Dear [redacted],

Thank you for your request for information that we received on 16 January 2026. We have handled your request under the Freedom of Information Act 2000.

Your request
I am writing to formally request disclosure of information held by the Veterinary Medicines Directorate (VMD) in relation to the approval, safety assessment, and post-authorisation monitoring of the veterinary medicinal products Librela and Solensia (Zoetis).
Please provide the following information:

Approval criteria and decision-making

1. All documents, reports, assessments, and internal or external correspondence relating to the criteria, evidence, and data used by the VMD in reaching its approval decisions for Librela and Solensia.
2. Details of any risk–benefit assessments, pharmacovigilance evaluations, and post-authorisation safety considerations reviewed during the approval process.
3. Details of how the VMD interpreted and relied upon the EU CVMP Assessment for Librela (EMA/518235/2020) when reaching its own approval decision.

Conflicts of interest

4. Information relating to the involvement of any VMD employee who held or holds shares in Zoetis at the relevant time or after the release of the drugs, or who had or has a spouse or close family member holding shares in Zoetis.
5. The nature of that employee's role in the approval process for Librela and/or Solensia.
6. Any conflict-of-interest declarations, mitigation measures or recusal decisions applied in relation to that individual.
7. Was the person or people involved in the assessment of Librela pre-licensing qualified and competent to assess this new type of biological substance?

Field trial attrition

8. Details of what steps the VMD took to establish why a number of dogs and cats were withdrawn or dropped out of the field trials for Librela and Solensia.
9. Any analysis or investigations undertaken by the VMD to assess whether withdrawals may have been linked to adverse events, deterioration in health or deaths.
10. Whether the VMD ascertained if the manufacturer screened the field-trial animals in a manner that benefited the trials and, if so, how this was assessed.

Field trial outcomes

11. Rough calculations for Librela field trials establish that from the 273 dogs receiving Librela, 45 dogs dropped out before the end of the trials. This equates to a drop out rate of 1 in 6.25 dogs. In view of the fact that had the outcome been successful, the pet owners would have completed the 6 month trial, what did the VMD do to establish the reason for this unusually high withdrawal rate?
12. There were 6 dogs recorded as dying during these field trials, that could be an estimated death rate of 1 in 38 dogs (228 dogs completing the trial / 6 dead) What steps were taken by the VMD to ascertain the reasons for these deaths?

13. On realising this potentially abnormally high death rate, what did the VMD do to protect pet owners?
14. Copies of, or summaries derived from, the serious adverse event (SAE) reports relating to these deaths and withdrawals that were submitted to or reviewed by the VMD.
15. Why did the VMD refuse to add death as a side effect of Librela even after reports of deaths being recorded by them?
16. Given the known role of NGF in heart function, as stated by Zoetis in the EU CVMP Assessment Report for Librela (p12), please advise what specific steps were taken to ensure that the six reported deaths were not related to this mechanism.
17. What action was taken to assess any connection to the deaths and other potential complications listed among the many possible adverse events Zoetis have declared?
18. Zoetis has recorded adverse effects for nine issues that occurred fewer than six times. Given that Zoetis has listed multiple rare adverse effects occurring fewer than six times, please explain why deaths—the most serious possible adverse outcome—were omitted from UK product information and what action the VMD took to investigate and justify this omission.

Adverse-event rate calculations

19. Documentation explaining how adverse-event rates were calculated for Librela and Solensia, including the rationale for using "one dose = one pet treated."
20. An explanation of how the VMD accounted for the fact that Librela and Solensia are monthly administered products, with many animals receiving multiple doses over extended periods.
21. Why the VMD continues to allow adverse-event figures to be published using this methodology, which results in artificially low reporting rates and disproportionately benefits the manufacturer.
22. The qualifications, role descriptions and training of the person or persons at the VMD responsible for calculating and approving these figures.
23. Whether the VMD has considered adopting cumulative-dose reporting methodologies for these two biological veterinary medicines.
24. Why the VMD has failed to acknowledge independent scientific evidence, provided on several occasions, which—using Zoetis's own data—estimates that the risk of serious adverse events for Librela would be at least 1 in 111 dogs.
25. What reason the VMD has for disregarding such evidence, when doing so benefits the manufacturer and is detrimental to the welfare of UK pets and their owners finances and mental health?

Impact on related products

26. How does the VMD consider these artificially low adverse-event reporting rates (arising from dose-based rather than) may affect current or future regulatory decisions, including decisions relating to Lenvia and Portela?

Neurobiological safety considerations

27. On the drug data sheet, Zoetis states that: "Primates receiving high doses of anti-NGF monoclonal antibodies had anatomical changes in postganglionic cell bodies (reduced size and number of neurons). The change in cell body size returned to normal after anti-NGF monoclonal antibody administration was

discontinued." There is no mention of whether the number of postganglionic cells returned to normal after the drug was discontinued, nor any mention of Zoetis testing for this effect on dogs at normal doses during laboratory or field trials. It is a fact that once the number of postganglionic cells have reduced, they will not typically increase again.·Did the VMD take steps to establish whether Zoetis undertook appropriate testing for this aspect, including at normal dose levels in dogs and cats?

28. Bearing in mind that reduced postganglionic cell numbers could lead to many of the issues reported in association with Librela and Solensia what action does the VMD propose in this respect?
29. Given that the consequences of reduced postganglionic cells are indirect but biologically important for bone, organ, and tissue maintenance and because these neurons regulate blood flow, growth signals and repair processes, rather than causing immediate structural damage—how was this risk assessed?· If the VMD did not take steps to question this with Zoetis, what was the rationale behind that decision?

Laboratory necropsy findings and clinical risk amplification

30. Necropsy reports on laboratory Beagles show gliosis in the spinal cord, which is considered an unusual finding in 17–18-month-old, previously healthy dogs. In view of the known detrimental effects of glucocorticoids in the presence of spinal cord gliosis, why did the VMD fail to highlight this risk?
31. Given that many reported adverse effects of Librela and Solensia—such as weakness, paresis, loss of coordination, ataxia, stumbling, wobbliness, unsteady gait, partial or total paralysis, abnormal posture or gait, knuckling over on paws, dragging paws, hunched back, head tilting, muscle atrophy, pain, spinal sensitivity, reluctance to move, trembling, panting, loss of sensation, incontinence, lethargy, depression, and behavioural changes—may prompt veterinary surgeons to administer glucocorticoids as a first-line response, a comprehensive explanation is required. This failure has resulted in the loss of many pets, with massive emotional and financial consequences for owners.

EU CVMP warnings and failure to communicate risk

32. In the EU CVMP Assessment for Librela (EMA/518235/2020, pages 11–12), Zoetis explicitly warns that NGF signalling is involved in numerous adaptive physiological processes beyond pain, including neuronal development and maintenance, musculoskeletal repair, autonomic nervous system regulation, cardiovascular innervation balance, vasomotor control, wound healing, renal, respiratory and gastrointestinal function, endocrine signalling, and immune modulation. Disruption of sensory or adrenergic function is recognised as a contributing factor to sudden cardiac death in specific disease states. The assessment further notes that NGF-mediated effects encompass autonomic nervous system function, integrating sensory, hormonal and humoral signals and triggering reflex responses to physiological stressors.
    In view of these warnings:
    a. Why did the VMD fail to ensure these risks were clearly communicated to UK veterinary surgeons?
33. Given that Librela and Solensia represent a new class of veterinary medicine, why did the VMD not highlight these risks to encourage heightened vigilance and adverse-event reporting?

34. Why did the VMD not require the manufacturer's data sheets to include this information clearly and prominently?

Off-label and concomitant use (critical safety gap)

35. The VMD has repeatedly cited off-label use on adverse event reports. If the VMD is aware of widespread off-label use of Librela and Solensia: Why has the VMD not issued a formal warning to veterinary surgeons making clear that Librela and Solensia have not been tested in combination with any other drugs, as explicitly stated by Zoetis on their documentation?
36. Why have veterinary surgeons and pet owners not been warned that concomitant use with other medications is therefore experimental? Pet owners have a right to be informed when treatment is, in effect, experimental and unproven.

Effectiveness evidence, risk–benefit justification, and regulatory inaction

37. There is currently no independent peer-reviewed evidence establishing long-term effectiveness and safety sufficient to justify widespread use of these drugs. With Librela demonstrating a treatment success rate of only 25.6% above placebo in the EU three-month field trial (49.9% Librela versus 24.3% placebo): What criteria did the VMD use to determine that the benefit–risk balance justified approval of this new class of drug, particularly in light of the extensive biological warnings contained in the EU CVMP assessment?
38. With over 30 million doses of Librela and over 10 million doses of Solensia sold worldwide on the basis of trials involving only a limited number of dogs with osteoarthritis, less than 300 dogs, why has the VMD not conducted an urgent review to protect pets from harm?
39. With all the information available both before and after the release of these drugs, what is the reason the VMD has not called for an immediate withdrawal pending further, unbiased, independent peer-reviewed testing?
40. Our own, esteemed UK veterinary surgeon, pain specialist and researcher, Dr Michael Farrell has gone on record saying "Newly published research reveals a deeply concerning issue for animal welfare: important discrepancies between Librela's adverse event reports submitted by attending veterinarians and the final reports filed by Zoetis."
    https://www.facebook.com/groups/3299613933662015/search/?q=animal%20welfare%20issue / https://doi.org/10.3389/fvets.2025.1581490
    Can the VMD explain why such important research is not being provided by the VMD to veterinarians?
41. What action is the VMD taking to ensure that reports from Zoetis are not being downgraded?
42. Zoetis has restricted or banned home use of these products in other countries. These are species-specific biological products containing canine or feline proteins and recombinant hamster ovary tissue and the VMD reports at least one person having self injected at home: Despite this, home use remains permitted in the UK and in fact these dangerous drugs are being sold on social media marketplaces. Why has the VMD failed to implement equivalent safeguards in the UK or issue clear warnings to protect the public?
43. On what basis did the VMD override Zoetis's restrictions applied elsewhere.
44. Did the VMD ensure that updated risk information was passed to the medical professionals involved in the care of the affected individual?

45. Why, despite repeated requests, has the VMD failed to ensure equivalent protections for the UK public? (Reference: https://www.petscripts.com.au/blog/baransa-no-longer-available — Librela is marketed as Beransa in Australia.)

Post-authorisation review

46. Following publication of the Edinburgh University Paper dated 01/02/2023, describing the evidence base for Librela as "weak," what action did the VMD take to re-evaluate the information provided by Zoetis to protect UK pet owners?
47. Were any additional safety reviews, data requests, or changes to pharmacovigilance requirements initiated as a result?

If any of the requested information is held in whole or in part by Zoetis but was relied upon by the VMD in its decision-making, please indicate this and specify the extent to which the VMD has access to that information.

Our reply

Your request includes a significant number of individual questions covering a wide range of topics. To assist you, we have provided general information about our regulatory role, the authorisation process, and where relevant, links to material that is already publicly available.

If there are specific pieces of recorded information you would like us to consider, please let us know and we will be happy to assist you in refining your request. This helps ensure that we can respond proportionately and provide meaningful information.

For questions relating to the approval process and supporting documentation:

Both products were originally authorised via the European Centralised procedure which is a unified authorisation route overseen by the European Medicines Agency (EMA). It results in a single Marketing Authorisation (MA) valid across all EU Member States and EEA countries. See also Authorisation of medicines | European Medicines Agency (EMA).

We do not hold a recorded explanation setting out the detailed reasoning for these specific decisions because at the time decisions of this nature were taken in line with established regulatory processes rather than documented individual rationales.

When the UK left the EU, Northern Ireland remained in the EU regime and Great Britain transitioned to the national Veterinary Medicines Regulations. In January 2021, the VMD automatically converted existing marketing authorisations for Centralised products to GB authorisations.

For questions relating to 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).

In response to a previous request, FOI2025/00333, we have explained many of the questions you pose. This is not yet published so for convenience we have attached a copy of that response.

For questions relating to conflicts of interest:
As a regulatory authority, the VMD abide by the Regulators Code and staff by the Civil Service's core values of integrity, honesty, objectivity and impartiality.

Declarations of interest are used to determine the constraints placed on individuals in conducting our regulatory functions. We confirm that no individual where a declaration exists was permitted to work on products, or be involved in discussions, related to their conflict of interest, and in certain areas this extends to 5 years after the conflict ceases.

For questions relating to off-label and concomitant use:
Once a product is authorised, decisions about how it is used in an individual animal are a matter of professional clinical judgement for the attending veterinary surgeon. This includes decisions to prescribe or administer a medicine outside the terms of its authorisation (commonly referred to as "off-label" use).

Off-label use is permitted under UK law through the prescribing cascade, which explicitly places responsibility on the veterinary surgeon to determine that such use is:

- clinically justified for the individual animal,
- in accordance with their professional judgement and experience, and
- supported by appropriate consideration of risks and benefits.

The veterinary surgeon is also responsible for:

- informing the animal's owner of the nature of the treatment,
- considering potential interactions with other medicines,
- monitoring the animal's response, and
- reporting suspected adverse events.

For questions relating to the adverse event rate calculation:
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

Advice and assistance:
If you consider that specific recorded information has not been provided, you may submit a new request clearly identifying the documents, records or categories of information you believe are held by the VMD and have not been addressed.

Clearly defining the recorded information sought will enable us to assess whether it is held and to consider the request in accordance with our obligations under the Freedom of Information Act.

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.

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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]