

# Does the prescribing 'cascade' affect affordability of medicines in UK veterinary practice?

## A survey of practising veterinary surgeons

David Mills MA VetMB PhD CertAVP(VC) CertAVP(AWSEL) MRCVS  
Arlo Guthrie, Editor, vetsurgeon.org & vetnurse.co.uk

### Introduction

When prescribing medical treatments, veterinarians in the EU and UK must abide by the 'cascade' as per the Veterinary Medicinal Products Regulation (EU 2019/6) and, in the UK, the Veterinary Medicine Regulations 2013.

Simply put, the cascade works in a step-wise manner: firstly medication licensed for the condition and species must be used; if these are not available then medications licensed for another (non-human) species must be used; lastly if no licensed veterinary medication exists, then human or generic medications can be used.

The cascade may be bypassed if there exists an exceptional reason but cost of medication has not been deemed as such (VMD, 2024).

Many veterinary medicines have human generic equivalents that are significantly cheaper to purchase. One such example amongst many would be meloxicam, for which the human 7.5mg tablets have a list price of 23p per tablet<sup>1</sup> whereas the veterinary licensed equivalent (Metacam 2.5mg tablets, Boehringer Ingelheim) would be around £2.80<sup>2</sup> (for 7.5mg), a 10-fold difference. The requirement to use veterinary-licensed medication over human generics therefore potentially represents a significant cost factor for owners.

The cascade was introduced to give some flexibility to EU Directives 81/851/EEC which had been introduced primarily to safeguard public health by requiring veterinary medicines to be subject to authorisation and quality control.<sup>3</sup>

It also safeguards pharmaceutical companies' investment in licensing products by mandating their use.

Whilst this has undoubtedly led to the development of new and effective drugs for veterinary use supported by high-quality research (e.g. pimobendan in canine cardiology), there has also emerged a trend of licensing human drugs that have been in safe widespread use for years (e.g. metoclopramide, apomorphine).

Publicly, some companies have stated the importance of such 'retro-licensing' to their ongoing profitability.<sup>4</sup> Licensed veterinary agents would typically be expected to be many times more expensive than their human equivalents, with at best questionable improved safety profiles. These agents are more straightforward and cheaper to bring to market than novel agents, involving development but little research, and represent a shrewd investment for pharmaceutical companies.

No such cascade exists outside of the UK/EU and there is no convincing evidence that animals in other jurisdictions, commonly prescribed human drugs, are provided with a lower standard of care or at risk of more adverse medication reactions.

In recent years, the veterinary industry in the UK has attracted sustained public attention centred around its affordability to owners, especially with above-inflation increases in veterinary fees being widely reported.<sup>5</sup>

On 23 May 2024, the UK Competition and Markets Authority (CMA) launched a formal investigation into competition in the companion animal veterinary sector, specifically looking at how ownership may impact pet owner consumer choice around pricing, ownership and service levels, within which the impact of the cascade on affordability may be considered. Concerns about the affordability of veterinary care for owners, which may be significantly impacted by cost of medications, have never been more pertinent within the professional and wider public discourse.

In this study, the authors sought to determine practising UK veterinary surgeons' perception of how much the requirements of the cascade impact affordability of veterinary care for owners.

This was part of wider survey-based research into factors affecting clinical decision-making. To the authors' knowledge, this is the first time the UK profession has been surveyed for its views on this topic.

## **Methods**

### *Survey*

Between 6 November and 15 December 2024, UK veterinary surgeons were invited to fill out an online survey of nine questions related to their approach to clinical practice, one of which related to the effect of the cascade on affordability.

The cascade-related question: "In recent years several drugs have been given a veterinary licence when previously much cheaper human generics were used effectively (e.g. amlodipine, apomorphine, metoclopramide, mirtazapine). How often do you find that your clients are unable to afford veterinary licensed drugs which you are legally required to prescribe under the cascade?", had 5 possible answers of "very often" (at least once a week), "often" (1-4 times a month), "occasionally" (once a month), "rarely" (less than every 2 months), or "never". Details about participants' field and type of practice, nature of employer, and years in clinical practice were also collected.

The open-access survey link was disseminated to veterinary surgeons via a veterinary online forum, social media and by both authors to colleagues.<sup>6</sup> Surveys were not mailed directly to participants. Responses were excluded if they were duplicated, respondents were not UK practising veterinary surgeons, or if surveys were returned incomplete, that is, all questions related to clinical practice, employment type, and experience had to be completed for the responses to be used. The survey was run through Alchemer.<sup>7</sup>

### *Ethical approval*

The methodology described for data collection was approved by the RCVS Ethics Review Panel in November 2024.<sup>8</sup>

## **Results**

1144 responses were received. 234 were excluded due to being incomplete (n=225) or being non-UK practising (n=9), leaving 910 usable responses.

### *Respondent population factors*

Most responses came from companion animal (90%) and first-opinion (87%) practitioners (Table 1). Corporate<sup>9</sup> group employees were the largest group (53%), following by employees of independent practices (37%) which together made up 90% of responses. More experienced clinicians (10-20 years and 20-40 years in practice) represented almost two-thirds of responses (64%). Very low numbers of responses came from farm, exotics, charity and academic practitioners.

Area of practice			Practice type			Employer type			Years in clinical practice		
	n	%		n	%		n	%		n	%
Companion	822	90	First opinion	788	87	Corporate	482	53	20-40 years	318	35
Mixed	42	5	3ry referral	46	5	Independent	335	37	10-20 years	260	29
Equine	32	4	2ry referral	42	5	Other	42	5	0-5 years	170	19
Farm	7	1	Other	34	4	Charity	35	4	5-10 years	162	18
Exotics	6	1				Academic	16	2			

Table 1. Completed responses grouped by area of practice, practice type, employer type and years in clinical practice.

Approximately 80% of practising veterinary surgeons in the UK work within companion animal practice, with 10% in each of equine and farm animal,<sup>10</sup> though there is some crossover in mixed practice environments; respondents' area of practice appeared to correlate with this distribution. 'Corporate' groups own approximately 60% of UK veterinary practices<sup>11</sup> and would therefore be expected to employ a similar proportion of the veterinary surgeon workforce, correlating with respondent employer type distribution seen here.

In terms of years in clinical practice, correlation with UK-practising veterinary surgeons was also reasonable: with 20-40 years made up 35% of respondents (UK-practising vets 26%), 5-10 years 20% (28%), 10-20 years 29% (28%) and 0-5 years 19% (26%).<sup>12</sup> At the time of the survey, there were 16237 UK-practising companion animal veterinary surgeons,<sup>13</sup> meaning a completion rate of 6% for the largest respondent group.

#### *Perception of frequency that the cascade affects affordability of medication for owners*

Across all respondents, in answer to how often they find that owners are unable to afford licensed drugs that veterinary surgeons are legally obliged to prescribe under the cascade, "often" (1-4 times per month) was the most common (38.8% of responses), followed by "very often" (at least once per week, 25.8%) (Table 2). Together these represented almost two-thirds (64.6%) of all responses, which rose to 89% when considered along with "occasionally" (once per month, 24.6%). These response distributions were closely mirrored across most subgroups (Figure 1) but especially so in the companion animal practitioner, first opinion, corporate employer and independent employer subgroups (Table 2) which made up the largest respondent subgroups. "Rarely" (less than every 2 months) and "never" represented only 10% of responses. Although respondent numbers were low (n=7), the farm subgroup did not follow this trend, with almost half (42.9%) of responses detailing that the cascade "never" caused issues with affordability of medication for owners.

#### *Calculation of number of companion animals / owners affected in the UK*

Despite data on the number of veterinary consultations occurring per unit of time in the UK not being available, it can be estimated how many animals/owners are affected by affordability issues created by the cascade (Table 3). Applying the responses of companion animal practitioners to the whole of the UK-practising veterinary surgeon workforce (n=16237), a conservative estimate is that 8400 owners per week (33700 per month; 438000 per year)<sup>14</sup> are unable to afford licensed medication for their animal. It is estimated that there are 22.2 million companion animals in the UK, made up of 10.6 million dogs, 10.8 million cats and 0.8 million rabbits in the UK.<sup>15</sup> The claim rate on animal insurance, which gives an indication of 'illness prevalence', is estimated at 26% over a 3-year period, relating to 8.7% per year.<sup>16</sup> which would mean 1914000 animals requiring veterinary attention per year. Potentially, 23% of owners seeking requiring veterinary attention each year would have trouble affording licensed medication for their animals, based on these survey results.

<b>Overall</b>					
	<b>Very often (n, %)</b>	<b>Often (n, %)</b>	<b>Occasionally (n, %)</b>	<b>Rarely (n, %)</b>	<b>Never (n, %)</b>
<b>All response (n=910)</b>	235 (25.8%)	353 (38.8%)	224 (24.6%)	82 (9%)	16 (1.8%)
<b>Area of practice</b>					
Companion (n=822)	216 (26.3%)	320 (38.9%)	201 (24.5%)	74 (9%)	11 (1.3%)
Mixed (n=42)	12 (28.6%)	20 (47.6%)	8 (19%)	1 (2.4%)	1 (2.4%)
Equine (n=32)	6 (18.8%)	9 (28.1%)	11 (34.4%)	5 (15.6%)	1 (3.1%)
Farm (n=7)	0 (0%)	1 (14.3%)	2 (28.6%)	1 (14.3%)	3 (42.9%)
Exotics (n=6)	1 (16.7%)	2 (33.3%)	2 (33.3%)	1 (16.7%)	0 (0%)
<b>Practice type</b>					
First opinion (n=788)	217 (27.5%)	308 (39.1%)	182 (23.1%)	71 (9%)	10 (1.3%)
2ry referral (n=42)	8 (19%)	15 (35.7%)	15 (35.7%)	3 (7.1%)	1 (2.4%)
3ry referral (n=46)	2 (4.3%)	21 (45.7%)	15 (32.6%)	6 (13%)	2 (4.3%)
Other (n=34)	8 (23.5%)	9 (26.5%)	12 (35.3%)	2 (5.9%)	3 (8.8%)
<b>Employer type</b>					
Independent (n=335)	72 (21.5%)	130 (38.8%)	87 (26%)	40 (11.9%)	6 (1.8%)
Corporate (n=482)	143 (29.7%)	183 (38%)	117 (24.3%)	33 (6.8%)	6 (1.2%)
Charity (n=35)	9 (25.7%)	15 (42.9%)	7 (20%)	1 (2.9%)	3 (8.6%)
University (n=16)	1 (6.3%)	6 (37.5%)	6 (37.5%)	3 (18.8%)	0 (0%)
Other	10 (23.8%)	19 (45.2%)	7 (16.7%)	5 (11.9%)	1 (2.4%)
<b>Years in clinical practice</b>					
0-5y (n=170)	61 (35.9%)	66 (38.8%)	26 (15.3%)	13 (7.6%)	4 (2.4%)
5-10y (n=162)	51 (31.5%)	71 (43.8%)	29 (17.9%)	9 (5.6%)	2 (1.2%)
10-20y (n=260)	66 (25.4%)	98 (37.7%)	68 (26.2%)	23 (8.8%)	5 (1.9%)
20-40y (n=318)	57 (17.9%)	118 (37.1%)	101 (31.8%)	37 (11.6%)	5 (1.6%)

Table 2. Frequency of the cascade's effect on owners' ability to afford medication over all respondents and within different areas of practice, type of practice, employer type and respondents' years in clinical practice. "Very often" (at least once a week), "often" (1-4 times a month), "occasionally" (once a month), "rarely" (less than every 2 months), or "never".

## Discussion

Veterinary surgeons working in the UK perceive that the legal restrictions of following the cascade frequently cause affordability issues around medications for owners. In two-thirds of responses received, veterinary surgeons detailed that owners very often (at least once per week) or often (1-4 times a month) were unable to afford licensed medications to treat their animals; in nearly 90% of responses this issue was encountered very often, often or occasionally (once per month).

Respondents closely mirrored the make up of the UK veterinary profession in terms of clinical area of practice, practice type, employer type and years in clinical practice: they were heavily weighted (90% of respondents) towards working in first opinion, private (corporate and independently owned) companion animal practice so the survey can be considered representative.

**Based on this survey**, up to 23% of owners in companion animal practice may face affordability concerns linked to the use of licensed medication. These results were observed regardless of practice or employer type or years' experience of responding veterinary surgeons.

In the context of the current CMA review, a NOAH Statement supporting the cascade focused on safety and efficacy of licensed medications, encouraging the development of new medicines and how using non-licensed drugs (extemporaneous or human preparations) could be more costly.<sup>17</sup>

The cascade helping to ensure the safety and efficacy of medication is predicated on the 'rigorous testing' required to obtain a veterinary licence. Safety aspects may be contentious, given that a considerable number of veterinary medicines are adapted from the human pharmaceutical market (either used in humans (e.g. antimicrobials) and veterinary patients concurrently) or having been unsuitable for human therapy but efficacious in animals (e.g. pimobendan) and so have already undergone extensive pre-clinical testing in a variety of species.

Excipients in drug formulations may differ between human and veterinary medications, but are often very similar (e.g. meloxicam tablets);<sup>18,19</sup> in any case whilst veterinary medications may cause reactions if consumed by humans, the reverse – again from extensive pre-clinical/animal testing – is extremely unlikely.

Moreover, were safety of non-licensed medications a real-life concern then jurisdictions where no cascade exists – such as the US – would be expected to see greater issues with adverse reactions or treatment failures. Given there are an estimated 90 million dogs and 74 million cats in the US<sup>20</sup> – 8 times that of the UK – then these would be voluminous.

Improved efficacy afforded by the cascade is also somewhat contentious. Whilst for novel agents efficacy studies showing a positive benefit are required for market authorisation (e.g. bedinvetmab), for drugs that are being added to an existing class (e.g. NSAIDs) normally only a non-inferiority study – scientifically far less 'rigorous' – against a current licensed agent is required.

For new formulations of established active ingredients (e.g. meloxicam) no such efficacy study is required.

In recent years, many human medications have been licensed for use in animals after years of use as human generic medications; clinical effectiveness is only established by post-hoc evidence of benefit which itself is rooted in clinician experience. It is unlikely that clinicians would continue to use products that appeared clinically ineffective.

It does not follow that veterinary licensed agents are, due to their market authorisation requirements, inherently better. Take, for instance, veterinary licensed methadone – whilst, based on a small study population, it is efficacious against severe pain, it does not entail that it is more efficacious than human generic morphine, used for decades years in many millions of animals with high clinical effectiveness.

To an extent this has been mirrored in recent years with veterinary licensing of agents that have been used safely and effectively in their human generic form for decades (Table 3); clinical effectiveness of such agents had been established through experience and there is no evidence that the newer licensed forms are any

more effective. Such a practice predates the cascade, given many anaesthetic agents (e.g. medetomidine, propofol, ketamine) were used in their human form for years before a veterinary licence was obtained for them often in exactly the same concentration and very similar pharmacological mixture. To champion the cascade as a defender of safety and efficacy, therefore, appears at best highly questionable.

Drug	Veterinary licensed cost (£ per tablet or unit)	Human generic cost (£ per equivalent unit)	Order of cost difference <sup>^</sup>
Amoxicillin 250mg	0.60	0.05	12
Amlodopine 1.25mg	0.32	0.08	11
Apomorphine	88.91	1.46	61
Doxycycline 100mg	1.52	0.11	14
Lactulose*	0.26	0.012	22
Meloxicam	0.93	0.08	12
Metoclopramide oral liquid	0.21	0.04	6
Metronidazole 200mg	0.30	0.07	4
Mirtazapine*	46.28	0.8	58
Paracetamol/codeine	0.37	0.038	10
Spirolactone 50mg	1.44	0.14	10
Tramadol 50mg	0.19	0.008	24

Table 3. Cost comparison of a selection of veterinary licensed drugs with human generic equivalents. Order of cost difference is how many times more expensive the veterinary licensed drug is compared to the human equivalent. Veterinary cost is per tablet or millilitre of drug. Prices are veterinary wholesale prices except where denoted by \* = online private customer price. Human generics prices taken from British National Formulary. Prices correct as of June 2025. ^ = to nearest whole number. BNF: [bnf.nice.org.uk](http://bnf.nice.org.uk)

The idea that non-licensed medication may increase the cost to owners is based on such drugs possibly lacking efficacy and therefore requiring repeated treatment courses. Treatment failures are routinely underreported in veterinary medicine, and there is no mechanism for reporting issues in non-licensed drugs;<sup>21</sup> it is impossible therefore to determine whether licensed or non-licensed medications are subject to more suboptimal outcomes. Any opinion on such matters is just that, rather than being evidence-based.

It is straightforward to argue that given the close similarity between human and veterinary products (active ingredients same, excipients very similar) then there is no compelling scientific reason as to why treatment failures would be expected to be more in non-licensed medications.

Veterinary licensed medications are also not immune from quality issues.<sup>22</sup> It is clear that veterinary licensed medications, with very similar compositions, are significantly more expensive both to veterinary practices and, subsequently, owners.

For example, Pardale-V, a licensed paracetamol/codeine mixture costs around 30p at wholesaler prices; by comparison an almost identical human generic (including excipients) would be 3p per tablet. There are many examples of similar 10-20 fold differences in cost per unit across licensed veterinary medicines compared to their human counterparts to the extent that, on a basic level, even if there were more suboptimal treatment outcomes with non-licensed medications these would have to be of a significant magnitude for it to adversely financially affect the owner.

The cascade is often cited as encouraging new drug development as its framework ‘protects’ a new licensed product by mandating its use, thereby ensuring pharmaceutical company income. In the UK, active ingredients, the process to obtain them, and the formulation of the drug (ingredients, presentation (e.g.

liquid, flavouring) can also be patented for up to 25 years; once the patent expires, then other companies can gain market authorisation for the active ingredient.

Veterinary medicines represent about 2-3% of the market value of human pharmaceuticals.<sup>17</sup> It is therefore not surprising that annual frequency of market authorisations is low – in the last 3 years, the EMA has approved only 49 new products, with 14 new active ingredients; of these, most were vaccines for agricultural animals. So if the cascade does encourage pharmaceutical innovation for the animal sector, it appears somewhat modest.

To the authors' knowledge, truly novel products in the companion animal sector in the last few years have been similarly modest, restricted to monoclonal antibodies, JAK-1 and JAK-3 inhibitors, velagliflozin, and some anti-parasitocides. Further, most of these are variations on similar molecules that have been in use in human medicine for some time, and the vast majority have been developed by just one company (Zoetis Inc.) Characterising the cascade as a protective and promotional of research and development therefore seems difficult to justify based on current evidence.

The cascade may actually discourage research whilst promoting development via the practice of 'retro licensing' drugs that have been in common use for years if not decades and for which a large volume of clinical experience of both apparent effectiveness and safety exists.

These are typically human drug formulations used in animals. Pharmaceutical companies have openly stated their intentions: "The cascade...any products licensed specifically for animals must be used instead of a human ethical or generic product irrespective of price. Most of our products utilise existing pharmaceutical entities that are typically used within the human market and therefore the majority of product creation is development and not research based".<sup>23</sup> It makes financial sense to do so as "development products have a relatively low cost; research based projects are usually expensive with a low probability of success".

To be clear, this is not the fault of the pharmaceutical companies who, operating in a broadly capitalist economic system are legally-bound to maximise profits for shareholders. Rather, it is the cascade within the EU and UK that enables and protects this practice. The animal-licensed products are minimally (if at all) different to human generics other than the 10-20 fold higher price.

The study has several potential weaknesses. The results detail veterinary surgeons' perceptions of the cascade affecting owners' ability to afford licensed medication, which are potentially open to several biases.

Confirmation bias is a particular risk, as veterinary surgeons may already see the cascade in a negative light meaning they may over-report issues. Veterinary surgeons with a particularly negative underlying view of the cascade may have been more likely to complete the survey, though this is mitigated by the cascade question being part of a wider survey on influences on clinical decision-making and advice rather than being solely about the cascade. Even veterinary surgeons reporting accurately may be stating owners' unwillingness to pay a perceived high price for medication rather than true unaffordability.

The timing of the survey during a widely-reported 'cost of living crisis' may also have caused over-reporting of unaffordability but that does not necessarily affect the results' reliability. Approximately 5% of the UK practising profession completed the survey questions, meaning they may not be fully representative of the whole profession; however this is ordinarily regarded as a reasonable rate of response for this type of study. Alternative study design such as a prospective, case-number based study may have better captured the true data and would have allowed more accurate estimation of the percentage of cases per day/week/year where following the cascade negatively affects affordability.

According to the results of this study, the cascade regulations negatively assess affordability of medications for up to 23% of owners. The purported benefits of improved safety, effectiveness, promotion of new drug research and development seem modest at best, and in some cases, unsupported.

The negative welfare effects of continuing to use the cascade, especially where cheaper human generics exist and licensed products' higher price lead to less treatment due to lack of affordability, are difficult if not impossible to justify for the profession and from wider moral and legal perspectives.

Rather than protecting animal welfare through safer, more effective and increasingly innovative treatment, the cascade instead appears geared to protecting the economic interests of pharmaceutical companies especially where retro-licensing is widespread.

The cascade does appear to have a direct effect on affordability of veterinary care, and, in the authors' opinion, should form a part of the CMA investigation into that very matter. Yet there appears no appetite for regulatory bodies to consider change, something that, following Brexit, would be eminently possible in the UK.

A more dynamic patent system for truly innovative drugs rather than 'development only' drugs, a decoupling of mandatory use of licensed medication when a human generic exists, or even simply allowing discretionary use of unlicensed medication on the grounds of cost are all simple solutions that would better serve animal welfare, reduce costs to owners and promote research of new drugs all to the ultimate benefit of veterinary patients.

#### **Conflicts of interest**

The authors declare they have no conflicts of interest related to this work. All authors have reviewed and approved the manuscript and there are no financial or personal relationships that could inappropriately influence the research.

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