VETERINARY PHARMACOVIGILANCE

REPORT FOR SUSPECTED ADVERSE REACTIONS IN ANIMALS OR IN HUMANS AFTER THE USE OF A VETERINARY MEDICINE

DRAFT REPORT

SENDER REPORT IDENTIFICATION-CASE REF.No: 2024-UK-016305

Safety issues in animals ☒ in humans ☐
Lack of expected efficacy ☐
Withdrawal period issues ☐
Environmental problems ☐

Reporting country: United Kingdom
Purchase country: United Kingdom
Report source: Owner

1. ADDRESS OF COMPETENT AUTHORITY

[redacted]

2. NAME AND ADDRESS OF SENDER

[redacted]

Date complaint received by sender: --UNKNOWN-- (dd-Mon-yyyy)

Type of report Initial ☒ Follow-up ☐ (date, case number)

Person who reported the reaction : veterinarian ☐ owner ☒ physician ☐ pharmacist ☐ other:

3. VETERINARIAN/ PHYSICIAN/ PHARMACIST

[redacted]

4. ANIMAL OWNER / HUMAN PATIENT

[redacted]

5. ANIMAL DATA

No. of animals treated: 1 **No. of animals showing signs: 1** **No. of animals died: 1**

Animal characteristics (animal(s) showing signs):

Species: Dog
Breed/ production type: Spaniel - Springer English
Sex/ physiological status: female ☐ male ☒ pregnant ☐ neutered ☒ lactating ☐ other:
Weight (kilos): 20
Age: 11 Year(s)
State of health at time of treatment: good ☐ fair ☐ poor ☐ critical ☐ unknown ☐
Reason(s) for treatment (prevention against what disease(s) or initial diagnosis):
--UNKNOWN--

6. PRODUCT DATA #1

Trade name (include dosage form and strength): Librela 10 mg Solution for Injection for Dogs; Dosage Form: Solution for injection
M.A. number: 42058/5030
Active substance(s) (INN): Bedinvetmab
ATC vet code: QN02BG91
Batch No.: --UNKNOWN--
Expiry date: --UNKNOWN--
Storage details: --UNKNOWN--
Treatment Details: --UNKNOWN--

Dose/ frequency: --UNKNOWN--
Route/ site of administration: --UNKNOWN--
Start date of treatment: 27-Aug-2024
Stop date or duration: 28-Aug-2024
Who administered the product: Veterinarian
veterinarian ☐ owner ☐ other ☒
Use according to label: yes ☐ unknown ☐ no ☐ explain: --UNKNOWN--
Action taken after reaction: drug withdrawn ☐ dose reduced ☐ other ☐
Did reaction abate after stopping drug? yes ☐ no ☐ not applicable ☐
Did reaction reappear after reintroduction? yes ☐ no ☐ not applicable ☐
List all other relevant medications given to animal(s):

Product name/	Company	Batch No.	Route and site of admin	Dose, frequency, indication, duration of treatment (dates of beginning and end)

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7. REACTION DATA

Date of onset of unexpected signs: 29-Aug-2024

Duration of reaction: 7 Week(s)

Describe the sequence or events including administration of product(s), all clinical signs, site of reaction, severity, pertinent lab tests, necropsy results, possible contributing factors (if necessary use extra sheet): *See continuation page*

Adverse Events

A male-neutered 11 year old 20kg English Springer Spaniel canine was administered Librela [NCA selected Librela 10 mg Solution for Injection for Dogs] on 27 AUG 2024. Adverse event on 29 AUG 2024, paralysis, incontinence, suffering for 7 weeks. The dog died despite treatment being administered. No post mortem examination was performed. No further information expected. (Urinary incontinence, General pain, Death, Paralysis), (Outcome : Unknown)

Medical History

Were the unexpected signs treated? If yes, give the details of treatment including product(s) used:

Outcome of reaction to date:

	Killed/ euthanised	died	under treatment	alive with sequelae	recovered	unknown
No of animals:	0	1	0	0	0	0
Date when:		--UNKNOWN--				

8. ATTENDING VETERINARIAN'S LEVEL OF SUSPICION THAT DRUG CAUSED

possible ☐ unlikely ☐ no attending vet ☐ --UNKNOWN--

9. PREVIOUS EXPOSURE AND REACTION(S) TO PRODUCT(S)

Previous exposure to the suspect product? no ☒ yes ☐ Date(s):

Previous reaction to the suspect product? no ☐ yes ☐ Describe: --UNKNOWN--

De-challenge information: --UNKNOWN--

10. DETAILS OF SUSPECTED ADVERSE REACTION(S) IN HUMANS

Patient details Sex: --UNKNOWN-- Pregnant ☐ Age/ date of birth: --UNKNOWN-- Occupation (if relevant): --UNKNOWN--

Date of exposure: --UNKNOWN-- Date of reaction: --UNKNOWN--

Nature and duration of exposure, reaction details (including symptoms) and outcome:

--UNKNOWN--

[redacted]

[redacted]

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7. REACTION DATA (continued)