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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

27/02/2025

Dear Sir/Madam,

Regarding Competition and Markets Authority Working Papers, February 2025

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. NOAH wishes to provide specific feedback on some elements that featured in the latest CMA working papers that were published in February 2025.

The Legislative Framework for Veterinary Medicines - The Prescribing Cascade

The veterinary prescribing cascade is a long-standing regulatory requirement in both UK and EU law. It empowers veterinarians to prescribe human medicines or unauthorised products responsibly and legally when no licensed veterinary medicinal product is available or suitable for a specific condition or species. This system allows veterinary professionals to prioritise animal health and welfare while maintaining high standards of safety, quality, and efficacy. The veterinary prescribing cascade requires veterinarians to use licensed veterinary medicines first. If no suitable veterinary medicine is available, they may then consider human medicines or unlicensed veterinary medicines (often referred to as extemporaneous preparations) as an exemption to this rule. It's important to note that neither human medicines nor extemporaneous preparations are specifically developed or authorised for animal use by regulatory authorities.

The prioritisation of licensed veterinary medicines that are specifically authorised for a specific species and condition helps to maintain high standards of care and safety, thereby enhancing animal health and welfare. However, the cascade also provides flexibility, allowing veterinarians to prescribe the most appropriate medicine if the authorised option is unavailable or unsuitable for an individual animal or specific case. This balance ensures that while regulatory guidelines are followed, veterinarians can still address unique medical

needs effectively, ultimately enhancing animal health and welfare by providing tailored and responsive care.

Unlicensed products, including human medicines,lack the regulatory oversight that licensed veterinary medicines must undergo, including assessment for safety and efficacy in the treated animal species. Consequently, the risk of adverse outcomes (for both the animal and the end user) and treatment failures may be higher. Additionally, the human medicines industry is not required to participate in veterinary pharmacovigilance systems, monitoring any adverse outcome from use of the product, thus ensuring safety and efficacy remains under continuous regulatory review, which are mandatory for animal health companies.

Failure to adhere to the prescribing cascade by using human medicines over licensed veterinary products can negatively impact the sustainability and availability of veterinary medicines in the UK market. It makes the development of new veterinary medicines less attractive. The veterinary medicines sector is relatively small, with only 2-3% of the market value of its human counterpart across Europe. Therefore, the business case for developing and registering authorised veterinary medicines relies on a legal framework that prioritises their use over human medicines or unauthorised products (extemporaneous preparations). In addition to this, the human medicine industry does not provide technical support, educational events, or active engagement with the veterinary community in the UK. In contrast, the animal health industry has a proven track record of supporting veterinary professionals and supporting animal health and welfare.

We are concerned that any amendments to the prescribing cascade as part of broader market changes may inadvertently undermine animal health and welfare by encouraging the use of products not assessed for safety and efficacy in the treated species. Such changes could also hinder the long-term development of licensed veterinary medicines.

While NOAH acknowledges the CMA's commitment to addressing consumer concerns, such as the affordability of veterinary care, adjusting the prescribing cascade for financial reasons could undermine the licensed veterinary medicines that support high-quality animal care in the UK. NOAH remains committed to collaborating with regulators, veterinary professionals, and industry partners to uphold the highest standards of animal health and welfare.

Reclassification of Veterinary Medicines

The CMA papers refer to the classification of veterinary medicines and there being a need to consider reclassification of veterinary medicines. The CMA papers state the following:

"Determination of the initial classification for a veterinary medicine, and decisions to reclassify those medicines are, in most cases, driven by the marketing authorisation holders

*(that is, manufacturers) who propose the (re)classification for which they wish to apply, though the decision on which distribution category to grant is made by the VMD. The concern is the possibility some products might be classified at a more restrictive level than is necessary, in turn limiting choice and/or increasing costs for consumers. For example, if a product is classified as 'POM-V', it can only be administered after prescription by a veterinary surgeon, in contrast with a classification which permits 'over the counter' purchase (**POM-V**)."*

NOAH wishes to highlight to the CMA that for many, many veterinary medicinal products, the main driver of the classification has been regulatory policies and legislative requirements and have not been within the marketing authorisation holders control. For example, rightly and correctly, it is government policy to require antibiotics to always be classified as POM-V medicines. Similarly, there are many sedatives and anaesthetic agents that for both human and animal safety reasons, must always be classified as POM-V. Furthermore, veterinary medicines that require a veterinary diagnosis for safe and effective use, will be classified as POM-V, for example, companion animal cardiology medicines. In summary, this classification systems ensures that these medicines are administered following prescription by a qualified veterinarian, minimising the risks to animals, humans, and the environment. Therefore it is a misconception to state that decisions to reclassify medicines are mostly driven by marketing authorisation holders.

NOAH broadly supports the idea of consideration being given to reclassification of veterinary medicines where appropriate, provided a thorough risk-benefit assessment is conducted and provided that the regulatory authorities are content that the risk profile of the product would deem this to be an appropriate step and provided that any risks relating to the use of the product can be mitigated against and managed through the advice on the packaging.

In the UK, the classification of veterinary medicines is strictly regulated by the Veterinary Medicines Directorate (VMD). The authorities evaluate the safety, efficacy, and potential risks of veterinary medicines to determine the most appropriate classification, ensuring that these medicines are used safely and effectively with the necessary level of professional oversight.

Under the Veterinary Medicine Regulations (VMRs), vets, pharmacists, and suitably qualified persons (SQPs), collectively known as registered qualified persons (RQPs), can prescribe or supply certain categories of authorised veterinary medicines. The distribution categories for authorised veterinary medicines are:

Prescription Only Medicine – Veterinarian (POM-V)	These medicines can only be prescribed by a veterinary surgeon and are used for treatments requiring professional oversight.

Prescription Only Medicine – Veterinarian, Pharmacist, SQP (POM-VPS)	These medicines can be prescribed by a veterinarian, pharmacist, or SQP, allowing for broader access while still ensuring professional guidance.
Non-Food Animal – Veterinarian, Pharmacist, SQP (NFA-VPS)	These medicines are for non-food producing animals and can be prescribed by a veterinarian, pharmacist, or SQP, providing expert advice on access.
Authorised Veterinary Medicine – General Sales List (AVM-GSL)	These medicines can be sold without a prescription and are deemed safe for use without direct veterinary supervision.

Reclassifying certain medicines can improve accessibility for pet owners, ensuring they can obtain necessary treatments more conveniently, which benefits animal health and welfare. For example, the AVM-GSL category allows for greater accessibility of veterinary medicines, provided they are used according to instructions and are deemed safe without direct veterinary supervision.

The NFA-VPS classification can also significantly enhance the availability of veterinary medicines for pet owners. Unlike AVM-GSL, the VPS routes not only increase access to these medicines, but also provides the benefit of expert advice. By allowing pharmacists and SQPs to prescribe and dispense these medications, pet owners can more easily obtain necessary treatments. Additionally, the guidance from SQPs helps to enhance the safe and effective use of these medicines, protecting animal, human, and environmental health.

As previously mentioned, SQPs play a crucial role in this process. These trained professionals can offer valuable advice on the correct use of medicines, ensuring safe and effective treatment. SQPs undergo rigorous training and are required to stay up-to-date with the latest developments in veterinary medicine, ensuring they can provide accurate and reliable advice. Their expertise helps mitigate the potential risks that could arise from reclassification, providing additional safety and assurance for owners.

CMA Comments Regarding List Prices

On a point of accuracy, we noted that 'list prices' have been consistently described in the Working Paper for Medicines as a 'retail price suggested by manufacturers' (paragraphs 2.27 and 3.7). On behalf of our members we would like to clarify that, along with classification, manufacturers do not provide a suggested retail price for medicines, and wholesalers and veterinary clinics in the supply chain have discretion as to their own price-setting.

Conclusion

In conclusion, the reclassification of veterinary medicines could present an opportunity to enhance accessibility and improve animal health and welfare. By ensuring that pet owners can access necessary treatments with greater ease, availability of licensed veterinary medicinal products can support animal health and welfare across the UK. However, it is crucial that any changes to the regulatory framework, including product classification are implemented with careful consideration of the potential risks and benefits and that the regulatory authorities are comfortable and confident that any risks arising from such changes in classification can be managed and mitigated against.

We urge the CMA to maintain the integrity of the veterinary prescribing cascade, which has long been a cornerstone of responsible and safe use of veterinary medicines. This system ensures that veterinarians can prioritise animal health and welfare while adhering to high standards of safety, quality, and efficacy. Any changes to this system should be approached with caution to avoid unintended consequences that could undermine the development and availability of licensed veterinary medicines.

NOAH remains committed to collaborating with regulators, veterinary professionals, and industry partners to uphold the highest standards of animal health and welfare. Should you have any futher questions or wish to discuss these matters further, please do not hesitate to contact us.

Yours sincerely,

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