[redacted]
To: [redacted] VetsMI
[redacted]
Subject: [redacted] Comments on Remedies Paper
Date: 24 May 2025 21:21:03
[redacted]

Hi,

Please find below a few comments from the VMD. I would also be interested in hearing more about the remedy concerning publication of similar / same medicines, particularly who would have the responsibility. There may be practical difficulties to overcome – vets or wholesale dealers would not know if products are identical in terms of product formulation (qualitatively and quantitatively) and the regulator is required to keep that information secure as it is deemed to be commercially sensitive information belonging to the marketing authorisation holder.

Section and Para	Question number	Comments for CMA
3.16-3.20	10	Need to ensure that any information published on prescription medicines does not breach advertising regulations and put pressure on vets to prescribe according to what the owner wants, rather than what the vet diagnoses is the best course of treatment.
3.93	33	As above, risk that it leads to vets prescribing based on price rather than the animal's need
3.100-3.106	37	Any monitoring will incur costs, to practices and to a regulator if any enforcement is required.
4.8-4.47	41	Increased prescriptions would likely result in increased prescription fraud
4.73-4.92	48	Risk of confusion over the term "generic" and risk to vet of prescribing an unsuitable medicine
4.73-4.92	53	This would be challenging to manage when new authorisations are granted or when a product is varied.
4.93-4.104	56	The CMA review only covers pets. This would allow vets to charge different amounts for a prescription for food-producing animals compared to pets, which may lead to confusion in the sector if practices charge different amounts depending on type of animal. Some species are FPAs, but kept as pets which also needs to be considered
4.128-4.130	63	This would require significant resource for a regulator to monitor and enforce, which would divert resource from monitoring the safety and efficacy of medicines. Or it would lead to increased fees for the sector in order for a regulator to cover the costs of monitoring and enforcement action.
6.1-6.30	73	Potential issue with RCVS being responsible for regulating professionals and practices due to conflicts of interest. This will also increase costs to vet practices as fees would need to increase to cover additional monitoring and enforcement activity. To state as well, there is already regulation of compliance at all vet practices under the VMR. Whilst the VMR may have limited scope, premises are regulated in accordance with these regulations.

6.31-6.49	77	Costs need to be addressed. A non-PSS premises companion animal practice pays £536 roughly every 4 years for an inspection (plus £38 annual fee ea). A PSS stand alone premises pays £79 application fee, £646 assessment fee plus £582 annual fee ea. A considerable increase that will either be out of reach of some practices or lead to increased costs for clients.
6.50-6.64	82	As above, costs will increase for premises not already part of PSS. There are several small premises who provide services who need to be considered, such as ambulatory euthanasia practices. Also, CQC and GPhC are referenced as examples, however these are independent regulators. RCVS is not an independent regulator.
6.50-6.65	83	Costs would need to be recouped through fees to the premises, which would likely lead to increased costs to consumers
6.66-6.78	84	The VMD already has those powers and uses them as necessary for premises that breach the VMR. Any regulator requires those powers to enforce the regulations they are responsible for effectively.
6.108-6.117	99	Any changes to vet nurse prescribing would also require changes to the VMR. If this led to changes to legal categories of medicines this would also require packaging changes for marketing authorisation holders.
Context and summary- Para 12	n/a	Regulatory system that does not require monitoring of quality or clinical outcomes. The lack of monitoring or suitable record keeping may reduce the likelihood of reporting Adverse Events (AEs), partly because, if no timely, consistent and suitable recording of clinical information and VMP use is made, there is no reinforcement of the importance to report this evidence, and it requires additional effort on behalf of the practitioner to do so. Furthermore, this lack of record keeping has an impact on the quality of the information that is provided when an AE is presented to the practitioner a few days or weeks after the VMP use. Together these reduce the power of the Pharmacovigilance (PhV) systems to maintain the Benefit-Risk balance of the MAs in the marketplace.
Context and summary- Para 24	n/a	"to the extent that our remedies help ensure that pet owners have a choice of reasonably priced, good quality and innovative veterinary services, they will be contributing to improved animal welfare." Must ensure there is effective PhV, particularly post-authorisation as this is central to the ongoing availability of safe, effective and quality assured VMPs, which is required to maintain animal welfare. Consequently, any remedies must include comment on PhV requirements, including relevant data for regulatory function.
Section 3, Para 3.12-3.14	n/a	Minimum PhV requirements should be made of all practices and practitioners as part of their wider animal, human and environmental health responsibilities.
Section 3, table 3.1-3	n/a	Medications and chronic conditions – Adverse event reporting

		should be included in this section as a “free” service, which would reinforce the commitment to post-authorisation surveillance and remind practitioners to inform clients of the need to raise concerns when VMP don’t work according to expectations. [is this what is referred to in para 3.20 (a) “Some services may benefit from FOPs and referral providers being able to provide further explanation for what is included in a given line item. For these, providers could provide free text alongside the prices or through a hyperlink (where the information is not necessary to understanding the price).”?]
Section 3	3	All practices/practitioners should support PhV activities and inform clients that they do this ‘free of charge’ to the client. This would improve the oversight, safety, efficacy and quality of VMPs. Accompanied by this, the RCVS code of conduct should be firmer in the requirements for practitioners to report suspected AEs and provide the required information to the MAH, or, if not appropriate, to the VMD in a timely way.
Section 3	12	Any price comparison website would need to include mechanisms of comparing the cost of supply of medicines by suppliers, not just practices. AE reporting should be publicised as a veterinary responsibility and therefore included as an activity undertaken by all practices. Requiring the display/confirmation that the practice fulfils this requirement and should include details of who in the practice should be contacted in the event of an AE.
Section 3	13	A section on the safe use, and disposal of medicines should be included on all practice and comparison websites. This should also include clear instructions or links to the VMD webpage for details on how to submit AER and efficacy concerns. Note: VMD webpage should aid the direction of reports (e.g. via email link or portal) to the relevant MAH for products being used/queried.
Section 3	33	The supply or printing of up-to-date SPCs or identifying when variations have been made to the SPC may be challenging. Whilst directing clients to the VMD PID page may be appropriate to ensure they are aware of the most up-to-date information; these are not always available to clients e.g. those without internet access. Solutions may involve the use of smart technologies and the sharing of electronic information becoming the norm.
Section 3	37	This should form part of the practice standards, so an assurance of the governance being in place and a survey of clients that they are receiving the necessary information and know what to do in the event of an AE being identified, should suffice.
Section 4	40	Some medications would not be appropriate via written prescription, either because they come in large packs (for example large multidose bottles of injectable antibiotics or large bottles of liquid medication), are scheduled drugs (e.g. ketamine), or have risks to the end user (for example injectable steroids, euthanasia medications). For some of these could in theory give written prescription that is then delivered directly to the practice, where an injection fee could then be charged, but without a prescription portal or specific instructions for the order there would be no way of preventing owners from changing the address to delivering at home instead.
Section 4	41	Increase in compulsory written prescriptions results in increased risk of falsified prescriptons if not accounted for in final remedy option. This increases likliehood of off-label use. Also, if mandatory written prescription, many practices will choose to reduce significantly the variety and amount of veterinary medicinal products they keep in stock, especially as keeping stock can be expensive and time consuming. This could be an issue if they have not stocked something in the belief it is a non-urgent medication, only to later realise it is needed urgently. This may also affect the choice of treatments available instantly to an owner (for example a practice may only have one type of wormer in stock, so the owner may choose a wormer that is not ideal for the individual situation due to its immediate availability). Also concerns importance of time between treatment being required and decision on prescription v.s. in practice, it may be preferable for written prescriptions to be submitted via portal/ directly to pharmacy etc. As the owner could confirm once they have decided c.f. having to decide there and then to prevent another trip to the practice to

		collect the written prescription. This delay could also be used for owners to review SPC and make fully informed decision re: treatment. However could also result in owners not opting to pursue treatment which could lead to welfare issues e.g. low grade osteoarthritis cases where owner is not keen to treat as does not perceive this as painful despite limping- often owner persuaded in consult to treat, then tries treatment rapidly after and is surprised at change in their pet, prompting the pursual of further treatment. A gap in this may prevent more people from treating. 4.65 confirms extended interval not feasible.
Section 4	42	Clarification on re-check intervals/ length of prescription, and a database for written prescriptions to prevent falsified prescriptions
Section 4	45	SPC (adverse events) should be included
Section 4	49	This should not permit the use of human medicines as an unintended consequence. The legislation around the cascade requires a veterinary medicines to be used first. VMD already warned re: differences between generics, however for human medicines concerns that vet could prescribe generic but different generics may have different compositions e.g. one may be tablet with a certain list of excipients, one may be a liquid with xylitol (toxic for animals). Also could prescribe paracetamol to a dog and the owner could take this prescription to a human pharmacy and get human paracetamol (off cascade) or could prescribe a human medicine for which there are animal versions but where there is a specific reason the human medicine has been picked. So would need to distinguish between animal and human medication prescriptions (may need to print on prescription vet meds only except if specified).
Section 4	51	Care to not have mandatory generic prescribing for active ingredients which are used in humans as well as animals.
Section 4	64	Prescription portal which could automate links to SPC information to reduce off-label use and increase awareness of adverse events that could occur post administration would be ideal
Section 6, para 6.11	n/a	There is only regulatory framework for vets and nurses but not for vet businesses and non-vets who own and work in practices. It is limited and its contents don't appear to result in costumers receiving good, relevant and timely information re price, quality and treatment options so that they can make informed decisions. There are no sufficient mechanisms for the monitoring and enforcement of vets and vet nurses compliance with the RCVS Code. RCVS relies on complaints rather than monitoring compliance and it's unable to take enforcement action for breaches that fall short of serious professional misconduct. RCVS does not appear to take learnings from complaints to drive standards up as much as they could.
Section 6	n/a	6.63 The RCVS is largely reliant on complaints made to it, rather than proactive forms of monitoring 6.67 RCVS's formal powers are limited to cases of serious professional misconduct. A balanced and effective system should contain provision for the regulator to investigate, and impose a range of sanctions for, breaches of these requirements. Agree with implementing monitoring measures (that would include complying with phv requirements for vets) Effective complaints and redress mechanisms- no comments Effective use of veterinary nurses-no comments
	41	Increase likelihood of prescription fraud. Written prescriptions can be very time consuming and if more are required, this means that vets will have less time for their other responsibilities.
4.79	47/48	Currently in our VMRs, vets can state just the active substance or brand name on a prescription and if they want to add a few brand name options they can do so. Making it mandatory for all vets to write more than one option is potentially altering their decision process. More education and awareness of their prescribing responsibilities is essential and as previously discussed the VMD is actively engaging with and trying to educate the veterinary community.
		A lot of this is considered confidential information. This could lead to certain products having commercial advantages/disadvantages, which may in turn result in pharmaceutical companies being less incentivised to produce generics. Vets can easily search the Product Information Database to find potential alternatives with the

4.86(a)(b)(c)	53	same active substance, indicated for the same condition in the same target species but as previously discussed there can be different safety information for the consumer/ target species/ environment and it is the responsibility of the vet to check the product literature of all VMPS they prescribe and relay this information to the owner. There is a risk that vital safety information could be missed with having several brand options on one written prescription.
4.81		the active substance is not the same as the generic name, this section should be amended as follows: The VMD has told us that "A prescriber can either state the active substance or brand name on the prescription. If a brand name is stated, the supplier must supply only that product. If the active substance is used on the prescription, the supplier can supply any brand of that product they choose or check with the prescribing vet if needed'

As ever, happy to discsss further should you wish.

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The VMD Information Hub contains communications on current and future regulatory changes

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To: VetsMI
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Subject: Comments - Remedies Paper
Date: 02 June 2025 08:07:54
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Hi,

Apologies for missing the deadline, but here are some further comments from the VMD. Due to leave, half-term and bank holiday it was not possible to submit all the comments in one go.

1.19-1.21	1	Concerns with splitting the regulatory regime into domestic pets/food producing species - this will increase burden for those practices that provide services to both sectors as they will have to manage two separate regulatory regimes. How is a domestic pet defined?
2.22		"lack of information about quality of medicines sold online". VMD have a registration scheme for online retailers - all retailers supplying online within the UK should have been inspected by either the VMD/RCVS or GPhC.
	12	Need to sure that any price comparison website is compliant with the advertising restrictions in the VMR.
3.65 (b)	14	Multiple comparison sites would not aid in providing clarity to the consumer.
3.65	18	Costs should be borne by the industry that is being regulated. However IT development can be very expensive, if these costs are passed to the vet sector, they will pass the costs on to the consumer. This may result in increased costs to the consumer.
3.73 (b)	15	The requirement to provide a printable version of the website seems unworkable - it would quickly become out of date and may run to hundreds of pages.
3.95		Need to ensure that vets are allowed to prescribe the most suitable medicine - not simply the cheapest one
4.24	40 and 41	Need to consider the types of medicines that this applies to - is this suitable for Controlled Drugs (CD) that carry a higher risk of divergence? How would this system work with instalment prescriptions? CD legislation is led by the Home Office so any remedies that impact on the sale and supply of CDs should be discussed with them.
4.32	41	HO requirement for CD prescriptions to have wet signature - need to consider this in any electronic prescribing system
4.1	57	Option B with individual price caps on medicines would create a large burden on the regulator responsible to creating monitoring and enforcing these price caps
Remedy 11		Will these price caps apply to all medicines retailers or just vets? What about SQP retailers and pharmacies? Price caps on individual medicines could affect prescribing decisions.
	62	Limiting price controls to individual medicines may cause an increase in price to those medicines that are not price controlled.
6.50-6.53	78	Further clarity needed on scope of what services would be included in consumer and competition duty
6.106-6.107	97	Further clarity needed on scope and role of veterinary ombudsman

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Best regards,

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