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NOAH
Supporting the future of animal health

Representing the UK Animal Health Industry

NOAH response to consultation on the proposal to make a market investigation reference into veterinary services for household pets in the UK, 11/04/24

About NOAH:

NOAH is the leading trade association representing the animal health industry. Its membership represents over 97% of the UK licensed veterinary medicine market.

Consultation questions (with NOAH response in green text)

- Do you consider that our analysis is correct with respect to the suspected features of concern in the supply of veterinary services and related services for household pets in the UK?

  This is outside of our remit, so NOAH does not have an opinion on this.

  You may wish to answer this in relation to specific points such as:
  – Whether consumers are given enough information to enable them to choose the best veterinary practice or the right treatment for their needs;

  This is outside of our remit, so NOAH does not have an opinion on this.

  – Whether concentrated local markets may be leading to weak competition in some areas;

  This is outside of our remit, so NOAH does not have an opinion on this.

  – Whether large integrated groups may have incentives to act in ways which reduce choice and weaken competition;

  This is outside of our remit, so NOAH does not have an opinion on this.

  – Whether pet owners might be overpaying for medicines or prescriptions.

  This is outside of our remit, so NOAH does not have an opinion on this.

  – Whether the regulatory framework remains fit for purpose.

  The Veterinary Services for Household Pets in the UK Consultation on proposed Market Investigation Reference (MIR) report states the following:

  25. We also received several complaints from independent veterinary practices that online pharmacies sell animal medicines to consumers at a price lower than those available to many vet practices via the wholesale channel. The regulatory regime stipulates that vet

practices need to buy their medicines from a provider that is licenced for wholesale supply, so this cheaper channel is not available to them.

NOAH wishes to make the CMA aware that veterinary medicines are highly regulated goods with in-depth regulatory requirements throughout the supply chain as stipulated in the UK Veterinary Medicines Regulations 2013, under the oversight of the regulatory authority, the Veterinary Medicines Directorate.

A non-exhaustive list of the regulatory requirements throughout the supply chain includes the need for products to be stored at particular, specified temperatures throughout the supply chain, record keeping requirements, storage keeping requirements to prevent damage via sunlight, and keeping the products stored in a way to prevent inappropriate access to the products.

Wholesalers are subject to regulatory control, inspections and are required to hold a Wholesale Dealers Authorisation (WDA) and to have a Wholesale Dealers Authorisation Qualified Person, who must carry out specified duties including carrying out regular checks on all storage areas, samples of records, the quality system and keeping records of the checks they do.

The requirements for a WDA are not simply meaningless red tape and administrative burden; these requirements are in place to ensure the quality, safety and efficacy of veterinary medicinal products along the supply chain and at point of final use. In conclusion, the requirement that vet practices must buy their medicines from a provider that is licensed for wholesale supply, exists for a very good reason, to assure the safety, quality and efficacy of licensed veterinary medicinal products. It should also be noted that online pharmacies acquire their products from the same wholesalers as the Veterinary Practices.

A further point from the CMA report regarding the regulatory context, that NOAH wishes to comment on is as follows:

2.55 In part to overcome this limitation, the RCVS runs a Practice Standards Scheme which applies to the vet practice rather than individuals. This encourages best practice, including in areas such as how prices are communicated to consumers. However, as the report of the RCVS Legislation Working Group has pointed out, 'it is a voluntary scheme and as a result there is no mechanism, to ensure standards across all practices through assessments.' Moreover, while we understand that around 69% of eligible practices have signed up to this voluntary scheme, that means that almost a third of the market has not committed to this approach.

It must be noted that in addition to RCVS Practice Standards, there is also a practice inspection scheme overseen by the Veterinary Medicines Directorate, where the VMD carry out inspections to ensure compliance with the Veterinary Medicines Regulations.

- Do you consider that our analysis is correct with respect to the reference test being met in relation to the supply of veterinary services and related services for household pets in the UK?

This is outside of our remit, so NOAH does not have an opinion on this.

- Do you agree with our proposal to exercise our discretion to make a reference in relation to the supply of veterinary services for household pets in the UK?

  This is outside of our remit, so NOAH does not have an opinion on this.

- Do you consider that the proposed scope of the reference, as set out in the draft Terms of Reference published alongside this document, would be sufficient to enable any adverse effect on competition (or any resulting or likely detrimental effects on customers) caused by the features referred to above to be effectively and comprehensively remedied?

  This is outside of our remit, so NOAH does not have an opinion on this.

- Do you have any views on our current thinking on the types of remedies that an MIR could consider?

  This is outside of our remit, so NOAH does not have an opinion on this.

- Are there other measures we should consider?

  This is outside of our remit, so NOAH does not have an opinion on this.

- Do you have any views on areas where we should undertake further analysis or gather further evidence as part of an MIR in relation to the supply of veterinary services for household pets in the UK? We would particularly welcome any specific evidence from respondents in support of their views.

  This is outside of our remit, so NOAH does not have an opinion on this.

Further comments:

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 and support responsible prescribing via the NOAH Compendium as well as through active engagement in numerous responsible veterinary medicine usage initiatives. 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.

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 (currently under review) 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). These rigorous standards for the registration process 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, Veterinary Medicinal Products (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 RQP (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 though 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 where suitable UK licensed veterinary medicines are not available.

The veterinary medicines sector is a small 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) as these 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.

DOCUMENT ENDS