



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

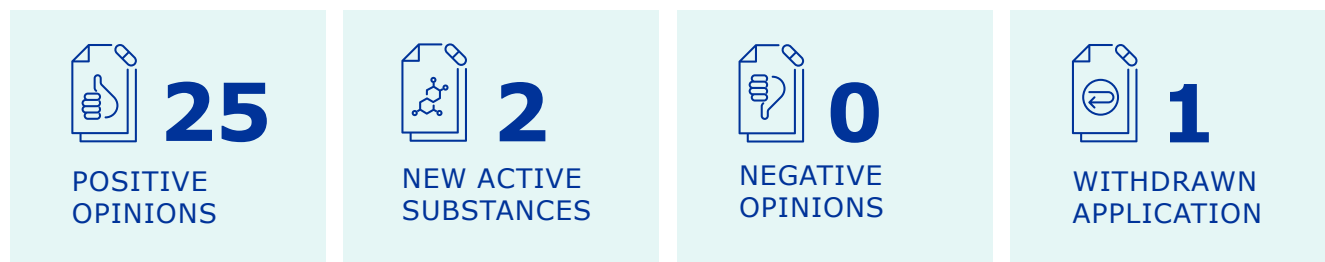
VETERINARY MEDICINES IN 2024













AUTHORISATION OF NEW MEDICINES

Recommendations for the authorisation of new veterinary medicines in 2024 at a glance:



New veterinary medicines recommended for authorisation in 2024:

PRODUCT NAME	New active substance	Atlantic salmon	Cattle	Cats	Chickens	Dogs	Pigs
							
Alcort						•	
ArthriCox						•	
BRAVECTO TriUNO						•	
CARPROFEN ORION				•		•	
Cepeloron						•	
Cevac Salmune ETI K					•		
Cirbloc M Hyo							•
DIVENCE IBR Marker Live			•				
DIVENCE PENTA	•		•				
DIVENCE Tetra			•				
DuOtic						•	
Ichtiovac ERM		•					
Innovax-ND-H5	•				•		
Lexylan			•			•	

PRODUCT NAME	New active substance	Atlantic salmon 	Cattle 	Cats 	Chickens 	Dogs 	Pigs 
Lotimax						•	
Nobilis Multiriva RT+IBm+ND+EDS					•		
Nobilis Multiriva RT+IBm+ND+Gm+REOm					•		
Nobilis Multiriva RT+IBm+ND+Gm+REOm+EDS					•		
Porcilis PCV M Hyo ID							•
Poulvac Procerta HVT-IBD-ND					•		
RESPIVAC aMPV					•		
TOLFENAMIC ACID VMD			•	•		•	•
Trilocur						•	
Trilorale						•	
VAXXON ND CLONE					•		



INNOVATIVE VETERINARY MEDICINES

Cevac Salmune ETI K

A new vaccine for the active immunisation of chickens (breeders and layers) from 10 weeks of age to reduce faecal excretion of *Salmonella* Enteritidis, *Salmonella* Typhimurium and *Salmonella* Infantis.

Cirbloc M Hyo

A new biotech vaccine for the active immunisation of pigs to reduce viraemia (presence of viruses in the blood), virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection, the severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection, and to reduce the loss in body weight gain.

DIVENCE IBR Marker Live

A new biotech vaccine for the active immunisation of cattle from 10 weeks of age to reduce virus shedding, hyperthermia (high body temperature) and clinical signs caused by bovine herpesvirus type 1 (BoHV-1).

DIVENCE PENTA

A new biotech vaccine for the active immunisation of cattle from 10 weeks of age to reduce virus shedding, hyperthermia (high body temperature), clinical signs and lung lesions caused by bovine respiratory syncytial virus and parainfluenza virus 3; to reduce virus shedding, hyperthermia and clinical signs caused by infectious bovine rhinotracheitis virus; to reduce viraemia (presence of viruses in the blood), hyperthermia and leukopenia (decrease in the number of white blood cells) caused by bovine viral diarrhoea virus 1 and bovine viral diarrhoea virus 2 and virus shedding caused by bovine viral diarrhoea virus 2; and for the active immunisation of heifers and cows to reduce births of persistently infected calves and transplacental infection of bovine viral diarrhoea virus (type 1 and 2).

DIVENCE Tetra

A new biotech vaccine for the active immunisation of cattle against bovine respiratory syncytial virus and parainfluenza-3 virus to reduce virus shedding, hyperthermia (high body temperature), clinical signs and lung lesions and against bovine viral diarrhoea virus (type 1 and 2) to reduce viraemia (presence of viruses in the blood), hyperthermia and leukopenia (decrease in the number of white blood cells) caused by bovine viral diarrhoea virus 1 and bovine viral diarrhoea virus 2 and virus shedding caused by bovine viral diarrhoea virus 2; and for active immunisation of heifers and cows to reduce births of persistently infected calves and transplacental infection of bovine viral diarrhoea virus (type 1 and 2).

Icthiovac ERM

A new vaccine for the active immunisation of Atlantic salmon fry to reduce mortality caused by serotype O1 (biotypes 1 and 2) and serotype O2 (biotype 1) of *Yersinia ruckeri* in freshwater.

Innovax-ND-H5

A new biotech vaccine for the active immunisation of one-day-old chicks or 18–19 day-old embryonated chicken eggs to reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic avian influenza (HPAI) virus of the H5 type.

Nobilis Multriva RT+IBm+ND+EDS

A new vaccine for the active immunisation of chickens for reduction of egg drop caused by avian metapneumovirus, reduction of respiratory signs and egg drop caused by infectious bronchitis virus strains, reduction of mortality and clinical signs caused by Newcastle disease virus and reduction of egg drop and eggshell defects caused by egg drop syndrome '76 virus.

Legend:

 Atlantic salmon  Cattle  Cats  Chickens  Dogs  Pigs

Nobilis Multriva RT+IBm+ND+Gm+REOm

A new vaccine for the active immunisation of chickens for reduction of egg drop caused by avian metapneumovirus, reduction of respiratory signs and egg drop caused by infectious bronchitis virus strains, reduction of mortality and clinical signs caused by Newcastle disease virus and for the passive immunisation of the progeny of the vaccinated chickens to reduce mortality and clinical signs of disease caused by strains of infectious bursal disease virus, and to reduce viraemia and clinical signs of disease caused by avian reovirus.

Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS

A new vaccine for the active immunisation of chickens for reduction of egg drop caused by avian metapneumovirus, reduction of respiratory signs and egg drop caused by infectious bronchitis virus, reduction of mortality and clinical signs caused by Newcastle disease virus, passive immunisation of the progeny of the vaccinated chickens to reduce mortality and clinical signs of disease caused by very virulent strains of infectious bursal disease virus (IBDV) and to reduce viraemia and clinical signs of disease caused by avian reovirus, and reduction of egg drop and eggshell defects caused by egg drop syndrome virus.

Porcilis PCV M Hyo ID

A new biotech vaccine for the active immunisation of pigs to reduce viraemia (presence of viruses in the blood), virus load in lungs and lymphoid tissues, and faecal virus shedding caused by porcine circovirus type 2 (PCV2) infection and severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection and to reduce the loss of daily weight gain during the finishing period in face of infections with PCV2 and/or *Mycoplasma hyopneumoniae*.

Poulvac Procerta HVT-IBD-ND

A new biotech vaccine for the active immunisation of one-day-old chickens and 18-19 day old embryonated chicken eggs to reduce mortality, clinical signs and lesions caused by Marek's disease (MD) virus; reduce mortality, clinical signs and lesions caused by infectious bursal disease (IBD) virus; and reduce mortality and clinical signs caused by Newcastle disease (ND) virus.

RESPIVAC aMPV (previously Respivac TRT)

A new vaccine for the active immunisation of chickens to reduce the detrimental effect caused by virulent avian metapneumovirus on the ciliary activity, which may be manifested in respiratory clinical signs.

VAXXON ND CLONE

A new vaccine for the active immunisation of chickens from day 1 to reduce mortality and clinical signs of disease caused by infection with Newcastle disease virus.

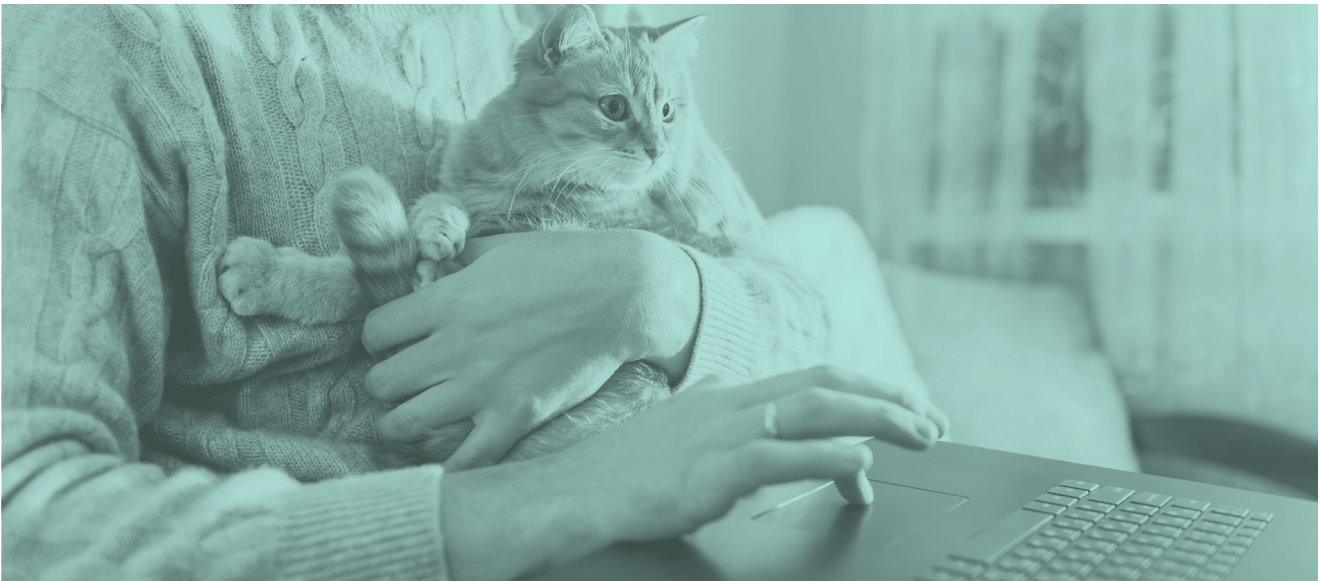


Legend:

 Atlantic salmon  Cattle  Cats  Chickens  Dogs  Pigs

NEW USES FOR EXISTING MEDICINES

The use of an already-authorized medicine in a new species or a new indication offers new treatment opportunities. The use of four known products was expanded in 2024:



Metacam

Metacam 5mg/ml solution for injection for dogs and cats to also be used for alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats (e.g. orthopaedic and soft tissue surgery).

Simparica Trio

To also be used for the treatment of the lungworm *Angiostrongylus vasorum*.

Stronghold Plus

To also be used for the treatment of notoedric mange (*Notoedres cati*) in cats.

YURVAC RHD

To also be used for passive immunisation against rabbit haemorrhagic disease (RHD) of the offspring of the does vaccinated with YURVAC RHD vaccine.

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 2024 included:

AdTab and Credelio

Amendment to the product information on potential side effects following administration of AdTab and Credelio in cats, to include hyperactivity, ataxia (incoordination), muscle tremor, tachypnoea (rapid shallow breathing), pruritus (itching), anorexia (appetite loss), and lethargy. Furthermore, amendment to the product information on potential side effects following administration of AdTab and Credelio in dogs, to include bloody diarrhoea, polydipsia (increased thirst), pruritus, inappropriate urination, polyuria (increased urination), and urinary incontinence.

Eluracat

Amendment to the product information on potential side effects following administration of Eluracat, to include bradycardia (slow heart rate) and hypotension (low blood pressure). In addition, recommendation for a change concerning the warning for use of the product in cats with hypersomatotropism (excessive growth particularly of the jaws, skull and other parts of the body caused by too much growth hormone) was upgraded to a contraindication.

Kexxtone

Recommendation for suspension of the marketing authorisation of Kexxtone 32.4 g continuous-release intraruminal device for cattle (monensin) due to a quality defect which has resulted in cases where cattle regurgitated the device while it still contained monensin tablets. This resulted in increased accidental exposure, including deaths, in non-target species (dogs) and potential lack of efficacy in cattle. To minimise the risk of exposure to non-target species, all batches of Kexxtone have been recalled from the market.

Librela

Amendment to the product information on potential side effects following administration of Librela, to include ataxia (incoordination) together with proprioceptive ataxia, urinary incontinence, anorexia (often related to a transient reduced appetite), and lethargy.



Profender

Amendment to the product information on potential side effects following administration of Profender, to include diarrhoea, anorexia (loss of appetite), lethargy and behavioural disorders, such as hyperactivity, anxiety and vocalisation.

Strangvac

Amendment to the product information on potential side effects following administration of Strangvac, to include muscle stiffness around the injection site, as well as injection site swellings exceeding 8 cm, to note that the majority of these have been observed in the pectoral muscle.

MAXIMUM RESIDUAL LIMITS (MRL) RECOMMENDED IN 2024

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](#).

A positive opinion was adopted recommending MRLs for the following active substance in 2024:

- **Ketoprofen**
Establishment of numerical MRLs in all ruminants, porcine and *equidae* (animals of the horse family).





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