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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

27/05/2025

Dear Sir/Madam,

Regarding Competition and Markets Authority Remedies Working Paper, May 2025

NOAH is the trade association that represents 97% of the UK animal health industry. We promote the benefits of safe, effective, quality veterinary products and services for the health and welfare of all animals. NOAH wishes to provide specific feedback on some elements that featured in the latest CMA working paper that was published in May 2025.

Importance of Licensed Veterinary Medicines

In section 4.82 the CMA state that: "*there can be clinically relevant differences in terms of the indications, target species or safety warnings, based on the information an applicant has. We note that the CC identified in the 2003 Market Study into Veterinary Medication that there might be differences between medicines that have the same active ingredients*". We welcome the CMA's recognition of the differences that can exist even where the same active ingredients are used and we believe that this demonstrates the importance of vets being legally required to use licensed veterinary medicines authorised for specific species and conditions, ahead of unauthorised products (human medicines and extemporaneous preparations) where no safety and efficacy studies or regulatory review have been undertaken. Prioritising these licensed veterinary medicines over unauthorised alternatives (human medicines and extemporaneous preparations) is crucial for maintaining high standards of care and safety, thereby ensuring animal health and welfare.

Unlicensed products lack the regulatory oversight that licensed veterinary medicines must undergo, including assessments for safety and efficacy in the treated animal species. Using these alternatives can increase the risk of adverse outcomes for both the animal and the end user, and treatment failures may be higher. Additionally, these alternatives are not required to participate in veterinary pharmacovigilance systems, which monitor for suspected adverse events, a key safety system for regulating licensed veterinary medicines. Human medicines

companies will also not provide any technical support for prescribers on safe and correct use of their products.

Furthermore, the use of unlicensed alternative products can negatively impact the sustainability and availability of veterinary medicines in the UK market. The veterinary medicines sector is relatively small, being only 2-3% of the market value of its human counterpart across Europe. Thus, the business case for developing and registering authorised veterinary medicines relies on a legal framework that prioritises their use over unlicensed alternative products. Overall the supply side of veterinary medicines market is working efficiently as was confirmed by the CMA working papers. It is therefore important that the remedies proposed do not unintentionally disrupt the well functioning supply side. This may pose a risk to availability of veterinary medicines in the UK.

Guidance for Veterinary Surgeons

One remedy proposed by the CMA in section 4.86 (a) is to update the "*guidance to permit vets to prescribe a narrow category of active ingredient medicines (ie specify both the active ingredient and the brand names of the specific generics the prescription covers). This might sit alongside a requirement for vets to prescribe, on any given written prescription, all of the clinically effective generic medicines of which they are aware for that species and condition*".

NOAH wishes to emphasise that any guidance provided to veterinary surgeons regarding prescribing generics should specify that this refers to licensed veterinary medicinal product generics, not human medicines generics, due to key differences between these medicines and the requirements of the prescribing cascade detailed previously.

Licensed generic Veterinary Medicinal Products are developed specifically for animals, ensuring safety, efficacy, and appropriate species-specific dosages, and are approved for use by the Veterinary Medicines Directorate (VMD). In contrast, human generic medicines are intended for human use, tested accordingly, and are approved by the Medicines and Healthcare Products Regulatory Agency (MHRA). Crucially, formulation differences also exist, meaning that using human medicine generics for animals can pose risks due to potential differences in metabolism and physiology, making it essential to use medicines specifically approved for veterinary use.

Any change to guidance for veterinary surgeons and pharmacists should make it clear that they are required to prescribe and dispense licensed veterinary medicines where such products are avilable and suitable for use. Such guidance should ensure that this does not lead to dispensing of human medicines where the are suitable licensed veterinary medicines that are suitable for use.

CMA Consultation Questions

In addition to the aforementioned topics, NOAH would like to address the following consultation questions, specifically those related to Remedy 8 (Transparency of medicine prices), Remedy 9 (Generic Prescribing), Remedy 10 (Prescription Price Controls), and Remedy 11 (Interim Price Controls).

Remedy 7: Changes to how consumers are informed about and offered prescriptions

Question 40: We would welcome views as to whether medicines administered by the vet should be excluded from mandatory prescriptions and, if so, how this should be framed.

Yes, medicines administered by a vet should be excluded from mandatory prescriptions. These treatments, such as injectables, ear medications, and antibiotics, are often necessary at the time of examination. Requiring a prescription in these cases could delay essential care if owners choose to purchase the medicine online, potentially compromising animal welfare. It may also increase costs for owners who would need to schedule a second appointment for administration of the medicine.

Moreover, mandating prescriptions for such treatments would place an unnecessary administrative burden on veterinary practices, especially when there is little to no likelihood that clients would seek these medicines elsewhere. In some cases, this could even lead pet owners to attempt administering Prescription-only Medicines (POM-V) themselves, which should only be handled by a vet. This poses serious risks to both treatment compliance and animal welfare.

Remedy 8: Transparency of medicine prices so pet owners can compare between FOPs and other suppliers

Question 44: What price information should be communicated on a prescription form? Explain your views.

In our view, for pet owners to be able to take the benefit of price comparison, any comparison site for medicine prices must be a like-for-like comparison. This must take into account, amongst other things, the price per dose, price per box, the species (including weight categories), doses required, etc. Without the full range of information pet owners will not be able to effectively evaluate their options. In our opinion price comparisons will only function when products with Stock Keeping Units (SKUs) of the same size / volume are compared.

Remedy 9: Requirement for generic prescribing (with limited exceptions) to increase inter brand competition for medicine sales.

Question 47: How could generic prescribing be delivered and what information would be needed on a prescription? Please explain your views.

If this was deemed a necessary remedy, the prescription must list the different licensed veterinary medicines as options and potentially include different treatment plans if they are not clinically interchangeable. This approach would help ensure that pharmacists do not mistakenly dispense human medicines when there are authorised veterinary medicines available. Should the prescribing vet be writing a prescription for a human medicines, in compliance with the prescribing cascade, then this is of course acceptable.

Should generic prescribing for animal medicines be introduced, to maintain confidence in the prescribing process and in the medicine/s being prescribed and dispensed, and to address the concerns highlighted by the CMA (paragraph 4.83) that prescribing by active ingredient could result in unsuitable medicines being dispensed to pet owners, it is considered that including both the name of the branded medicine and any animal health generic clinical equivalent medicine would be the most appropriate option.

Question 48: Can the remedies proposed be achieved under the VMD prescription options currently availably to vets or would changes to prescribing rules be required? Please explain your views.

If the proposed remedies were implemented, we believe that changes would be necessary for both the VMD guidance and the RCVS Code of Conduct.

Question 49: Are there any potential unintended consequences which we should consider? Please explain your views.

As previously mentioned, it is crucial to distinguish between human and veterinary generic medicines due to their inherent formulation differences. Using human medicines for animals can be risky because of differences in metabolism and physiology. Therefore, it is essential to use licensed veterinary medicines specifically approved and authorised for veterinary use. Any system developed must ensure that pharmacists do not dispense human medicines when appropriate and authorised veterinary medicines are available.

In a previous submission (available here) the UK regulator, the VMD commented: *"The VMD is particularly concerned about veterinary prescriptions detailing only the active substance(s), rather than a specific product. It is considered likely that this would lead to*

medicines being selected and dispensed by those other than the prescribing veterinary surgeon, thereby failing to appropriately consider their clinical suitability for a given patient. This is considered incongruent with a veterinary surgeon taking full responsibility for any prescribing decision they make, and the fact that such decisions must be clinically justified. It stands to reason that even with the best intention, when given a choice between two seemingly identical products, owners may select the cheaper option to be dispensed, unaware that there may be significant additional safety and efficacy considerations for the product they have ultimately selected. VMD wishes to explain that there can be clinically relevant differences between generics in terms of the indications, target species or safety warnings, based on the information an applicant has provided. Therefore, this could potentially be an issue if a written prescription only stated a particular strength of an active substance."[1]

NOAH fully supports the VMD opinion as detailed above. Generic veterinary medicine authorisation may/may not always exhibit the same safety requirements and clinical and safety indications may vary for licensed generics (as generics, you don't need to prove bio-equivalence), therefore the choice is best left to the prescribing veterinary surgeon.

As discussed in the CMA's working paper on Remedies, generic prescribing may not take into account the "*clinically relevant differences in terms of the indications, target species or safety warnings"* which may exist between generic medicines. Any changes relating to generic prescribing should take into account the risk of an increase in the number in pharmacovigilance cases being raised where adverse events occurred not due to the medicine itself, but the manner in which it has been used.

It is also important to highlight the complexities that exist in the animal health industry, whereby human pharmaceutical products containing the same active ingredient may not have an equivalent SPC (Summary of Product Characteristics) for veterinary use. This lack of equivalence can lead to difficulties for the animal and those involved in its care, particularly when clinical decisions are based solely on active ingredients without considering the broader regulatory and safety context.

Another potential unintended consequence is that animal health companies may shift research and development (R&D) investment away from vet-administered products and toward non-POM-V products that can be marketed directly to end users. This could lead to reduced investment in developing POM-V medicines for chronic conditions.

[1] VMD Response to CMA Working Paper (Available here: VMD.pdf)

Question 50: Are there specific veterinary medicine types or categories which could particularly benefit from generic prescribing (for example, where there is a high degree of clinical equivalence between existing medicines)? Please explain your views.

NOAH does not believe that there are any specific veterinary medicine types or categories which could particularly benefit from generic prescribing.

Question 51: Would any exemptions be needed to mandatory generic prescribing? Please explain your views.

NOAH does not believe that any exemptions would be needed to mandatory generic prescribing.

Question 52: Would any changes to medicine certification/the approval processes be required? Please explain your views.

NOAH does not believe changes to the current medicine certification or approval processes are necessary as the existing regulations are already stringent and comprehensive. Medicines undergo rigorous scientific evaluation, continuous safety monitoring, and strict quality assurance, with robust oversight from the Veterinary Medicines Directorate (VMD). These standards collectively maintain high standards of safety, efficacy, and quality.

Nevertheless, should the CMA decide that a category of equivalence was to be introduced, then this could result in changes to the medicines certification/ the approval process, and with it, major significant additional burden to both manufacturers and the VMD. NOAH would strongly oppose such a requiremenet as to do so could undermine the viability of authorising products for the UK market.

Question 53: How should medicine manufacturers be required to make information available to easily identify functionally equivalent substitutes? If so, how could such a requirement be implemented?

In section 4.86 (b), the CMA "*Recommend legislative change such that the VMD is required to assess (or mandate manufacturers to assess) and publish information on which veterinary medicines are considered clinically interchangeable for a given species and condition (updated with any product changes), with vets required to prioritise prescriptions based on such 'generic equivalency categories' rather than medicine brands*".

NOAH strongly opposes this proposed remedy. Each manufacturer only possesses information about their own products. Therefore, requiring comparative information between companies and their competitors' products to determine comparability would be

inappropriate. Such a requirement would represent a major administrative, financial and regulatory burden on animal health companies. This could pose a risk to the availability of veterinary medicines by requiring animal health companies to generate more data to access the market, which may not be justifiable steps for companies to obtain the required return on investment. Such data is not required anywhere else in the world, and a measure of this nature could make the UK an unattractive place to do business as compared to other parts of the world.

Question 54: How could any e-prescription solution best facilitate either (i) generic prescribing or (ii) the referencing of multiple branded/named medicines. Please explain your views.

No comment.

Remedy 11: Interim Medicines Price Controls (Qs. 60-63)

We understand the CMA's intention to explore mechanisms that address consumer affordability in the veterinary medicines market. However, it is important that any intervention carefully considers potential unintended consequences for the supply chain. The CMA's own working papers do not raise significant concerns with the functioning of the supply side, which is described as having broad product availability, robust wholesaler coverage, and established distribution mechanisms.

Given the complexity of veterinary medicines manufacturing and supply — particularly for specialised or low-volume products — any policy relating to price controls, *were it to become the long term approach that is applied*, that affects pricing dynamics could have wider implications for supply resilience, investment predictability, and continuity of access. We encourage the CMA to ensure that any remedy supports a sustainable supply ecosystem and avoids disincentivising future innovation or investment in UK-specific infrastructure.

(It should be noted that the above response in relation to remedy 11 is not made on behalf of all NOAH members, specifically Boehringer Ingelheim Animal Health UK Limited).

In conclusion, 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 further questions or wish to discuss these matters further, please do not hesitate to contact us.

Yours sincerely,