EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

VETERINARY MEDICINES IN **2025**

An agency of the European Union

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AUTHORISATION OF NEW MEDICINES

Recommendationsfortheauthorisationofnewveterinary medicines in 2025 at a glance:

30 POSITIVE OPINIONS

13 NEW ACTIVE SUBSTANCES

NEGATIVE OPINIONS

5 WITHDRAWN APPLICATIONS

New veterinary medicines recommended for authorisation in 2025:

PRODUCT NAME	New active substance	Cats	Cattle	Chickens	Dogs	Ducks	Goats	Horses	Pigs	Sea breams	Sheep	Turkeys
BioBhyo Bluevac-3	•								•			
BRAVECTO CombiUNO			•								•	
CEVAC REOMUNE					•							
Ecovaxxin MS Elmaro				•								
Emevet Epizootic haemorrhagic disease vaccine (recombinant protein) Laboratorios Syva S.A.	•			•								
Firocoxib CP-Pharma		•			•							
Fluralaner Intervet	•		•		•							
Hemosyvet					•							
Hepizovac					•							
Innovax-ND-IBD-ILT		•		•	•		•	•	•			
Lenivia	•		•									
Nobilis Multriva	•			•								
Gm+REOm	•				•							
				•								

PRODUCT NAME	New active substance	Cats	Cattle	Chickens	Dogs	Ducks	Goats	Horses	Pigs	Sea breams	Sheep	Turkeys
Nobilis Multriva IBm+ND				•								
Nobilis Multriva IBm+ND+EDS				•								
Nobilis Multriva IBm+ND+Gm+REOm +EDS				•								
Nobilis Multriva REOm				•								
Numelvi	•				•							
Omeprazole TriviumVet					•							
Portela	•	•										
Prazivetin										•		
Prevestrus vet	•				•							
Syvazul BTV 3			•								•	
Varenzin	•	•										
Vaxxinact H5	•			•		•						•
Vaxxitek HVT+IBD+H5	•			•								•
Vectormune HVT-AIV				•								
Zenrelia	•				•							

INNOVATIVE VETERINARY MEDICINES AND VACCINES

BioBhyo
A new vaccine for the active immunisation of pigs against infections caused by *Brachyspira hyodysenteriae*.

Bluevac-3
A new vaccine for the active immunisation of sheep to reduce the viraemia (presence of viruses in the blood), mortality and clinical signs caused by the serotype 3 of the bluetongue virus. The vaccine is also intended for active immunisation of cattle to reduce the viraemia against the serotype 3 of the bluetongue virus.

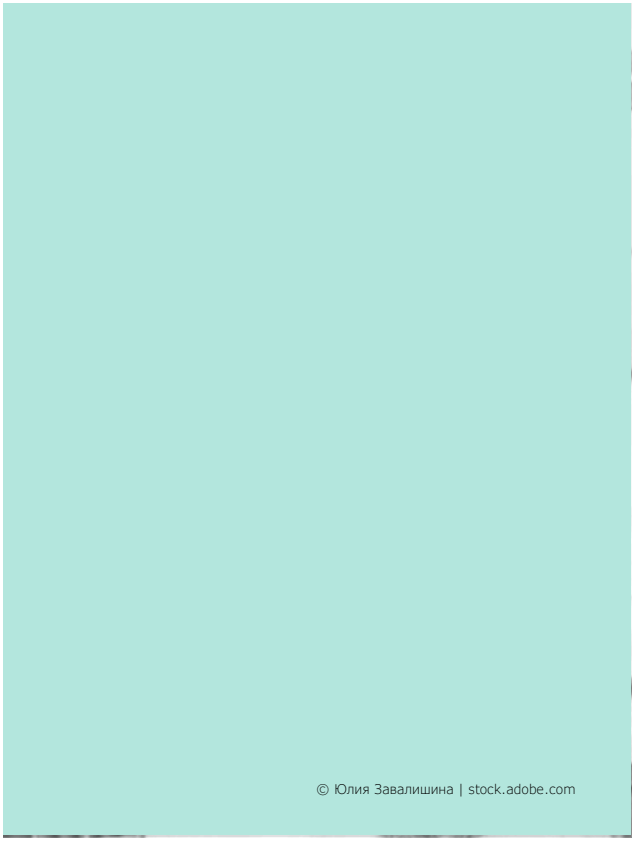
CEVAC REOMUNE A new vaccine for passive immunisation of broilers induced by active immunisation of broiler breeders to reduce clinical signs of tenosynovitis induced by avian reovirus infection.

Ecovaxxin MS A new vaccine for the active immunisation of future layer and breeder chickens from 4 weeks of age to reduce air sac lesions, foot pad lesions (synovitis), ovarian regressions and egg production losses caused by *Mycoplasma synoviae* infections.

Epizootic haemorrhagic disease vaccine (recombinant protein) Laboratorios Syva S.A.
A new biotech vaccine for the active immunisation of cattle to reduce viraemia and fever caused by epizootic haemorrhagic disease virus serotype 8.

Hepizovac
A new vaccine for the active immunisation of cattle to prevent viraemia caused by epizootic haemorrhagic disease virus serotype 8.

Innovax-ND-IBD-ILT
A new biotech vaccine for the active immunisation of one-day-old chicks or 18-19 day-old embryonated chicken eggs to reduce mortality and clinical signs caused by Newcastle disease virus and to reduce mortality, clinical signs and lesions caused by avian infectious laryngotracheitis virus, Marek's disease virus and infectious bursal disease virus.



Nobilis Multriva REOm
A new vaccine for the active immunisation of chickens and for passive immunisation of their progeny to reduce viraemia and clinical signs of disease caused by avian reovirus genotypes 1 and 4.

Nobilis Multriva Gm+REOm
A new vaccine for the active immunisation of chickens and for passive immunisation of their progeny to reduce:

- mortality and clinical signs of disease caused by very virulent (CS89) and classical (STC) strains of infectious bursal disease virus;
- viraemia and clinical signs of disease caused by avian reovirus genotypes 1 and 4.

Legend:
Cats Cattle Chickens Dogs Ducks Pigs Sea breams Sheep Turkeys

Nobilis Multriva IBm+ND
A new vaccine for the active immunisation of chickens to reduce:

- respiratory signs and egg drop caused by infectious bronchitis virus strains Massachusetts (GI-1 genotype) and 4/91-793B (GI-13 genotype);

- mortality and clinical signs caused by Newcastle disease virus.

Nobilis Multriva IBm+ND+EDS
A new vaccine for the active immunisation of chickens to reduce:

- respiratory signs and egg drop caused by infectious bronchitis virus strains Massachusetts (GI-1 genotype) and 4/91-793B (GI-13 genotype);

- mortality and clinical signs caused by Newcastle disease virus;

- egg drop and eggshell defects caused by egg drop syndrome-1976 virus.

Nobilis Multriva IBm+ND+Gm+REOm+EDS
A new vaccine for the active immunisation of chickens to reduce:

- respiratory signs and egg drop caused by infectious bronchitis virus strains Massachusetts (GI-1 genotype) and 4/91-793B (GI-13 genotype);

- mortality and clinical signs caused by Newcastle disease virus;

The vaccine is also intended for the passive immunisation of their progeny to reduce:

- mortality and clinical signs of disease caused by very virulent (CS89) and classical (STC) strains of infectious bursal disease virus;

- viraemia and clinical signs of disease caused by avian reovirus genotypes 1 and 4;

- egg drop and eggshell defects caused by egg drop syndrome-1976 virus.

Prazivetin
A medicine for the treatment of ectoparasitic infestations of the gills of sea breams caused by monogenean trematodes principally of the species *Sparicotyle chrysophrii*.

Prevestrus vet
A medicine intended to shorten the pro-oestrus and oestrus period, reduce clinical signs of heat and reduce the risk of pregnancy in dogs (bitches).

Syvazul BTV 3
A new vaccine for the active immunisation of sheep to reduce viraemia, mortality, clinical signs and lesions caused by bluetongue virus serotype 3.

Varenzin
A medicine for the management of non-regenerative anaemia associated with chronic kidney disease in cats, by increasing haematocrit/ packed cell volume.

Vaxxinact H5
A new biotech vaccine for the following indications associated with highly pathogenic avian influenza serotype 5, including the circulating clade 2.3.4.4b:

- active immunisation to prevent mortality, clinical signs and to reduce viral excretion in chickens and mulard ducks;

- to reduce mortality, clinical signs and viral excretion in muscovy ducks and turkeys;

- to reduce viral excretion in pekin ducks.

Vaxxitek HVT+IBD+H5
A new biotech vaccine for:

- active immunisation of one-day-old chicks or 18-day-old embryonated chicken eggs to reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic avian influenza virus of the H5 subtype, including the circulating clade 2.3.4.4b.

- active immunisation of one-day-old turkeys to reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic avian influenza virus of the H5 subtype, including the circulating clade 2.3.4.4b.

Vectormune HVT-AIV
A new biotech vaccine for the active immunisation of one-day-old chickens to reduce mortality, clinical signs, and virus excretion due to infection with highly pathogenic avian influenza virus of the H5 subtype.

NEW USES FOR EXISTING MEDICINES

The use of an already authorisedmedicineinanew species or for a

new indication offers new treatment opportunities. The use of 11 known products was expanded in 2025:

Bravecto TriUNO
To be also used for the treatment of infections with *Angiostrongylus vasorum* in dogs.

Credelio, Credelio Plus and Lotimax
To be also used for the treatment of sarcoptic mange (*Sarcoptes scabiei*) and by killing the vector *Dermacentor reticulatus*, the medicines reduce the risk of transmission of the vector-borne pathogen *Babesia canis canis* in dogs.

Daxocox
To be also used for the treatment of pain and inflammation associated with orthopaedic or soft tissue surgery in dogs.

Dexdomitor 0.5 mg/ml solution for injection
To be administered intravenously as a constant rate infusion in dogs and cats as part of a multimodal protocol during inhalation anaesthesia.

Frontpro
To be also used for the treatment of tick infestation with *Hyalomma marginatum*, reduction of the risk of infection with *Dipylidium caninum* via transmission by *Ctenocephalides felis* for 30 days, and reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for 28 days in dogs.

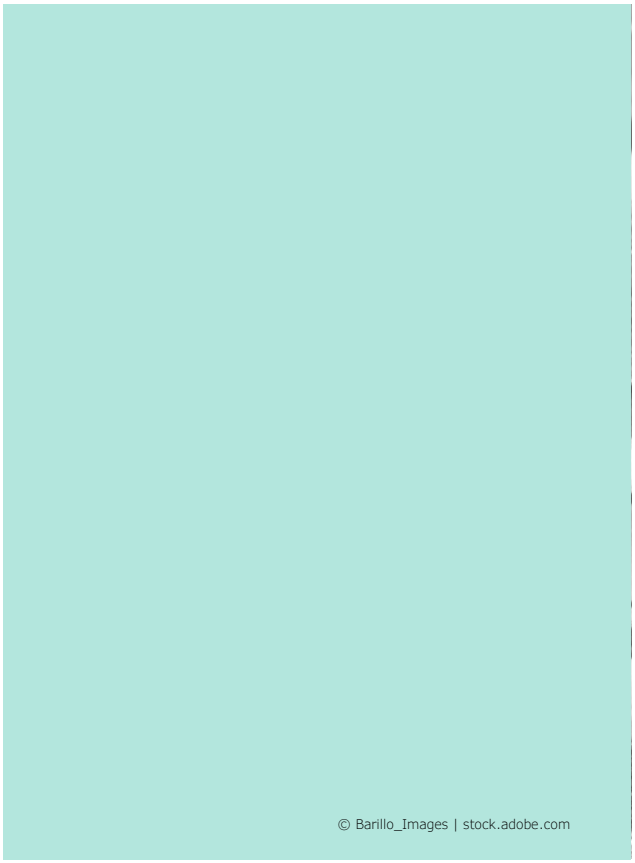
Nexgard and Nexgard spectra
To be also used for reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for 28 days and for reduction of the risk of infection with *Dipylidium caninum* via transmission by *Ctenocephalides felis* for 30 days in dogs.

Stronghold Plus
To be also used for reduction of the risk of infection with *Dipylidium caninum* via transmission by *Ctenocephalides felis* for up to one month after treatment in cats.

Syvazul BTV 3
To be also used for the active immunisation of cattle to reduce viraemia caused by bluetongue serotype 3.

KEEPING MEDICINES SAFE

Once a medicine has been put on the market, EMA and European Union (EU) Member States continue to monitor its quality and benefit/risk balance.



Important safety procedures in 2025 included:

Bravecto chewable tablets
Amendment to the product information on potential side effects following administration of Bravecto chewable tablets, to include pruritus (itching).

Bravecto spot-on solution for cats Amendment to the product information on potential side effects following the administration of Bravecto spot-on solution for cats, to include pruritus (itching) and ataxia (incoordination).

Bravecto spot-on solution for dogs
Amendment to the product information on potential side effects following administration of Bravecto spot-on solution for dogs, to include diarrhoea and pruritus (itching).

Divence IBR Marker Live, Divence Penta and Divence Tetra Amendment to the product information on potential side effects following administration of Divence IBR Marker Live, Divence Penta, as well as Divence Tetra, to include milk production decrease, reduced food intake and decreased activity observed in dairy cows.

Eluracat
Amendment to the product information on potential side effects following administration of Eluracat, to include anorexia (loss of appetite), behavioural disorder, dyspnoea (difficulty breathing), loss of consciousness, sedation, recumbency (lying down), muscle weakness and hiding.

Felpreva
Amendment to the product information on potential side effects following administration of Felpreva, to change the frequency of application site reaction (e.g. scratching, erythema (reddening), hair loss, inflammation) from very rare to rare.

Librela
Amendment to the product information on potential side effects following administration of Librela, to include diarrhoea, emesis (vomiting), joint pain, lameness and swelling in multiple joints (immune-mediated polyarthritis), weakness (paresis), loss of movement (paralysis) and convulsion (seizure). In addition, special precautions should be taken when treating dogs 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) or when treating dogs with pre-existing convulsion (seizure) disorder.

Mhyosphere PCV ID
Amendment to the product information on potential side effects following administration of Mhyosphere PCV ID, to change the frequency of elevated temperature from common to very common.

Neptra
Amendment to the product information on potential side effects following administration of Neptra, to include facial paralysis (loss of movement).

Osurnia
Amendment to the product information for Osurnia, to include new special precautions: 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 and ataxia (incoordination), internal ear disorder (mainly head tilt), facial paralysis and nystagmus (involuntary eye movements) have been reported in very rare cases in post-authorisation experience.

Yurvac RHD
Amendment to the product information on potential side effects following administration of Yurvac RHD, to include anorexia (loss of appetite) and intestinal stasis (inactivity).

MAXIMUM RESIDUAL LIMITS (MRL) RECOMMENDED IN 2025

Where a medicine is marketed for use in food-producing animals, any human safety concerns that might result from exposure to residues of the medicine remaining in animal-derived food need to be addressed.

The maximum residue limits (MRLs) recommended by EMA reflect how much residue of the veterinary medicine in food derived from a treated animal is safe for consumption. The MRL is established before the medicine for food-producing animals is authorised in the EU and entered in the annex to Commission Regulation (EU) No 37/2010.

Positive opinions were adopted recommending the extension of MRLs for the following active substances in 2025:

- **Fluralaner**
  extension to salmonidae and other fin fish

- **Lidocaine**
  modification in porcine

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European Medicines Agency

Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

+31 (0)88 781 6000

www.ema.europa.eu

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