Dear [redacted],

Thank you for your request for information that we received on 10 December 2025. We have handled your request under the Freedom of Information Act 2000.

Your request

1. In light of the Farrell report showing that Zoetis have downgraded some of the most serious side effects reported to them in relation to Librela, what action has the VMD taken to ensure that the information they have received from Zoetis in relation to Librela and Solensia adverse events has been checked to ensure that what vets or pet owners reported has been correctly recorded?
2. Following on from that, what action has the VMD taken to update those recorded side effects to be in line with the actual reports?
3. Death is still not reported as a side effect on UK documents despite Zoetis declaring this in other Counties. I personally have knowledge of more than 15 dogs being reported as dying as a result of Librela. What reason does the VMD have for failing to protect the interest of the UK public by declaring death as a side effect?
4. Has the VMD updated their written information to include RPOA as a side effect from Librela? If not, in view of the reported cases, why has this not been done?
5. Despite the VMD being made aware that Zoetis provide a client information sheet for Librela in the US and Canada, why has the VMD failed to protect the interest of the UK public by not ensuring that Zoetis provide this in the UK?
6. After the VMD was provided with independent scientist figures (using Zoetis data) where the side effect rate was estimated as at least 1 dog in 110 suffering severe side effects to Librela, what action has the VMD taken to ensure that more correct information has been recorded?
7. The VMD has been notified and proof provided which shows that Zoetis side effects are based on 1 dose equals 1 dog treated which is absurd considering this is a monthly injection with many dogs receiving multiple doses. What has the VMD done to resolve this issue which is favourable only to Zoetis and prejudicial to UK pet owners?
8. Why has the VMD not protected the interest of the UK pet owners as the US FDA has?
9. Why has the VMD not updated information provided to vets in the UK?
10. Have vets been advised that the Zoetis trial data for Librela is available on line and that they should update their knowledge?
11. In view of the public outcry about their pets dying from Librela and Solensia, what action has the VMD taken to try to minimise the risk?
12. Please provide the dates when your adverse events reporting line was in operational for the 4 years up to the release of Librela and the 4+ years after release.
13. Please provide details of any funding, resources or gifts provided by Zoetis to the VMD for the 4 years prior to the release of Librela and Solensia and the 4+ years after release of the drugs.
14. What has the VMD done to ensure that the risk to human life is minimised by stopping the practice of administration of Librela and Solensia at home? The VMD was made aware that this was stopped by Zoetis in other Countries.
15. Has the VMD contacted Zoetis to establish why administration of the drugs at home has been stopped in other Countries because of safety reasons yet not in the UK?
16. After at least one person accidentally self administering the drug at home, what action did the VMD take to stop this happening again?

17. Did the VMD ensure that doctors treating any person affected by self administration were made fully aware of the severety of the side effects and risk of death? Bearing in mind that this information can be difficult to find online unless you know what to look for, this should have been a top priority. If the answer to the previous question is nothing, then why was nothing done when the VMD knows this drug can kill within hours. The necropsy reports from the young, previously healthy lab trial dogs show what damage can be done internally and to joints and bones. Has this information been passed to the medical staff helping the person/people who self administer?

Our reply

1. **In light of the Farrell report showing that Zoetis have downgraded some of the most serious side effects reported to them in relation to Librela, what action has the VMD taken to ensure that the information they have received from Zoetis in relation to Librela and Solensia adverse events has been checked to ensure that what vets or pet owners reported has been correctly recorded?**

After the article cited from *Farrell et al*, there has been a publication confirming that after reconciliation of the VMD and Zoetis adverse event databases, none of the statements of the Farrell report were true Frontiers | Commentary: Musculoskeletal adverse events in dogs receiving bedinvetmab (Librela) (29th October 2025). Any data downloaded from the EMA system EV-ADR is a snapshot in time. Pharmacovigilance data is dynamic, and cases are updated as more information becomes available to the reporting regulator or marketing authorisation holder (MAH). As such, discrepancies may arise if updates to case records are not reflected in the publicly accessible version at the time of data extraction.

Seriousness classification in our database is based on the internationally recognised VICH definition and guidance, referred to in our VMD guidance. The VICH definition of a serious adverse event, as per VICH GL24 is: “any adverse event which results in death, is life-threatening, results in persistent or significant disability/incapacity, or a congenital anomaly or birth defect. For animals managed as a group only an increased incidence of serious adverse events as defined above exceeding the rates normally expected in that particular group is considered a serious adverse event.” All adverse events are included in our pharmacovigilance activities, regardless of seriousness classification.

The VMD Pharmacovigilance team is actively working to ensure the availability of safe and efficacious veterinary medicinal products in the UK following globally recognised pharmacovigilance procedures, continuously monitoring quality, safety and efficacy of authorised veterinary medicinal products.

VMD Post-authorisation monitoring:
Once a product is on the market there is a process of surveillance in place to monitor its continued positive benefit/risk balance; this is known as pharmacovigilance. This activity is undertaken, independently, by both the VMD and the Marketing Authorisation Holder (MAH).

The VMD’s Pharmacovigilance team monitors all reports of adverse events (both adverse reactions and lack of efficacy reports) from authorised veterinary medicinal

products that are submitted to the VMD via the reporting routes described here: Report a suspected problem with an animal medicine or microchip - GOV.UK.

The Veterinary Medicines Regulations also require MAHs to monitor and report on the benefit-risk of their veterinary medicines on a continuous basis, including reporting adverse events within 30 days of awareness as per paragraph 57 of The Veterinary Medicines Regulations 2013 and the accompanying guidance in Guideline III Adverse event reporting - GOV.UK. The VMD constantly undertake monitoring and surveillance actions, such as signal detection and data mining of their database of adverse events. These include statistical calculations to identify potential associations between VMPs and adverse events, using disproportionality measures such as proportional reporting ratio (PRR), reporting odds ratio (ROR) and Bayesian methods. This is used in combination with qualitative assessment, which examines the details of the individual adverse event reports submitted.

The VMD inspects MAHs to ensure that they comply with their pharmacovigilance obligations as described in the VMR 2013 (as amended), including the sending of adverse event reports to the VMD.

2) Following on from that, what action has the VMD taken to update those recorded side effects to be in line with the actual reports?

Please see answer to Question 1.

3) Death is still not reported as a side effect on UK documents despite Zoetis declaring this in other Counties. I personally have knowledge of more than 15 dogs being reported as dying as a result of Librela. What reason does the VMD have for failing to protect the interest of the UK public by declaring death as a side effect?

There are differences between jurisdictions related to the regulation of veterinary medicinal products. In UK following VMR 2013 (as amended) and EU 2019/6, information on adverse events that have been known to occur following administration of a particular product is available in the product leaflet but also in sections 3.6/4.6 of the Summary of Product Characteristics (SPC). The SPC is a document describing the properties and the officially approved conditions of use of a medicine. No medicine is 100% risk free, and the SPC and associated product information are updated in an evidence-based manner with all the data available.

The frequency of adverse events is defined using the following internationally recognised convention:
- very common (more than 1 in 10 animals treated displaying adverse event(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

There is no specific threshold or trigger when emerging patterns are reported, all significant concerns are considered signals and the VMD has an extensive process to ensure the detection, validation, and assessment of signals. Evaluation is dependent on the accuracy and quality of data received from veterinary professionals and animal

owners. Outcomes of signal assessment can include regulatory actions, such as close monitoring or changes to the product literature.

A rolling 6-month list of Summary of Product Characteristic (SPC) changes for veterinary medicines can be found on the monthly medicines update page Vet practice & supply (VMD Connect), and further information on licensed veterinary medicines can be found in the Product Information Database Product Information Database - Home.

In addition to the information available on SPCs, the VMD may publish adverse event incidences for a specific active substance, a specific veterinary medicinal product (VMP), or groups of VMPs. Incidences may be published within safety updates added to the Urgent and clinically significant safety updates for veterinary medicines - GOV.UK. or within product/active substance-specific publications, like Librela solution for injection in dogs - GOV.UK.

It is important to note that whilst incidences are a useful tool for identifying changes in rates of adverse events over time and for giving a general overview of the frequency of adverse events occurring, many other factors are considered when analysing a specific concern and deciding on further regulatory actions. Therefore, there is no specific threshold for regulatory actions to be triggered. Sufficient scientific evidence is always required as all decisions must be evidence-based. The fact that adverse events have occurred following administration of a product, does not necessarily mean that those adverse events were caused by the product.

The VMD constantly undertake monitoring and surveillance actions, such as signal detection and data mining of their database of adverse events. These include statistical calculations to identify potential associations between VMPs and adverse events, using disproportionality measures such as proportional reporting ratio (PRR), reporting odds ratio (ROR) and Bayesian methods. This is used in combination with qualitative assessment, which examines the details of the individual adverse event reports submitted.

4) Has the VMD updated their written information to include RPOA as a side effect from Librela? If not, in view of the reported cases, why has this not been done?

Please see answer to Question 3.

5) Despite the VMD being made aware that Zoetis provide a client information sheet for Librela in the US and Canada, why has the VMD failed to protect the interest of the UK public by not ensuring that Zoetis provide this in the UK?

The VMD publicly gives access to the information on adverse events that have been known to occur following administration of a particular product. That information is available in the product leaflet but also in sections 3.6/4.6 of the Summary of Product Characteristics (SPC). The SPC is a document describing the properties and the officially approved conditions of use of a medicine. The SPC and associated product information are updated as new information is available.
A rolling 6-month list of Summary of Product Characteristic (SPC) changes for veterinary medicines can be found on the monthly medicines update page Vet practice

& supply (VMD Connect), and further information on licensed veterinary medicines can be found in the Product Information Database Product Information Database - Home. In addition to the information available on SPCs, the VMD may publish adverse event incidences for a specific active substance, a specific veterinary medicinal product (VMP), or groups of VMPs. Incidences may be published within safety updates added to the Urgent and clinically significant safety updates for veterinary medicines - GOV.UK. or within product/active substance-specific publications, like Librela solution for injection in dogs - GOV.UK.

6) After the VMD was provided with independent scientist figures (using Zoetis data) where the side effect rate was estimated as at least 1 dog in 110 suffering severe side effects to Librela, what action has the VMD taken to ensure that more correct information has been recorded?

Please see answer to Question 1.

7) The VMD has been notified and proof provided which shows that Zoetis side effects are based on 1 dose equals 1 dog treated which is absurd considering this is a monthly injection with many dogs receiving multiple doses. What has the VMD done to resolve this issue which is favourable only to Zoetis and prejudicial to UK pet owners?

Please see information publicly available on how incidences are calculated:
ttps://www.gov.uk/guidance/calculation-of-adverse-event-incidence-for-veterinary-medicines
Further technical detail on how the estimated number of animals treated is calculated can be found in Annex 3 of the following:
guidance: Technical_guidance_for_completion_of_the_Pharmacovigilance_Sales_Submission__PSS.pdf

8) Why has the VMD not protected the interest of the UK pet owners as the US FDA has?

Please see answer to Question 3.

9) Why has the VMD not updated information provided to vets in the UK?

Please see answer to Question 3.

10) Have vets been advised that the Zoetis trial data for Librela is available on line and that they should update their knowledge?

Please see answer to Question 3.

11) In view of the public outcry about their pets dying from Librela and Solensia, what action has the VMD taken to try to minimise the risk?

Please see answer to Question 1.

12) Please provide the dates when your adverse events reporting line was in operational for the 4 years up to the release of Librela and the 4+ years after release.

The web reporting system is one of the routes for receiving adverse events and has been under review since 17th December 2024. VMD has continued to receive adverse events directly from Marketing Authorisation Holders and from vets and members of the public as described in the Gov.uk page Report a suspected problem with an animal medicine or microchip - GOV.UK:

Report a problem with an animal medicine

You can report:

- a reaction in an animal or a person
- times when a medicine has not worked

You can report a problem by:

- telling your vet
- using the contact details on the leaflet that came with the medicine - if the product is an approved animal medicine (if you do not have the leaflet, search for the company also known as the MA holder)
- contacting the Veterinary Medicines Directorate (VMD) - if an animal has been given a human medicine or a medicine that is not approved for use in animals

If you report a problem to the company, they must share that report with the VMD within 30 days.

The VMD will use reports to check if medicines continue to be safe and work as expected.

Contact the VMD

To report a problem if an animal was given human medicine or medicine that is not approved for use in animals, email adverse.events@vmd.gov.uk to request a form.

You can also contact the VMD if you have questions about how to report a problem.

adverse.events@vmd.gov.uk

Further information on VMD reporting routes is available here: VMD Strengthens Pharmacovigilance Framework Whilst Addressing Reporting Concerns - GOV.UK

13) Please provide details of any funding, resources or gifts provided by Zoetis to the VMD for the 4 years prior to the release of Librela and Solensia and the 4+ years after release of the drugs.

The VMD has not received any funding or resources from Zoetis during this period.

Regarding gifts and hospitality, there were two occasions where an inspector was offered hospitality and a small gift. The hospitality consisted of lunch valued at approximately £10 and dinner valued at approximately £20, while the gift was a scarf valued at approximately £10. The total value of these items was less than £30 per occasion, and all were recorded in accordance with VMD's policies on gifts and hospitality. No other gifts, funding, or resources have been provided by Zoetis to the VMD during this period.

The VMD Annual Report and accounts are publicly available. The 2024/2025 report can be found in the following link:
E03385611_HC992_Veterinary_Medicines_Directorate_ARA_24-25.pdf

14) What has the VMD done to ensure that the risk to human life is minimised by stopping the practice of administration of Librela and Solensia at home? The VMD was made aware that this was stopped by Zoetis in other Countries.

The Veterinary Medicines Regulations do not restrict the administration of such veterinary medicines to veterinary professionals. It is the responsibility of the prescribing veterinarian to ensure that they will be administered correctly and safely, where they have decided that it is appropriate they are administered by a pet owner.

15) Has the VMD contacted Zoetis to establish why administration of the drugs at home has been stopped in other Countries because of safety reasons yet not in the UK?

The VMD has not contacted Zoetis to establish why administration of the drugs at home has been stopped in other countries.

16) After at least one person accidentally self-administering the drug at home, what action did the VMD take to stop this happening again?

As with any reports of user self-administration of veterinary medicines, the VMD assesses the seriousness and sequalae attributed to the exposure reported, as well as the number of reported incidents. The VMD has had no reports of serious adverse events resulting from accidental self-injection of these products.

17) Did the VMD ensure that doctors treating any person affected by self-administration were made fully aware of the severity of the side effects and risk of death? Bearing in mind that this information can be difficult to find online unless you know what to look for, this should have been a top priority.

Each veterinary medicinal product undergoes an assessment of the safety of the user of the product before it is allowed to be marketed. The hazards are identified, the likely exposure scenarios are considered, including accidental self-injection, and any risks that are identified are mitigated, whether by using a particular type of packaging or including safety information for the user, or both.

In the cases of Librela and Solensia, the risk of potentially severe immune responses, such as anaphylaxis, has been identified on the information leaflet that is supplied with the product, and the advice as to what to do in the event of self-injection is to immediately seek medical advice and to provide the product information to the physician. Attending doctors would then have all the available information to work with in the treatment of their patient.

If the answer to the previous question is nothing, then why was nothing done when the VMD knows this drug can kill within hours. The necropsy reports from the young, previously healthy lab trial dogs show what damage can be done internally

and to joints and bones. Has this information been passed to the medical staff helping the person/people who self administer?

It should be noted that the doses administered to laboratory animals would exceed by far the likely amount that would be administered after accidental self-injection by a user of the product. The adverse reaction reports for humans that have been submitted to the VMD do not include any that have anything more serious than needlestick injuries with localised soreness and inflammation.

Information releasable to the public
In keeping with the spirit and effect of the FOIA, EIR and the government's Transparency Agenda, we may place this request on GOV.UK, in due course. We will not place information identifying you on GOV.UK.

Copyright
The information supplied to you continues to be protected by copyright. You are free to use it for your own purposes, including for private study and non-commercial research, and for any other purpose authorised by an exception in current copyright law. Documents (except photographs or logos) can be also used in the UK without requiring permission for the purposes of news reporting. Any other re-use, for example commercial publication, would require the permission of the copyright holder.

Most documents produced by VMD will be protected by Crown Copyright. Most Crown copyright information can be re-used under the Open Government Licence (nationalarchives.gov.uk). For information about the OGL and about re-using Crown Copyright information please see The National Archives.

Copyright in other documents may rest with a third party. For information about obtaining permission from a third party see the Intellectual Property Office's website.

Our Service
If you are unhappy with our service in relation to your request you may make a complaint or appeal against our decision under section 17(7) of the FOIA or under regulation 11 of the EIRs, as applicable, within 40 working days of the date of this email. Please write to the Data Protection Manager at postmaster@vmd.gov.uk who will arrange an internal review of your case.

If you are not content with the outcome of the internal review, section 50 of the FOIA and regulation 18 of the EIRs gives you the right to apply directly to the Information Commissioner's Office (ICO) for a decision. Please note that generally the ICO cannot make a decision unless you have first exhausted VMD's own complaints procedure.

The Information Commissioner can be contacted at www.ico.org.uk/foicomplaints

Kind regards,

[redacted]