VETERINARY SERVICES FOR HOUSEHOLD PETS

Appendix J: Regulation of veterinary medicines

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CMA
Competition & Markets Authority

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The Competition and Markets Authority has excluded from this published version of the final report information which the inquiry group considers should be excluded having regard to the three considerations set out in section 244 of the Enterprise Act 2002 (specified information: considerations relevant to disclosure). The omissions are indicated by [✂]. Some numbers have been replaced by a range. These are shown in square brackets. Non-sensitive wording is also indicated in square brackets.

Contents

1. Introduction

1.1 In this Appendix we set out aspects of the regulatory framework that are relevant to how competition works in the supply of Prescribed Veterinary Medicines for household pets in the UK, including:

(a) the main sources of the regulatory framework;

(b) the 'cascade' provisions of the VMRs that govern the circumstances in which vets may prescribe a non-authorised medicine (such as a human generic product) to treat an animal (the **Cascade Restriction**);

(c) restrictions on the advertisement of Prescribed Veterinary Medicines (the **Advertising Restriction**)

(d) the regulations and guidance governing the prescribing of Prescribed Veterinary Medicines, including the 'under care' provisions which informs the context in which these medicines can be prescribed (such as when a physical examination of the pet is required) (the **Under Care Restriction**); and

(e) the 'classification' system that determines which medicines can only be prescribed by vets (**Classification Restriction**);

(f) the restriction on retailers supplying FOPs (the **Wholesale Restriction**);

1.2 We outline the concerns we have encountered on whether the regulatory framework restricts access to certain products, or the way in which they can be prescribed, and therefore may impact competition in the supply of veterinary medicines.

1.3 We also discuss the potential policy reasons for some of these restrictions, and our emerging views on points for consideration by policy makers when weighing these priorities.

2. Sources of veterinary medicines regulation

Overview

2.1 There are three sources of veterinary medicines regulation relevant to the issues we consider in this Appendix:

(a) the Veterinary Medicine Regulations 2013 (**VMRs**), which govern the manufacture, wholesaling, retailing and administration of veterinary medicines in the UK;

(b) The RCVS' professional conduct rules and guidance on prescribing and dispensing of veterinary medicines (given the role of veterinary professionals in prescribing and administering Prescribed Veterinary Medicines); and

(c) in relation to Prescribed Veterinary Medicines containing controlled substances (Controlled Drugs), the Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001.

The VMRs

2.2 The VMRs were made under section 2(2) of the European Communities Act 1972, which created the power to transpose EU law requirements by way of secondary legislation.[1]

2.3 The current version of the EU veterinary medicines regulation is Regulation (EU) 2019/6 (**EU VMPRs**).

2.4 The Windsor Framework means that EU law on veterinary medicines continues to apply to Northern Ireland post-EU exit date.[2]

2.5 For the rest of the UK, Part 3 of the Medicines and Medical Devices Act 2021 (**MMDA**) empowers the Secretary of State to amend the VMRs by statutory instrument, but only where the overarching objective is one or more of:

(a) 'the health and welfare of animals;

(b) the health and safety of the public;

(c) the protection of the environment'.[3]

[1] Explanatory Note to 2024 amendment.
[2] VMD Guidance: Veterinary medicines legislation (Legislation in NI).
[3] MMDA, section 10(2).

2.6 Where the relevant regulations '…may have an impact on the safety of veterinary medicines, the appropriate authority may make the regulations only if the authority considers that the benefits of doing so outweigh the risks.'[4]

2.7 Further, in 'considering whether regulations…would contribute to this objective, the appropriate authority must have regard to—

(a) the safety of veterinary medicines;

(b) the availability of veterinary medicines;

(c) the likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to—

(i) develop veterinary medicines, or

(ii) manufacture or supply veterinary medicines.'[5]

2.8 In Northern Ireland, under the Windsor Framework and Northern Ireland Protocol, aspects of EU law (including the EU VMPR [6]) on Prescribed Veterinary Medicines continue to apply.[7] At present, until 31 December 2025, a 'grace period' for veterinary medicines means that existing rules for moving veterinary medicines between the rest of the UK and Northern Ireland remain in effect.[8] We understand that work on finalising arrangements post-expiry of the 'grace period' is continuing.

2.9 At present, the requirements of the VMRs are (via the EU VMPR) largely reflected in Northern Ireland (including, for example, the Cascade).

2.10 The VMD is responsible for ensuring compliance with the VMRs, including the registration and inspection of vet practices (noting that practice inspections for PSS FOPs are delegated to the RCVS as described below).[9] It also administers the approval and authorisation of veterinary medicines, monitors adverse events from veterinary medicines and advises government on veterinary medicines policy (including updates to the VMRs).[10]

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[4] MMDA, section 10(4).
[5] MMDA, section 10(3).
[6] VMD Guidance: Veterinary medicines legislation (Legislation in NI).
[7] Veterinary medicines legislation - GOV.UK.
[8] European Commission announces three-year extension to the grace period for veterinary medicines - GOV.UK, 19 December 2022.
[9] VMD Guidance: Registration and inspection of veterinary practice premises.
[10] About us - Veterinary Medicines Directorate - GOV.UK (https://www.gov.uk/government/organisations/veterinary-medicines-directorate/about) (Accessed 3 February 2025)

RCVS Code and Guidance and the PSS

2.11 The RCVS Code states that 'Veterinary surgeons who prescribe, supply and administer medicines must do so responsibly'.[11] The Guidance contains more specific requirements regarding the prescription, administration and sale of veterinary medicines.

2.12 The PSS includes a module on medicines. Practices that participate in the PSS are exempt from VMD inspection as the VMD has delegated this function to the RCVS PSS Assessors.[12] The VMD reserves the right to attend any PSS assessment and to enter any vet practice at any time under its own powers of enforcement. [13]

Controlled drugs legislation

2.13 Some veterinary medicines contain substances which are controlled drugs under the Misuse of Drugs Act 1971 and The Misuse of Drugs Regulations 2001. Prescribed Veterinary Medicines containing these substances must therefore be stored, supplied and disposed of in accordance with these additional provisions.[14]

Prescribing regulations

2.14 Vets' prescribing activities are regulated under the VMRs, through RCVS Guidance and (in relation to controlled drugs) the Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001.

Verbal and written prescriptions

2.15 VMRs require that vets who prescribe POM-V medicines 'must first carry out a clinical assessment of the animal, and the animal must be under that veterinary surgeon's care'.[15]

2.16 A vet can issue a prescription either verbally or in writing. A verbal prescription amounts to a vet determining that a given medical product should be supplied and recording that fact in their clinical records and then dispensing the product themselves. A written prescription involves documenting the prescription in the

[11] RCVS Code, paragraph 1.5.
[12] RCVS website, Inspection of practice premises (https://www.rcvs.org.uk/registration/veterinary-premises/) (accessed 4 February 2025).
[13] CMA, Practice Standards Rules, 1 January 2024, Rule 41.
[14] These requirements include the need for a Controlled Drugs register and to keep certain CDs in secure storage Veterinary Medicines Directorate, Controlled drugs: recording, using, storing and disposal, published 3 November 2014, last updated 17 May 2024 and Veterinary Medicines Directorate, Controlled drugs in veterinary practice: a VMD inspectors top tips, 20 February 2025
[15] VMRs schedule 3, paragraph 4(1).

way the VMRs stipulate, which other vets or pharmacists can rely on to supply to that pet owner POM-V medicines in the absence of the prescribing vet.

2.17 If a vet issues a prescription verbally, they must:

(a) supply the product themselves (which they can do by individually authorising the supply and satisfying themselves that the person handing the product over to the pet owner is competent to do so);[16]

(b) maintain records of the reason for giving the verbal prescription;[17] and

(c) where the verbal prescription is an on-going or repeat prescription (for example, permitting a monthly supply of a drug until a check-up of the animal due in six months' time), record additional details such as the product name, the pack size/volume/quantity of the product, dosage instructions, necessary warnings/instructions and details of the frequency of the repeat and time period it covers (for example, the date of the next check-up).[18]

2.18 In practice, as a verbal prescription will coincide with the supply of the product by that vet's practice, the vet's practice will also need to comply with the record-keeping requirements for the supply of a POM-V product.[19]

2.19 For written prescriptions, vets must (among other things) include: the name, address and telephone number of the person prescribing the medication; the name and amount of the veterinary medicine prescribed; the dosage and administration instructions; and detail any necessary warnings for the use of this medication.[20]

2.20 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. The VMD has also told us a vet may name a number of brand options on a prescription, where they deem this clinically appropriate.[21]

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[16] VMRs schedule 3, paragraph 9
[17] VMRs, schedule 3, paragraph 5(1A)
[18] For further details, see VMD, Guidance on Retail of Veterinary Medicines 'Ongoing and repeat verbal prescriptions'
[19] VMRs regulation 23. Specifically, in this context: the date of the transaction under which the product was received or supplied; the name of the veterinary medicinal product; the pharmaceutical form and strength of the product; the batch number; the quantity of product received or supplied; the company name and the permanent address or registered place of business of the recipient; and the expiry date.
[20] VMRs schedule 3, paragraph 6. Specifically, a written prescription must include: the name, address and telephone number of the person prescribing the product; the qualifications enabling the person to prescribe the product; the name and address of the owner or keeper; the identification (including the species) of the animal or group of animals to be treated; the premises at which the animals are kept if this is different from the address of the owner or keeper; the date of the prescription; the signature or other authentication of the person prescribing the product; the name and amount of the product prescribed; the dosage and administration instructions; any necessary warnings; the withdrawal period if relevant; and if it is prescribed under the cascade, a statement to that effect.
[21] VMD Remedies Working Paper Response (relating to paragraphs 4.79 and 4.81).

2.21 A written prescription is valid for up to six months, or 28 days in the case of controlled drugs. The VMRs include a statutory list of requirements the information a written prescription should include, such as the name of the product, dosage, applicable warnings, and details of the prescribing vet and animal to which the prescription relates.[22]

2.22 Note that a written prescription for repeat dispensing may continue to be used to dispense the specified number of repeats after its validity period has expired, provided the first dispensing is made prior to that written prescription's expiration date.[23]

2.23 Written prescriptions must be signed, but this can be an e-signature (unless for a controlled drug, in which case the prescription must be in wet-ink).[24]

2.24 Any prescription – verbal or written – for antimicrobials must be 'for the most limited period that is consistent with the risk to be addressed'.[25]

[22] The full list of requirements can be found in the VMRs, schedule 3, paragraph 6.
[23] VMD Guidance, 'Retail of veterinary medicines' | 'Written prescriptions'.
[24] The Misuse of Drugs Regulations 2001 para 15(1)(a)
[25] The Veterinary Medicines Regulations 2013 schedule 3, paragraph 7(2).

3. How regulation affects the supply of prescribed veterinary medicines.

The Cascade Restriction

Cascade Restriction: what medicines may be administered to a household pet?

3.1 Regulation 8 of the VMRs provides that no person may administer a veterinary medicine product to an animal unless it:

(a) has a Marketing Authorisation (MA);[26] or

(b) it is administered under either Schedule 4 VMRs (the Cascade) or Schedule 6 VMRs (which sets out a simplified authorisation procedure for medicines intended for a closed list of 'small pet animals' for example, cage birds and small rodents).[27]

3.2 The Cascade[28] operates as an exception to the requirement that only a Prescribed Veterinary Medicine with an MA can be administered to animal, by providing that if '…there is no authorised veterinary medicinal product in the United Kingdom for a condition the veterinary surgeon responsible for the animal may, in particular to avoid unacceptable suffering, treat the animal concerned with the following ('the cascade'), cascaded in the following order—

(a) a veterinary medicinal product authorised in the United Kingdom for use with another animal species, or for another condition in the same species; or

(b) if there is no such product that is suitable, either—

(c) a human medicinal product authorised in the United Kingdom; or

(d) a veterinary medicinal product not authorised in the United Kingdom but authorised in another country for use with any animal species (in the case of a food-producing animal, it must be a food-producing species); or

(e) if there is no such product that is suitable, a veterinary medicinal product prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorisation authorising the manufacture of that type of product.'

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[26] As explained further below, a veterinary medicine with a Market Authorisation means it is authorised for a specific condition for a specific target species based on assessed data.
[27] The equivalent EU VMPR provision is Article 106(1).
[28] VMRs, schedule 4, paragraph 2 and EU VMPR, Article 112.

Cascade: VMD Guidance

3.3 The VMD publishes guidance on the use of the Cascade by veterinary professionals.[29] Extracts relevant to the issues in this section include:

(a) '**Misuse of the cascade**: You must not promote or facilitate any use of the cascade which is not in accordance with Schedule 4 of the VMRs. This does not prevent a vet from discussing treatment options with the owner or keeper of the animal under treatment.'

(b) '**Human medicines**: You are not allowed to prescribe a human medicine simply because it is cheaper than using an authorised veterinary medicine. Human medicines and veterinary medicines containing the same active substance may not be interchangeable.'

(c) '**Unavailability of product**: If a product cannot be obtained despite a thorough search and in a reasonable time, you may conclude that in these circumstances it does not exist. You may follow the cascade to identify a suitable alternative. However, there may be cases where urgency dictates you use whatever is to hand, whether authorised or not. We publish details of supply issues which have the potential to cause animal welfare issues and provide information on alternative products, where possible. If you cannot obtain authorised products from your usual wholesaler, you may issue a written prescription for the animal owner to use with another supplier.'

(d) '**Animal owner considerations**: You may conclude that an animal owner, perhaps due to age or disability, would have difficulties in administering the authorised product. In the interest of animal welfare and treatment compliance you could consider an alternative treatment under the cascade.'

(e) '**Medicines commonly found around the home**: In exceptional emergency circumstances, you may judge there is a need to alleviate a pet's discomfort until a home visit can be made or the animal brought to the surgery. You could recommend that an animal owner use a human medicine that they already have in their possession, such as antihistamine tablets. This does not mean a pet owner should be encouraged to go into a pharmacy and ask for a human medicine for their pet.'

Cascade: RCVS Supporting Guidance on additional steps

3.4 The RCVS Supporting Guidance (**Guidance**) reiterates the VMRs' requirements and adds that a 'decision to use a medicine which is not authorised for the

[29] VMD Guidance, The cascade: prescribing unauthorised medicines

condition in the species being treated where one is available should not be taken lightly or without justification.'[30]

3.5 Clients are to be 'made aware of the intended use of unauthorised medicines and given a clear indication of potential side effects. Their consent should be obtained in writing'.[31]

Stakeholder views on the Cascade Restriction

3.6 In our regulation working paper, we referred to stakeholder views that highlighted potential negative impacts of the Cascade Restriction.[32] These generally focused on the cost implications of the Cascade Restriction, in circumstances where the Cascade Restriction prohibits vets from prescribing an (often cheaper) human generic in place of the authorised medicine.

3.7 We also noted stakeholders' views on why the Cascade Restriction may be necessary: these submitted that the Cascade Restriction is necessary so that veterinary medicine benefit from the VMD's authorisation process in health and welfare terms and the way the Cascade Restriction incentivises the development of veterinary-specific medicines.

3.8 We also noted that concerns about the cost impacts of the Cascade Restriction, particularly in relation to household pets, are not new: in 2001, an independent review (the Marsh Report) recommended changes to the cascade to permit more prescribing flexibility for companion animals, and the 2003 Competition Commission report on veterinary medicines also considered recommending changes to the Cascade to allow more prescribing flexibility for 'non-food producing animals', but declined to make a recommendation to that effect after consultation.[33]

3.9 While appreciating the rationale behind the Cascade, some attendees at our roundtable sessions said they would like to see changes to the regulation of the cascade, so that either the human or animal version could be prescribed once the patent period has ended.[34] Others expressed frustration at the higher cost of medicines that are licensed for animals compared to the human versions which they used before amendments to the Cascade.[35] Some attendees from corporate groups added that this price differential can sometimes cause friction between the

[30] Guidance, Veterinary medicines, paragraph 4.25.
[31] Guidance, Veterinary medicines, paragraph 4.26.
[32] Regulation Working Paper, paragraph 6.31
[33] Regulation Working Paper paragraphs 6.33 – 6.37 for an overview of the Marsh Report and 2003 CC Report's approach to the Cascade.
[34] Summary of Edinburgh roundtable discussions , paragraph 29. Note the VMD have stated that it is not aware of patents being a significant barrier to generics once the data protection period has elapsed (VMD response to CMA February 2025 Working Papers, p4)
[35] Summary of Manchester roundtable discussions, paragraph 11 and Summary of Cardiff roundtable discussions, paragraph 8 and Summary of vets who recently set up a practice roundtable discussions, paragraph 14.

vet and the pet owner.[36] The newly qualified vets told us that the consideration of a clients ability to pay for certain medicines when interpreting the Cascade led to ambiguity and represented a disconnect between reality and the regulation.[37]

3.10 Responses to our working papers continue to highlight similar themes.

3.11 In response to our regulation working paper:

(a) Respondents (including the VMD[38]) noted the importance of the cascade in safeguarding animal and public welfare, and urged caution regarding any amendments to it.[39]

(b) The VMD suggested that the Cascade Restriction ought not to be described as such, given it allows clinical freedom for vets to determine the most appropriate medication for the animal under their care.[40] It also noted the degree of risk vets undertake when prescribing non-authorised medicines under the Cascade.[41]

(c) The VMD did say that it considered there are 'significant misconceptions' regarding the use of the Cascade among vets, and that it is taking steps to engage with the veterinary community to promote awareness.[42]

(d) Respondents did recognise the cost implications for pet owners[43] may justify a review of the cascade, recognising cost as a factor together with animal welfare. [44]

(e) An independent vet expressed the view that while the Cascade Restriction was needed, vets should not be forced to replace existing human cascade medicines that are effective with newly-licensed (expensive) authorised products.[45]

(f) CVS and IVC expressed support for the Cascade Restriction, citing (for example) animal welfare benefits, and incentives on drug manufacturers to innovate.[46] Linnaeus and Medivet said any changes to the Cascade Restriction must be carefully considered,[47] and Medivet suggested introducing a cost element into the Cascade Restriction might increase

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[36] Summary of vets who work at large corporate groups roundtable discussions, paragraph 14
[37] Summary of vet students and new graduates roundtable discussions, paragraph 10
[38] VMD Feb WP response, p4. Respondent_B.pdf p17
[39] XLVets response to February Working Papers; BVA/BVNA/BSAVA/SPVS/VMG response to February Working Papers, p6
[40] VMD response to February Working Papers, p5
[41] *Ibid*
[42] *Ibid*
[43] FIVP response to the February Working Papers, p5
[44] BVA/BVNA/BSAVA/SPVS/VMG response, p6
[45] Veterinary practice A's response to February Working Papers, p1
[46] IVC response to February 2025 Working Papers, p61; CVS response to February Working Papers, p6
[47] Linnaeus response to February 2025 Working Paper, pp 47-48

ethical dilemmas for vets.[48] Pets at Home supported changes to the Cascade Restriction that would allow cost to be taken into account for non-food producing animals.[49]

3.12 In response to our Remedies Working Paper:

(a) Some vets were critical of the Cascade. This included describing themselves as being 'shackled to using POM-V licensed for one condition in one species where an alternative generic exists that is much cheaper'.[50] Others have told us that the Cascade is a 'systemic issue that directly impacts drug costs'[51] and provides no incentive for pharmaceutical companies to lower the prices of their medications as long as they have the only licenced option. [52]

(b) Some individual/independent vets[53] supported changes to the Cascade to permit the use of human medicines as a way of relieving cost pressures on pet owners, while others highlighted the protective role the cascade plays in animal health. Others told us that changes to the Cascade may be welcomed so long as it does not have the unintended consequence of limiting research into new veterinary drugs given the small size of the market compared to human medicines.[54]

(c) Other individual vets/FOPs[55], LVGs[56] and NOAH[57] suggested prescribing by active ingredient (rather than medicine brand(s)) may be incompatible with the Cascade Restriction, presumably because prescribing by active ingredient could create a written prescription that did not discriminate between authorised and non-authorised medicine products containing the same active ingredient.

(d) The VMD also noted the fact that prescribing by active ingredient could lead to breach of the Cascade Restriction (through human medicines being administered inadvertently) though suggested this could be overcome by stipulating that the written prescription was for authorised veterinary medicine only.[58]

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[48] Medivet response to February Working Papers, pp 71-72
[49] Pets at Home response to February Working Papers, pp 55-56
[50] [✂] response to Remedies Working Paper
[51] [✂] response to Remedies Working Paper
[52] [✂] response to Remedies Working Paper
[53] [✂] response to Remedies Working Paper; [✂] response to Remedies Working Paper
[54] [✂] response to Remedies Working Paper; [✂] response to Remedies Working Paper
[55] For example, [✂] response to Remedies Working Paper; [✂] response to Remedies Working Paper; [✂] response to Remedies Working Paper
[56] For example, CVS Response to Remedies Working Paper p28; Pets at Home Response to Remedies Working Paper, p26.
[57] NOAH response to Remedies Working Paper, p4. NOAH also clarified through subsequent correspondence that any such system would need to ensure that licensed veterinary medicines were considered for prescription and dispensing ahead of unauthorised products such as human medicines.
[58] VMD response to Remedies Working Paper

3.13 [✂] have also submitted to us that the Cascade system 'originally implemented as an EU regulation may now be considered obsolete. This system prohibits the use of human pharmaceuticals in animals, despite the fact that such medications are often more cost-effective and efficient' and added that 're-evaluation this regulation could lead to potential cost savings.'[59]

Cascade Restriction: points for wider consideration

3.14 There appears to be evidence that, at least in certain instances, the Cascade Restriction may be acting as a barrier to entry or expansion for products which otherwise might serve the needs of consumers at a lower price than the authorised medicine which the Cascade Restriction requires vets to prescribe.

3.15 We also see force in the view that the Cascade Restriction could have an adverse impact on animal welfare in certain circumstances. That could occur if, for example, the restriction results in animals going untreated and/or euthanised in circumstances where its owner could afford a Cascade alternative, but not the authorised Prescribed Veterinary Medicine.

3.16 The VMD has told us that, while financial reasons alone are never justification to use a human medicine over an authorised veterinary medicine, each case must be dealt with by a vet on a case-by-case basis. The VMD submitted that the Cascade is a risk-based decision tree that the prescribing vet needs to review in line with the circumstances of an individual patient. Potential risks to the target species increase with each step down the Cascade. The VMD further noted that there may be situations where there is clinical justification for Cascade use of alternative medicines if 'all the options of using an authorised veterinary medicine have been explored and the benefit:risk balance have been appropriately weighed…informed consent has been obtained from the owner' and [the Cascade use] is 'in the interest of preventing animal suffering'.[60]

3.17 However (noting the published guidance referred to above), this VMD view does not appear to us to counter the evidence above of the Cascade Restriction potentially preventing consumers from accessing less expensive alternative medicines in certain circumstances.

3.18 We are mindful of the possibility there could be increased risks associated with widespread use of Cascade alternatives, and the potential costs which managing those risks could involve. We acknowledge that in a well-functioning market, regulation will reflect animal welfare, public health and safety considerations. We

[59] Although they did not that this could lead to unintended consequences if deployed. For example, reduced availability of medicines and less support by the pharmaceutical industry for new products. [✂]
[60] VMD written response to CMA queries, Q1 and evidence provided by the VMD, 24 January 2025.

also recognise that incentives to research, develop and innovate in the field of medicines are important.

3.19 Regulation can affect competition and consumers too, though. Its impact on competition and consumers can be considerable where it restricts consumer choice or leads to consumers paying higher prices than they otherwise would (which impacts may also affect animal welfare and public health and safety if, for example, the Cascade Restriction leads to animals going untreated or suffering detriment in their treatment).

3.20 For those reasons, it seems to us important that the regulatory framework, including the Cascade Restriction, reflects the right balance of considerations – including animal welfare, public health and safety, and competition and consumer interests. We have concerns that this may not currently be the case for the Cascade Restriction.

3.21 We recognise that the CMA may not be best placed to draw conclusions on the most effective weighting of competition (including consumer cost and choice) factors against the wider public policy issues involved.

3.22 Our provisional view is that, where competition may be affected because the regulatory framework does not reflect the right balance of considerations, the public bodies responsible for regulating the prescribing of medicines (Defra, VMD, RCVS) should consider whether animal welfare, public health and environmental protection are appropriately weighted against the need to ensure veterinary services in the UK can deliver competitive prices, innovation and growth in step with technological change and consumer demand. This could involve, for example, introducing more flexibility in the Cascade for specific circumstances (including in the provision of charitable care), or requiring products that are displacing a widely-used Cascade alternative to demonstrate value-for-money.

Cascade Restriction: points for wider consideration on clarity

3.23 Our stakeholder engagement highlighted some of the difficulties veterinary professionals may experience implementing the Cascade Restriction in practice. The VMD has stated in published guidance[61] that vets 'are not allowed to prescribe a human medicine simply because it is cheaper than using an authorised veterinary medicine' and the RCVS has stated that '…the cost of the medication cannot be taken as justification for prescribing under the cascade, and instead the decision should be made only to avoid unacceptable suffering.'[62]

[61] VMD Guidance, The cascade: prescribing unauthorised medicines
[62] As stated on the RCVS website, Standards & advice update, November 2020 (https://www.rcvs.org.uk/news-and-views/features/standards-and-advice-update-november-2020/ - paracetamol) (accessed 31 January 2025).

3.24 However, in the course of our engagement with stakeholders in the investigation, it has not always been possible to clarify whether a clinical decision – for example to avoid unacceptable suffering – might be made to resort to the Cascade, where the circumstances giving rise to that clinical situation are linked with cost (for example, the unaffordability to the pet owner of the authorised medicine).

3.25 Taken together with the perceived increased risk to vets resulting from the new criminal offence of promoting misuse of the Cascade[63], the evidence so far suggests this lack of clarity is likely to restrict veterinary professionals when making prescribing decisions in difficult circumstances, particularly in a context when, for many consumers, cost of living concerns are relevant.

3.26 We have previously noted the VMD and the RCVS may wish to consider clarifying (for example, with case studies) the circumstances in which cost might, or might not, feature in circumstances that a VMRs-compliant clinical decision-making process might respond to.[64] In its response, the VMD stated that 'allowing cost to be a factor would essentially be putting a price on animal welfare.' Our concern, however, is that cost is already a factor in the treatment of pets (whether acknowledged or not); where the regulatory framework allows, acknowledging in guidance the role cost could play in a treatment decision is likely helpful to vets and pet owners making choices about their pet's treatment.

Restrictions on advertising POM-V medicines

3.27 The VMRs prohibit retailers advertising POM-V medicines to pet owners (the **Advertising Restriction**).[65] This is consistent with the policy intention of ensuring that vets, rather than pet owners, determine the suitability of a given medicine product for treating an animal's condition.

3.28 Advertising is widely defined as any activity in connection with a veterinary medicine that is aimed or designed to promote the sale, distribution, supply, prescription or the use of veterinary medicine, whether for profit or not. Examples include postal flyers, website banners or pop ups, and texts providing information about animal illness that specifically promotes a particular veterinary medicine, presentations and other verbal communications.[66]

3.29 The VMD have also produced guidance to aid in the interpretation of these regulations.[67] This clarifies aspects of the VMD's approach to enforcing the VMRs, including:

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[63] Note that prescribing in breach of the Cascade Restriction has long been a criminal offence.
[64] CMA Working Paper: Regulatory framework for veterinary professionals and veterinary services, paragraph 6.50.
[65] The offences for non-compliance with these requirements are under Regulation 43, (f), (fa) and (g) of the VMRs.
[66] VMD Guidance, Advertise veterinary medicines legally, published 1 June 2015, last updated 16 September 2024
[67] *Ibid*

(a) Price lists are not considered as advertising materials as long as all products are listed with equal prominence.

(b) Online retailers are permitted to direct customers to their websites in response to a search for a specific POM-V or POM-VPS medicines but cannot use generic terms such as 'arthritis in dogs' in order to channel online pet owners to their sites.[68]

Stakeholder views on the Advertising Restriction

3.30 A number of online pharmacies have referred to the impact of these restrictions on either the current competitiveness of the online pharmacy channel:

(a) [✂] submitted the Advertising Restriction hinders their ability to inform pet owners of their options for POM-V online, and suggested awareness campaigns should be permitted.[69]

(b) [✂][70] noted the difficulties breaking through to a mass audience in light of the restrictions (although they noted they were able to achieve awareness of their business as such while staying within the Advertising Restriction).

(c) Vets4u[71] noted that to be compliant with the VMD's accreditation scheme meant having a website layout that was not optimised for online search result 'hits'. They also suggested there is a 'grey area' in the regulations that means some businesses advertise by brand or ailment.

(d) [✂][72] noted that they relied on word-of-mouth and organic growth in the context of a regulated sector where demand often arises post-prescription.

(e) CVS noted that in its experience, restrictions on advertising are strictly monitored and enforced by the VMD (and that CVS online pharmacy made significant efforts to comply with this).[73]

Our provisional view on the Advertising Restriction

3.31 The Advertising Restriction would be expected to affect competition, as it prevents the direct marketing of POM-V products to pet owners. This may have an impact on competition between POM-V medicine brands, and on competition between retail channels for those products (for example, online pharmacies versus FOPs). This is consistent with the evidence from online pharmacies referred to above.

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[68] *Ibid*
[69] [✂] response to CMA RFI [✂], Q7
[70] [✂] response to CMA RFI [✂] Q7
[71] Vets4U response to CMA RFI [✂] Q7
[72] [✂] response to CMA RFI [✂]
[73] CVS response to CMA RFI [✂]

3.32 The Advertising Restriction is therefore likely to contribute to pet owners being less informed about their choices in purchasing POM-V products.

3.33 We do note that the publication of price lists is exempted from the Advertising Restriction. It also appears that in practice pet owners can access online pharmacies' pricing for products they search, and the VMD's guidance envisions pet owners being able to access the websites where these prices are listed when they search for particular POM-V products online.

3.34 Overall, while we consider the Advertising Restriction is likely to weaken the competitive constraint online pharmacies might otherwise be able to provide, we are also aware of the animal and public health policy reasons underlying it. In light of those considerations, we do not conclude that the Advertising Restriction by itself is inconsistent with a well-functioning market, but the VMD may wish to consider whether there is further scope to minimise the impact of the Advertising Restriction on competition and entry by online pharmacies without disproportionate negative effects on public and animal health.

The Under Care Restriction and the prescription of parasiticides

3.35 The principles underpinning the 'under care' requirements are consistent with our understanding of the role of the vet as clinically responsible for the treatment they select for the animal under their care, and we recognise the animal and public health considerations that underpin it. However, in the course of our investigation, we have seen evidence that the way this requirement is applied could have an impact on competition, including within the context of the prescription of parasiticides, particularly on repeat prescription.

3.36 The terms 'clinical assessment' and 'under care' are not defined further in the VMRs, but the RCVS Guidance provides additional (professional) requirements on the interpretation of these concepts for practising vets. These include:

(a) a requirement that the vet, or another veterinary service provider on their behalf, must be able 'on a 24/7 basis' to physically examine the animal. They should be able to carry out 'any necessary investigation in the event that animals taken under their care do not improve, suffer an adverse reaction or deteriorate';[74] and

(b) confirmation that a 'clinical assessment is any assessment which provides the veterinary surgeon with enough information to diagnose and prescribe

[74] Guidance, Veterinary medicines, paragraphs 4.13 and 4.14

safely and effectively. A clinical assessment may include a physical examination; however, this may not be necessary in every case.'[75]

3.37 The RCVS Guidance explains the factors that may be relevant in determining whether a physical examination is necessary. Notably, a 'physical examination is required at the time of prescription in all but exceptional circumstances where a veterinary surgeon prescribes antibiotics, antifungals, anti-parasitics or antivirals' for, among others, household pets.[76]

3.38 The VMD have told us that it is 'up to the prescribing vet alone to deem how often they need to physically examine the animal. In other words, there is no legal or regulatory restriction in 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.'[77]

Under care requirements: stakeholder views on 'under care' requirement for prescribers of parasiticides

3.39 Some stakeholders have informed us that recent changes to how the RCVS interprets the 'under care' guidance on this,[78] particularly as it relates to parasiticides, has meant that vets are required to conduct a physical examination before prescribing relatively routine parasiticides, with an impact on consumers in terms of cost and choice:

(a) Some vets who participated in our qualitative research reported that these changes were badly received by vets and pet owners; for example, one vet suggested animals are sometimes unnecessarily required to attend consultations when alternatives would be feasible (such as a phone call), while another said the changes left pet owners feeling as though vets were seeking financial gain by requiring additional consultations.[79]

(b) Another vet in our qualitative research also highlighted that parasiticides are included in most pet care plans on a routine basis which may be encouraging them to be prescribed more often than in the absence of such a plan, and that a more individualised approach could therefore be beneficial.[80]

[75] Guidance, Veterinary medicines, paragraph 4.16
[76] Guidance, Veterinary medicines, paragraph 4.29(a)
[77] VMD Response to the CMA's working papers, p5
[78] RCVS website, 'Under care' - guidance (https://www.rcvs.org.uk/setting-standards/advice-and-guidance/under-care-new-guidance/) (accessed 30 July 2025).
[79] Qualitative Research with Veterinary Professionals, p79
[80] Qualitative Research with Veterinary Professionals, p99

(c) An independent FOP submitted that the new requirements for a consultation prior to prescribing such products increase administration times and professional fees to clients.[81]

(d) A large veterinary group noted the changes could frustrate pet owners given the increased cost and time required by the regulatory requirement of a vet's physical examination before prescribing parasiticides, therefore leading them to purchase lower-priced, alternative over-the-counter drugs. These nonprescription products would be less effective for the pet's condition, or be administered by the owner at an inappropriate dosage given the lack of clinical assessment and guidance from vets.[82]

3.40 In response to our February working paper on medicine regulation:[83]

(a) The BVA/BSAVA/SPVS/BVNA/VMG response recognised concerns caused by the changes to RCVS 'under care' guidance, while noting the need to tackle the growing risk of anti-microbial resistance caused by misuse and overuse, and environmental contamination. Given the negative impacts experienced by vets and owners, however, the response also acknowledged the requirement for a repeat examination may have caused inconvenience and possible additional cost, which may have outweighed the benefits of the resulting discussions around the responsible use of parasiticides, and expressed support for a review of the requirement, led by the RCVS.[84]

(b) A medicine manufacturer told us in its response that the benefit of a specific requirement to examine an animal before prescribing parasiticides is questionable (especially where the prescription is preventative), and that it has observed a reduction in FOPs changing parasiticide treatments following the introduction of this change.[85]

(c) A vet said that a physical examination had always been required, but that an opportunity had been missed to clarify that where a recent physical examination had taken place, re-examination may not be necessary (though this response considered remote examination via telemedicine in lieu of any physical examination as insufficient).[86]

(d) In the context of the exceptions to requiring a physical examination (which we consider below in the context of telemedicine), the RCVS noted the

[81] [✂] response to RFI [✂]
[82] [✂] response to RFI [✂]
[83] CMA Working Paper: Regulatory Framework for veterinary professionals and veterinary services'
[84] BVA/BSAVA/BVNA/SPVS/VMG joint response to CMA February working papers, paragraphs 35-36.
[85] Respondent A Working Paper Response, paragraph 5. The same manufacturer considers that vets should be able to exercise appropriate autonomy and judgement in relation to when they examine animals.
[86] Respondent B Working Paper Response, p17

importance of limiting this to exceptional circumstances because of the potential impact of antimicrobial resistance on animal and human health.[87]

3.41 In response to our Remedies Working Paper, Vet-AI submitted that the restriction on remote prescribing of antiparasiticides was not justified, as most parasites are not microbes.[88] It also said that in most countries other than the UK, Isoxazolines (which are POM-V products in the UK) are generally subject to a lower-level classification, permitting more effective competition.

Under care requirements for prescribers of parasiticides: wider considerations

3.42 The concerns caused by the 'under care' changes that require vets to physically (re-)examine pets when prescribing veterinary medicines such as parasiticides appear to be common. To the extent these changes make certain business models – particularly those focused on lower-cost or less intensive treatments – less feasible, they may constrain consumer choice and adversely affect competition.

3.43 We recognise that there are potentially wider policy and clinical concerns in play, relating to animal welfare and public health and safety. In a well-functioning market, we would expect competitive impacts (including on costs for consumers) to be factors that are considered when weighing relevant policy choices and setting the regulatory framework. These factors could also affect animal welfare and public health and safety if, for example, restricted choice or high prices mean animals go untreated. As explained throughout our investigation, we do not see these factors are counterintuitive of one another. Rather, we see the promotion of competition for the benefit of consumers as a way to improve animal welfare outcomes.

3.44 Although competition may be improved by the relaxation of these regulations, we recognise that the need to foster effective competition in a market is one consideration within a broad range of public interest factors that must be weighed. The development of 'under care' and 'clinical assessment' is underpinned by the need to ensure that animal welfare and public health remain at the heart of veterinary care in whatever form that may take.

3.45 Our provisional view is that the public bodies responsible for regulating the prescribing of parasiticides (Defra, VMD, RCVS) should consider the way the framework takes account of animal welfare and public health considerations and competition and consumer interests and whether each of these factors is being

[87] RCVS response to CMA February 2025 working papers, p14
[88] VetsAI response to CMA February 2025 Working Papers, p2

given the appropriate weight given the developing nature of how veterinary services are now supplied in the UK.

3.46 Specific points to consider include whether, in respect of parasiticides, there could be alternative ways of ensuring responsible prescribing other than a specific physical examination for that purpose (for example, by stipulating a wider range of exceptions to the present requirement). It might also include consideration of the classification of Prescribed Veterinary Medicines (as discussed in subsection (Re-)Classification: points to consider, which could reduce the number of products categorised as POM-V and broaden the range of medicines available for prescription outside the Under Care restrictions. It could likewise include defining the concept of Veterinary Client Pet Relationship (VCPR)[89] in a way that might provide a clearer framework for helping to determine when physical re-examination of pets to receive repeat parasiticides should take place and further the development of innovative business models such as Telemedicine.

Under Care Restriction and Remote Prescribing (including telemedicine)

3.47 We have heard concerns that the regulations governing the provision of veterinary care and the prescription of medicines may be inhibiting consumers from being offered a range of options when seeking to obtain veterinary services, including innovative new services. Examples of such services include the use of telemedicine for certain treatments or prescribing and additional routes for vets or consumers to obtain medicines. This is predominantly due to the requirement to perform a physical examination of a pet before prescribing certain medications, as described above, which poses challenges for services provided remotely or otherwise outside of the traditional FOP setting.

3.48 The RCVS has defined telemedicine as the use of electronic communication and information techniques to provide clinical healthcare remotely. This includes the provision of veterinary services via video-link, text, instant messaging or telephone,[90] or by other remote means to carry out:[91]

(a) **Remote Veterinary Consultation**: where the vet has access to clinical notes and can perform activities such as check-ups following an initial appointment, ongoing management of chronic conditions and preventative care;

(b) **Remote Prescribing**: prescribing without veterinary clinical examination or direct observation at the time of prescribing or providing where any requisite

[89] Which, in response to RCVS consultations, some organisations put forward as vital for understanding how veterinary services are provided today. CVS Response to RCVS Review of "Under Care" and 24/7 Emergency Cover, pp5-6
[90] As contained in RCVS review of the use of telemedicine within veterinary practice, Summary Analysis, March 2018, p2
[91] As contained in BVA Policy statement, BVA policy position on under care and the remote provision of veterinary services, January 2021, p5.

clinical assessment is made remotely. This may include new or repeat prescriptions; and

(c) **Remote Triage**: a service offered to clients in which a member of the vet-led team uses technology to make an initial assessment which does not include veterinary clinical examination or veterinary inspection and does not involve a diagnosis or prescribing. This can occur without access to clinical notes and will often result in referral to a vet, RVN or appropriately regulated allied professional

(d) (together, **Telemedicine**).

3.49 Our pet owners survey indicates that the use of Telemedicine is currently very limited. 7% of respondents said that they had used 'remote consultations and/or telemedicine services' in the past two years, with only 3% saying that they still used them.[92] Additionally, the survey indicates that a majority of respondents (58%) were unaware of these services.[93]

3.50 Though current usage of Telemedicine is limited, even before the COVID-19 pandemic the RCVS noted that 'the industry is changing rapidly... [there] are increasing numbers of businesses seeking to develop telemedicine services such as video consultations and chat apps directly to clients'[94]

3.51 This reflects both the development and improvement of the technology required to carry out these services as well as a growing demand for such services exacerbated by the onset of the COVID-19 pandemic.[95] The RCVS has acknowledged that human healthcare appears to be ahead of the veterinary profession in terms of developing regulatory regimes that allow for the provision of Telemedicine services.[96]

3.52 Telemedicine provides an additional avenue for consumers to access veterinary services and therefore widens access to professional care and broadens choices

[92] Pet owners survey, Q124.
[93] Pet owners survey, Q124.
[94] As contained in RCVS review of the use of telemedicine within veterinary practice, Summary Analysis, March 2018, p2
[95] As part of its Vet Futures initiative launched in 2015, the RCVS "recognised the need to review the regulatory framework for veterinary businesses to ensure a level playing field, enable a range of business models to coexist, ensure professionalism in commercial settings, and explore the implications for regulation of new technologies (eg telemedicine)". Vet Futures, Taking charge of our future: a vision for the veterinary profession for 2030, 20 November 2015. During the COVID-19 pandemic, the RCVS temporarily permitted vets to remotely prescribe veterinary medicines: RCVS Press Release, Coronavirus: RCVS Council temporarily permits vets to remotely prescribe veterinary medicines, March 2020. One professional online vet advice provider saw a 900% increase in demand due to the impact of COVID-19: Summary of Pet Parent research commissioned by Vets-AI and Joii Pet Care, 5 May 2021, p3.
[96] As contained in RCVS review of the use of telemedicine within veterinary practice, Summary Analysis, March 2018, p3.

available to pet owners. Compared to in-person examinations, Telemedicine can sometimes offer a quicker and less expensive solution.[97]

3.53 Telemedicine can be beneficial for vets, too, as another tool at their disposal[98] for them to reach existing and new patients (including those whose owners live in remote areas or have accessibility needs), prescribe certain medicines and communicate with pet owners where a visit to the consultation room may not be necessary, practical or may cause undue stress on the patient.[99] Maximising the appropriate use of Telemedicine can mean more pets can be seen by vets more often which comes with benefits to animal welfare, and efficient resource utilisation.[100]

3.54 Veterinary businesses would benefit from Telemedicine as an additional service that they are able to charge for, and being able to provide it may improve their ability to win or retain customers who value the option of remote care.[101] Submissions have also been made to the RCVS that Telemedicine offers a new way to deal with lower value items (particularly where there is no prescription or treatment needed) which means practices can concentrate on higher fee-earning consultations.[102]

3.55 There is therefore scope for the benefits of Telemedicine to be further realised within the context of veterinary services to help improve consumer choice, reduce the resource burden on vets and promote animal welfare in a greater number of settings.

3.56 Nevertheless, the offering of Telemedicines as separate services or adjuncts to traditional veterinary services requires appropriate legal and regulatory safeguards to protect the health and welfare of animals as well as maintaining public confidence in the veterinary profession.[103] A cornerstone to ensuring this protection remains in place across varying degrees of physical proximity between vet and animal is the doctrine of 'under care' including the definition of 'clinical assessment' as defined above.

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[97] Pet owners survey, Q125. 13% of respondents to our pet owners survey mentioned using remote consultations, telemedicine, or video vet services because they were cheaper than in-person services. As part of the RCVS Telemedicine Consultation, efficiency and convenience was identified as an advantage by vet professional respondents. Lower cost, convenience and speed of access to vet were identified as advantages by public respondents: RCVS review of the use of telemedicine within veterinary practice, Summary Analysis, March 2018, p15.
[98] RCVS Council Papers, January 2023, p13.
[99] RCVS review of the use of telemedicine within veterinary practice, Summary Analysis, March 2018, p5.
[100] PDSA Response to RCVS survey, January 2023 RCVS Council Papers, 16 January 2023, p63. The official policy position of the World Veterinary Association acknowledges that "telemedicine can provide benefits to animal welfare, in reduced costs and in ease of service where owners cannot travel, where there are shortages of veterinarians and in remote areas: WVA Position Statement on Veterinary Telehealth Services, 22 April 2021.
[101] 8 in 10 (82%) cat and dog owners believe online veterinary services and support should be available to those who wish to use them (JOII) Summary of Pet Parent research commissioned by Vets-AI and Joii Pet Care, 5 May 2021, p2.
[102] RCVS response to RFI [✂], Question 12. [✂] which includes minutes from a presentation from [✂] made to the RCVS.
[103] RCVS review of the use of telemedicine within veterinary practice, Summary Analysis, March 2018, p2.

How the requirements around the continued requirement for physical examination may be hindering the development of Telemedicine

3.57 First, there is a lack of clarity on the exact meaning of 'telemedicine'.[104] There have been claims that this confusion has not been helped by a lack of transparency over the RCVS Council's discussions on proposals for reform in this area.[105] The BVA argues that, as the term has been developed within the context of medicines, this limits the concept to a temporal relationship to the act of prescribing even though the practice of veterinary medicine is much more than examining and prescribing.[106]

3.58 Second, our provisional view is that there is a lack of clarity on the applicability of 'under care' and 'clinical assessment' outside of Remote Prescribing.

(a) 'Clinical assessment' is not defined or contained in the VSA at all nor in the RCVS Code or Guidance outside of the context of Remote Prescribing.

(b) Whether an animal is under the care of a vet is referenced in Schedule 3 but is only in relation to delegation to nurses and student veterinary nurses when it comes to minor surgery.[107] The concept of care and the responsibilities that come with having an animal under one's care is referenced throughout the RCVS Code and Guidance[108] but the definition of when an animal is under the care of a vet is only used specifically in relation to the prescription of POM-Vs.

(c) Third, there is a lack of clarity on the definition of 'exceptional circumstances' – that is, under what conditions vets can Remote Prescribe antibiotics, antifungals, antiparasitic or antivirals without carrying out (or being able to provide) a physical examination. This is because, although the RCVS has issued case studies which include some examples of exceptional decisions (for example a dangerous animal),[109] the Guidance does not stipulate what 'exceptional circumstances' are.[110]

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[104] For example, BVA, Policy Position on Under Care and the Remote Provision of Veterinary Services, January 2021, p4.
[105] RCVS, RCVS provide reassurance over recent Council decision to review 'under care' and 24/7 cover, 19 June 2019.
[106] BVA, Policy Position on Under Care and the Remote Provision of Veterinary Services, January 2021
[107] Treatment and operations which may be given or carried out by unqualified persons: sections 6 and 7 of the VSA and Guidance, Schedule 3 exemption, paragraph 18.4.
[108] For example, the Guidance on Veterinary Care, states at paragraph 2.1, 'The Codes of Professional Conduct state that veterinary surgeons and veterinary nurses must provide veterinary care and veterinary nursing care that is appropriate and adequate.'
[109] The case study for what would constitute an 'exceptional circumstance' in the case of a controlled drug does involve only a phone-call given the animal is distressed and unable to be transported to the practice. Nevertheless, although the vet suspects the animal will need antibiotics, the case study indicates this assessment will wait until the vet comes into the practice.
[110] The RCVS have told us that it is not possible to give an exhaustive list of what might be 'exceptional' and rely on individual vets to use their own professional judgement and use the RCVS Advice Line should they have any specific queries. The RCVS have also reiterated that it is very important that exemptions are limited to exceptional circumstances

3.59 Where there is uncertainty or confusion within the provision of regulated services, this can lead to a chilling effect on innovation as those looking to provide services within a regulatory 'grey area' do not have the required confidence they can operate in a different way to traditional practice. When regulation fails to keep up with developments in technology and changes in consumer demand, this arguably stifles innovation.[111]

3.60 The retention of the need to perform a physical examination, in all but limited circumstances, to adhere to the Guidance when Remote Prescribing restricts the provision of Telemedicine. We note that:

(a) While the temporary guidance which allowed for Remote Prescribing without a physical consultation was in place during the COVID-19 pandemic, no serious safety concerns were identified.[112]

(b) During this period the RCVS noted that clients were not making many complaints to it about remote consultations.[113]

(c) There has not been any disciplinary action brought against a vet for Remote Prescribing[114] which suggests the ongoing relaxation of the rules is not leading to an uptick in complaints for gross misconduct and therefore an increased risk to animals.

3.61 In addition to the concerns raised by pet owners and vets in subsection Under care requirements and the prescription of parasiticides, business models looking to offer an alternative to bricks and mortar premises are arguably constrained by this requirement. The RCVS has also considered that the 24/7 emergency care and pain relief requirement could be seen as anticompetitive in favouring larger groups with national coverage over smaller groups.[115]

Under care requirements: stakeholder views on Telemedicine impact

3.62 We have received submissions from vets who underscore the importance of having 'hands on the animal' not only because this increases their confidence in accurately diagnosing[116] and prescribing the best treatment, but also to ensure other symptoms are identified which are outside the initial purpose of a

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because of the potential impact of resistance to antimicrobials on both human and animal health. RCVS Response to CMA February 2025 Working Papers, p14.

[111] CMA Competition Assessment Guidelines, Part 2: guidelines, p25, paragraph 4.1

[112] RCVS survey, January 2023

[113] RCVS response to RFI1, Q12. We note that the COVID-19 pandemic did have an impact on complaints made to the VCMS: VCMS Insight Report 2020-21 determined that Covid-19 may have contributed to and exacerbated complaints.

[114] RCVS response to RFI [✂], Q23.

[115] RCVS response to RFI [✂], Q12.

[116] While the temporary guidance which allowed for Remote Prescribing without a physical consultation was in place during the COVID-19 pandemic, data was collected which showed that respondents felt less confident in carrying out their services remotely when compared to conducting a physical assessment: ies Report, RCVS Covid-19 Survey 2020, September 2020, p107.

consultation.[117] Other concerns and views that we have been made aware of during this investigation include:

(a) Leaving the need for a physical examination to the individual judgement of each vet has the potential to put undue pressure and challenge upon individuals and leaves scope for an increase in complaints. This pressure is said to be a greater cause of concern for less-experienced vets.[118]

(b) The reduction in the need for a physical examination between vets and pets erodes the unique and important relationship between vet, pet and owner.[119]

(c) There is a fear that telemedicine companies would be able to find a centralised/national out-of-hours provider and that this would disadvantage independent practices.[120]

(d) Because the costs for a FOP to function (to cover premises and equipment, for example) is greater than that required by Remote Prescribers, this will lead to 'cherry picking the bread-and-butter income' that FOPs are legally required to provide.[121]

3.63 We received a number of responses to our February 2025 working papers on Telemedicine:

(a) The BVA/BSAVA/SPVS/BVNA/VMG response outlined the value that a effective Telemedicine can add to veterinary services, while expressing the view that Telemedicine 'should be limited to offering generic information and advice only and making an onward referral to physical veterinary services'. It supported the view that the 'RCVS, as part of their review of the implementation of the Under Care guidance, could consider defining the concept of the VCPR in a way that might provide a clearer framework for developing telemedicine'. [122]

(b) The FIVP noted that regulatory restrictions requiring physical examinations before prescribing certain medicines disproportionately impact the ability of independent FOPs to offer telemedicine services, and supported a review of the regulatory framework to ensure it supports competitive processes and good consumer outcomes while safeguarding animal and public welfare.[123]

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[117] For example, a pet could receive a Remote Veterinary Consultation for its long-term condition but the owner does not have enough knowledge to identify certain symptoms for another ailment which would be picked up in the physical presence of a vet. ies Report, RCVS COVID-19 Survey 2020, September 2020, p107.
[118] RCVS response to RFI1, Q12, which summarises a response from [✂] to the RCVS's under care survey
[119] BVA Policy statement, BVA policy position on under care and the remote provision of veterinary services, January 21, p13
[120] RCVS RFI [✂], Q28, summarising SPVS views as expressed in October 2022 on under care/out-of-hours.
[121] RCVS, RFI [✂], Q12, referencing SPVS views in response to the RCVS under care consultation.
[122] BVA/BSAVA/BVNA/SPVS/VMG joint response to CMA February working papers, paragraphs 37-41.
[123] FIVP response to CMA February 2025 Working Papers, pp5-6.

(c) An independent vet submitted that telemedicine cannot replace a physical VCPR, and that effective telemedicine is an adjunct to deliver services already under care of a vet (which will include a physical examination).[124]

(d) As noted above, the RCVS considers it is important to limit the number of 'exceptional circumstances' under which vets can prescribe antibiotics, antifungals, antiparasitic or antiviral medication because of antimicrobial resistance concerns.[125]

Under care requirements: points to consider on Telemedicine

3.64 Overall, the evidence above suggests that more could be done to facilitate the use of Telemedicine to deliver more choice and, potentially, more competitive pricing, to consumers. However, we also recognise that complex clinical, health and safety considerations likely be involved in any such adjustment of the regulatory framework.

3.65 Our provisional view is that there may be opportunities to enhance competition if Defra, the VMD and RCVS, as the public bodies responsible for regulating the delivery of veterinary services (including the prescribing of medicines) keep under review, and actively identify, aspects of the regulatory framework that could be adjusted to enable more widespread, responsible use of Telemedicine.

Classification Restriction: (Re-) classification of Prescribed Veterinary Medicines

3.66 Determination of the initial classification for a veterinary medicine (for example, POM-V, POM-VPS or AVM-GSL,[126] and decisions to reclassify those medicines are granted by the VMD following submissions made to them by the MA holders.[127] 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 'off the shelf' purchases.

[124] Respondent B Working Paper Response, pp 3 and 17.
[125] RCVS response to CMA February 2025 working papers, p14.
[126] RCVS Code, Veterinary Medicines
[127] VMD response to CMA Working Papers

Observations and evidence on (re-) classification of Prescribed Veterinary Medicines

First Authorisation

3.67 When setting the distribution category at first authorisation, the VMD told us it will always use the less restrictive classification that is possible when considering the use, diagnosis and safety profile of a product upon first registration.[128] The VMD also noted to us that this facilitates availability and thereby improves animal health/welfare.[129] The VMRs also specify, for certain veterinary medicines, the initial distribution category: for example, products containing antimicrobials (except Northern Ireland) or those 'intended for administration following a diagnosis or clinical assessment by a veterinary surgeon' must be categorised as POM-V.[130]

3.68 If the product is a generic, it will be granted the same distribution category as that of the reference product. If the MA applicant requests a higher distribution category, they will be 'advised that a lower distribution category is available' after assessment of the application.[131] It is unclear whether this sufficiently motivates MA holders to choose a lower distribution category for their generic and therefore widen the accessibility of certain medicines. Even when there is precedent for a lower distribution category for another generic of the same reference product, the new generic has to have the same distribution category as the reference product initially. The MA holder will then need to subsequently apply for a variation post-authorisation.[132] It is possible this involves additional cost and resources for the MA holder; if so, this might discourage the MA holder from pursuing a lower categorisation (and may therefore be a reason for revising the approach to permit a lower distribution category upon authorisation, if warranted from a safety perspective.).

Review / change of the distribution category

3.69 Though there is evidence manufacturers have sought lower classifications in a number of instances, there is the possibility that products could be retained at a higher distribution category than is required vis-à-vis their risk profiles. Although the VMD is legally permitted to require a compulsory variation to change the distribution category, this is only to raise the distribution category to mitigate risks (the VMD is also permitted to require the distribution category to be lowered, but

[128] VMD Response to CMA February 2025 Working Papers, p7.
[129] VMD letter to CMA. 9 October 2024.
[130] VMRs, Schedule 3, paragraph 1
[131] VMD letter to CMA. 9 October 2024.
[132] VMD letter to CMA. 9 October 2024.

has told us it cannot envisage an example where this would be required or appropriate)[133]

3.70 Therefore, the only route to re-classification to a lower category and thus access to wider distribution channels appears to be through a decision by each MA holder to seek a variation to its licence for its specific product. AMTRA in its response to our Issues Statement submitted that although 'those best placed to make safety assessments on existing authorised medicines are the Marketing Authorisation Holder and the VMD…it is not clear to AMTRA that all existing POM-V medicines, having demonstrated a five-year period of safe use in the field, continue to justify a POM-V classification.'[134] We note that recent amendments to the VMRs removed the requirement to renew an MA five years following initial authorisation in England, Scotland and Wales.[135] We have been told that the removal of this renewal process was to reduce burdens on pharmaceutical companies but may result in keeping medicines at POM-V as this removes an opportunity to reconsider reclassification.[136]

3.71 The distribution category is generally considered on a product specific basis. Once the first product in a class achieves a lower than initial distribution category, other MA holders may follow suit and submit a variation for their similar products. This is a decision for the MA holders as the VMD does not mandate that the distribution category of all similar products is changed.[137] It is therefore possible that very similar products sit at different distribution levels simply because certain MA holders are not sufficiently incentivised to go through the re-classification process.

3.72 In the 2003 CC Report, the Competition Commission had concerns that 'manufacturers can have a commercial interest in the choice of distribution classification (including deciding whether to seek reclassification), going beyond questions of safety, quality and efficacy'.[138]

3.73 The 2003 CC Report recommended that the VMD automatically review classification at MA renewal, to address these concerns.[139] Though government responded positively to this recommendation, it was noted that legislative amendment may be required to implement it.[140] We are not aware of any such legislative change, and the VMD does not routinely carry out such reviews at present (other than as a result of pharmacovigilance monitoring of adverse event signals).[141]

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[133] VMD letter to CMA. 9 October 2024.
[134] AMTRA IS Response, 30 July 2024, page 2.
[135] Explanatory Memorandum to The Veterinary Medicines (Amendment etc.) Regulations 2024, paragraph 7.6(e).
[136] Note of CMA meeting with AMTRA, 25 May 2025
[137] VMD letter to CMA. 9 October 2024.
[138] 2003 CC report, p53, paragraph 2.204.
[139] 2003 CC report, Recommendations on classification, p53 onwards.
[140] House of Commons, Written Ministerial Statements, Veterinary Medicines, 9 July 2003.
[141] VMD letter to CMA. 9 October 2024.

3.74 VMD have told us 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.[142]

Stakeholder views on (re-) classification of Prescribed Veterinary Medicines

3.75 Some stakeholders suggested that some Prescribed Veterinary Medicines may be retaining their 'high' classification (eg POM-V) for longer than necessary, due in part to the way re-classification is driven by the MA holder (the manufacturer).[143] This may make it more difficult – and expensive – than necessary for consumers to access these products. This is because the restrictions around POM-Vs (for example, the need for a prescription from a vet) means the pet owner will likely have fewer options for purchasing the product, which in turn may mean additional cost: for example, the payment of a consultation fee, and/or prescription/dispensing fees. Specifically, we note:

(a) [✂][144]

(b) We have also seen internal documents from manufacturers suggesting that, in certain instances, re-classifying to 'off the shelf' status was explored (even if as an isolated event) to drive sales of a medicine [✂],[145] [✂],[146] from which we infer there may be commercial incentives to seek such re-classification in specific cases.

(c) Medivet told us that the current classification rules work well for the sector and protect medicines from being sold outside of regulated channels which is a risk to both animal and in the case of parasiticides, environmental health.[147]

(d) The National Office for Animal Health (NOAH)[148] have told us that classification is not driven by MA holders but regulatory and legislative requirements. They broadly support the idea of reclassification in appropriate cases, where a thorough risk-benefit assessment has been conducted and where usage risks can be mitigated through information on the packaging.[149]

(e) An independent vet gave examples where reclassification had, in his view, negative effects on the environment and explained that it is often better that medicines retain a POM-V classification to ensure appropriate control.[150]

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[142] VMD response to CMA Working papers, p7
[143] AMTRA Response to the Issues Statement (AMTRA IS Response), 30 July 2024.
[144] [✂]
[145] Medicine manufacturer response to RFI of August 2024.
[146] Medicine manufacturer response to RFI of August 2024.
[147] Medivet response to February 2025 Working Papers, paragraph 7.39
[148] NOAH is the trade association representing the UK animal health industry - including companies that research, develop, manufacture and market licensed animal medicines in the UK.
[149] NOAH response to February Working Papers, p3
[150] Respondent B Working Paper Response, p18

3.76 AMTRA told us that:

(a) the reclassification of parasiticides as POM-VPS (one classification lower than POM-V which allows other regulated professionals to prescribe) could offer the advantage of making a wider choice of parasiticides more accessible to pet owners without removing clinical oversight altogether.[151]

(b) There are several active ingredients within the isoxazoline group which have been on the market for over five years which is the typical timeline for reclassification but which still remain at POM-V.[152] AMTRA considers that though there are no legislative barriers to reclassification, the ability of non-POM-V medicines to compete is constrained by the limited range on the market.[153]

3.77 Similarly, in response to our Remedies Working Paper, Vet-AI submitted that in most countries other than the UK, Isoxazolines (which are POM-V products in the UK) are generally subject to a lower-level classification, permitting more effective competition.[154]

3.78 The VMD has told us that 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.[155]

Re-classification: points to consider

3.79 Overall, taking this evidence into account, our provisional review is that the Classification Restriction in principle is not creating significant barriers for pet owners to access a wider range of medication, including those which may be of a lower cost to them (including by removing the need to pay for a vet consultation). The Classification Restriction is driven by the policy goals of retaining necessary clinical oversight over the prescription of veterinary medication for the benefit of animal health and environmental protection and we recognise the importance of this.

3.80 Nevertheless, as part of our investigation it has been communicated to us that there are examples of products (particularly certain parasiticides) which either (a) have a safety record spanning several years which in theory would allow them to be re-classified to a lower category or (b) have been re-classified but could have potentially been re-classified sooner. It therefore seems to us that the VMD [and other relevant bodies] could consider reflecting on ways to further stimulate the re-

[151] AMTRA response to February Working papers
[152] Note of CMA meeting with AMTRA, 25 May 2025
[153] AMTRA response to February Working Papers
[154] Vet-AI response to Remedies Working Paper, p2
[155] VMD response to CMA working papers, p6

classification of veterinary medicines to increase access to these products outside of the FOP setting. This is particularly in light of the recent removal of the need to renew MAs, which represents the loss of a touchstone between manufacturers and the VMD to stress-test whether a POM-V classification continues to be appropriate after five years of use in the market.

3.81 Part of this consideration could be a renewed look at the role of other regulated professionals such as SQPs and pharmacists could play in providing a level of clinical oversight and (in the case of parasiticides, environmental protection determinations) to provide comfort that more medications could be re-classified one step down to POM-VPS. In conjunction, work would need to be done to raise the awareness of these alternative regulated channels to acquire medication from these professions as opposed to a vets consultation room.

Wholesale restriction

3.82 Under the VMRs, FOPs are permitted to obtain supplies of Prescribed Veterinary Medicines only from businesses holding a 'wholesale dealer's authorisation' (WDA).[156] Businesses that obtain such a licence must comply with the requirements of Good Distribution Practice (GDP) and the VMRs in managing the procurement, storage, transportation and supply of medicines into the veterinary market.[157]

3.83 Consistent with that requirement, only businesses holding a WDA are permitted to supply veterinary medicines wholesale. Exceptionally, retailers of veterinary medicines are permitted to supply one another 'for the purpose of alleviating a temporary supply shortage that could be detrimental to animal welfare'.[158]

Observations on the wholesale restriction

3.84 In principle, the Wholesale Restriction could affect competition by limiting the number of sellers of veterinary medicines from whom FOPs can purchase.

3.85 We are also aware that the Wholesale Restriction may not be the primary factor that prevents such sales: in principle, we expect an online pharmacy business that wished to engage in equivalent wholesale to FOPs could obtain a Wholesale Dealer's Authorisation and do so – either as a wholesaler or by utilising an alternative business model that allows for both business-to-business and retail sales of medicines.

[156] VMRs regulation 13, and schedule 3 paragraphs 2 and 16.
[157] VMD, Good Distribution Practice for Veterinary Medicinal Products in Great Britain, published June 2025
[158] VMRs, schedule 3, subparagraph 2(5)

Stakeholder views on the wholesale restriction

3.86 The VMD told us that the requirement for wholesalers to possess a Wholesale Dealer's Authorisation is important as it safeguards the supply chain for Prescribed Veterinary Medicines: for example, the quantities that are involved in wholesale supply require a greater degree of control and scrutiny, which the requirement to hold a Wholesale Dealer's Authorisation involves.

3.87 An LVG told us that the Wholesale Restriction 'act[s] as a barrier to veterinary businesses accessing medicines at competitive prices and therefore limits their ability to set retail prices more competitively'.[159] They explained that allowing veterinary businesses to purchase directly from other retailers would increase purchasing options which potentially could reduce costs, noting that they have not identified any material risks involved with this avenue of purchase. This LVG would 'likely consider acquiring POM from retailer should this become an alternative.'[160]

3.88 Another LVG told us that they would 'not see an issue with online retailers being allowed to sell to FOPs' but noted that they thought it would be very rare for online prices to be below wholesale prices for independents in practice given the impacts of buying group membership these practices are able to benefit from.[161]

3.89 The NVS said that 'online pharmacies with a Wholesale Dealer's Authorisation could choose to pursue wholesale supply but currently choose not to' explaining that online pharmacies are primarily established as direct-to-consumer businesses rather than supplying the full range of medicines that wholesalers provide.[162]

3.90 As part of our investigation, we have asked a number of online pharmacies why they have chosen not to enter the market as wholesalers.

(a) We received evidence that a number of online pharmacies do hold a wholesale license,[163] which suggests that the requirement to have such a licence is not a barrier to entry.

(b) One online pharmacy explained to us that they are not set up as a wholesaler, particularly as wholesaling requires significant scale and the capacity to provide certain medications which are not made available direct to buyer, such as those used in euthanasia.[164]

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[159] Medivet response to February 2025 Working Papers. They added that they are in favour or 'easing the regulatory restrictions that currently prescribe a very limited list of wholesalers from whom veterinary practices are allowed to purchase medicines' and that 'veterinary practices should be allowed to purchase from other retailers, such as online pharmacies.' p72
[160] *Ibid*
[161] IVC response to CMA February 2025 Working Papers, p61
[162] NVS response to CMA February 2025 Working Paper, paragraphs 1.3.3 and 4.2
[163] VMD Register of veterinary-only Wholesale Dealer Sites.
[164] Note of CMA call with [✂]

3.91 Wholesalers have also offered us a number of explanations for the lack of online pharmacies entering the wholesale market. These include:

(a) The stringent controls the Wholesale Dealers Authorisation imposes on the supply chain to which online pharmacies are not obligated to comply with.[165] And the costs associated with adhering to these requirements.[166]

(b) Management and logistical challenges, staffing requirements and administrative burden of liaising with FOPs.[167]

(c) A lack of incentive for market entry as the majority of wholesaler discount is passed on to the online pharmacy (14% of 15% of list price).[168]

3.92 We also spoke to a number of independent FOPs and a membership organisation about the likelihood of them wanting to switch from their wholesale provider to an online pharmacy. Their responses included:

(a) Wholesalers provide an excellent service (for example, next day delivery) and tend to have good relationships with their clients.[169]

(b) Purchasing from online pharmacies would benefit LVGs given they own a number of online pharmacies.[170]

(c) Purchasing from online pharmacy would lower rebates received from manufacturers as these purchases would not count towards their rebate calculations.[171]

(d) One independent FOP told us they would consider purchasing from online pharmacies if the prices were sufficiently competitive.[172]

3.93 Overall, taking this evidence into account, our provisional view is that the Wholesale Restriction is unlikely to be a primary factor that prevents the number of sellers of veterinary medicines from whom FOPs can purchase. It appears to us that an online pharmacy which obtained a Wholesale Dealer's Authorisation may face other barriers in effectively supplying FOPs. This includes the limited demand from FOPs to purchase medicines from an online pharmacy rather than their current wholesalers.

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[165] [✂] response to CMA RFI [✂]. These include document management, temperature controls, hygiene principles, return and disposition of product, qualified persons and audits [✂] response to CMA RFI [✂]
[166] [✂] response to CMA RFI [✂]
[167] [✂] response to CMA RFI [✂]; [✂] response to CMA RFI [✂]; [✂] response to CMA RFI [✂]
[168] [✂] response to CMA RFI [✂]
[169] [✂] response to RFI [not 174] [✂]; [✂] response to RFI [not 174] [✂]
[170] [✂] RFI response [not 174] [✂]; [✂] response to RFI [not 174] [✂]
[171] [✂] response to RFI [not 174] [✂]
[172] *Ibid*