Dear [redacted],

Thank you for your request for information that we received on 13 February 2026. We have handled your request under the Freedom of Information Act 2000.

Your request
Please provide information held by the Veterinary Medicines Directorate relating to suspected adverse reaction reports for Librela (bedinvetmab) in dogs, within the territory of Great Britain, for the period from 17 November 2021 (the date of UK authorisation) to the date of this request.

Specifically, I request the following information:

1) The total number of suspected adverse reaction reports received in relation to Librela during the period specified, including reports submitted by veterinarians, animal owners, and the marketing authorization holder.

2) A tabulated summary of all adverse reaction terms recorded in those reports, expressed as:

* VeDDRA Preferred Terms (PTs); and
* the number of reports in which each Preferred Term appears, with one row per Preferred Term.

3) The information in paragraph (2) broken down by calendar year (2021, 2022, 2023, 2024, 2025, and 2026 to date).

4) Where recorded, aggregate counts of reports classified as:

* serious versus non-serious; and
* outcome categories (including, but not limited to: recovered, not recovered, fatal, euthanised, and outcome unknown).

If Preferred Term–level data cannot be provided, please confirm the specific exemption relied upon and provide the closest available level of VeDDRA coding.

If any part of this request is considered likely to exceed the appropriate cost limit under section 12 of the Act, please:

* identify which elements of the request cannot be provided within the limit; and
* provide the information that can be disclosed within scope (for example, data at System Organ Class level and/or the most frequently reported Preferred Terms).

Our reply
Librela is a veterinary medicinal product (VMP) used for alleviation of pain associated with osteoarthritis in dogs. There are five different strengths authorised in the United Kingdom: Librela 5 mg Solution for Injection for Dogs, Librela 10 mg Solution for Injection for Dogs, Librela 15 mg Solution for Injection for Dogs, Librela 20 mg Solution for Injection for Dogs and Librela 30 mg Solution for Injection for Dogs.

Please be aware the data provided below are not subject to independent verification and the VMD does not guarantee their accuracy. The figures are based on adverse events submitted to the VMD for the purposes of pharmacovigilance.

We have included all adverse event reports. This includes:

- where an adverse event has occurred that is already listed on the Summary of Product Characteristics
- where more than one product was used. There may have been prior exposure to the reported product or to other products, and other products may have been administered at the same time.
- when the product was used off-label, that is using a medicine in a way that is not specified on the product's label, including prescribing of unauthorised medicines following the prescribing cascade
- where, on further evaluation, there were other reasons for the adverse event occurring such as underlying illnesses or an alternative cause for the clinical signs seen.

Duplicate cases are combined, however if there is doubt as to whether two cases are true duplicates then both cases will be included. VMD databases change over time as new and follow-up information is constantly being received and reviewed.

Evaluation is dependent on the accuracy and quality of data received from veterinary professionals and animal owners, and reporting frequency can vary over time (reporting frequency may be affected by a product being new to the market or social media interest, for example).

We have provided you with the total number of adverse event reports for Librela in dogs in Great Britain from the date of authorisation until 13th February 2026. All adverse events submitted to the VMD have their clinical signs coded using the Veterinary Dictionary for Drug Regulatory Activities (VeDDRA). We are able to provide the number of reports coded to system organ class (SOC) which is one of the hierarchical levels of VeDDRA. Further information regarding VeDDRA can be located on the European Medicines Agency website, including the VeDDRA list of clinical terms for reporting suspected adverse events and the Guidance notes on the use of VeDDRA terminology. The data in the table below is divided into calendar years based on the year the report was first received by the VMD or the MAH from the reporter. Please be aware that some adverse event reports may contain more than one animal.

SOC term	2021	2022	2023	2024	2025	2026	Total
Systemic disorders	65	181	304	797	2517	73	3937
Neurological disorders	36	155	215	434	699	35	1574
Renal and urinary disorders	20	77	130	299	865	19	1410
Digestive tract disorders	25	83	161	270	647	25	1211
Investigations	26	52	104	271	632	25	1110
Musculoskeletal disorders	15	54	87	242	519	34	951
Behavioural disorders	10	52	83	173	394	12	724
Skin and appendages disorders	9	21	40	135	316	10	531
Respiratory tract disorders	10	44	94	120	183	9	460

Ear and labyrinth disorders	5	29	33	69	106	5	247
Immune system disorders	14	26	28	54	56	1	179
Neoplasia	13	13	26	52	59	5	168
Cardio-vascular system disorders	7	17	30	48	60	5	167
Medication and product use errors	0	1	30	67	58	4	160
Eye disorders	4	10	26	39	55	8	142
Application site disorders	2	4	6	23	75	1	111
Blood and lymphatic system disorders	3	10	14	25	40	4	96
Other event	0	1	2	49	36	0	88
Endocrine system disorders	5	9	14	22	18	2	70
Hepato-biliary disorders	1	3	14	16	17	2	53
Reproductive system disorders	1	2	2	16	20	2	43
Mammary gland disorders	0	0	0	0	3	1	4
Metabolism and nutrition disorders	0	0	0	0	3	0	3

We have provided the number of reports classified as serious and non-serious. Seriousness categories are based on the definition of a serious adverse event as per VICH guideline 24 (Guidelines | vichsec): “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.”

Serious reports	1959
Non-serious reports	4741

You have also requested information on outcome categories. The table below shows the categories for outcome of the reaction as reported to us with the following information contained in rows:

- Died: This is the number of animals that died. Deaths following euthanasia are not included in this number. The number of animal deaths is not the number of confirmed deaths. In many of these cases further investigations and post-mortem examinations were not performed, or the results were not reported to us, and therefore it is not known whether the product was linked to the cause of death. The number of animal deaths also includes all reports when the product was used off-label (i.e., not according to manufacturer’s recommendations), or reports where, on further evaluation, it was confirmed that there were other reasons for the death.
- Euthanized: This is the number of animals that died following euthanasia. Animals that died without euthanasia are not included in this number. The number of animals euthanized is not the number of confirmed deaths. In many of these cases further investigations and post-mortem examinations were not performed, or the results were not reported to us, and therefore it is not known whether the product was linked to the cause for euthanasia. The number of animals euthanized also

includes all reports when the product was used off-label (i.e., not according to manufacturer's recommendations), or reports where, on further evaluation, it was confirmed that there were other reasons for euthanasia.

- Alive with sequelae: This is the number of animals alive with sequelae.
- Recovered: This is the number of animals that recovered from the adverse event.
- Unknown: This is the number of animals where the outcome was unknown.

Died	172
Euthanized	318
Alive with sequelae	79
Recovered	1084
Unknown	4315

Although adverse event report information can be useful to provide a general overview of a VMP, it is important for any clinical decisions regarding the use of a VMP to be based on a risk-benefit discussion specific to the animal or group of animals being administered the VMP. An overall frequency of an adverse event occurring for a VMP does not reflect the actual risk for an individual animal, as there are many individual factors that may contribute to the likelihood of an adverse event occurring.

All medicines whether for human or animal use come with risk, and the benefits of use in wider populations need to outweigh the potential risks. Information on adverse events that have been known to occur following administration of a particular product are summarised 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, and the latest version of an SPC can be found on our publicly available Product Information Database. We continually assess and update our findings relating to products used within the United Kingdom and should there be sufficient data to suggest that an SPC requires alteration or that another appropriate action is required, this will be carried out within the required timeframe, as set out by the current legislation surrounding that veterinary medicinal product or region.

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

(nationalarchives.gov.uk). For information about the OGL and about re-using Crown Copyright information please see The National Archives.

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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]