CMA PAPERS – 27 02 25

How people purchase veterinary services

The CMA have reported that it is difficult for pet owners to know what their pet's health needs are. Perhaps more could be done to raise awareness to the public of the potential costs associated with health care particularly for cat and dog owners. Outside of charity organisations Veterinary Services can be viewed as a private medicine provision. Access to the pricing associated with routine veterinary services should be more easily accessible to an owner, thereby increasing transparency on the costs involved and possible more widely than practice notices or posters. Perhaps something to cover when registering an animal with a practice.

The CMA have noted that based on the PDSA PAW report, there was no significant increase in the UK pet population or pet acquisition levels between 2020 and 2022. However. it is our understanding from NOAH reports and from a report in the Vet Times indicated that the dog population in the UK may be considerably higher than previously determined.

The veterinarian is accountable for any recommendation with regards to diagnostics, and any treatment/medicines they prescribe. Although vets are obliged to consider (but not assume) an owner's financial situation when making clinical decisions (as per the RCVS Code of Professional Conduct for Veterinary Surgeons). Other external pressures that may be applied to impact these decisions, should not be taken into account, particularly if these pressures have no clinical justification. This also applies to pet care/subscription plans, especially with growing concerns on the development of anthelmintic resistance in the UK. There should be no standard or routine anti-parasitic treatment for animals. The individual needs of the pet based on risk of exposure to certain parasites should be considered first and foremost, then balanced against the risks of resistance developing and the risk to the environment. This will help determine the level of financial incentive that exists for the owner. Pet plans should be based on the individual risk assessment and consequent anti-parasitic treatment recommendations. For instance, there could be different pet care plans based on whether a cat lives only indoors, or not.

Business models, provision of veterinary advice and consumer choice

The CMA have presented a balanced and fair review of the business models and consumer choice based on the information collated. Vets seem to have described having more clinical freedom in independent practices.

The CMA is also asked to consider the number of companion animal pets compared to vets and how this has changed since COVID. There is feedback from owners that they are not

receiving contextualised care and have not been provided with all the information in order to make an informed decision. There are also comments from recent graduates that they find this difficult to interpret without experience behind them. Based on the information provided, the question remains whether there is a vet shortage in the country. This is partially highlighted in article from the British Veterinary Association regarding veterinary workforce shortages (UK's veterinary workforce crisis deepens as EU registrant numbers drop by over two-thirds since Brexit | British Veterinary Association) and the RCVS workforce summit (retention-recruitment-and-return-in-the-veterinary-profession-preliminary-study-updated-2022.pdf).

Competition in the supply of veterinary medicines

Interesting to see that a barrier to pet owners buying meds online (and thereby cheaper) is that some of them are injectable. VMD considers that having multiple options for treatment of the same indication increases availability of vet drugs and clinical options. Overarching issue is that some vets charge way more (4-5x) for meds than they get them for from wholesalers, but due to differing business models, this may be subsidising other areas of the business. It is assumed that the CMA have considered this unit price rise, in the context of the cascade and the end price paid by the animal owner.

AVM-GSL is wrongly called 'over-the-counter'; it should be 'off-the-shelf' or similar. NFA-VPS would be 'over-the-counter'. Also mentioned here are 'dietary supplements', which are not Veterinary Medicines and nor is there any mention of those product exempted from the need to be issued with a marketing authorisation under the small animal exemption scheme.

The CMA has considered that in a veterinary practice there are a lot of financial commitments the practice is accountable for, and there are certain areas in the business which do not make a profit. Therefore, the less financially profitable areas are offset by upscaling the price of other areas, which in this instance is likely to involve the cost of veterinary medicines. The pricing of medicines in a human or online pharmacy compared to a veterinary practice are not comparable. These are different business models that cannot be directly compared. However, the VMD does agree that clients need to be directly informed of the availability of written prescriptions. Nevertheless, the CMA should be aware of the potential (and documented) abuse of written prescriptions by owners.

There may need to be a consideration of the standardisation of prescription fees, dispensing fees, and injection fees across veterinary practices to make this a standardised fair price. There should be increased awareness and knowledge for owners as to their options when purchasing medicines.

With regards written prescriptions for injectable medications, this is significantly limited by the trust the veterinary surgeon has in an owner's ability to safely and effectively administer such products. Additional considerations include whether the owner can/will safely dispose of any syringes, needles or empty vials, whether medicines will be delivered when the owner is at

home, and the suitability of storage conditions in the home environment. These will all be important factors when determining whether a veterinary surgeon is willing to provide a written prescription, not least as the responsibility of an adverse outcome lies primarily with the prescribing veterinary surgeon.

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.

Generic medicines are considered clinically interchangeable with their reference medicinal product and the applicant (prospective marketing authorisation holder) will have provided evidence to support this. However, to support the position outlined above, the 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. When human medicines are prescribed to animals, there is an increased risk to the target species, compared to generic veterinary medicines. There is no officially authorised information with regards to whether human medicines that contain the same active substance, but different excipients, are clinically interchangeable with the authorised veterinary medicinal product(s). The only data pertaining to safety and efficacy of human medicines in animals may be through published literature online. One also needs to consider that these medications might contain certain excipients such as xylitol, which are toxic to companion animals. The responsibility and accountability of any adverse outcome of that medicine falls to the prescribing veterinary surgeon. For this very reason, only vets are sufficiently qualified to assess the risk(s) and prescribe what they deem is clinically justified. The VMD appreciates the concerns regarding corporate groups stocking their own brands, or owning online pharmacies, to maintain their business and it is accepted that this would appear to limit the immediate ability for their clients to purchase medicines outside of that corporate group’s supply chain. However, the CMA should note that vets are legally able to prescribe whichever product they deem to be the most clinically justified in the circumstances of the patient (and owner). Beyond an urgent clinical need for treatment, this provides vets with the clinical freedom to prescribe products other than those immediately available within the practice, and potentially outside a corporate group’s supply chain. The VMD is aware that there needs to be more education surrounding written prescriptions and has already updated some of their guidance documents and will continue to endeavour to provide educational opportunities for veterinary surgeons.

In 2.15, the CMA refer to generics as "copies" of reference products, which is not the case; this likely links with their thinking and understanding with regards to prescribing using active substance rather than product, and this should be clarified as per the comments relating to

bioequivalence under the regulatory framework working paper. The CMA states that "the limited evidence available to date suggests that pet owners are likely to make substantial cost savings when purchasing some medicines from online pharmacies compared with purchasing them directly from their FOP.

The CMA should note that when using the term human generics as an alternative to an authorised veterinary medicinal product is misleading. Human products are not generics of veterinary medicinal products. They may be a generic of another pioneer human medicine, but this is not true in comparison to a veterinary medicine.

In 2.17 I would replace parasiticides (which don't need to be POM-V) with antobiotics that do.

In 2.24 Note the following comment "As with other markets for pharmaceutical products, the entry of new veterinary medicines is further constrained by some being patented" the VMD is not aware that this is significant barrier to generics once data protection period has elapsed.

In 2.c noted that mark up on sale of veterinary medicines is between 300% and 400% and para 2 .c.4. allows these inflated prices to be off-set against the provision of other veterinary services. We have heard from the CMA that the costs charged by the manufacturer for specialised animal medicines are more expensive than the perceived human equivalents (if one exists) and that owners are unable to pay. It is assumed that this apparent contradiction is recognised by the CMA where the cost of specialist animal medicines at manufacturers prices would in itself not necessarily be a significant financial barrier to animal owners. After 2.18 there should be some indication that data provided by the manufacturer are assessed to ensure the quality of manufacture, shelf-life, storage conditions, safety to the user, safety to the animal, safety to the environment and in the cases of medicines for food animals, safety to the consumer; and that the product is efficacious. In other words, there is regulated evidence that the benefits of using a product specifically developed for the target species and the indication being treated, when used in accordance with the approved packaging outweigh the risks of use and thus provides assurances to the purchaser.

Regulatory Framework for Veterinary Professionals and Veterinary Services

The cascade restriction concerns would see vets being allowed to use price as a justification when choosing which product to prescribe to an animal. However, this could result in a situation where vets routinely prescribed medicines under the cascade that may not have been assessed by the VMD for the safety and quality of the product for that use. This could result in unintended negative impacts on the animal being treated or to the environment, with a supporting vigilance system in place to ensure continued benefit:risk; or leading to increased price rises for authorised veterinary medicines, operating in a smaller market, for owners who prefer the assurances of using a medicine specifically manufactured for their animal.

In regards to restrictive prescriptions, the VMD has a standard line that states "A prescriber can either state the active ingredient (generic name) or brand name on the prescription. If a brand name is stated, the supplier must only supply that product. If a generic name is used on the prescription, the supplier can supply any brand of that product they choose or check with the prescribing vet if needed." We would not seek to interfere with the vet's judgement on the best treatment for the animal.

In response to paragraph 6.50, clarifying where cost could be considered in the clinical justification of a vet using the cascade, allowing cost to be a factor would essentially be putting a price on animal welfare.

Overall, the CMA has produced a fair and balanced document regarding the regulatory framework based on the information they have been provided with. However, the CMA has not elaborated further on the four distribution categories. Only one of which (POM-V), requires solely a veterinary surgeon to prescribe the veterinary medicinal product. For POM-V medicines, the RCVS Code of Professional Conduct for Veterinary Surgeons states that it is up to the prescribing veterinary surgeon alone to deem how often they need to physically examine the animal. In other words, there is no legal or regulatory restriction to the interval between physical examinations to enable ongoing prescriptions. However, the nature of POM-V medicines and potential need for continued monitoring means that vets will naturally want to clinically examine the animal on an ongoing basis. Furthermore, the VMD does consider the availability of medicines and any associated impacts on animal welfare as part of the benefit:risk assessment of all new veterinary medicinal products and believe that we are being no more restrictive than we should be to ensure safe and effective use of authorised veterinary medicinal products.

The VMD disagrees with statement 6.3 (a). The cascade fundamentally allows veterinarians to legally exercise clinical freedom to choose the most appropriate medication for an animal under their care, provided that such decisions have a clinical justification. Cascade restriction is therefore not considered an appropriate term, as vets are able to prescribe any medicine, when based primarily on clinical need. In this context, the VMD believes that the cascade is the very opposite of a restriction as it opens up the possibility of veterinary surgeons prescribing medicines that are otherwise unauthorised for the proposed use. There may be an authorised veterinary medicinal product available, but when its use is not immediately clinically justified, e.g., due to a different disease or target species being treated, vets can use this risk-based decision tree to find a suitable alternative based on the contextualised care for their patient. One should also highlight the degree of risk that the vet assumes responsibility for when prescribing under the cascade. The VMD is aware that there are significant misconceptions within the veterinary industry about how to apply the cascade, and concerns about criticism/ backlash from its use, especially within recent graduates. Many vets are unaware that they use the cascade on a daily basis without acknowledging their responsibility in doing so, and it is acknowledged that their cascade-based prescribing decisions are sometimes influenced by what is stocked on the shelves of the practice. The VMD are already proactively engaging with veterinary universities and practicing professionals, e.g., via London Vet Show and BSAVA to clarify how the cascade can be used. The VMD is also in the process of creating a webinar on this topic and will continue to actively engage with the veterinary community to promote awareness surrounding the cascade. Based on the feedback from veterinary engagement at these events, the VMD will review if further guidance is required regarding cascade use. The CMA has considered that some legislative requirements, such as

the cascade, protect the veterinary market by maintaining a market that pharmaceutical companies are still incentivised to produce innovative veterinary medicines for (novel or generic). This will ultimately impact animal welfare through a reduction in/lack of novel therapies to provide new/better treatment options. This could also potentially increase the cost of veterinary medicinal products due to a more limited supply overall, but also a reduction in the number of generic medicines, which often drive down the cost of medicines.

With regards to statement 6.3 (c), the VMD would state that the owners can still obtain a written prescription to obtain the veterinary medicines from these online pharmacies and the VMD has set these requirements regarding wholesalers to ensure the safety and the quality of the veterinary medicinal products that the veterinary practices receive.

The first change of an active substance to a different distribution category is assessed not only by the VMD but also by the Veterinary Products Committee (VPC) who have a broad range of specialists from different backgrounds on their panel. The VPC is a panel of independent experts appointed to advise the VMD and Ministers, who review this information and either agree or disagree with the conclusions of the VMD. It is a carefully considered decision and as the CMA have already mentioned, unlike human medicinal products, there are more environmental aspects and consumer safety aspects to consider in the benefit: risk decision. The CMA has also considered that for most MAH, it is in their interest to change the distribution category of their product if possible as this will generally lead to an increase in sales. This generally means that generic products that may have applied for a higher distribution category end up at the same lower distribution category of the reference product.

The VMD would also like to comment that with a variation to change distribution category, additional product-specific evidence is required, and this data cannot necessarily be extrapolated between generic products. When demonstrating bioequivalence, there is a percentage window that pivotal pharmacokinetic parameters need to fall within. Therefore, generics can be clinically interchangeable with a reference product but not between other generics. This in part explains why when one active substance achieves a change in distribution category, this cannot be automatically applied to all products with the same active substance. An MAH is always allowed to apply for a change in distribution category, and as previously discussed, the VPC is always involved in these decisions when the first new active substance(s) is not yet available at the lower distribution category.

The CMA should be aware that due to the established need for veterinary oversight to ensure safe (and effective) use, a significant number of veterinary medicinal products are unlikely to change to a lower distribution category. Despite potential widespread use, multiple authorised POM-V veterinary medicinal products are contraindicated for many conditions that only a veterinary surgeon is qualified to diagnose. Owners do not have the experience or expertise of vets and even if they can see that their animal is suffering, there are a plethora of causes that might not be limited to those the owner is able to recognise themselves. In these cases, the administration of certain medicines (including POM-V products) could worsen the clinical progression of a case without a prior clinical assessment by a vet to help establish the risks involved. Even following a vet's clinical assessment, these drugs should always be used with due consideration of the risks involved.

The CMA should also be aware that any decision regarding euthanasia is multi-factorial and is very rarely based solely on the cost of a medicine. Other factors such as future costs regarding diagnostics, monitoring and repeat consultations alongside animal welfare are all considered in this decision.

Could the CMA provide further clarification regarding the on comment 6.37 and where it came from: 'The report went on to recommend that the Government encourage the European Commission to amend the cascade legislation 'to allow veterinarians to prescribe generic treatments for companion animals where, after consultation with the owner, they come to the conclusion that this is the best treatment for the animal concerned'. Ultimately, this recommendation was not adopted by Government.'

In the summary section more could be done to separate out / spell out the two regulatory frameworks and supporting pieces of legislation in place so that the role and remit of the VMRs is clearly delineated from that of the vet surgeons act 1966. On 2.18(g) - not just equine anthelmintic resistance, but resistance in all species. On 6.3 should avoid using the term human generic. This gives the impression that the veterinary medicine and human medicine are qualitatively and quantitively the same and are interchangeable - this is not the case with veterinary medicines specifically developed to treat animals, although there may be commonality in active substance. Furthermore, the cascade is in place to protect animal health and welfare with the optimal position of treating an animal with a veterinary medicine designed for that use. Using lower tiers of the cascade introduces additional risks to animal health and welfare. Cost is mentioned is this the manufacturers cost or the charged rate to animal owners which in previous papers is noted as being marked up between 300 %- 400%.

On 6.3(d) the VMD on initial grant will always use the less restrictive classification that is possible when considering the use, diagnosis and safety profile of the product. On 6.32(g) the human sector also operates a phv system. The point being made is that any adverse effects of using a human product to treat animals is not considered by the manufacturer of the human medicine as the animal is not the intended recipient.

On 6.58 - the VMD does not encourage, it requires the MAH to follow the classification set by the VMD. This is the same as generic medicine applications which will follow the classification of the product it is copying - para 6.59 refers.