



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

VETERINARY MEDICINES HIGHLIGHTS 2023



AUTHORISATION OF NEW MEDICINES

Recommendations for the authorisation of new veterinary medicines in 2023 at a glance:



New veterinary medicines recommended for authorisation in 2023:

PRODUCT NAME	New active substance	Cattle	Cats	Chickens	Dogs	Rabbits
Bovilis Cryptium	•	•				
Bovilis Nasalgen-C	•	•				
Eluracat	•		•			
Eurican L4	•				•	
Innovax-ILT-IBD	•			•		
Loxitab					•	
Newflend ND H9	•			•		
Nobivac LoVo L4					•	
Oxmax	•				•	
Poulvac Procerta HVT-IBD				•		
Prevexxion RN+HVT				•		
Prolevare					•	
Senvelgo	•		•			
YURVAC RHD	•					•



INNOVATIVE VETERINARY MEDICINES

Bovilis Cryptium

A new biotech vaccine for the active immunisation of pregnant heifers and cows to raise antibodies in their colostrum against Gp40 of *Cryptosporidium parvum*. This is expected to provide passive immunisation of calves to reduce clinical signs (i.e. diarrhoea) caused by *C. parvum*.

Bovilis Nasalgen-C

A new vaccine for the active immunisation of cattle from the day of birth onwards to reduce clinical signs of upper respiratory tract disease and nasal viral shedding from infection with bovine coronavirus.

Eurican L4

A new vaccine for the active immunisation of dogs from 7 weeks of age to prevent or reduce mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions due to canine leptospirosis.

Innovax ILT-IBD

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 lesions caused by avian infectious laryngotracheitis (ILT) virus and Marek's disease virus and to prevent mortality and reduce clinical signs and lesions caused by infectious bursal disease (IBD) virus.

Newflend ND H9

A new biotech vaccine for the active immunisation of one-day-old chicks or 18-day-old chicken embryonated eggs to reduce clinical signs, lesions and virus shedding caused by Newcastle disease virus (NDV) and to reduce mortality, clinical signs, lesions, and virus shedding caused by H9 subtype of low pathogenic avian influenza virus (LPAIV-H9).

Nobivac LoVo L4

A new vaccine for the active immunisation of dogs against *Leptospira interrogans* serogroup Canicola serovar Canicola to reduce infection and urinary excretion, *L. interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni to reduce infection and urinary excretion, *L. interrogans* serogroup Australis serovar Bratislava to reduce infection and *L. kirschneri* serogroup Grippotyphosa serovar Bananal/Liangguang to reduce infection and urinary excretion.

Poulvac Procerta HVT-IBD

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

Prevexxion RN+HVT

A new biotech vaccine for the active immunisation of one-day-old chicks to prevent mortality and reduce clinical signs and lesions caused by Marek's disease virus, including very virulent Marek's disease virus.

YURVAC RHD

A new biotech vaccine for the active immunisation of rabbits from 30 days of age to reduce mortality of rabbit haemorrhagic disease (RHD) caused by classical RHD virus (RHDV) and variant strains (RHDV2), including highly virulent strains.



Legend:

 Cattle  Chickens  Dogs  Rabbits

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 8 known products was expanded in 2023:

Bravecto

To be also available as 150 mg/ml powder and solvent for suspension for injection for dogs and to introduce a new route of administration.

Bravecto Plus

To be also used for the prevention of lungworm disease caused by *Aelurostrongylus abstrusus* in cats.

Coxevac

To be also used for the active immunisation of sheep.

Frontpro

To be also used for the treatment of tick infestations with *Ixodes hexagonus* in dogs.

Gumbohatch

To be also used for the active immunisation of future layer chickens (for egg production).

Nexgard Combo

To be also used for immediate and persistent tick killing activity against *Ixodes hexagonus* and for persistent tick killing activity against *Rhipicephalus sanguineus* in cats.

Suvaxyn PRRS

To add nasal use as an additional route of administration and to be also used for protection against heterologous subtype-1 AUT15-33, subtype-2 BOR57 and subtype-3 Lena strains of the porcine respiratory and reproductive syndrome (PRRS) virus.

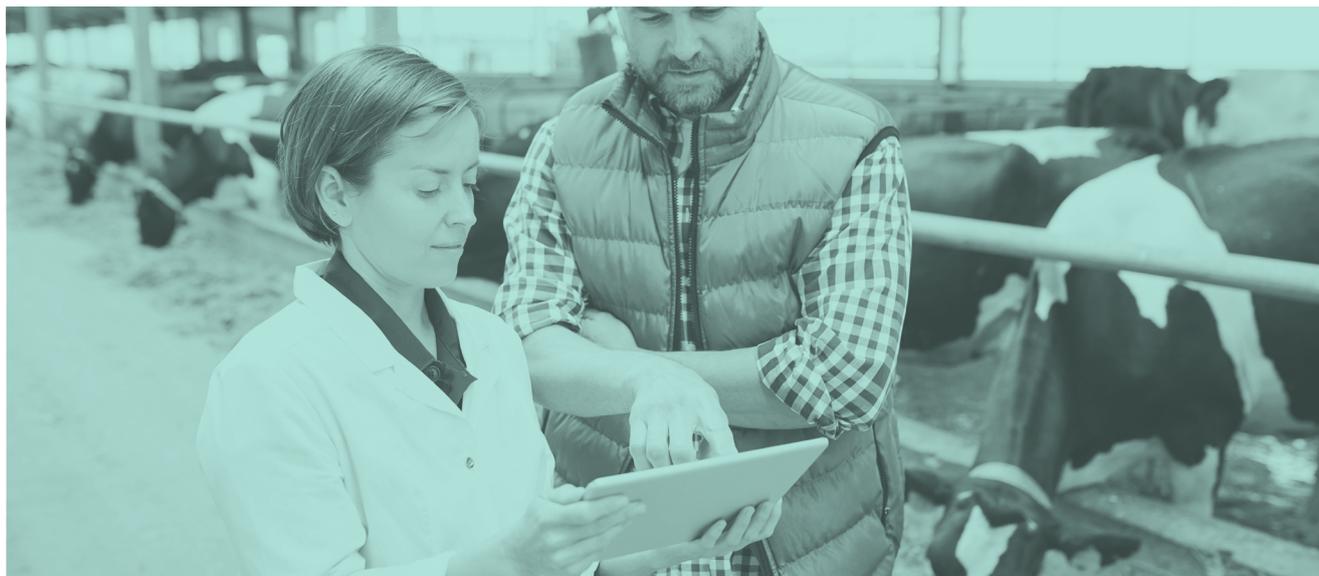
Zeleris

To be also used for the treatment of bovine respiratory disease due to *Mycoplasma bovis* associated with pyrexia (fever).



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 2023 included:

Apoquel

Amendment to the product information on potential side effects following administration of Apoquel, to include convulsion.

Cimalgex

Amendment to the product information on potential side effects following the administration of Cimalgex, to include frequent urination and/or excessive thirst. A statement was also added to reflect that severe adverse events in the gastrointestinal tract and kidneys may be fatal.

Galliprant

Amendment to the product information on potential side effects following the administration of Galliprant, to include pancreatic inflammation.

Injectable veterinary medicines containing procaine benzylpenicillin

Recommendation not to use these veterinary medicines for the treatment of infections caused by certain pathogens. In addition, recommendation to update the product information to add potential

side effects following the administration of these medicines in young piglets and new warnings to ensure their efficacious use. For some of these medicines, the dose and treatment duration were increased, and consequently the meat and offal withdrawal periods for all target species to ensure consumer safety.

Neptra

Amendment to the product information for Neptra, to include new special precautions for use in cats as it can be associated with neurological signs (including ataxia (incoordination)), Horner's syndrome with protrusion of membrane nictitans (translucent third eyelid), miosis (constricted pupil), anisocoria (unequal pupil size), internal ear disorders (head tilt), anorexia and lethargy.

Solensia

Amendment to the product information on potential side effects following the administration of Solensia, to include anaphylaxis (severe allergic reaction) and skin disorders (e.g. skin scab, skin sore). In case of anaphylaxis, appropriate symptomatic treatment should be administered.

MAXIMUM RESIDUAL LIMITS (MRL) RECOMMENDED IN 2023

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 2023:

- **Sodium salicylate**
Extension to poultry except turkey
- **Ketoprofen**
Extension to poultry
- **Rafoxanide**
Extrapolation to bovine, ovine and other ruminants' milk





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