21 April 2026
EMA/CVMP/PhVWP/37249/2026
European Medicines Agency

Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2026

This document is updated monthly with the adopted outcomes of the Committee for Veterinary Medicinal Products (CVMP).

Products are listed alphabetically. Updates for the latest month are identified as '**New**' in the first column of the table.

Previous regulatory recommendations and procedures are outlined in pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during **2025** (EMA/CVMP/PhVWP/101663/2025), **2024** (EMA/CVMP/PhVWP/75148/2024), **2023** (EMA/CVMP/PhVWP/137199/2023), **2022** (EMA/CVMP/PhVWP/48138/2022), **2021** (EMA/CVMP/PhVWP/105691/2021) and **2020** (EMA/CVMP/PhVWP/112926/2020).

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<table>
<tr><th>Product
(active substance(s))</th><th>CVMP meeting date</th><th>Recommendation – Summary of Product Characteristics (SPC)/Package Leaflet (PL) change
(additions to text in bold, deletions in ~~strikethrough~~)</th></tr>
<tr><td>Bravecto
(fluralaner)</td><td>10-12 February 2026</td><td>
Section 3.5 of SPC and Section 6 of PL for Bravecto 150 mg/ml powder and solvent for suspension for injection for dogs:
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Hypersensitivity reactions to fluralaner or benzyl alcohol in humans have been reported, which can potentially be serious. Also, injection site reactions may occur. Care should be taken to avoid accidental self-injection and dermal exposure when administering this veterinary medicinal product. In case of accidental self-injection with adverse effects, hypersensitivity reactions or injection site reactions, contact a physician and show the label or package leaflet. If accidental skin exposure occurs, wash the skin immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with clean water. Wash hands after use.
This veterinary medicinal product is to be administered only by veterinarians or under their close supervision.

Section 3.6 of SPC for Bravecto 150 mg/ml powder and solvent for suspension for injection for dogs:

<table>
<tr><td>Common
(1 to 10 animals / 100 animals treated)</td><td>Injection site swelling[1]</td></tr>
<tr><td>Uncommon
(1 to 10 animals / 1,000 animals treated)</td><td>Decreased appetite;
Tiredness;
Hyperaemic mucous membranes.</td></tr>
<tr><td>Rare
(1 to 10 animals / 10 000 animals treated)</td><td>Emesis, Diarrhoea.</td></tr>
<tr><td>Very rare
(<1 animal / 10 000 animals treated, including isolated reports)</td><td>Muscle tremor, Ataxia, Convulsion;
Allergic oedema, Hypersensitivity reaction; Pruritus.</td></tr>
</table>
[1]Palpable and/or visual swellings, non-inflammatory, non-painful, self-resolving over time
</td></tr>
</table>

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<tr><td></td><td></td><td>Section 7 of PL for Bravecto 150 mg/ml powder and solvent for suspension for injection for dogs:

<table>
<tr><td>Common
(1 to 10 animals / 100 animals treated):</td><td>Injection site swelling[1]</td></tr>
<tr><td>Uncommon (1 to 10 animals / 1 000 animals treated):</td><td>Decreased appetite, Tiredness, Hyperaemic mucous membranes.</td></tr>
<tr><td>Rare (1 to 10 animals / 10 000 animals treated):</td><td>Emesis (vomiting), Diarrhoea.</td></tr>
<tr><td>Very rare (<1 animal / 10 000 animals treated, including isolated reports):</td><td>Muscle tremor, Ataxia (Incoordination), Convulsion, Allergic oedema (swelling), Hypersensitivity reaction, Pruritus (itching).</td></tr>
</table>
[1]Palpable and/or visual swellings, non-inflammatory, non-painful, self-resolving over time</td></tr>
<tr><td>Coxevac
(Coxiella burnetii vaccine (inactivated))</td><td>10-12 February 2026</td><td>Section 3.5 of SPC for COXEVAC suspension for injection for cattle, goats and sheep
Special precautions for safe use in the target species:
It is advisable to vaccinate all the animals in the herd at the same time.
~~Under field conditions, vaccination with COXEVAC has commonly been followed by a decrease in milk production in goats. Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.~~

Section 3.6 of SPC and Section 7 of PL for COXEVAC suspension for injection for cattle, goats and sheep
Cattle:

<table>
<tr><td>Very common
(>1 animal / 10 animals treated):</td><td>Injection site swelling*</td></tr>
<tr><td>Rare</td><td>Lethargy, Hyperthermia, Anorexia
Milk production decrease**</td></tr>
</table></td></tr>
</table>

Product (active substance(s))	CVMP meeting date	Recommendation – Summary of Product Characteristics (SPC)/Package Leaflet (PL) change (additions to text in bold, deletions in ~~strikethrough~~)

(1 to 10 animals / 10,000 animals treated):	

* Palpable, of 9 to 10 cm diameter maximum, which may last for 17 days, reduces gradually and disappears without need for treatment.

**** Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.**

Goats:

Very common (>1 animal / 10 animals treated):	Injection site swelling* Hyperthermia**
Common (1 to 10 animals / 100 animals treated):	**Milk production decrease*****
Uncommon (1 to 10 animals / 1,000 animals treated):	Lethargy, Malaise, Anorexia
Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea

* Palpable, of 3 to 4 cm diameter maximum, which may last for 14 days, reduces and disappears without need for treatment.

** For 4 days post-vaccination.

***** Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.**

Sheep:

Very common (>1 animal / 10 animals treated):	Injection site inflammation, application site thickening*

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Rare (1 to 10 animals / 10,000 animals treated):	Lethargy, Hyperthermia, Anorexia **Milk production decrease****

* Palpable, of 5 cm diameter maximum, which may last for 14 days, reduces and disappears without need for treatment. Reactions are expected to be more severe after the second injection.

**** Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.**

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also section "Contact details" of the package leaflet.

Section 3.7 of SPC for COXEVAC suspension for injection for cattle, goats and sheep

Pregnancy and lactation:

Cattle and goats:

The safety of the veterinary medicinal product has not been established during pregnancy.

The vaccine can be used during lactation.

~~Under field conditions, vaccination with COXEVAC has been followed by a decrease in milk production, commonly in goats and rarely in cattle. Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.~~

Section 6 of PL for COXEVAC suspension for injection for cattle, goats and sheep

Special precautions for safe use in the target species:

Vaccination of animals already infected at the time of vaccination will have no adverse reaction.

No efficacy data are available concerning the use of COXEVAC in male animals. However, in safety laboratory trials, the use of COXEVAC in males proved to be safe. In the case that it is decided to vaccinate the whole herd, it is advisable to vaccinate the male animals at the same time.

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<tr><td></td><td></td><td>There are no benefits of the vaccine (as described in the indications for cattle), when used in infected and/or pregnant cows.
The biological significance of the levels of reduction shown in shedding in cattle, goats and sheep is not known.
It is advisable to vaccinate all the animals in the herd at the same time.
~~Under field conditions, vaccination with COXEVAC has commonly been followed by a decrease in milk production in goats. Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.~~

Pregnancy and lactation:
Cattle and goats:
The safety of the veterinary medicinal product has not been established during pregnancy.
~~Under field conditions, vaccination with COXEVAC has been followed by a decrease in milk production, commonly in goats and rarely in cattle. Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.~~
The vaccine can be used during lactation.</td></tr>
<tr><td>Librela
(bedinvetmab)
New</td><td>19-21 May 2026</td><td>Section 3.5 of SPC and section 6 of PL for Librela:
Special precautions for safe use in the target species:
(…)
Where a dog presents with new or increased joint swelling and/or joint pain following Librela treatment (see section 3.6), consideration should be given to perform additional diagnostics and discontinue treatment on a case-by-case basis.

Section 3.6 of SPC and Section 7 of PL for Librela:
Dogs:

<table><tr><td>Uncommon
(1 to 10 animals / 1 000 animals treated):</td><td>Injection site reaction (e.g. injection site swelling, injection site warmth)[1].</td></tr></table></td></tr>
</table>

Product (active substance(s))	CVMP meeting date	Recommendation – Summary of Product Characteristics (SPC)/Package Leaflet (PL) change (additions to text in bold, deletions in ~~strikethrough~~)

Rare (1 to 10 animals / 10 000 animals treated):	Diarrhoea, Emesis. Ataxia[2]. Polyuria, Urinary incontinence. Anorexia[3], Lethargy, Polydipsia.
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersensitivity reaction (anaphylaxis, facial swelling, pruritus)[4], Immune-mediated haemolytic anaemia, Immune-mediated polyarthritis, Immune-mediated thrombocytopenia. **Joint swelling, Joint pain, Bone and Joint disorder[5], Arthritis[6]** Paresis, Paralysis, Seizure.

[1]Mild.
[2]Including proprioceptive ataxia.
[3]Often related to a transient reduced appetite.
[4]In case of such reactions, appropriate symptomatic treatment should be administered.
[5]Extraarticular new bone formation, coupled with joint swelling and/or pain, affecting the joint capsule and adjacent soft tissues following repeated administration.
These changes may present unilaterally or bilaterally, can affect multiple joints, may be progressive and in very rare cases associated with fracture.
[6]New onset of arthritis primarily affecting distal joints like elbow, carpus and tarsus accompanied by joint swelling and joint pain, or deterioration of existing arthritis. In some cases, arthritis appears to show atypical radiological findings.

Section 3.8 of SPC and section 6 of PL for Librela:
Interaction with other medicinal products and other forms of interaction:
(…)
~~Dogs have no reported equivalent of human rapidly progressive osteoarthritis.~~

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<tr><td>Neptra
(florfenicol, terbinafine hydrochloride, mometasone furoate)
New</td><td>19-21 May 2026</td><td>Section 3.6 of SPC and Section 7 of PL for Neptra:
Dogs:
<table><tr><td>Very rare
(<1 animal / 10,000 animals treated, including isolated reports):</td><td>Application site erythema, Application site inflammation, Application site pain[1]

Hyperactivity, Vocalisation[1]

Emesis

Deafness[2], Impaired hearing[2], Internal ear disorder, Head shake[1]

Eye disorder (e.g. blepharospasm, conjunctivitis, corneal ulcer, eye irritation, keratoconjunctivitis sicca).

Ataxia, Facial paralysis, Nystagmus

Anorexia

Hypersensitivity reactions (e.g. facial oedema, urticaria and anaphylaxis)</td></tr></table>[1]Observed to occur shortly after product administration.
[2]Mainly in elderly animals.</td></tr>
<tr><td>Senvelgo
(velagliflozin)</td><td>EC decision date:
16 April 2026</td><td>Section 3.5 of SPC and section 6 of PL for Senvelgo:
<u>Prior to treatment start:</u>
Diabetic ketoacidosis (DKA) is a potential complication of diabetes mellitus. DKA (including euglycaemic DKA) is also a commonly reported adverse event during treatment with the veterinary medicinal product, and fatal cases have been reported. Therefore, screening for DKA must be performed and a check for ketone bodies in the urine or blood is required prior to use and during treatment. Treatment should not be initiated or resumed, if ketone bodies at concentrations indicative of DKA are present, as treatment with the veterinary medicinal product in cats with ongoing DKA could contribute to a worsened clinical condition and is therefore contraindicated (see section 3.5).</td></tr>
</table>

Product (active substance(s))	CVMP meeting date	Recommendation – Summary of Product Characteristics (SPC)/Package Leaflet (PL) change (additions to text in bold, deletions in ~~strikethrough~~)
		Initial monitoring recommendations (first two weeks): Discontinue treatment immediately in the event of confirmed or suspected diabetic ketoacidosis (DKA) or diabetic ketonuria and investigate accordingly. **Delay in diagnosis and treatment of DKA may result in increased severity of DKA and fatality.** (…) Checking for ketones is required at the initiation of therapy and every 1 to 3 days for the first two weeks **(preferably daily for the first 7 days)** as well as whenever the cat is showing clinical signs of illness, such as reduced food intake, acute vomiting or decreased activity. **Owners are encouraged to bring cats to the veterinary clinic/practice for monitoring of ketones as** screening for the presence of ketone bodies should ideally be performed on ~~plasma~~ **blood** at the veterinary clinic**. Alternatively, ketone bodies** can be checked by the cat owner at home **either using a ketone meter on blood or** by dipping a respective urine test stripe into the cat's urine, e.g. in the cat litter. If ketones are detected, therapy should be discontinued and the cat evaluated by a veterinarian at once. Routine monitoring recommendations: (…) Whenever clinical signs of DKA occur, **immediate veterinary consultation is necessary, as** the cat should be evaluated for the presence of ketone bodies (e.g. ketonuria and/or ketonaemia) indicating DKA. If the cat develops DKA, ketonuria or ketosis or if the cat´s clinical condition declines or blood glucose or fructosamine values worsen after initial improvement, additional diagnostics or alternative therapies may be required. Evaluation of haematology, serum chemistry, urinalysis and hydration status are recommended. **Section 3.6 of SPC and Section 7 of PL for Senvelgo:** Cats:

Very common (>1 animal / 10 animals treated):	Diarrhoea or loose stool[1] Polydipsia or polyuria[2] Weight loss[3] Dehydration[4] Vomiting[5]
Common	Diabetic ketoacidosis (DKA)[6]

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<table>
<tr><td>(1 to 10 animals / 100 animals treated):</td><td>Diabetic ketonuria[6]
Urinary tract infection (UTI)
Hypersalivation[7]
Hypercalcaemia[8]</td></tr>
</table>
(…)
[6] In case of DKA or diabetic ketonuria: Stop treatment and initiate insulin therapy. Fatal outcome was reported in post-marketing cases reporting DKA during treatment with Senvelgo. See also sections 3.3 and 3.5.
(…)
</td></tr>
<tr><td>Solensia
(frunevetmab)</td><td>14-16 April 2026</td><td>
Section 3.6 of SPC for Solensia:
Cats:
<table>
<tr><td>Common
(1 to 10 animals / 100 animals treated):</td><td>Alopecia, Dermatitis, Pruritus</td></tr>
<tr><td>Rare
(1 to 10 animals / 10 000 animals treated):</td><td>Injection site reaction (e.g. pain and alopecia)[1]
Skin disorders (e.g. skin scab, skin sore)</td></tr>
<tr><td>Very rare
(<1 animal / 10 000 animals treated, including isolated reports):</td><td>Anaphylaxis[2]
Ataxia
Polyuria
Polydipsia</td></tr>
</table>
[1]Mild.
[2]In case of such reactions, appropriate symptomatic treatment should be administered.

Section 7 of PL for Solensia:
Cats:
<table>
<tr><td>Common
(1 to 10 animals / 100 animals treated):</td><td>Alopecia (hair loss), Dermatitis, Pruritus (itching)</td></tr>
<tr><td>Rare</td><td>Injection site reaction (e.g. pain and alopecia)[1]
Skin disorders (e.g. skin scab, skin sore)</td></tr>
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<tr><td>(1 to 10 animals / 10 000 animals treated):</td><td></td></tr>
<tr><td>Very rare
(<1 animal / 10 000 animals treated, including isolated reports):</td><td>Anaphylaxis (severe allergic reaction)[2]
Ataxia (incoordination)
Polyuria (increased urination)
Polydipsia (increased thirst)</td></tr>
</table>
[1] Mild.
[2] In case of such reactions, appropriate symptomatic treatment should be administered.
</td></tr>
<tr><td>Versican Plus DHPPi/L4
(Canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine (inactivated))</td><td>10-12 February 2026</td><td>Section 3.6 of SPC and Section 7 of PL for Versican Plus DHPPi/L4 lyophilisate and suspension for suspension for injection for dogs:
Dogs:
<table>
<tr><td>Common
(1 to 10 animals / 100 animals treated):</td><td>Injection site swelling[1]</td></tr>
<tr><td>Rare
(1 to 10 animals / 10 ,000 animals treated):</td><td>Injection site lump, Injection site mass, Injection site nodule
Hypersensitivity reaction[2] (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting)
Anorexia, Decreased activity</td></tr>
<tr><td>Very rare
(<1 animal / 10 ,000 animals treated, including isolated reports):</td><td>Hyperthermia, Lethargy, Malaise
Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthritis</td></tr>
</table>
</td></tr>
<tr><td>Versican Plus Pi/L4
(Canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine (inactivated))</td><td>10-12 February 2026</td><td>Section 3.6 of SPC and Section 7 of PL for Versican Plus Pi/L4 lyophilisate and suspension for suspension for injection for dogs:
Dogs:
<table>
<tr><td>Common
(1 to 10 animals / 100 animals treated):</td><td>Injection site swelling[1]</td></tr>
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<tr><td>Rare
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Anorexia, Decreased activity</td></tr>
<tr><td>Very rare
(<1 animal / 10 ,000 animals treated, including isolated reports):</td><td>Injection site lump, Injection site mass, Injection site nodule
Hyperthermia, Lethargy, Malaise
Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthritis</td></tr>
</table></td></tr>
<tr><td>Versican Plus Pi/L4R (Canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine and rabies vaccine (inactivated))</td><td>10-12 February 2026</td><td>Section 3.6 of SPC and Section 7 of PL for Versican Plus Pi/L4R lyophilisate and suspension for suspension for injection for dogs:
Dogs:<table>
<tr><td>Common
(1 to 10 animals / 100 animals treated):</td><td>Injection site swelling[1]</td></tr>
<tr><td>Rare
(1 to 10 animals / 10 ,000 animals treated):</td><td>Hypersensitivity reaction[2] (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting)
Anorexia, Decreased activity</td></tr>
<tr><td>Very rare
(<1 animal / 10 ,000 animals treated, including isolated reports):</td><td>Injection site lump, Injection site mass, Injection site nodule
Hyperthermia, Lethargy, Malaise
Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthritis</td></tr>
</table></td></tr>
<tr><td>Versican Plus L4 (Canine leptospirosis vaccine (inactivated))</td><td>10-12 February 2026</td><td>Section 3.6 of SPC and Section 7 of PL for Versican Plus L4 lyophilisate and suspension for suspension for injection for dogs:
Dogs:</td></tr>
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<tr><td>Common
(1 to 10 animals / 100 animals treated):</td><td>Injection site swelling[1]</td></tr>
<tr><td>Rare
(1 to 10 animals / 10 ,000 animals treated):</td><td>Hypersensitivity reaction[2] (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting)
Anorexia, Decreased activity</td></tr>
<tr><td>Very rare
(<1 animal / 10 ,000 animals treated, including isolated reports):</td><td>Injection site lump, Injection site mass, Injection site nodule
Hyperthermia, Lethargy, Malaise
Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthritis</td></tr>
</table>
</td></tr>
<tr><td>Versican Plus DHPPi/L4R
(Canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) and canine leptospirosis and rabies vaccine (inactivated))</td><td>10-12 February 2026</td><td>Section 3.6 of SPC and Section 7 of PL for Versican Plus DHPPi/L4R lyophilisate and suspension for suspension for injection for dogs:
Dogs:
<table>
<tr><td>Common
(1 to 10 animals / 100 animals treated):</td><td>Injection site swelling[1]</td></tr>
<tr><td>Rare
(1 to 10 animals / 10 ,000 animals treated):</td><td>Hypersensitivity reaction[2] (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting)
Anorexia, Decreased activity</td></tr>
<tr><td>Very rare
(<1 animal / 10 ,000 animals treated, including isolated reports):</td><td>Injection site lump, Injection site mass, Injection site nodule
Hyperthermia, Lethargy, Malaise
Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthritis</td></tr>
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<tr><td>Yurvac RHD
(rabbit haemorrhagic disease and RHDV2 vaccine (recombinant))</td><td>10-12 February 2026</td><td>Section 3.6 of SPC and Section 7 of PL for YURVAC RHD:
Rabbits, including pet (dwarf) rabbits:

<table>
<tr><td>Very common
(> 1 animal / 10 animals treated):</td><td>Elevated temperature[1]
Injection site inflammation[2]</td></tr>
<tr><td>Very rare
(< 1 animal / 10 000 animals treated, including isolated reports):</td><td>Anorexia[3], Lethargy[3]
Intestinal stasis[3]
Lameness[3]</td></tr>
</table>
[1] ~~The highest individual rectal temperature increase was~~ Up to 1.15 ºC ~~which returned~~ returning to normal values within 24 hours~~ later~~.
[2] Inflammation (< 2 cm) at the injection may ~~can~~ be observed. These local reactions gradually reduce and disappear without need for treatment.
[3] Transient.</td></tr>
</table>