ASSURING THE SAFETY, QUALITY & EFFICACY
OF VETERINARY MEDICINES

ATI 298

Request

From: [Redacted under section 40 of the FOIA]
Sent: 12 May 2014
Subject: Public Law Offences

I am again asking you to send all the information regarding the investigation of my case.
I completely disagree with your assessment and conclusion.
[My dog] was stated on the records to be having an allergic airway attack. Although we saw no sign of this, a Veterinary Feline inhaler is the normal way vets treat this condition.
Therefore to ignore this choice of treatment and to inject with the Human Medicine Bricanyl is clearly illegal and each administration at the a Criminal offence.
The dosage itself for a 66lbs plus human give to a cat are clearly illegal.
On the subject of Convenia I have information from the VMD stating any administration over two courses is illegal.
These facts are on the record and the fact that the VMD and the RCVS have worked together to suppress this case to prevent the vet going to court and having her license removed is shameful and those responsible themselves should face charges for Misconduct.
I am again requesting all the information regarding this case.

VMD Reply

Sent: 9 June 2014
To: [Redacted under section 40 of the FOIA]
Subject: Public Law Offences

Your Request

Thank you for your email to my colleague [Redacted under section 40 of the FOIA] dated 12 May 2014. We have dealt with your request under the Freedom of Information Act 2000 (FOIA). You asked for all the information regarding “the investigation of your case”.

Our Reply

As a general point you should note that the FOIA gives you an entitlement to information rather than documents and it is in this context that we have answered your request taking account of the information we hold.

VMD email exchanges leading to our reply to you of 3 April 2012

We have attached [below] the VMD email exchanges that led to our reply to you of 3 April 2012. We have redacted the names of junior officials as the disclosure of the names would breach the first data protection principle and fail to meet any of the relevant conditions set out in Schedule 2 of the Data Protection Act 1998 (DPA) . The First Principle in the DPA requires that disclosure must be fair and lawful, and, in particular, personal data shall not be processed unless at least one of the conditions in Schedule 2 is satisfied. The people concerned would not have expected their names to be disclosed to the public and so disclosure would not be "fair" in the manner contemplated by the DPA. Furthermore, disclosure would not satisfy any of the conditions for data processing set out in Schedule 2 of the DPA. In particular, we do not consider that there is a legitimate interest in disclosure in this case. There is no public interest in making information about such individuals available in this way contrary to what would have been their legitimate expectation at the time.

We have also redacted your personal data as we will at some point post this reply (with your name redacted) and the information we have released to you on the VMD's website FOIA Disclosure Log.

For the same reason we have redacted the name of the Veterinary Centre (and its employee) involved (though these names are already known to you) from the attached document (that we will post on our website), the former under section 43 of the FOIA. Section 43 relates to the commercial sensitivity of the information. We consider that the disclosure of the information would be likely to prejudice the commercial interests of the Centre concerned. Section 43 is also subject to a public interest test balance. After careful consideration we have concluded that the public interest in withholding the information from general publication strongly outweighs that for disclosure in this case. The information in question if taken out of context and used maliciously could lead to reputational damage to the Centre and in consequence prejudice the commercial interests of the business given that the veterinary practice records together the VMD's own investigations confirmed that the Centre was not in breach of the Veterinary Medicines Regulations 2009 – see below.

As you will see from the attached document we have also redacted some information in these exchanges under section 42(1) (legal professional privilege (LPP)) of the FOIA - see below.

Understanding what the VMD said in the email exchanges

We would like you to take account of the following to help you understand what colleagues said in these email exchanges and how that led the VMD to write to you on 3 April in the way it did. The email exchanges are a series of views from VMD officials which informed the development of the letter of 3 April 2012, which in turn express the

corporate view of the VMD.

The exchanges were made on the basis of your correspondence and before you provided the veterinary practice records, so before the VMD had the full facts of the case. The veterinary practice records together the VMD's own investigations confirmed that the actions of the Veterinary Centre were not in breach of the Veterinary Medicines Regulations 2009. As we said in our letter to you of 8 August 2013:

"The VMD's view is that the prescribing of Convenia was carried out under the first tier of the cascade. Furthermore, the summary of product characteristics states that the antimicrobial activity of Convenia following a single injection will last up to 14 days; it does not say that Convenia must not be re-administered during the 14 day period. Therefore on the prescribing of Convenia; in our view there was not a breach of the Veterinary Medicines Regulations 2009.

As you are aware Bricanyl is a human medicine and the use of human medicines to treat animals is permitted under the second tier of the cascade. Given that there are no equivalent veterinary medicines authorised for cats, the first consideration would have been for the available dog product, which is in capsule form. Nevertheless it is noted that [your dog] was unable to take tablets and so Bricanyl was chosen. Once again in our view this was not a breach of the Veterinary Medicines Regulations 2009.

Furthermore, the VMD finds that none of the actions taken by the Veterinary Centre in [this] case breached the Veterinary Medicines Regulations 2009. Accordingly, this now concludes the VMD's investigation and as there is no case to answer we have now closed the case."

Email exchanges between the VMD and you

We hold copies of all email exchanges between the VMD and you; and other correspondence that we sent to you. We judge that Section 21 of the FOIA means that we are not required to resend this material to you. Section 21 applies to information that is already reasonably accessible to the applicant. It recognises that the right of access under the Freedom of Information Act 2000 is supplementary to the very many ways in which public authorities already provide information to members of the public. We judge that the 'Clinical Notes Listing' of 13 September 2013 that we hold is also covered by this exemption as you sent it to us.

Email exchanges between Dr Renn and other parties about arrangements for his visit to the Veterinary Clinic

We hold email exchanges between [Redacted under section 40 of the FOIA] and other parties in which [Redacted under section 40 of the FOIA] makes arrangements for his visit to the Veterinary Clinic and reports his conclusions to a colleague in the VMD. The content of these emails are essentially procedural or are covered in his letter to you on 8 August 2013.

Legal advice and the request for legal advice

We also hold email exchanges from March 2013 between VMD staff and lawyers that discuss the basis for the VMD's reply to you of 3 April 2012. We judge that this information consists of legal advice and the request for legal advice, and as such the exemption at section 42(1) (legal professional privilege (LPP)) of the FOIA applies. The information we are withholding under section 42(1) consists of "legal professional privilege (advice privilege)". Section 42(1) is subject to the public interest test, but the Information Commissioner and the Tribunal recognizes that this exemption is unique inasmuch as the public interest arguments are already weighted in favour of withholding information that is subject to LPP.

In applying this exemption we have had to balance the public interest in withholding the information against the public interest in disclosure. We recognise that there is a public interest in disclosure of information concerning legal advice relating to, for example, some aspects of the development of the Veterinary Medicines Regulations because it would show how the Government reached its conclusions. However, there is also a strong public interest in the VMD being able to receive frank advice from legal advisers in respect of its legal rights and obligations without fear of intrusion and to protect the confidential relationship between legal adviser and the VMD. Having carefully considered the public interest arguments for and against disclosure in this case, we believe that the public interest arguments in favour of disclosure neither are equal to nor outweigh the public interest in maintaining the exemption. Therefore, we have concluded that, in this case, the public interest falls in favour of withholding the information under section 42(1) of the FOIA.

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Our Service

If you are unhappy with the service you have received in relation to your request and wish to make a complaint, you may request an internal review within two calendar months of the date of this e-mail. If you would like to request an internal review please write to [Redacted under section 40 of the FOIA] at the VMD via ati@vmd.defra.gsi.gov.uk. If you are not content with the outcome of the internal review you have the right to apply directly

to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

[Redacted under section 40 of the FOIA]
Chief Executive's Office
Veterinary Medicines Directorate
Woodham Lane
New Haw, Addlestone
Surrey KT15 3LS
From: [Redacted under section 40 of the FOIA]
Sent: 03 April 2012 16:19
To: Borriello, Peter; Atkinson, Jackie; Green, Paul
Cc: [Redacted under section 40 of the FOIA]
Subject: RE: Postmaster Enquiry Re: [Redacted under section 40 of the FOIA]

Pete, all done, Paul is content too so I will send the letter later on today. I mentioned our approach to [Redacted under section 40 of the FOIA] (RCVS) and [Redacted under section 40 of the FOIA] is content too, and we will discuss the issue of interface between the RCVS and us in a meeting in May.

Thanks

[Redacted under section 40 of the FOIA]
From: Borriello, Peter
Sent: 03 April 2012 14:58
To: [Redacted under section 40 of the FOIA]; Atkinson, Jackie; Green, Paul
Cc: [Redacted under section 40 of the FOIA]
Subject: RE: Postmaster Enquiry Re: [Redacted under section 40 of the FOIA]
[Redacted under section 40 of the FOIA]

I am content with a version that captures Jackie's edits. Paul is in a meeting 'till 4.00, which gives you an opportunity for a final check with him late today.

Pete

From: [Redacted under section 40 of the FOIA]
Sent: 02 April 2012 14:18
To: Atkinson, Jackie; Borriello, Peter; Green, Paul
Cc: [Redacted under section 40 of the FOIA]
Subject: RE: Postmaster Enquiry Re: [Redacted under section 40 of the FOIA]

All,

I've prepared a new draft taking Jackie's points on board.

Pete we discussed the use of the cascade last week.

#742681v1

Could Pete and Paul advise if the letter is now good to go please? I would like to send it today or tomorrow please.

Happy to discuss

[Redacted under section 40 of the FOIA]

From: Atkinson, Jackie
Sent: 28 March 2012 16:56
To: [Redacted under section 40 of the FOIA]
Cc: [Redacted under section 40 of the FOIA]; Borriello, Peter; Green, Paul
Subject: RE: Postmaster Enquiry Re: [Redacted under section 40 of the FOIA]

[Redacted under section 40 of the FOIA]
I have mainly embedded my comments (in red) in your email of 27 March and I think depending on how others view this the draft below may need further adjusting.
Jackie

From: [Redacted under section 40 of the FOIA]
Sent: 28 March 2012 16:11
To: Atkinson, Jackie; Borriello, Peter; Green, Paul
Cc: [Redacted under section 40 of the FOIA]
Subject: FW: Postmaster Enquiry Re: [Redacted under section 40 of the FOIA]

Directors,

I've modified the version of my draft to take on board the wording I must include in my response (from the SOP). Also, the SOP gives me 15 days to respond and this means that I need to send a response by Monday 2 April. But please read the string of emails, where I discuss some relevant points.

Thanks [Redacted under section 40 of the FOIA]

Dear [Redacted under section 40 of the FOIA]

Thank you for your email, where you ask me whether we would investigate the systematic use of Convenia and Bricanyl on Joey, because in your opinion the cascade has been illegally contravened with no clinical rationale. We talked on the phone on Wednesday, 14th March, about this and I welcome the opportunity to set out in writing the legislation on the use of the cascade.

But it may help initially if I explain the VMD's role. The VMD is an Executive Agency of Defra and is the veterinary medicines regulatory authority for the UK. We set and enforce the legislation covering the authorisation, manufacture and supply of veterinary medicines in the UK, but we do not have legislative power to consider matters of professional conduct for veterinary surgeons. Such action is reserved for the Royal College of Veterinary Surgeons (RCVS), the regulatory body for veterinary surgeons in the UK. The RCVS regulates the professional conduct of veterinary surgeons in the UK, and is responsible for

providing the guidance on professional conduct, setting out the responsibilities of the veterinary profession to the public.

The Veterinary Medicines Regulations (VMR) set out the controls on veterinary medicines, including their manufacture, supply and administration. But the legislation recognises that there are clinical situations where a veterinary surgeon, in the interest of animal welfare, needs to prescribe medicines that are not authorised for a particular animal if the clinical situation so requires. The use of the cascade increases the range of medicines that veterinary surgeons can use to treat animals under their care. But it is for the veterinary surgeon to use his/her clinical judgment when choosing an appropriate medicine to treat an animal under his care under the cascade. You are questioning the veterinary surgeon's rationale on the choice of medicine to treat Joey. The VMD considers that complaints against clinical decisions taken by veterinary surgeons (suggest delete: when deciding to use products under the cascade) are a matter of professional conduct. The RCVS are the body that are able to investigate and consider clinical decisions taking into account the complete set of circumstances surrounding the case. You have told me that you have reported the case to the RCVS and I suggest therefore that you await the outcome of the RCVS's investigations. (Suggest delete -Meanwhile, the VMD will visit the practice in question to investigate your allegations of breaches of the VMR). We are in dialogue with the RCVS concerning the case and if the RCVS's opinion is that the vet may have contravened the cascade they will inform us of this and we will consider whether a prosecution under the VMRs should be progressed.

If you are still not fully satisfied with the way your complaint has been handled you can contact the VMD Chief Executive. He will ensure that it is thoroughly investigated and will provide you with a full explanation within 21 working days. If this is not possible, the Chief Executive will write to you to explain why and tell you when you can expect a full response.

From: [Redacted under section 40 of the FOIA]
Sent: 27 March 2012 18:08
To: Atkinson, Jackie
Subject: RE: Postmaster Enquiry Re: [Redacted under section 40 of the FOIA]

Hi Jackie,

Re whether or not a complaint has been sent to the RCVS:

The RCVS told me that they have received [Redacted under section 40 of the FOIA] complaint on the 7/3, and the allegation is that the vet failed to obtain consent to treat the cat with unauthorised medicines and failed to keep good clinical records.
The RCVS raised allegations and asked the vet for a response to the complaint.
The vet responded and the response was sent to [Redacted under section 40 of the FOIA] for comments (the case is at this stage now). Depending on [Redacted under section 40 of the FOIA] comments, the case examiner may close the case or send it to the Professional Conduct Committee. I suggest we ask the RCVS to inform us if they find through their investigation any evidence that the cascade has not been used appropriately.

[Redacted under section 40 of the FOIA] complaint to us is slightly different from what [Redacted under section 40 of the FOIA]raised with the RCVS: to us, [Redacted under section 40

of the FOIA] is complaining that Convenia and Bricanyl were used in a healthy cat, that this "destroyed his health and led to suffering until he died" and that the vet contravened the cascade.

I asked [Redacted under section 40 of the FOIA] yesterday about the use of Bricanyl in the cat and [Redacted under section 40 of the FOIA] thinks that it would be justifiable under the cascade – the use of Convenia is less justifiable.

Re Legal's advice on the enforcement of the cascade:

[Redacted under section 42(1) (legal professional privilege (LPP))]

Re this specific complaint:

The vet works in a practice that is PSS. However, if we suspect that there is a breach of the VMR we can send a vet to inspect, as we are responsible for enforcement. Should we ask one of our inspectors to go there? Fine by me – but I don't think we have to tell [Redacted under section 40 of the FOIA], we don't usually tell people how we are approaching enforcement)

For convenience, please find here [Redacted under section 40 of the FOIA] email to me and a draft response (in green) [Redacted under section 42(1) (legal professional privilege (LPP))]

Perhaps we should let the RCVS see our response before we send it to [Redacted under section 40 of the FOIA]. Good idea

This is now a complaint case, but should I respond to [Redacted under section 40 of the FOIA] myself as [Redacted under section 40 of the FOIA] wrote to me? The email was addressed to you so you should reply.

Thanks [Redacted under section 40 of the FOIA] Sorry for the long email.

[Redacted under section 40 of the FOIA]**email:**

Dear [Redacted under section 40 of the FOIA]

I intend to make a formal complaint regarding the VMD. I would first like to give you the opportunity comment of the communications between myself and the VMD on this matter as seen in emails below.

Further to our conversation yesterday. I still expect the VMD to investigate the systematic use of Convenia and Bricanyl on a healthy cat, that destroyed his health and led to suffering until he died, contravening the provision of the Cascade. The legal and illegal use of the cascade is very simple.

The example you gave of cascade use of a human medicine administered to a dog with bone cancer as no veterinary product exists, is obviously legal under the cascade to "avoid unnecessary suffering"

I am fully aware of that.

As head of the legislation team for The VMD you have defined what constitutes criminal offences in Veterinary Medicine Regulations and with regard to the Cascade. I am asking you to investigate because the cascade has been illegally contravened again and again with not clinical rationale. In fact as cleanly revealed by the clinical record caused suffering to a healthy animal. I expect the whole of Joey's case to be investigated. I do not think this is normal 'veterinary negligence.'

Your position carries the responsibility of investigating allegations of criminal acts as your legislation team has defined them. It is your duty to investigate, enforce the law and bring to court those that break it. Veterinarians are not above the law, it is up to a court to decide how to deal with crimes of this nature. I asked the VMD to investigate this matter on the 17th January 2012. [Redacted under section 40 of the FOIA] assured me this was being done. It is causing me further distress that the VMD are leaving it to me to bring this to court, when it is clearly the VMD's responsibility.
I trust the VMD will put animal safety first and investigate to prevent this happening again.

I look forward to your response.

Yours sincerely

[Redacted under section 40 of the FOIA]

Our draft response:

Dear [Redacted under section 40 of the FOIA]

Thank you for your email, where you ask me whether we would investigate the systematic use of Convenia and Bricanyl on Joey, because in your opinion the cascade has been illegally contravened again and again with no clinical rationale. We talked on the phone on Wednesday, 14th March, about this and I welcome the opportunity to set out in writing the legislation on the use of the cascade.

But it may help initially if I explain the VMD's role. The VMD is an Executive Agency of Defra and is the veterinary medicines regulatory authority for the UK. We set and enforce the legislation covering the authorisation, manufacture and supply of veterinary medicines in the UK, but we do not have legislative power to consider matters of professional conduct for veterinary surgeons. Such action is reserved for the Royal College of Veterinary Surgeons (RCVS), the regulatory body for veterinary surgeons in the UK. The RCVS regulates the professional conduct of veterinary surgeons in the UK, and is responsible for providing the guidance on professional conduct setting out the responsibilities of the veterinary profession to the public.

The Veterinary Medicines Regulations (VMR) set out the controls on veterinary medicines, including their manufacture, supply and administration. But the legislation recognises that there are clinical situations where a veterinary surgeon, in the interest of animal welfare, needs to prescribe medicines that are not authorised for a particular animal if the clinical situation so requires. The use of the cascade increases the range of medicines that veterinary surgeons can use to treat animals under their care. But it is for the veterinary surgeon to use his/her clinical judgment when choosing an appropriate medicine to treat an animal under his care under the cascade. You are questioning the veterinary surgeon's rationale on the choice of medicine to treat Joey. The VMD considers that complaints against clinical decisions taken by veterinary surgeons when deciding to use products under the cascade are a matter of professional conduct. The RCVS are the body that are able to investigate and consider clinical decisions taking into account the complete set of circumstances surrounding the case. You have told me that you have reported the case to the RCVS and I suggest therefore that you await the outcome of the RCVS's

investigations. Meanwhile, the VMD will visit the practice in question to investigate any breaches of the VMR.

From: Atkinson, Jackie
Sent: 27 March 2012 09:59
To: [Redacted under section 40 of the FOIA]
Subject: RE: Postmaster Enquiry Re: [Redacted under section 40 of the FOIA]

[Redacted under section 40 of the FOIA]

[Redacted under section 42(1) (legal professional privilege (LPP))]

I looked into Bricanyl a bit more and went back to the early emails. Thoughts that occur to me are:

1) One email refers to "Joey was given Bricanyl for 72 hours after it was agreed he should not be given it" – for me this begs the question what dosage form was used. I don't think we can tell from the info, but it could be infusion or potentially nebuliser (latter seems a bit unlikely)
2) In terms of UK authorised VMPs for respiratory conditions in cats for immediate impact (i.e. injection) we have Millophylline Injection – etamiphylline, indications include respiratory failure and also Dopram V Injection – doxampram which is a respiratory stimulant. I have not checked with the vet if there are more.
3) A key point is we don't know exactly what indication the vet was using Bricanyl for and hence can't accurately identify if there is a UK authorised product
4) My own view is the repeated use of Convenia is far more worrying and whilst I have not checked the SPC I suspect this use corresponds to cascade use (off label) as the clinical requirements within the SPC would not envisage so many administrations and in some cases at very short intervals.
5) I think we could try asking the RCVS if they are aware of this case and can they confirm they are dealing with it. If they can do in our response we can use pretty much the current draft with something tacked on at the end to say we have liaised with RCVS and we are content that they are dealing with the case under their procedures.

Jackie

From: [Redacted under section 40 of the FOIA]
Sent: 27 March 2012 09:40
To: [Redacted under section 40 of the FOIA]; Borriello, Peter; Green, Paul; Atkinson, Jackie
Cc: [Redacted under section 40 of the FOIA]
Subject: RE: Postmaster Enquiry Re: [Redacted under section 40 of the FOIA]

Thanks [Redacted under section 40 of the FOIA]. I have draft a response to [Redacted under section 40 of the FOIA] email, discussed it with [Redacted under section 40 of the FOIA] and [Redacted under section 40 of the FOIA] advice is enclosed. I am doing some preparation for my talk this afternoon but as soon as I get this out of the way I will study [Redacted under section 40 of the FOIA] advice in more detail and will suggest some options on how to respond to [Redacted under section 40 of the FOIA] (in view of [Redacted under section 40 of the FOIA] response).

[Redacted under section 40 of the FOIA]
From: [Redacted under section 40 of the FOIA]
Sent: 26 March 2012 17:07
To: [Redacted under section 40 of the FOIA] Borriello, Peter; Green, Paul; Atkinson, Jackie

Cc: [Redacted under section 40 of the FOIA]
Subject: RE: Postmaster Enquiry Re: [Redacted under section 40 of the FOIA]

Dear All

To let you know that [Redacted under section 40 of the FOIA] called in at 10am this morning as [Redacted under section 40 of the FOIA] wanted to lodge an official complaint about the lack of VMD's ability to police the cascade. I told [Redacted under section 40 of the FOIA] that Directors are aware of the case and the issue is being discussed.

I had recorded the first mention from [Redacted under section 40 of the FOIA] via [Redacted under section 40 of the FOIA] a telephone conversation on to our CMS as a record of 'Expression of Dissatisfaction'. Please can [Redacted under section 40 of the FOIA] confirm if this is being treated as a Complaint already and I will check the SOP to see what needs to be recorded etc.

From Round-up, I am aware that a response is in hand with Legal.

Thanks
[Redacted under section 40 of the FOIA]

[Redacted under section 40 of the FOIA]
Chief Executive's Office
Veterinary Medicines Directorate
Woodham Lane
New Haw, Addlestone
Surrey KT15 3LS
[Redacted under section 40 of the FOIA]
From: [Redacted under section 40 of the FOIA]
Sent: 20 March 2012 12:00
To: [Redacted under section 40 of the FOIA]; Borriello, Peter; Green, Paul; Atkinson, Jackie
Cc: [Redacted under section 40 of the FOIA]
Subject: RE: Postmaster Enquiry Re: [Redacted under section 40 of the FOIA]

Pete,

We discussed. In my view the VMR does not give us powers to "authorise" the use of specific medicines under the cascade, the legislation simply sets the order of choice and the vet is free to make his/her decision. As agreed, I will double check with Legal and if they agree too I will say in my response to [Redacted under section 40 of the FOIA] that the legislation does not give us powers to police the choices made by vets.

I will send [Redacted under section 40 of the FOIA] a holding reply, meanwhile.

[Redacted under section 40 of the FOIA]

From: [Redacted under section 40 of the FOIA]
Sent: 20 March 2012 11:35
To: Borriello, Peter; Green, Paul; Atkinson, Jackie
Cc: [Redacted under section 40 of the FOIA]

#742681v1

Subject: RE: Postmaster Enquiry Re: [Redacted under section 40 of the FOIA]

Pete,

[Redacted under section 40 of the FOIA] considers that the vet used medicines (human – Brycanil and veterinary - Convenia) under the cascade inappropriately, on a healthy cat. [Redacted under section 40 of the FOIA] considers that we should police the use of medicines under the cascade, but our legislation simply sets out the tiers of the cascade, and the vet is at liberty to choose the best medicine to treat a particular animal based on his clinical assessment of the case. So even if there are authorised medicines for a particular condition in a particular animal, the vet may decide that a human medicine is more suitable (for example because the human medicine is a liquid form and the owner cannot administer a tablet to the cat)

But this means that if challenged the vet has to be able to defend his choice of treatment. In such situation the RCVS investigates the case as a matter of professional conduct.

Re reporting of adverse reactions: our scheme records suspect events to human medicines and VMPs used under the cascade, and monitors them. A few years ago I prepared a paper to the Vet Rec describing the adverse reactions we received to human medicines, which I hoped would be of some use to vets.

Happy to go up and explain the situation if it is easier.

Thanks [Redacted under section 40 of the FOIA]

From: [Redacted under section 40 of the FOIA] **On Behalf Of** Borriello, Peter
Sent: 20 March 2012 11:04
To: [Redacted under section 40 of the FOIA] ; Green, Paul; Atkinson, Jackie
Cc: [Redacted under section 40 of the FOIA]
Subject: RE: Postmaster Enquiry Re: [Redacted under section 40 of the FOIA]

[Redacted under section 40 of the FOIA]
I agree with the comments made by Paul and Jackie. In order to ensure clarity of response, I am trying to understand exactly what [Redacted under section 40 of the FOIA] believes [Redacted under section 40 of the FOIA] case is with respect to the use of Bricanyl. As I understand it, it is that:

1. The vet had no grounds to use the product. Our interpretation is that this was the vets clinical judgement and therefore the vets responsibility. [Redacted under section 40 of the FOIA] implication is that this was an unauthorised use of the cascade and therefore the responsibility of VMD to bring sanction.
2. [Redacted under section 40 of the FOIA] may believe that the VMD has a role in identifying ("authorising") which human medicines can be used for veterinary purposes and in which animal species for the cascade use system.
3. With respect to RCVS and VMD, I suspect [Redacted under section 40 of the FOIA] wish is not either/or, but both.

Is it the case that a vet can choose any human medicine they believe appropriate when a specific authorised veterinary is not available, and that no other individual or body has to sanction that use?. Also, if it were the case that either a specific vet product or alternative vet medicine that could have been used under the cascade, were available, would that have been breach of the VMR's.

For my interest, would this incident be captured as an adverse event under pharmacovigilence, and if not, how are cascade use adverse events captured to enable better cascade guidance?.

Pete

Professor S P Borriello
Chief Executive
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey. KT15 3NB
Tel: 01932 338302
E:mail: p.borriello@vmd.defra.gsi.gov.uk

From: [Redacted under section 40 of the FOIA]
Sent: 19 March 2012 18:38
To: Green, Paul; Atkinson, Jackie
Cc: [Redacted under section 40 of the FOIA]
Subject: RE: Postmaster Enquiry Re: [Redacted under section 40 of the FOIA]

All, please see below my draft reply to [Redacted under section 40 of the FOIA]. Grateful for your comments. I enclosed a previous response from [Redacted under section 40 of the FOIA] to [Redacted under section 40 of the FOIA].

[Redacted under section 40 of the FOIA]

Dear [Redacted under section 40 of the FOIA]

Thank you for your email, where you ask me whether we would investigate the systematic use of Convenia and Bricanyl on Joey, because in your opinion the cascade has been illegally contravened again and again with not clinical rationale. We talked on the phone on Wednesday, 14th March, about this and I welcome the opportunity to explain to you again the legislation on the use of the cascade.

But it may help initially if I explain the VMD's role. The VMD is an Executive Agency of Defra and is the veterinary medicines regulatory authority for the UK. We set and enforce the legislation covering the authorisation, manufacture and supply of veterinary medicines in the UK, but we do not have legislative power to consider matters of professional

conduct. Such action is reserved for the Royal College of Veterinary Surgeons (RCVS), the regulatory body for veterinary surgeons in the UK. The RCVS regulates the professional conduct of veterinary surgeons in the UK, and is responsible for providing the guidance on professional conduct setting out the responsibilities of the veterinary profession to the public.

The Veterinary Medicines Regulations (VMR) set out the controls on veterinary medicines, including their manufacture, supply and administration. But the legislation recognizes that there are clinical situations where no suitable authorised medicine is available, and allows a veterinary surgeon to legally prescribe medicines that are not authorised for a particular animal if the clinical situation so requires. These provisions are Regulation 8 and Schedule 3 (1) of the VMR, which I reproduce below for your convenience:

Administration of the product

8. It is an offence to administer a veterinary medicinal product to an animal unless—

(a)the product has a marketing authorisation authorising its administration in the United Kingdom, and the administration is in accordance with that marketing authorisation; or

(b)it is administered in accordance with Schedule 4 (administration of a veterinary medicinal product outside the terms of a marketing authorisation) or Schedule 6 (exemptions for small pet animals

Administration under the cascade

1.—(1) A veterinary surgeon acting under this paragraph who prescribes a veterinary medicinal product may either administer it personally or may direct another person to do so under the responsibility of the veterinary surgeon.

(2) 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—

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

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

(c)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.

(3) In the case of a veterinary medicinal product imported from another Member State, if the veterinary surgeon has not obtained a certificate from the Secretary of State under regulation 25(5) permitting importation, the veterinary surgeon must obtain a certificate from the Secretary of State before administration.

(4) Any pharmacologically active substances included in a medicinal product administered to a food-producing animal under the cascade must be listed in Table 1 in the Annex to Commission Regulation (EU) No 37/2010.

The aim of the legal provisions in the legislation ultimately is to increase the range of medicines that veterinary surgeons can use to treat animals under their care, and to ensure that unauthorized medicines are used when there are no suitable authorized products. But it is for the veterinary surgeon to use his/her clinical judgment when choosing an appropriate medicine to treat an animal under his care under the cascade. You are questioning the veterinary surgeon's rationale on the choice of medicine to treat Joey, and we consider that this should be dealt with under the RCVS guidance on professional conduct rather than as an offence committed under the Veterinary Medicines Regulations. I suggest therefore that you contact the RCVS if you have not yet done so.

I understand that this is not the outcome you desire to hear from the VMD but it is our advice on the matter based on the interpretation of the VMR.

From: post master
Sent: 16 March 2012 15:59
To: [Redacted under section 40 of the FOIA]
Subject: Postmaster Enquiry Re: [Redacted under section 40 of the FOIA] Dear [Redacted under section 40 of the FOIA]

Please could you let us know when this enquiry has been dealt with?

Thank you
[Redacted under section 40 of the FOIA]

From: [Redacted under section 40 of the FOIA]
Sent: 16 March 2012 13:40
To: post master
Subject: [Redacted under section 40 of the FOIA]

From: [Redacted under section 40 of the FOIA]
To: [Redacted under section 40 of the FOIA]
Subject: RE: Criminal offence
Date: Thu, 15 Mar 2012 14:25:42 +0000

Dear [Redacted under section 40 of the FOIA]

#742681v1

I intend to make a formal complaint regarding the VMD. I would first like to give you the opportunity comment of the communications between myself and the VMD on this matter as seen in emails below.
Further to our conversation yesterday. I still expect the VMD to investigate the systematic use of Convenia and Bricanyl on a healthy cat, that destroyed his health and led to suffering until he died, contravening the provision of the Cascade. The legal and illegal use of the cascade is very simple.
The example you gave of cascade use of a human medicine administered to a dog with bone cancer as no veterinary product exists, is obviously legal under the cascade to "avoid unnecessary suffering" I am fully aware of that.
As head of the legislation team for The VMD you have defined what constitutes criminal offences in Veterinary Medicine Regulations and with regard to the Cascade. I am asking you to investigate because the cascade has been illegally contravened again and again with not clinical rationale. In fact as clealy revealed by the clinical record caused suffering to a healthy animal. I expect the whole of Joey's case to be investigated. I do not think this is normal 'veterinary negligence.'
Your position carries the responsibility of investigating allegations of criminal acts as your legislation team has defined them. It is your duty to investigate, enforce the law and bring to court those that break it. Veterinarians are not above the law, it is up to a court to decide how to deal with crimes of this nature. I asked the VMD to investigate this matter on the 17th January 2012. [Redacted under section 40 of the FOIA] assurred me this was being done. It is causing me further distress that the VMD are leaving it to me to bring this to court, when it is clearly the VMD's responsibilty.
I trust the VMD will put animal safety first and investigate to prevent this happening again.

I look forward to your response.

Yours sincerely

[Redacted under section 40 of the FOIA]

From: [Redacted under section 40 of the FOIA]
To[Redacted under section 40 of the FOIA]
Subject: RE: Criminal offence
Date: Fri, 9 Mar 2012 12:37:40 +0000

Dear [Redacted under section 40 of the FOIA]

I understand the provision of the Prescribing Cascade.
Where the Prescribing Cascade has been clearly contravened.
For example:
A human medicine can be used under the Cascade when no veterinary medicine exists and to alleviate unacceptable suffering.

'The cat seemed stressed so I administered Bricanyl,' classed as unacceptable suffering?
This is a clearly a criminal act.

It is my understanding the VMD responsible for bringing criminal acts of this nature to court.

I have so much evidence that the use of this product destroyed his health on the clinical record.

My cat suffererd anaphylactic shock again and again his health was destroyed and he is dead.

I expect the Government agency responsible to enforce the law.

If the legislation team is not responsible on this matter of bringing these criminal acts to court, who is?
Animal safety must come first and I do not expect a government department to ignore criminal acts that risk the lives of animals in this country.

Please send me the name and contact number.

Thank you

[Redacted under section 40 of the FOIA]

Subject: FW: Convenia: Unlicensed use and overdosing
Date: Thu, 8 Mar 2012 14:29:42 +0000
From: [Redacted under section 40 of the FOIA]
To: [Redacted under section 40 of the FOIA]CC[Redacted under section 40 of the FOIA]

Dear [Redacted under section 40 of the FOIA]

Thank you for your email below and again I apologise for the delay in answering your follow-up question.

As explained in my previous email the cascade seeks to allow veterinary surgeons to use their clinical judgement to treat an animal under his/her care and is a risk based decision tree to help veterinary surgeons decide which product to use when there is no UK authorised veterinary medicine available. However, If there is no such product available then the veterinary surgeon may, in order to avoid unacceptable suffering, treat an animal with a product from one of the following categories:

a) a veterinary medicines authorised in the UK for the same condition in another animal species or for another condition in the same animal species;

b) either:
i) a medicine authorised in the UK for human use; or
ii) a veterinary medicinal product not authorised in the UK but authorised in another Member State for use in any animal species;

c) a medicine prescribed by the veterinary surgeon responsible for treating the animal and prepared extemporaneously by a veterinary surgeon, a pharmacist or a person holding an appropriate manufacturer's authorisation (a "specials manufacturer").

The use of a human medicines under the Cascade is legal provided that the veterinary surgeon follows the Cascade as detailed above and is able to justify the choice of treatment based on animal welfare.
With kind regards
[Redacted under section 40 of the FOIA]
Legislation Team
Veterinary Medicines Directorate
[Redacted under section 40 of the FOIA]
From: [Redacted under section 40 of the FOIA]
Sent: 24 February 2012 12:00
To: [Redacted under section 40 of the FOIA]
Subject: RE: Convenia: Unlicensed use and overdosing

Dear [Redacted under section 40 of the FOIA]
Thank you for your kindness and your heartfelt words for the loss of my darling Joey. It is very rare from at

Government department.
Thank you and anyone else at the VMD to who worked so diligently to get this response to me yesterday.
The information you have given me is very helpful indeed.
If Bricanyl is a human medicine is it legal to give this to an animal? As it is not even cascade use, what are are right did they have to give it to him?
If you consider there is anything within Defra/VMD remit that can be done. Even raising official concerns. I would appreciate it.

Warmest regards

[Redacted under section 40 of the FOIA]

Subject: FW: Convenia: Unlicensed use and overdosing
Date: Thu, 23 Feb 2012 16:16:04 +0000
From[Redacted under section 40 of the FOIA]
To[Redacted under section 40 of the FOIA]
CC: [Redacted under section 40 of the FOIA]

Dear [Redacted under section 40 of the FOIA]

Further to our telephone conversation please accept my apologies for not contacting you sooner. I am very sorry to hear of the loss of your pet Joey.

I am now able to provide you with some information regarding the administration of veterinary medicines in the UK.

The Veterinary Medicines Regulations (VMR) 2011 set out the controls on the manufacture, authorisation, marketing, supply and post-authorisation surveillance of veterinary medicines in the UK. The VMR is available on the VMD website http://www.vmd.defra.gov.uk/public/vmr.aspx

It is acknowledged that insufficient authorised veterinary medicines are available for the treatment of every clinical case in every species, therefore the VMR allows veterinary surgeons to prescribe products that are not authorised for the relevant clinical case or for the relevant species – this provision is known as the prescribing cascade. This provision can be found in Schedule 4 of the VMR.

From the information you have given me in your emails I believe that the veterinary surgeon concerned has utilised the cascade in treating Joey. The cascade may be used where the clinical judgement of the prescribing veterinary surgeon considers it necessary. In these cases the veterinary surgeon must balance the benefits against the risks of doing so and thus take responsibility for their clinical decision.

The VMD cannot comment on the clinical judgement of veterinary surgeons, if you are unhappy with the conduct of the veterinary surgeon concerned I recommend that you contact the Royal College of Veterinary Surgeons who are responsible for regulating veterinary surgeons' educational, ethical and clinical standards. Further information is available on the RCVS website http://www.rcvs.org.uk/complaints/

In addition to the above I hope you find the following information useful;

As mentioned above the cascade allows veterinary surgeons to prescribe unauthorised veterinary medicines. With respect to Bricanyl, this is not an authorised veterinary medicinal product however it exists in various pharmaceutical forms as a human medicine.

The repeated use of Convenia beyond two injections 14 days apart would also be considered cascade use, as this is outside of the dosing schedule set down in the authorised Summary of Product Characteristics (SPC). The SPC for Convenia is available on the European Medicines Agency website http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/veterinary/000098/WC500062067.pdf.

You may wish to be aware that although it is not a legal requirement a veterinary surgeon is required to obtain written informed consent from an owner prior to their animal being treated under the cascade; this requirement is part of the Royal College of Veterinary Surgeon's (RCVS) Guide to Professional Conduct. The Guide is available on the RCVS' website http://www.rcvs.org.uk

In summary, I believe, based on the information you have given me the veterinary surgeon has utilised the prescribing cascade in treating Joey. As described above the provisions of the legislation do not prohibit a veterinary surgeon from exercising his/her clinical judgement in this way. However, I recommend contacting the RCVS if you have any concerns relating to the conduct or the treatment you have received.

Once again please accept my condolences on your loss.
With kind regards
[Redacted under section 40 of the FOIA] Legislation Team
Veterinary Medicines Directorate
[Redacted under section 40 of the FOIA]

From: [Redacted under section 40 of the FOIA]
Sent: 23 February 2012 12:49
To: [Redacted under section 40 of the FOIA]
Subject: RE: Convenia: Unlicensed use and overdosing

Dear [Redacted under section 40 of the FOIA] Please could you update me?
My cat Joey has died. I have to make a complaint to the RCVS.
It is clear there is no basis for the unlicensed administering of five doses of Convenia, which amount to seventy daily treatments, where a maximum of one couldn't be clearer. It is reprehensible that a vet can administer this knowing each dose stays in the body four to six weeks and the damage it can do, seizures, heart failure and breathing problems. I am still waiting to hear the rationale for this, which the [Redacted under section 43 of the FOIA] have never given.

Additionaly and even most shocking is Joey was given Bricanyl a medicine that he had an extreme reaction to.
A routine check up turned into a hospital stay from friday night to sunday morning.
He returned noticiably thinner. In his medical notes it is clear his breathing rate went up to 116 instead of 28
Instead of stopping this medication. I was given it to administer to him and his body went into shock.
[Redacted under section 40 of the FOIA] agreed after two commuincations on monday he should not have it anymore.

The following day when my cat sitter took him in for a follow up check up. Joey was given Bricanyl for 72 hours after it was agreed he should not be given it, while I was on holiday.
This led to an emergency heart scan and a fourteen day stay in hospital and deterioration until he died.

They deliberately inserted in his notes 'Bricanly calms him down' The notes contain many errors and appear to be hurriedly re-written. Is it possible there is an authority that can retrieve the computor history, so that the truth is clear.
I honestly feel that animal safety should be above anything, yes the [Redacted under section 43 of the FOIA] had a good reputation, that is why my cats were in their care. I cannot believe a vet would act in this way.
Could you advise me?
Yours sincerly

[Redacted under section 40 of the FOIA]

From [Redacted under section 40 of the FOIA]

To: Subject: RE: Convenia: Unlicensed use and overdosing
Date: Wed, 25 Jan 2012 19:18:48 +0000

Dear [Redacted under section 40 of the FOIA]
Thank you for your email. I am relieved to know attention is being given to this matter.
I look hearing from you.

Kind regards

[Redacted under section 40 of the FOIA]

Subject: RE: Convenia: Unlicensed use and overdosing
Date: Wed, 25 Jan 2012 14:35:28 +0000
From: [Redacted under section 40 of the FOIA]

To: [Redacted under section 40 of the FOIA]CC: [Redacted under section 40 of the FOIA]

Dear [Redacted under section 40 of the FOIA]

Thank you for your email below and further to your telephone conversation with [Redacted under section 40 of the FOIA], I must apologise for not acknowledging your original email.

Please be advised that this matter is receiving attention and I hope to be able to reply very shortly.
With kind regards
[Redacted under section 40 of the FOIA] Legislation Team
Veterinary Medicines Directorate
[Redacted under section 40 of the FOIA]
From: [Redacted under section 40 of the FOIA]
Sent: 25 January 2012 14:07
To: [Redacted under section 40 of the FOIA]
Subject: FW: Convenia: Unlicensed use and overdosing

[Redacted under section 40 of the FOIA]
17th January 2012

[Redacted under section 40 of the FOIA]

#742681v1

Dear [Redacted under section 40 of the FOIA]

I spoke to you yesterday regarding The [Redacted under section 43 of the FOIA] Veterinary Centre, [Redacted under section 43 of the FOIA] for overdosing and unlicensed use of Convenia on my cat Joey.
I am asking for the matter to be investigated by the VMD.
I took my Cat Joey to the [Redacted under section 43 of the FOIA] Veterinary Centre, last January as he had been retching and not eating.
After a range of test he had ' A homogenous bronchial pattern through lung fields'
They gave him two injection One depomedrone (Anti-inflammatory) and Convenia the long-lasting anti-biotic
He was much better eating again with two days and I thought that was the end of it.

The manufacturers Pfzier state very cleary that for cats one single injection is for a whole course of anti-biotic treatement and for wounds and abscesses only, which Joey didn't have.
Joey was given five courses Convenia on the following dates:
Please bear in mind one injection last for two weeks and remains in the system 4-6 weeks.
21st January 2011
4th February 2011
18th February 2011
22nd february 2011
10th March 2011
I raised my concerns and this is stated in the medical notes.
Despite Pfzier Animal Health very clear warning of dosage and use of this medicine and the fact Pfzier have published reports on their website that some animals have died and had seizures. My cat was give five course 'in case of underlying infection.'
This is totally unacceptable.

I have two sections to my complaint with the [Redacted under section 43 of the FOIA] treatment of my cat. The other relates to administration of the medicine Bricanyl which I reported to them he has an extreme reaction to in my absence requiring hospitalisation and an emergency heart scan.

My concerns with Joey's treatment have just been met with threats to send in debt collectors.

I look forward to your response.

Yours sincerly

[Redacted under section 40 of the FOIA]