16 September 2025
EMA/CVMP/PhVWP/101663/2025
Veterinary Medicines Division

# Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2025

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 **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<br>(active substance(s))</th><th>CVMP meeting date</th><th>Recommendation – Summary of Product Characteristics (SPC)/Package Leaflet (PL) change<br>(additions to text in bold, deletions in ~~strikethrough~~)</th></tr>
<tr><td>Bravecto<br>(fluralaner)</td><td>10-12 June 2025</td><td>
Section 3.6 of SPC for Bravecto chewable tablets:<br><br>
Target species: Dog<br>
<table>
<tr><td>Common (1 to 10 animals / 100 animals treated, including isolated reports):</td></tr>
<tr><td>Gastrointestinal effects (such as Anorexia, Hypersalivation, Diarrhoea, Emesis) #~~.~~</td></tr>
<tr><td>Very rare (<1 animal / 10 000 animals treated, including isolated reports):</td></tr>
<tr><td>Lethargy;<br>Pruritus;<br>Muscle tremor, Ataxia, Convulsion.</td></tr>
</table>
# mild and transient<br><br>
Section 7 of PL for Bravecto chewable tablets:<br><br>
Target species: Dog<br>
<table>
<tr><td>Common (1 to 10 animals / 100 animals treated, including isolated reports):</td></tr>
<tr><td>Gastrointestinal effects (such as Inappetence, Drooling, Diarrhoea, Vomiting) #.</td></tr>
<tr><td>Very rare (<1 animal / 10 000 animals treated, including isolated reports):</td></tr>
<tr><td>Apathy;<br>Itching;<br>Muscle tremor, Ataxia, Convulsion.</td></tr>
</table>
# mild and transient<br><br>
Section 3.6 of SPC for Bravecto spot-on solution:
</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~~) |
|---|---|---|
| | | Target species: Dog<br><br>*Common (1 to 10 animals / 100 animals treated, including isolated reports):*<br>Skin reactions at the application site (such as Erythema, Alopecia) #<br><br>*Very rare (<1 animal / 10 000 animals treated, including isolated reports):*<br>Lethargy, Anorexia<br>Emesis**,** **Diarrhoea**;<br>**Pruritus**;<br>Muscle tremor, Ataxia, Convulsion.<br><br># mild and transient<br><br>**Section 7 of PL for Bravecto spot-on solution:**<br><br>Target species: Dog<br><br>*Common (1 to 10 animals / 100 animals treated, including isolated reports):*<br>Skin reactions at the application site (such as Erythema, Alopecia) #<br><br>*Very rare (<1 animal / 10 000 animals treated, including isolated reports):*<br>Apathy, Inappetence;<br>Vomiting, **Diarrhoea**;<br>**Itching**;<br>Muscle tremor, Ataxia (Incoordination), Convulsion.<br><br># mild and transient<br><br>**Section 3.6 of SPC for Bravecto spot-on solution:**<br><br>Target species: Cat<br><br>*Common (1 to 10 animals / 100 animals treated, including isolated reports):*<br>Skin reactions at the application site (such as Erythema, Pruritus, Alopecia) #<br><br>*Uncommon (1 to 10 animals / 1,000 animals treated, including isolated reports):* |

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|---|---|---|
| | | Muscle tremor,;<br>Lethargy, Anorexia;,<br>Emesis, Hypersalivation.<br><br>*Very rare (<1 animal / 10 000 animals treated, including isolated reports):*<br>**Pruritus**;<br>**Ataxia**, Convulsion.<br><br># mild and transient<br><br>**Section 7 of PL for Bravecto spot-on solution**:<br><br>Target species: Cat<br><br>*Common (1 to 10 animals / 100 animals treated, including isolated reports):*<br>Skin reactions at the application site (such as Erythema, Pruritus, Alopecia) #<br><br>*Uncommon (1 to 10 animals / 1,000 animals treated, including isolated reports):*<br>Muscle tremor;,<br>Apathy, Inappetence;,<br>Vomiting, Drooling.<br><br>*Very rare (<1 animal / 10 000 animals treated, including isolated reports):*<br>**Itching;**<br>**Ataxia (Incoordination),** Convulsion.<br><br># mild and transient |
| **DIVENCE IBR Marker Live** ((Live gE- tk- double gene-deleted bovine herpesvirus type 1 (BoHV-1), strain CEDDEL)) | **15-17 July 2025** | **Section 3.6 of SPC and 7 of PL for DIVENCE IBR Marker Live :**<br><br>Cattle:<br><br>*Very common (1 to 10 animals / 10 animals treated):*<br>Injection site inflammation[1], elevated temperature[2] |

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|---|---|---|
| | | *Uncommon (1 to 10 animals / 1,000 animals treated):*<br>Anaphylactic-type reaction[3]<br>**Milk production decrease[4]**<br>**Reduced food intake[4], Decreased activity[4]**<br><br>[1] A slight to moderate transient injection site inflammation (up to 14 cm of diameter) may be observed, which rapidly decreases in diameter within 2 days and subsides within 2 weeks without treatment.<br>[2] An elevated temperature (mean increase 1.7 ºC, in individual animals up to 2.4 ºC) may occur after vaccination. This increase subsides spontaneously within 3 days.<br>[3] In cases of anaphylactic-type reactions, an appropriate symptomatic treatment should be administered.<br>**[4] Observed in dairy cows, mostly after application of primary dose.** |
| **Divence Penta** (bovine viral diarrhoea (subunit), bovine parainfluenza 3 virus (inactivated), bovine respiratory syncytial virus and bovine herpesvirus type 1 (live) vaccine) | **13-15 May 2025** | **Section 3.6 of SPC and section 7 of PL for Divence Penta:**<br>Cattle:<br>*Very common (>1 animal / 10 animals treated):*<br>Injection site inflammation[1], elevated temperature[2]<br>*Uncommon (1 to 10 animals / 1,000 animals treated):*<br>Anaphylactic-type reaction[3].<br>**Milk production decrease[4].**<br>**Reduced food intake[4], Decreased activity[4].**<br>[1] A slight to moderate transient injection site inflammation (up to 14 cm of diameter) may be observed, which rapidly decreases in diameter within 2 days and subsides within 2 weeks without treatment.<br>[2] An elevated temperature (mean increase 1.7 ºC, in individual animals up to 2.4 ºC) may occur after vaccination. This increase subsides spontaneously within 3 days. |

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<tr><td></td><td></td><td>[3] In cases of anaphylactic-type reactions, an appropriate symptomatic treatment should be administered.<br>**[4] Observed in dairy cows, mostly after application of primary dose**.</td></tr>
<tr><td>Divence Tetra<br>(bovine viral diarrhoea (subunit), bovine parainfluenza 3 virus (inactivated), bovine respiratory syncytial virus and bovine herpesvirus type 1 (live) vaccine)</td><td>09-10 September 2025</td><td>Section 3.6 of SPC and section 7 of PL for Divence Tetra:<br>Cattle:<br><table><tr><td>Very common (>1 animal / 10 animals treated):</td></tr><tr><td>Injection site inflammation[1], elevated temperature[2]</td></tr><tr><td>Uncommon (1 to 10 animals / 1,000 animals treated):</td></tr><tr><td>Anaphylactic-type reaction[3].<br>Milk production decrease[4].<br>Reduced food intake[4], Decreased activity[4].</td></tr></table>[1] A slight to moderate transient injection site inflammation (up to 14 cm of diameter) may be observed, which rapidly decreases in diameter within 2 days and subsides within 2 weeks without treatment.<br>[2] An elevated temperature (mean increase 1.7 ºC, in individual animals up to 2.4 ºC) may occur after vaccination. This increase subsides spontaneously within 3 days.<br>[3] In cases of anaphylactic-type reactions, an appropriate symptomatic treatment should be administered.<br>**[4] Observed in dairy cows, mostly after application of primary dose**.</td></tr>
<tr><td>Eluracat<br>(capromorelin)</td><td>15-17 July 2025</td><td>Section 3.6 of SPC for Eluracat:<br>Target species: Cats<br><table><tr><td>Very common (1 to 10 animals / 10 animals treated):</td></tr><tr><td>Hypersalivation[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~~) |
|---|---|---|

| *Common (1 to 10 animals / 100 animals treated):* |
|---|
| Diarrhoea, Vomiting<br>Anaemia<br>Skin lesions (on the mouth and chin)<br>Dehydration, Lethargy |
| ***Rare (1 to 10 animals / 10 000 animals treated)*** |
| **Anorexia**<br>**Behavioural disorder** |
| *Very rare (<1 animal / 10,000 animals treated, including isolated reports):* |
| Bradycardia, Hypotension<br>**Dyspnoea**<br>**Loss of consciousness, Sedation**<br>**Recumbency**<br>**Muscle weakness**<br>**Hiding** |

[1] At the time of dosing and resolved within a few minutes.

**Section 7 of PL for Eluracat:**

Target species: Cats

| *Very common (1 to 10 animals / 10 animals treated):* |
|---|
| Drooling[1] |
| *Common (1 to 10 animals / 100 animals treated):* |
| Diarrhoea, Vomiting<br>Anaemia<br>Skin lesions (on the mouth and chin)<br>Dehydration, Lethargy |
| ***Rare (1 to 10 animals / 10 000 animals treated)*** |

<table>
<tr><th>Product<br>(active substance(s))</th><th>CVMP meeting date</th><th>Recommendation – Summary of Product Characteristics (SPC)/Package Leaflet (PL) change<br>(additions to text in bold, deletions in ~~strikethrough~~)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>Anorexia (loss of appetite)<br>Behavioural disorder</td></tr>
<tr><td>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</td></tr>
<tr><td>Bradycardia (slow heart rate), Hypotension (low blood pressure)<br>Dyspnoea (difficulty in breathing)<br>Loss of consciousness, Sedation<br>Recumbency (lying down)<br>Muscle weakness<br>Hiding</td></tr>
</table>
[1] At the time of dosing and resolved within a few minutes
</td></tr>
<tr><td>Librela<br>(Bedinvetmab)<br>New</td><td>04-06 November 2025</td><td>
Section 3.5 of the SPC for Librela:<br><br>
<u>Special precautions for safe use in the target species:</u><br>
Caution should be used when treating patients with the following pre-existing conditions: immune-mediated haemolytic anaemia, immune-mediated polyarthritis, immune-mediated thrombocytopenia.<br>
Caution should be used when treating patients with pre-existing seizure disorder.<br><br>
Section 3.6 of the SPC for Librela:<br>
Dogs:<br><br>
<table>
<tr><td>Uncommon<br>(1 to 10 animals / 1,000 animals treated):</td><td>Injection site reaction (e.g. injection site swelling, injection site warmth)[1].</td></tr>
<tr><td>Rare</td><td>Diarrhoea, Emesis.</td></tr>
</table>
</td></tr>
</table>

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|---|---|---|

| | |
|---|---|
| (1 to 10 animals / 10 000 animals treated): | Ataxia[2].<br>Polyuria, Urinary incontinence.<br>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.<br>**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.

**Section 6. of the PL for Librela:**

Special precautions for safe use in the target species:
**Caution should be used when treating patients with the following pre-existing conditions: low amounts of red blood cells (immune-mediated haemolytic anaemia), lameness and swelling in multiple joints (immune-mediated polyarthritis), low amounts of platelets (thrombocytes) (immune-mediated thrombocytopenia).**
**Caution should be used when treating patients with pre-existing convulsion (seizure) disorder.**

**Section 7. of the PL for Librela:**
Dogs:

| | |
|---|---|
| Uncommon (1 to 10 animals / 1 000 animals treated): | Injection site reaction (e.g. injection site swelling, injection site warmth)[1]. |

<table>
<tr><th>Product<br>(active substance(s))</th><th>CVMP meeting date</th><th>Recommendation – Summary of Product Characteristics (SPC)/Package Leaflet (PL) change<br>(additions to text in bold, deletions in ~~strikethrough~~)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>Rare (1 to 10 animals / 10 000 animals treated):</td><td>Diarrhoea, Vomiting.<br>Incoordination (ataxia)[2].<br>Increased need to urinate (polyuria), Urinary incontinence.<br>Anorexia[3], Lethargy, Increased thirst (polydipsia).</td></tr>
<tr><td>Very rare (<1 animal / 10 000 animals treated, including isolated reports):</td><td>Hypersensitivity reaction (anaphylaxis, facial swelling, itching (pruritus))[4].<br>Low amounts of red blood cells (immune- mediated haemolytic anaemia); Joint pain, Lameness and Swelling in multiple joints (immune-mediated polyarthritis); Low amounts of platelets (thrombocytes) (immune-mediated thrombocytopenia).<br>Weakness (paresis), Loss of movement (paralysis), convulsion (seizure).</td></tr>
</table>
[1]Mild.<br>[2]Including incoordination due to reduced sensory function (proprioceptive ataxia).<br>[3]Often related to a transient reduced appetite.<br>[4]In case of such reactions, appropriate symptomatic treatment should be administered.
</td></tr>
<tr><td>Mhyosphere PCV ID<br>(Inactivated recombinant Mycoplasma hyopneumoniaecpPCV2, strain Nexhyon)<br>New</td><td>04-06 November 2025</td><td>Section 3.6 of the SPC for Mhyosphere PCV ID<br><br>Pigs:
<table>
<tr><td>Very common<br>(> 1 animal / 10 animals treated):</td><td>Injection site inflammation[1]<br>Depression[2]<br>Elevated temperature[3]</td></tr>
<tr><td>Common<br>(1 to 10 animals / 100 animals treated):</td><td>Injection site inflammation[4]<br>~~Elevated temperature~~</td></tr>
</table>
</td></tr>
</table>

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|---|---|---|

| | |
|---|---|
| Very rare (< 1 animal / 10 000 animals treated, including isolated reports): | Anaphylactic-type reaction[5] |

[1]Mild transient local reactions consisting of non-painful skin inflammations, of less than or equal to 3 cm in diameter.

[2]A slight depression, which subsides in less than 24 hours without treatment is very commonly observed.

**[3]Increase in body temperature (mean 1.6 ºC, in individual pigs less than 2.3 ºC) that subsides spontaneously within 24 - 48 hours without treatment.**

~~[3]Moderate inflammation (between 3-5 cm) at the inoculation site is observed from 4 hours post-vaccination to day three. These local reactions can be observed during the first week after vaccination and last for 1 to 5 days. One or two weeks later, these local reactions can reappear lasting for 1 to 7 days. Local reactions disappear completely within approximately 3 weeks after vaccination without treatment.~~

**[4]Slight to moderate inflammation (between 0.3-5 cm) at the inoculation site can be observed during the first week after vaccination. One or two weeks later, these local reactions can reappear. Local reactions disappear completely within approximately 3 weeks after vaccination without treatment.**

~~[4]Slight transient increase in body temperature (mean 0.6 ºC, in individual pigs less than 2 ºC) that subsides spontaneously within 48 hours without treatment.~~

[5]Anaphylactic-type reactions (e.g. vomiting, circulatory disorders, dyspnoea) which might be life-threatening, may occur in some sensitive animals. Under these circumstances, appropriate symptomatic treatment should be administered.

**Section 7. of the PL for Mhyosphere PCV ID**

Pigs:

| | |
|---|---|
| Very common | Injection site inflammation[1] |

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|---|---|---|

| | |
|---|---|
| (> 1 animal / 10 animals treated): | Depression[2]<br>**Elevated temperature[3]** |
| Common<br>(1 to 10 animals / 100 animals treated): | Injection site inflammation[4]<br>~~Elevated temperature~~ |
| Very rare<br>(< 1 animal / 10 000 animals treated, including isolated reports): | Anaphylactic-type reaction (severe allergic reaction)[5] |

[1]Mild transient local reactions consisting of non-painful skin inflammations, of less than or equal to 3 cm in diameter.

[2]A slight depression, which subsides in less than 24 hours without treatment is very commonly observed.

**[3]Increase in body temperature (mean 1.6 ºC, in individual pigs less than 2.3 ºC) that subsides spontaneously within 24 - 48 hours without treatment.**

~~[3]Moderate inflammation (between 3-5 cm) at the inoculation site is observed from 4 hours post-vaccination to day three. These local reactions can be observed during the first week after vaccination and last for 1 to 5 days. One or two weeks later, these local reactions can reappear lasting for 1 to 7 days. Local reactions disappear completely within approximately 3 weeks after vaccination without treatment.~~

**[4]Slight to moderate inflammation (between 0.3-5 cm) at the inoculation site can be observed during the first week after vaccination. One or two weeks later, these local reactions can reappear. Local reactions disappear completely within approximately 3 weeks after vaccination without treatment.**

~~[4]Slight transient increase in body temperature (mean 0.6 ºC, in individual pigs less than 2 ºC) that subsides spontaneously within 48 hours without treatment.~~

[5]Anaphylactic-type reactions (e.g. vomiting, circulatory disorders, dyspnoea) which might be life-threatening, may occur in some sensitive animals. Under these circumstances, appropriate symptomatic treatment should be administered.

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| **Neptra** (florfenicol, terbinafine and mometasone) | **15-17 July 2025** | **Section 3.6 of SPC and 7 of PL for Neptra ear drops solution:**<br><br>Target species: Dog<br><br>*Very rare (<1 animal / 10 000 animals treated, including isolated reports):*<br>Application site erythema, Application site inflammation, Application site pain[1]<br>Hyperactivity, Vocalisation[1]<br>Emesis<br>Deafness[2], Impaired hearing[2], Internal ear disorder, Head shake[1]<br>Eye disorder (e.g. blepharospasm, conjunctivitis, corneal ulcer, eye irritation, keratoconjunctivitis sicca).<br>Ataxia, **Facial paralysis**, Nystagmus<br>Anorexia<br><br>[1]Observed to occur shortly after product administration.<br>[2]Mainly in elderly animals |
| **Osurnia** (Terbinafine/Florfenicol/ Betamethasone acetate) | **11-13 March 2025** | **Section 4.5 of SPC and section 12 of the PL:**<br><br>The veterinary medicinal product may be irritating to eyes. Avoid accidental contact to the dog's eyes. If accidental ocular exposure does occur, the eyes should be flushed thoroughly with water for 10 to 15 minutes. If clinical signs develop, seek veterinary advice.<br>~~In very rare cases, eye disorders such as keratoconjunctivitis sicca and corneal ulcers have been reported in treated dogs, in absence of eye contact with the product. Although a causal relationship with the veterinary medicinal product was not definitively established, o~~**O**wners should be recommended to monitor ocular signs (such as squinting, redness and discharge) in the hours and days following the product application, and to promptly consult a veterinarian in case such signs appear. **See section 4.6 [PL: section 6] for details on ocular adverse events in dogs.** |

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<tr><td></td><td></td><td>Section 4.6 of SPC and section 6 of the PL:<br><br>Deafness or impaired hearing, usually temporary, have been reported after use in very rare cases in dogs, mainly in elderly animals, in post authorisation experience.<br>Application site reactions (i.e. erythema, pain, pruritus, oedema and ulcer) have been reported in very rare cases, in post authorisation experience.<br>Hypersensitivity reactions including facial oedema, urticaria and shock have been reported in very rare cases, in post authorisation experience.<br>In very rare cases, eye disorders such as neurogenic keratoconjunctivitis sicca, keratoconjunctivitis sicca, corneal ulcer, blepharospasm, eye redness and ocular discharge have been reported in treated dogs (see also section 4.5 [PL: section 12] – special precautions for use in animals).<br>Ataxia, internal ear disorder (mainly head tilt), facial paralysis and nystagmus have been reported in very rare cases in post authorisation experience.</td></tr>
<tr><td>Yurvac RHD<br>(rabbit haemorrhagic disease and RHDV2 vaccine (recombinant))<br>New</td><td>7-9 October 2025</td><td>Section 3.6 of the SPC and section 7. of the PL for Yurvac RHD:<br><br>Rabbits, including pet (dwarf) rabbits:<br><br>
<table>
<tr><td>Very common<br>(> 1 animal / 10 animals treated):</td><td>Elevated temperature[1]<br>Injection site inflammation[2]</td></tr>
<tr><td>Very rare<br>(< 1 animal / 10 000 animals treated, including isolated reports):</td><td>Anorexia[3]<br>Intestinal stasis[3]</td></tr>
</table>
[1] The highest individual rectal temperature increase was 1.15 ºC which returned to normal values 24 hours later.<br>[2] Inflammation (< 2 cm) at the injection can be observed. These local reactions gradually reduce and disappear without need for treatment.<br>[3] Transient.</td></tr>
</table>