterinary medicinal product which—

(a)is for administration to a horse that has been declared on its horse passport as not intended for slaughter for human consumption, and

(b)includes an active substance that has been classified under Article 14 of Regulation (EC) No 470/2009 of the European Parliament and of the Council as prohibited for use in food-producing animals.

(7) For the purposes of sub-paragraph (1)(c) the matters are—

(a)a copy of the written consent to the deliberate release into the environment of the genetically modified organisms for research and development purposes issued under the GMO Deliberate Release Regulations;

(b)the complete technical file containing the information provided in respect of the application for that consent under the GMO Deliberate Release Regulations;

(c)the environmental risk assessment provided in respect of the application for that consent under the GMO Deliberate Release Regulations;

(d)the results of any investigations performed for the purposes of research or development.

(8) In assembling the application for an authorisation under this Schedule, the applicant must—

(a)take into account the most up-to-date veterinary medicinal knowledge and scientific guidelines relating to the quality, safety and efficacy of veterinary medicinal products (including relevant monographs of the European Pharmacopoeia and British Pharmacopoeia);

(b)include in the application all information which is relevant to the evaluation of the veterinary medicinal product to which it relates, whether favourable or unfavourable to the product (including information relating to any incomplete or abandoned study or trial);

(c)ensure that the application supports, by reference to specific studies and trials, each claim made by the applicant with regard to the properties, effects and uses of the veterinary medicinal product to which it relates;

(cc) take into account the most up-to-date scientific knowledge relating to the direct or indirect risks to the environment arising from use of the product;

(d)otherwise ensure the accuracy of the information in the application.

(9) For the purposes of sub-paragraph (8)(c), pharmacological, toxicological, residue and pre-clinical studies and clinical trials must be carried out in conformity with the principles of good laboratory practice, where applicable.

Information with the application: format

2A.—(1) An application must be submitted electronically.

(2) Subject to sub-paragraph (3), the application must be structured as a single dossier in four parts—

(a)Part 1 (administrative information);

(b)Part 2 (pharmaceutical quality (physicochemical, biological or microbiological) data);

(c)Part 3 (safety documentation, including safety and residue tests);

(d)Part 4 (efficacy documentation, including pre-clinical studies and clinical trials);

(e) Part 5 (scientific documentation relating to the direct or indirect risks to the environment arising from use of the product);

(3) An application concerning the release of GMOs must set out the environmental risk assessment in respect of that release as a separate document, and that assessment must be presented in accordance with the following provision of the GMO Deliberate Release Regulations—

(a)as regards England or Scotland, regulation 6;

(b)as regards Wales, regulation 7.

SCHEDULE 1

Marketing authorisations in Great Britain

PART 2

Derogations from some of the requirements in Part 1

Bibliographic application

7.—(1) An applicant for a marketing authorisation need not provide the results of safety tests, residue tests, pre-clinical trials or clinical trials if the applicant demonstrates that the active substances of the veterinary medicinal product have been in well-established veterinary use for at least 10 years, that their efficacy is documented, that they provide an acceptable level of safety, **and that the most up-to-date scientific knowledge demonstrates only negligible direct or indirect risks to the environment arising from use of the product**;

(1A) Sub-paragraph (1) does not apply to applications for—

(a)biological (including immunological) veterinary medicinal products;

(b)novel therapies.

(2) The applicant may use any publicly available document.

(3) If an applicant makes use of scientific literature to obtain authorisation for a food-producing species, and submits, in respect of the same medicinal product and with a view to obtaining authorisation for another food-producing species, new residue studies, together with further clinical trials, a third party may not use those studies or trials in an application for a pharmacologically equivalent product for a period of three years from the grant of the authorisation for the additional species.

Application for a product using a new combination of active substances

8.— (1) If an application is for a veterinary medicinal product containing active substances already used in an authorised veterinary medicinal product but not previously used in that combination in a veterinary medicinal product, the applicant need not provide the safety and efficacy data for the individual active substances.

(2) Notwithstanding sub-paragraph (1) the applicant must provide a sound scientific justification based on valid therapeutic principles for the combination of active substances, including clinical data, which demonstrates the need for and contribution of all active substances at the moment of treatment **and that only negligible direct or indirect risks to the environment are expected from use of the product**;

Application for a generic veterinary medicinal product

10.—(1) Subject to sub-paragraphs (2A), (9) and (10) and paragraph 10A, an applicant need not provide the results of safety tests, residue tests, pre-clinical trials or clinical trials **and scientific documentation relating to direct or indirect risks to the environment arising from use of the product** if the applicant can demonstrate that the veterinary medicinal product is a generic of a veterinary medicinal product already authorised in the United Kingdom ("the reference veterinary medicinal product"), provided that the applicant provides data demonstrating the matters referred to in sub-paragraph (2) **and that only negligible direct or indirect risks to the environment are expected from use of the product.**

(2) For the purposes of this paragraph a product is a generic of an existing product if—

(a)it has the same qualitative and quantitative composition in active substances;

(b)it has the same pharmaceutical form as the reference product; and

(c)bioequivalence with the reference product has been demonstrated

(2A) Sub-paragraph (1) does not apply to applications for biological (including immunological) veterinary medicinal products.

(3) For the purposes of this paragraph—

(a)the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy; and

(b)if they do differ significantly in properties with regard to efficacy or safety, additional information intended to provide proof of the safety or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant.

(4) Different immediate-release oral pharmaceutical forms are regarded as the same pharmaceutical form.

(5) Bioavailability studies are not required if the bioequivalence guidelines produced by the European Medicines Agency or the Secretary of State exempt the product.

(6) . . . . . .

(7) For the purposes of these Regulations, subject to sub-paragraph (8), the summary of product characteristics of a generic veterinary medicinal product must be essentially similar to the summary of product characteristics for the reference product.

(8) The requirement in sub-paragraph (7) does not apply in relation to those parts of the summary of product characteristics of the reference product that refer to indications or pharmaceutical forms which are covered by patents at the time when the generic veterinary medicinal product is authorised.

(9) Notwithstanding sub-paragraph (1), in respect of generic veterinary medicinal products intended to be administered by intramuscular, subcutaneous or transdermal routes, the applicant must provide—

(a)administration site target animal tolerance data;

(b)in respect of products intended for administration to food-producing species only, residues depletion data from the site of administration.

(10) Notwithstanding sub-paragraph (1), in respect of generic veterinary medicinal products containing antimicrobial or antiparasitic substances, the applicant must provide all available data (including published data) on the current level of resistance, together with a review of that data as it relates to target pathogens to the active substances concerned.

(11) An applicant must provide an environmental risk assessment for a generic veterinary medicinal product where—

(a)the marketing authorisation for the reference veterinary medicinal product was granted before 1st October 2005, and

(b)no marketing authorisation has been granted since 1st October 2005 in respect of a veterinary medicinal product which has the same active substance and pharmaceutical form as the reference veterinary medicinal product, and which is indicated for use in the same target species when administered at the same or a higher total dose, unless the Secretary of State holds an environmental risk assessment for the reference veterinary medicinal product and has confirmed this to the applicant.

Marketing a product authorised in another country

16. If –

(i) the health situation so requires; **and**

(ii) the Secretary or State is satisfied that only negligible direct or indirect risks to the environment are expected from use of the product;

the Secretary of State may authorise the placing on the market of a veterinary medicinal product that has been authorised in another country.

SCHEDULE 1

Marketing authorisations in Great Britain

PART 3

Grant of a marketing authorisation

Grant of a marketing authorisation

22.— (1) The Secretary of State must, before granting a marketing authorisation—

(a)verify that the data submitted complies with the requirements set out in these Regulations;

(b)assess the application and data submitted in respect of the veterinary medicinal product; and

(c)reach a conclusion in relation to the benefit-risk balance of granting a marketing authorisation in respect of the veterinary medicinal product.

(2) When granting a marketing authorisation, the Secretary of State must inform the applicant of the summary of product characteristics that has been approved, and the distribution category of the product.

(3) The Secretary of State must set out any terms and conditions in connection with placing the product on the market when granting a marketing authorisation.

(4) Where the marketing authorisation relates to a veterinary medicinal product that contains an antimicrobial the Secretary of State may require the holder of the marketing authorisation to conduct post-authorisation studies in order to ensure that the benefit-risk balance**.**

Refusal of a marketing authorisation

24.—(1) The Secretary of State must refuse to grant a marketing authorisation if the application does not comply with these Regulations.

(2) In addition, the Secretary of State must refuse to grant it if—

(a)the data submitted with the application are inadequate;

(b)the benefit-risk balance of the veterinary medicinal product is unfavourable (negative);

(c)the applicant has not provided sufficient evidence of the efficacy of the product in relation to the target species;

(d)the withdrawal period proposed by the applicant is not long enough to ensure food safety, or is insufficiently substantiated;

(e)the veterinary medicinal product is for a prohibited use;

(f)the way that the product will be used will have an unnecessarily undesirable effect on the environment;

(ff) where the marketing authorisation applied for relates to a veterinary medicinal product that is to be categorised AVM-GSL and it is likely that the product will be used in a large number of companion animals, but a Phase II ecological risk assessment has not been provided;

(g)the veterinary medicinal product is a veterinary medicinal product which contains an antimicrobial which is presented for use in order to promote the growth of treated animals or to increase yields from treated animals;

(h)the risk for public health in case of development of antimicrobial resistance or antiparasitic resistance outweighs the benefits of the veterinary medicinal product to animal health;

(i)the risks to public or animal health or to the environment are not sufficiently addressed;

(j)the qualitative or quantitative composition of the veterinary medicinal product is not as stated in the application;

(k)the active substance within the veterinary medicinal product meets the criteria for being considered persistent, bio-accumulative and toxic and the veterinary medicinal product is intended to be used in food-producing

animals (except where it is demonstrated that the active substance is essential to prevent or control a serious risk to animal health).

(3) The Secretary of State may refuse to grant a marketing authorisation—

(a)if there is … legislation pending that is incompatible with the requested authorisation; or

(b)if additional data have been requested and those data are not provided within such time limit as may be stipulated.

(4) If the Secretary of State, on the grounds of safety, quality or efficacy, intends to refuse an application, or proposes to grant a marketing authorisation that is different from the one applied for, the Secretary of State must notify the applicant accordingly, and the applicant may appeal to the Veterinary Products Committee.

Publication following the grant, refusal, suspension, variation or revocation of a marketing authorisation

25.—(1) On granting a marketing authorisation the Secretary of State must publish—

(a)the notice granting the marketing authorisation;

(b)the summary of the product characteristics;

(c)the assessment report that has already been prepared but with any commercially confidential or personal information deleted, **except that information that relates to information on emissions as defined in Regulation 12(9) of the Environmental Information Regulations 2004 shall not be deleted**;

(2) The Secretary of State must update the assessment report whenever new information that is of importance and relates to the quality, safety or efficacy of the veterinary medicinal product **or relates to the direct or indirect risks to the environment arising from use of the product** becomes available.

(3) The Secretary of State must send a copy of the assessment report, and any update, to the holder of the marketing authorisation before publication to enable the holder to make representations concerning any confidential or personal information that may be in it, and may specify a date by which representations must be made, **except that no representations may be accepted concerning information that relates to information on emissions as defined in Regulation 12(9) of the Environmental Information Regulations 2004**.

(4) Where the Secretary of State refuses to grant a marketing authorisation or suspends or revokes an authorisation the Secretary of State must publish that fact.

(5) Where the Secretary of State varies a marketing authorisation in relation to the summary of product characteristics the Secretary of State must publish the terms of the variation.

remains positive in relation to the development of antimicrobial resistance.

Marketing authorisations in exceptional circumstances

26.—(1) In exceptional circumstances, and if there is no other product with a full marketing authorisation for the indicated condition in the target species, the Secretary of State may grant an exceptional marketing authorisation consisting of—

(a)a provisional marketing authorisation subject to a requirement for the applicant to provide further data, taking into account the benefit of the immediate availability on the market of the veterinary medicinal product in comparison to the risks; or

(b)a limited marketing authorisation for a product with a limited market, taking into account the benefit in relation to public or animal health of the availability of the product on the market in comparison to the risks.

(1A) An exceptional marketing authorisation may be granted subject to such further conditions, including any restrictions, as the Secretary of State considers appropriate.

(2) The Secretary of State must reassess each provisional or limited marketing authorisation annually.

(2A) **The Secretary or State may only grant an exceptional marketing authorisation if the Secretary of State is satisfied that only negligible direct or indirect risks to the environment are expected from use of the product.**

Records and supply of information

28.—(1) A marketing authorisation holder must immediately inform the Secretary of State on receipt of any new information that might adversely affect the benefit-risk balance of the veterinary medicinal product.

(2) The holder must immediately inform the Secretary of State of any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is authorised.

(3) The Secretary of State may at any time require the marketing authorisation holder to provide data relating to the benefit-risk balance.

(3A) The marketing authorisation holder shall immediately provide any new information on the direct or indirect risks to the environment arising from use of the product.

(3B) The Secretary of State must publish any information received under sub-paragraph (3A) within 20 working days of receipt.

(4) A marketing authorisation holder must retain all of the original documents from every clinical trial from which data was derived in support of the application for authorisation under this Schedule, and in support of any variation of the authorisation (whether granted or otherwise), **indefinitely.**

Placing on the market

31.—(1) A holder of a marketing authorisation must notify the Secretary of State when the veterinary medicinal product is first placed on the market in the United Kingdom, and the date on which it was placed on the market.

(2) A holder of a marketing authorisation who removes the veterinary medicinal product from the market in the United Kingdom must notify the Secretary of State at least two months (or a shorter period in exceptional circumstances) before doing so.

(2A) A holder of a marketing authorisation who identifies a shortage of the veterinary medicinal product must notify the Secretary of State as soon as is reasonably practicable.

(2B) For the purposes of sub-paragraph (2A) a shortage of a veterinary medicinal product occurs when supply does not meet demand at a national level within the United Kingdom.

(3) The marketing authorisation holder must provide to the Secretary of State by 31 January in each year data relating to the volume of each veterinary medicinal product sold in the previous year to include the total weight of each active ingredient sold; and

(4) The Secretary of State shall publish the data received under sub paragraph (3) relating to the previous year by 30 June in each year.

SCHEDULE 1

Marketing authorisations in Great Britain

PART 4

Variations of marketing authorizations on the application of the holder

Refusal of a variation of a marketing authorisation

34.— (1) . . . . . .

(2) The grounds on which the Secretary of State may refuse an application for a variation of a marketing authorisation are those set out in paragraph 24 of this Schedule (refusal of a marketing authorisation).

(3) The Secretary of State must give written reasons for refusing to grant a variation; and if—

(a)those reasons are on the grounds of safety, quality or efficacy **or direct or indirect risks to the environment arising from use of the product**; and

(b)the Secretary of State produced an assessment in respect of the variation under paragraph 33A(4),

the applicant may appeal to the Veterinary Products Committee.

SCHEDULE 1

Marketing authorisations in Great Britain

PART 5

Suspension etc of a marketing authorisation

Suspension, revocation, etc of a marketing authorisation: grounds

38.— (1) If the Secretary of State is satisfied at any time that the benefit-risk balance of a veterinary medicinal product is not positive or is insufficient to ensure food safety**,** the Secretary of State may—

(a)suspend the marketing authorisation;

(b)require the holder of the marketing authorisation to submit an application for its variation;

(c)revoke the marketing authorisation.

(1A) **If the Secretary of State is satisfied at any time that there are greater than negligible direct or indirect risks to the environment arising from use of the product, the Secretary of State must—**

(a)suspend the marketing authorisation and require the holder of the marketing authorisation to submit an application for its variation; or

(c)revoke the marketing authorisation.

(2) The Secretary of State may also suspend a marketing authorisation on being satisfied that a marketing authorisation holder has failed to make an application for a variation to take account of scientific and technical progress in manufacturing and control methods to enable the veterinary medicinal product to be manufactured and checked by means of generally accepted scientific methods.

(3) The Secretary of State may take the steps set out in sub-paragraph (1)(a), (b) and (c) on being satisfied at any time that—

(a)information given in the application documents is incorrect;

(b)any control tests required have not been carried out;

(c)changes have been made to the manufacturing process without the authority of the Secretary of State;

(d)any information required to be supplied to the Secretary of State has not been so supplied;

(e)the holder of the marketing authorisation has failed to comply with the requirements of these Regulations;

(f)the pharmacovigilance system in relation to a veterinary medicinal product is inadequate;

(g)in the case of a generic authorisation, the reference product is updated to show a reduction in antimicrobial resistance;

(h)the qualified person (pharmacovigilance) has failed to comply with the requirements of these Regulations

Revocation

40. The Secretary of State **must** revoke any marketing authorisation that has been suspended for more than 28 days unless there is a current appeal to the Veterinary Products Committee and **must** publicise a revocation in such manner as the Secretary of State sees fit.

SCHEDULE 1

Marketing authorisations in Great Britain

PART 7

Labelling and package leaflets

Labelling of immediate packaging of veterinary medicinal products

48.—(1) Subject to paragraph 50, the following information must be provided on the immediate packaging of a veterinary medicinal product—

(a)the name of the product, followed by its strength and pharmaceutical form;

(b)a statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using their common names;

(c)the batch number, preceded by the word "Lot";

(d)the name or company name or logo of the marketing authorisation holder;

(e)the target species;

(f)the expiry date, in the format 'mm/yyyy', preceded by the abbreviation "Exp.";

(g)special storage precautions, if any;

(h)the route of administration;

(i)if applicable, the withdrawal period, even if such period is zero; and

(j) direct or indirect risks to the environment arising from use of the product.

(2) Where there is no outer packaging for the product, the information set out in paragraph 49 must be included on the immediate packaging of the veterinary medicinal product.

(3) The information referred to in paragraph (1) must appear in easily legible and clearly comprehensible characters, or in abbreviations or pictograms.

Package leaflet of veterinary medicinal products

51.—(1) Subject to sub-paragraphs (5) and (7), a package leaflet must be supplied with each veterinary medicinal product.

(2) The package leaflet must provide the following information—

(a)the name and address of the marketing authorisation holder and of the manufacturer and, where applicable, the distributor;

(b)the name of the veterinary medicinal product, followed by its strength and pharmaceutical form;

(c)the qualitative and quantitative composition of any active substance;

(d)the target species, the dosage for each species, the method and route of administration and if necessary, advice on the correct administration;

(e)the indications for use;

(f)the contra-indications and adverse events;

(g)if applicable, the withdrawal period for each species, even if such a period is zero;

(h)special storage precautions, if any;

(hh) direct or indirect risks to the environment arising from use of the product.

(i)information essential for safety or health protection, including any special precautions relating to use and any other warnings;

(j)the words "use take-back schemes for the disposal of any unused veterinary medicinal product or associated waste materials in accordance

with local requirements and with any applicable national collection schemes";

(k)the marketing authorisation number;

(l)contact details for the marketing authorisation holder or its representative, as appropriate, for the reporting of suspected adverse events;

(m)classification of the veterinary medicinal product as referred to in the summary of product characteristics.

(3) Providing that it complies with the marketing authorisation, the package leaflet may include additional information concerning distribution, possession or any necessary precaution required, provided that this information is not promotional in character.

(4) The package leaflet must be in legible form and designed to be clear and understandable, in terms that are comprehensible to the general public.

(5) Only a package leaflet approved in the marketing authorisation may be published or included with the veterinary medicinal product.

(6) The Secretary of State may require the information set out in sub-paragraph (2) to be made available in written form or electronically, or both.

(7) Where the Secretary of State requires the leaflet to be made available electronically—

(a)an electronic package information leaflet which includes the information required by this paragraph must be provided in place of a leaflet in written form;

(b)the packaging of the veterinary medicinal product must include—

(i)a statement that the information which must be included on a package leaflet is provided electronically;

(ii)any necessary electronic link in order to access the relevant part of the website where the electronic package information leaflet is to be found;

(iii)a statement that a copy of the information in written form may be obtained on request; and

(iv)instructions on how to obtain such a copy.

(8) Any information required by this paragraph to be provided on a package leaflet in written form may be otherwise provided on the packaging of the veterinary medicinal product.

SCHEDULE 1

Marketing authorisations in Great Britain

PART 8

Pharmacovigilance

Duties of marketing authorisation holder in relation to pharmacovigilance

56.—(1) The marketing authorisation holder is responsible for pharmacovigilance in relation to a veterinary medicinal product for which it holds a marketing authorisation and must continuously evaluate, by appropriate means, the benefit-risk balance of this veterinary medicinal product and, if necessary, take appropriate measures to address any risk presented by the product.

(2) A marketing authorisation holder must carry out the signal management process mentioned in paragraph 56C in relation to any veterinary medicinal product for which it holds an authorisation.

(3) A marketing authorisation holder must comply with best practice in good veterinary pharmacovigilance practice.

(4) A marketing authorisation holder must establish and maintain a system for collecting, collating and evaluating information in relation to suspected adverse events and **direct or indirect risks to the environment arising from use of the product** in respect of any veterinary medicinal product for which it holds an authorisation;

(5) Subject to sub-paragraph (6), a marketing authorisation holder must establish and maintain one or more pharmacovigilance system master files describing in detail the pharmacovigilance system with respect to its authorised veterinary medicinal products.

(6) For each veterinary medicinal product, the marketing authorisation holder must not establish and maintain more than one pharmacovigilance system master file.

(7) A marketing authorisation holder must establish and maintain an adequate and effective local system for the purpose of receiving reports of suspected adverse events and **information on direct or indirect risks to the environment arising from use of the product**.

(8) The system mentioned in sub-paragraph (7) must be staffed by personnel trained for this purpose who are able to communicate in English.

(9) A marketing authorisation holder must designate not more than one qualified person responsible for pharmacovigilance (a "qualified person (pharmacovigilance)") in relation to each pharmacovigilance system master file whose services are available permanently and continuously.

(10) Where the pharmacovigilance functions or the functions of the qualified person for pharmacovigilance are performed by a third party, any such arrangement must be specified in detail in the pharmacovigilance system master file and within appropriate pharmacovigilance agreements.

(11) A marketing authorisation holder **must** introduce urgent safety restrictions where evidence comes to the attention of the holder of a risk posed to human or animal health or to the environment from the use of the product.

(12) Where a marketing authorisation holder takes any action under sub-paragraph (11) the holder must inform the Secretary of State no later than the following working day of the reasons for the action.

(13) A marketing authorisation holder must establish and maintain an adequate and effective quality management system for the performance of its pharmacovigilance activities.

(14) The Secretary of State may at any time by notice require a marketing authorisation holder to provide a copy of the pharmacovigilance system master file.

(15) A marketing authorisation holder who is given notice under sub-paragraph (14) must comply with the requirement within seven days of receipt of the notice.

Duties of qualified person (pharmacovigilance)

56B. A qualified person (pharmacovigilance) must—

(a)establish and maintain a system which ensures that all suspected adverse events **and information on direct or indirect risks to the environment arising from use of the product** which are brought to the attention of the marketing authorisation holder in relation to a veterinary medicinal product are collected and recorded;

(b)monitor the performance of each product which is the subject of a marketing authorisation, apply the signal management process mentioned in paragraph 56C and ensure that any relevant requirements in accordance with the process are carried out;

(c)maintain the pharmacovigilance system master file for each such product;

(d)provide to the Secretary of State any information relevant to detecting a change to the benefit-risk balance of a veterinary medicinal product including the results of any study or clinical trial carried out in relation to the product **and the most-up-to-date scientific knowledge relevant to direct or indirect risks to the environment arising from use of the product**;

(e)communicate the fact that a regulatory measure has been taken in a country other than the United Kingdom as a consequence of pharmacovigilance data and the nature of such measure to the Secretary of State within 30 days of the receipt of such information, if no equivalent to that regulatory measure has already been taken in the United Kingdom;

(f)answer fully and promptly any request from the Secretary of State for the provision of additional information necessary for the evaluation of the benefit-risk balance of that product;

(g)monitor the pharmacovigilance system and ensure that, if required, an appropriate preventative or corrective action plan is prepared and implemented on behalf of the marketing authorisation holder through the use of audits and routine monitoring;

(h)following any action taken in accordance with paragraph (g), ensure that any relevant amendments are made to the pharmacovigilance system master file;

(i)liaise with the Secretary of State in relation to any pharmacovigilance inspection carried out under paragraph 60A;

(j)ensure that any person employed by the marketing authorisation holder who is engaged in pharmacovigilance receives ongoing training which is relevant to that person's duties.

Adverse events following administration of a veterinary medicinal product]

57.—(1) A marketing authorisation holder must act in accordance with this paragraph on learning of any suspected—

(a) adverse event in respect of an animal;

(b)human adverse event;

(c)unintended transmission of an infectious agent through a veterinary medicinal product,

(d)occurrence of an adverse environmental event,

(dd) **direct or indirect risks to the environment arising from use of the product, or**

(e)lack of efficacy, following the administration of the product

(1A) A marketing authorisation holder must also act in accordance with this paragraph where—

(a)after the end of the withdrawal period a product of animal origin is found to include a pharmacologically active substance or marker residue exceeding the maximum residue limit established in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council; or

(b)there is evidence in published scientific literature of an adverse event **or direct or indirect risks to the environment arising** in connection with the product.**]**

(2) The holder must make a record of what happened.

(3) The holder must without delay and in any event within 30 days report it (electronically if this is practicable) to the Secretary of State.

(4) In addition, the holder must supply to the Secretary of State all relevant veterinary pharmacovigilance information that the holder possesses relating to the event, giving a full description of the incident and a list of all the symptoms using internationally recognised veterinary and medical terminology, **and any information on direct or indirect risks to the environment arising from use of the product** either with the report or, if the information becomes available after the report has been sent, as soon after it becomes available as is reasonably practicable.

(4A) The Secretary of State may require the marketing authorisation holder—

(a)to collect specific pharmacovigilance data (in addition to the data mentioned in sub-paragraph (4)) and submit those data to the Secretary of State; and

(b)to carry out specific post-marketing surveillance studies **or studies on direct or indirect risks to the environment arising from use of the product**.

(4B) Where the Secretary of State exercises the power mentioned in sub-paragraph (4A), the Secretary of State must—

(a)state the reason for the requirement; and

(b)state the time by which, or the period during which, the requirement must be complied with.

(5) On receipt of any information under this paragraph the Secretary of State must publish that information but with any commercially confidential or personal information deleted, except that information that relates to information on emissions as defined in Regulation 12(9) of the Environmental Information Regulations 2004 shall not be deleted.

Annual benefit-risk reports

59.—(1) The marketing authorisation holder must submit to the Secretary of State a summary of pharmacovigilance activity**]** in the form of an annual benefit-risk report for each marketing authorisation in accordance with this paragraph

(2) . . .

(3) Following the placing on the market in Great Britain, the marketing authorisation holder must submit a benefit-risk report to the Secretary of State immediately upon request and, in any event, once in the course of every year during the period of validity of the authorisation.

(4) Following the granting of a marketing authorisation, the marketing authorisation holder may apply to the Secretary of State to change the submission dates for the annual benefit-risk reports.

(5) The report must include a statement regarding the benefit-risk balance of the veterinary medicinal product.**]**

(6) The annual benefit-risk report must include—

(a)the volume of the product sold in the United Kingdom and in other countries in the period covered by the report, with the volume of the product sold in the United Kingdom in each calendar year identified;

(b)the notification of signals detected during the reporting period following pharmacovigilance activity in the United Kingdom or a country other than the United Kingdom for which further regulatory actions are required (including a summary of the regular review of adverse events carried out during the year);

(c)where it appears from the observed data that there is cause for concern in relation to the safety of the product, recommendations on the need for further intervention by the Secretary of State; and

(d) any new information on the direct or indirect risks to the environment arising from use of the product.

(6) On receipt of any annual benefit-risk report the Secretary of State must publish that report but with any commercially confidential or personal information deleted, except that information that relates to information on emissions as defined in Regulation 12(9) of the Environmental Information Regulations 2004 shall not be deleted.

END

WildFish.

Report finalised February 2026.

www.wildfish.org

info@wildfish.org