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NOAH
Supporting the future of animal health

Representing the UK Animal Health Industry

Competition and Markets Authority
Investigation into veterinary services for household pets

30 July 2024

Dear Sir/Madam,

Regarding Competition and Markets Authority Issues Statement, July 2024

NOAH represents the UK animal health industry. We promote the benefits of safe, effective, quality products and services, including veterinary medicinal products (VMPs), for the health and welfare of all animals. The association's membership represents around 97% of the UK animal medicines market.

About the animal health industry

NOAH is the leading trade association representing the animal health industry. Its membership represents over 97% of the UK licensed veterinary medicine market. It was formed in 1986, when it became independent of the ABPI (Association of the British Pharmaceutical Industry). NOAH members range from multi-national companies to small UK businesses, supplying a wide range of animal health products and solutions for all animals - including livestock, aquaculture, exotics and companion animals. For more information on NOAH and its membership see https://www.noah.co.uk/about/ and https://www.noah.co.uk/about/our-members/

Veterinary medicines are highly regulated; in addition, NOAH member companies are signatories to the 'NOAH Code of Practice for the Promotion of Animal Medicines' (the Code) and support responsible prescribing via the NOAH Compendium, as well as through active engagement in numerous responsible veterinary medicine usage initiatives. The Code requires animal health companies to market and promote their products in a responsible and ethical manner. The Code (and also the Veterinary Medicines Regulations) prohibit promotion of prescription products to the pet owning public. This restricts companies' ability to inform pet owners about their choices as they relate to prescription only veterinary medicines.

More information can be found here: https://www.noah.co.uk/services/our-code-of-practice/ https://www.noahcompendium.co.uk/?id=-312863

Veterinary medicines are a small market in comparison to human pharmaceuticals, representing approximately 3% by value. Around 60% of the licensed veterinary medicines market relates to medicines for companion animals. Of these, the vast majority of products require a prescription from a vet, in order to be supplied.

The animal health industry has no involvement in the setting of consumer prices for veterinary medicines. This is a matter for veterinary practices. The industry is involved only in pricing products they sell from manufacturers to their main customer base, which is the prescribing vet and wholesalers, rather than the pet owner.

As the industry association for veterinary medicines, NOAH would like to give some background to the market for authorised veterinary medicines and the regulatory framework that exists to protect human health, the environment and the health and welfare of all animals, including companion animals (pets).

The regulatory and authorisation process for veterinary medicinal products (VMPs)

All authorised veterinary medicines available in the UK for animals must undergo a strict regulatory approval process in accordance with the Veterinary Medicines Regulations 2013 (as amended to Great Britain Veterinary Medicines Regulations 2024) before they gain a Marketing Authorisation (MA) and are allowed to be prescribed or sold.

The regulatory authority in the UK is the Veterinary Medicines Directorate (VMD). The VMD oversee rigorous standards for the registration process that ensures only those VMPs that meet defined standard of quality, safety and efficacy are authorised. The discovery, research and development of an animal medicine is a lengthy and very expensive process with successful products taking 5-11 years to reach the marketplace.

The process of applying for an MA includes submission by the animal health company of an extensive and detailed dossier for assessment by the independent regulators, which consists of data that supports the safety (for animal, user and the environment), quality and efficacy of the product in accordance with the legal framework. This information helps the VMD to carry out an independent scientific assessment to ensure that all the regulatory criteria have been met, before a product can be placed on the market. The strict regulatory controls on veterinary medicines continue after products are placed on the market.

Controls include the continued monitoring of safety and efficacy, through pharmacovigilance activities where the regulators continue to monitor and evaluate any reports of Adverse Events (AEs) involving veterinary medicines.

In the UK, VMPs are classified by the regulator (VMD) based on their authorised supply route, which defines who is permitted to prescribe, dispense and retail veterinary medicines. A cornerstone of the classification system is the protection of animal health, public health, food safety and environmental health. It is also government policy on public health grounds, to restrict some products to only be available with a prescription from a veterinary surgeon, e.g. antibiotics are only available on prescription from a veterinary surgeon i.e. POM-V (prescription only medicines – through a veterinary surgeon).

The classification and distribution system achieves a balance between control and accessibility, giving pet owners appropriate options for advice and supply, but at the same time ensuring that products that require veterinary diagnosis and veterinary expertise to facilitate correct use, are only available on prescription from a veterinary surgeon.

There are four different legal categories under which authorised veterinary medicines can be sold in the UK, three of which are relevant to companion animal medicines.

• POM-V: Prescription Only Medicine – Veterinarian. A veterinary medicinal product which may only be supplied to the client once it has been prescribed by a veterinary surgeon following a clinical assessment of an animal, or a group of animals, under the veterinary surgeon's care. Across all species (farm and companion animal) this route represents around 80% of all sales.

• NFA-VPS: Non-Food Animal Medicine – Veterinarian, Pharmacist, Suitably Qualified Person. A medicine for companion animals may be supplied by any Registered Qualified Person (being a veterinarian,

pharmacist or Suitably Qualified Person) provided the requirements for supply are met. These medicines do not require a prescription.

• AVM-GSL: Authorised veterinary medicine – general sales list. There are no legal restrictions in the VMR for the retail supply of veterinary medicines as AVM-GSL, but a responsible approach to the supply of these medicines is still expected.

To ensure companion animals receive only those medicines that have been authorised and meet the strict criteria of quality, efficacy and safety, the illegal marketing and use of unauthorised products is monitored, and action taken, where appropriate, by the VMD through its enforcement activities. This regulatory process ensures pet owners can have confidence in authorised VMPs through whichever route.

For further information on controls on licensed medicines see: https://www.noah.co.uk/topics/regulation/controls-on-veterinary-medicines/ and on pharmacovigilance see https://www.noah.co.uk/topics/regulation/pharmacovigilance/

The prescribing cascade and veterinary medicines

If there is a veterinary medicine licensed for a particular species and condition for which a vet deems treatment appropriate, a vet must prescribe this first. This is important because without such a requirement, the business case for the development of veterinary medicinal products for animal use, simply does not exist.

Where there is no authorised veterinary medicine available (or suitable for that animal) to treat a particular species or condition, there exists a prescribing cascade to enable the vet to access a wider range of treatments to help (which may be, for example, a human medicine, an imported veterinary medicine or something specially formulated).

The cascade ensures the preservation of animal health and welfare by allowing vets to prescribe unauthorised products where suitable UK licensed veterinary medicines are not available. It should also be noted that neither human medicines or specially formulated products (extemporaneous preparations) have been authorised or assessed for safety and efficacy, meaning that prescribers and end users cannot benefit from the same level of regulatory oversight. This regulatory oversight, which forms part of the licensing procedure for veterinary medicines, ensures the safety (both for the treated animal and the person administering the medicines), and efficacy (i.e. that the product will be effective) of the product. Animal medicines containing the same active ingredient as human medicines may be formulated differently, and therefore metabolised differently in an animal's body, as opposed to in the human body e.g. the formulation needs to ensure they are properly absorbed through the gut. It cannot be assumed that such human medicines will be suitable for use in animals as they have not been assessed by the independent regulators for safety and efficacy in the relevant target species.

There are sound scientific reasons that mean it is preferable for animals to be treated with licensed veterinary medicines rather than unauthorised products or human medicines.

The veterinary medicines sector is a comparatively small industry (e.g. compared to human medicines industry), where the business case for developing and registering authorised veterinary medicines is dependent on them being used ahead of human medicines or unauthorised products (known as extemporaneous preparation products, sometimes referred to as veterinary specials). Authorised veterinary medicines have been specifically formulated and assessed for safety, quality and efficacy for

use in the species and condition in question. Veterinary medicines sold through routes other than a prescription by a vet can only be used for the species and condition specified in the MA.

Online pharmacies

It should be noted that it is possible for prescriptions to be fulfilled in online pharmacies or indeed in other veterinary practices, different to the practice that might have prescribed a product. It appears that this possibility may not be well understood by some owners and there may need to be greater publicity regarding this possibility.

If you would like to discuss any aspect of this in more detail or have questions regarding the veterinary medicines industry, please do come back to us.

Yours sincerely,

Dawn Howard
NOAH Chief Executive