Co-Space Stevenage, 25 Town Square, Stevenage, SG1 1BP, United Kingdom
Email: noah@noah.co.uk
Website: www.noah.co.uk www.noahcompendium.co.uk

Registered in England No: 2145809

Representing the UK Animal Health Industry

Q&A: Parasite treatment for pets; veterinary medicines and the environment

Introduction

- Recently, there has been much discussion and debate in the veterinary press about the use of licensed veterinary medicines and their potential impact on the wider environment. In this document, the safeguards that exist to prevent adverse outcomes are explained and the impact and meaning of some recently published papers are considered.
- The below also seeks to address some of the questions that arise around use of veterinary medicines and their impact on the environment.
- NOAH and our member companies are proud of the benefits for animal health, animal welfare and human health, that veterinary medicines bring to pets and owners.
- NOAH supports the responsible use of parasiticides.
- NOAH and its members care about sustainability and the health of the environment and wish to engage on this topic in an objective, science-based, evidence- led manner, which recognises that animal health and welfare needs must be met, while at the same time safe-guarding the environment.
- Veterinary medicines, including companion animal parasiticides, are essential for animal health and welfare and for the prevention of zoonotic disease – it is a good thing for society and for animals that products continue to be researched, developed and marketed.
- In order for companies to research, develop and market safe and effective animal health products, a robust regulatory system is needed – in the UK, that is in place and overseen by the Veterinary Medicines Directorate (VMD).
- The indications for use of products, legal classification and any warnings or limitations on use are determined by the regulators, who carry out a benefit/risk assessment of all veterinary medicinal products during the authorisation process and on an ongoing basis after the product is authorised.
- Companies are committed to the importance of product stewardship; monitoring and reporting on product safety and efficacy throughout a product's lifetime is a key aspect of this.

General Questions and Answers

1. **Do veterinary medicines, whether used in livestock or companion animals, cause damage to the environment?**

Before being placed on the market, all veterinary medicines undergo a detailed regulatory assessment by independent regulators, who consider the balance of the benefits provided from using the product,

compared with the potential risks. This benefit/risk assessment considers the product's safety (including environmental safety), quality and efficacy, and determines the product's legal supply classification (who can prescribe/supply) together with any warnings to be placed on the packaging or restrictions that should be placed on the product's use.

Any application for a Marketing Authorisation (licence to sell the product) must include an Environmental Risk Assessment (ERA) that details any potential risk posed to the environment. The ERA considers how the product will be used and helps determine any warnings and disposal instructions that will appear on the product labelling. Any animal medicines not meeting the requirements of this environmental risk assessment are denied authorisation for sale or supply. For pet parasiticides the ERA considers the extent of exposure to the environment and leads to warning statements on the labelling.

After veterinary medicines are authorised, the efficacy and safety of products, including environmental safety, is kept under review on an ongoing basis by both companies and the regulatory authorities.

Animal medicines have a built-in "One Health" approach as they are tested to evaluate animal, user, consumer (for products for use in animals producing food) and environmental safety, which are all considered as part of the authorisation process. Animal health companies comply with all relevant independent regulatory processes which are required for authorising medicines. Used appropriately and in accordance with the manufacturer's label and instructions, animal medicines pose minimal risks to the environment.

Protecting animals, people and the environment is, and will remain, a priority for our industry.

Both regulatory authorities and animal health companies continuously review scientific evidence about veterinary medicines, on an ongoing basis. Using this evidence, the regulatory authorities assess whether changes are needed using evidence-based policies.

2. Do scientific papers from recent years include any new data or evidence of harm to the environment caused by companion animal flea treatments?

Whilst certain pesticides have been detected in certain UK rivers, the origin of these is not clear, as the pesticides have multiple uses, for example as biocides, pest control, commercial horticulture, agriculture and even imported treated textiles. There is also no evidence that the levels detected have caused any environmental harm. Currently, there is no actual evidence of harm to the aquatic environment from the use of veterinary medicines. Any new monitoring data will be closely examined by NOAH and its members, who continue to take this matter very seriously.

A paper by *Anthe et al* [1] published in the peer reviewed journal, *Environmental Sciences Europe*, titled "Development of an aquatic exposure assessment model for Imidacloprid in sewage treatment plant discharges arising from use of veterinary medicinal products" (2020) has also considered this matter. The exposure modelling used in the paper was based on an established approach used in the biocides area. This paper concluded that current uses of ectoparasiticidal veterinary medicines for pets make only a very small contribution to the results of the UK water monitoring program.

Further studies are expected to be published concerning this issue, which the animal medicines companies and the independent regulatory authorities, will consider carefully when they become available. The development of further data is welcomed by NOAH to ensure an evidence-based approach to the subject continues to be taken.

3. **Are changes needed to the way in which the environmental risk posed by companion animal veterinary medicines are assessed?**

The current international guidance on Environmental Risk Assessments (ERAs) developed and agreed by the regulators from key Regulatory Authorities (EU, Japan, USA, and UK) remains appropriate. The approach of ERAs for companion animal products considers that exposure to the environment will be low when products are used in accordance with their label instructions. If conclusive scientific evidence becomes available (that the conclusion that 'exposure is low' is wrong) then regulators will decide on when and how to revise their approach to ERAs and the animal health industry will respond accordingly in the manner in which data that accompanies Marketing Authorisation applications must be developed and presented.

4. **Is year-round treatment against fleas and worms necessary?**

Preventive treatment has an important place for those parasites which are present all year round and for pets at risk of exposure. The consequences of failing to prevent certain parasites can have a high cost, not only to pets and their welfare, but also to pet owners due to the distress caused. People frequently live with their pets in the home with pets living closely alongside their owners and integrated into lifestyle throughout the home increases risk of exposure to zoonotic diseases.

A failure to prevent disease can also have a negative impact on human health, as some parasites, or the diseases they carry, can also infect people. While flea infestations peak in summer and autumn, the European Scientific Counsel for Companion Animal Parasites (ESCCAP) UK and Ireland, state in their guidelines for the control of ectoparasites in dogs and cats[2], that flea infestation can occur throughout the year and that year-round flea control is sometimes necessary and remains important to minimise the risks of UK household infestations (https://www.esccap.org/). Factors such as milder winters associated with climate change and the widespread use of modern central heating systems help to ensure that ectoparasite infestations can occur all year round. Furthermore, if animal owners rely purely on detecting fleas on the pet, at this stage there will be an environmental infestation requiring both treatment for the pet and also potentially environmental control measures such as household sprays to clear the infestation. This demonstrates the importance of prevention rather than treating such infestations.

5. **Are cat and dog flea treatments the source of detected pesticide compounds in UK aquatic environments?**

There are multiple sources of pesticide substances including biocides, pest control, agriculture and even imported treated textiles.

Veterinary medicines are unlikely to be the main source of detected pesticides in aquatic environments[2]. The UK Government view is that there is not currently a case to take any action regarding veterinary medicines or their approach to ERAs and that, instead, further evidence is required. Several scientific studies are underway to investigate this further.

It is important that prescribers and users of these products carefully consider and follow the administration advice on the product labelling and packaging.

6. **Should dog and cat flea, tick and worm treatments only be available from veterinary surgeons?**

Pet owners should carefully read product packaging before use regardless of where they obtained the product from, taking care to follow the instructions regarding administration and disposal.

Animal owners have been able to obtain pet flea, tick and worm treatments from sources other than vets for many years and this has served animal health and welfare needs well. It would not be an appropriate or proportionate step to take to remove this route. It would limit animal owner access to these important products with an associated negative impact on companion animal health and welfare.

Such a change could also lead to lack of access to animal medicines leading to animal owners skipping necessary treatments. It may also lead to owners accessing unregulated and unproven products or products from unregulated sources, with the associated dangers this poses.

Some companion animal parasiticide products can be supplied by professionals known as SQPs (Suitably Qualified Persons), as well as by veterinary surgeons. SQPs have an important and responsible role, contributing to animal health and welfare. They are permitted to prescribe and/or supply certain veterinary medicines under the Veterinary Medicines Regulations, but to do so must be trained, carry out Continuing Professional Development (CPD) and they must act professionally including following the rules of the Regulations and an associated Code of Practice. There is also a requirement for the SQP to obtain sufficient information about the animal and the way it is kept in order to prescribe and supply products.

7. **Are some veterinary medicines safer for the environment than others?**

Any veterinary medicine that has been authorised has been assessed by the Regulatory Body which has considered risks to the environment as part of the Environmental Risk Assessment process as described in point 1. All veterinary medicines, regardless of administration route, create the potential for the active substance (and for oral or injectable products, also their metabolites via excreted material) to reach the environment, but this has been assessed by the Regulatory Body before the product comes to market. Following the specified warnings on the product label will limit exposure to the environment. Decisions to authorise a veterinary medicine consider the balance of the benefits versus the risks of using a product.

8. **Is the use of endectocides an irresponsible choice?**

Endectocides are veterinary medicines which treat both internal and external parasites at the same time. Regular flea and tick protection (including reducing the risk of transmission of vector-borne diseases they transmit) and regular worming treatment against, for example, zoonotic roundworm and in dogs, potentially fatal lungworm, are sometimes required, due to the pet's lifestyle. The use of endectocides is not irresponsible where an animal is at risk from a range of harmful mixed parasite infestations.

The risks posed by all veterinary medicines are considered by the independent regulatory authorities before products can be placed on the market. Warnings on product labels and packaging should be followed for all products, including endectocides.

9. **Should substances banned for use on plants or in crops be automatically banned from use in animals?**

While the active ingredient used in a plant protection product may be similar, or even the same as those used in anti-parasitic veterinary medicines, the exposure of, for example, bees and other insects to the ingredient may be very different, depending on whether the products are used in plant protection or for

animal health. To investigate this, an Exposure Assessment is carried out as part of the Environmental Risk Assessment process. The Exposure Assessment attempts to identify who or what may be exposed to the ingredient, the exposure route and how much they may be exposed to. When this process is undertaken for veterinary medicines, the regulatory authorities may conclude that the environmental risk posed by an ingredient is quite different for veterinary medicines than for plant protection products, even where the same or similar active ingredient is used.

10. Are veterinary medicinal products killing bees and harming the wider environment?

Based on current scientific evidence, the risk of exposure of insects and bees to these compounds is considered to be negligible when they are used in companion animals. The environmental safety of veterinary medicines is constantly monitored and kept under review by both the regulatory authorities and the companies that make them to inform regulatory policy for the future. At present, there is no evidence that would indicate that changes are required to the regulation and availability of these products, which play an important role in the maintenance of animal health and welfare.

11. How are the periods of protection (how long the product works for) specified on the labelling and packaging of ectoparasiticidal products decided?

The manufacturer is required to conduct studies to show the product is effective. These studies examine the extent to which parasites are killed at different intervals following administration of the veterinary medicine. There are defined thresholds of parasite kill which have to be achieved e.g. at least 95% has to be demonstrated for fleas. The protection period stated on the packaging and the Summary of Product Characteristics (SPC) is the latest timepoint at which the required threshold of parasite kill has been proven to be achieved during robust studies.

It is the Regulatory Authority (VMD in GB) that decides on which protection period can be specified on the labelling, not the company who markets it. If the interval between treatments is extended beyond what is recommended on packaging and SPC, then the effectiveness of the product cannot be guaranteed, and lapses in parasite protection could occur.

References:

1. Anthe, M., Valles-Ebeling, B., Achtenhagen, J. *et al.* Development of an aquatic exposure assessment model for Imidacloprid in sewage treatment plant discharges arising from use of veterinary medicinal products. *Environ Sci Eur* **32,** 147 (2020). https://doi.org/10.1186/s12302-020-00424-4
2. ESCCAP Guideline 03 Seventh Edition: Control of Ectoparasites 3 in Dogs and Cats. January 2022 https://www.esccap.org/uploads/docs/eiw2uedg_0720_ESCCAP_GL3__English_v18_1p.pdf

Updated August 2023