



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



Veterinary medicines highlights 2019

Authorisation of new medicines

Overview of the European Medicines Agency's (EMA) recommendations for the authorisation of new veterinary medicines in 2019:

15 Positive opinions

5 New active substances

1 Negative opinion

0 Withdrawn applications

Authorisation of new medicines in 2019

15 Positive opinions

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1 Negative opinion

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New veterinary medicines

Dogs



Afoxolaner Merial
Chanhold
Evicto
Neptra
Simparica Trio
Stelfonta

Cats



Chanhold
Evicto
Felisecto Plus
Mirataz

Pigs



Baycox Iron
Forceris
ReproCyc ParvoFLEX

Cattle



Nasym

Horses



Aservo EquiHaler

Chicken



Gumbohatch

Rabbits



Nobivac Myxo RHD Plus

Medicines that contain a new active substance are highlighted in green

Particularly relevant recommendations*

Innovations advancing animal health



Horses

Aservo EquiHaler

For the treatment of horses with clinical signs of severe equine asthma.



Cattle

Nasym

A vaccine for the active immunisation of cattle to reduce virus shedding and respiratory clinical signs caused by bovine respiratory syncytial virus infection.



Pigs

ReproCyc ParvoFLEX

A vaccine for the active immunisation of gilts and sows from the age of five months to protect progeny against transplacental infection caused by porcine parvovirus.



Dogs

Stelfonta

For the treatment of non-resectable, non-metastatic cutaneous and subcutaneous mast cell tumours in dogs.

Vaccines



Chicken

Gumbohatch

Avian infectious bursal disease vaccine (live)
A vaccine intended to protect broiler chickens (reared for meat) against infectious bursal disease (IBD) virus infection caused by a very virulent IBD virus.



Cattle

Nasym

Bovine respiratory syncytial virus vaccine (live)
A vaccine for the active immunisation of cattle to reduce virus shedding and respiratory clinical signs caused by bovine respiratory syncytial virus infection.



Rabbits

Nobivac Myxo-RHD Plus ●

Myxomatosis and rabbit haemorrhagic viral disease vaccine (live recombinant)
A vaccine intended for active immunisation of rabbits from five weeks of age against myxomatosis and rabbit haemorrhagic disease.



Pigs

ReproCyc ParvoFLEX

Porcine parvovirus vaccine (inactivated)
A vaccine for the active immunisation of gilts and sows from the age of five months to protect progeny against transplacental infection caused by porcine parvovirus.

● Biotech vaccine

Medicines for minor use minor species (MUMS)**



Horses

Aservo EquiHaler

For the treatment of horses with clinical signs of severe equine asthma.



Rabbits

Nobivac Myxo RHD Plus

A live recombinant vaccine intended for active immunisation of rabbits from five weeks of age against myxomatosis and rabbit haemorrhagic disease.



Dogs

Stelfonta

For the treatment of non-resectable, non-metastatic cutaneous and subcutaneous mast cell tumours in dogs.

*The same veterinary product may appear in several categories.

** Minor use veterinary medicines are intended for use in major species such as cattle, sheep, pigs, chicken, atlantic salmon, cats and dogs, for the treatment of diseases that occur infrequently or occur in limited geographical areas. Minor species are all animals that are not one of the major species.

New uses for existing medicines

The use of ten known substances was expanded in 2019:



Bravecto

To be also used for the treatment of demodicosis caused by *Demodex canis* in dogs.

NexGard

To be also used for the treatment of tick infestations (*Ixodes hexagonus*).

Nexgard Spectra

To be also used for the prevention of establishment of thelaziosis (adult *Thelazia callipaeda* eyeworm infection).

Onsior

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

ProZinc

To be also used in dogs.



Advocate

To be also used for the prevention and treatment of *Aelurostrongylus abstrusus* in cats and the treatment of *Thelazia callipaeda* in cats.

Broadline

To be also used for the treatment of infections with *Ancylostoma ceylanicum* (L4 larvae and adults).

Bravecto Plus

To be also used for the treatment of infestations with ear mites (*Otodectes cynotis*).



Innovax ND-IBD

To be administered by *in ovo* route for chicken embryonated eggs.

Nobilis IB 4-91

To include the claim for associated non-mixed use with Innovax-ND-IBD.

If a medicine is supposed to be used in a food-producing animal, it needs to be safe for people to eat the food that comes from this animal.

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.

MRLs were established for the following active substances in 2019:



Rabbits

Bambermycin



Horses

Ciclesonide

Keeping medicines safe

Once a medicine has been put on the market, EMA and EU Member States continue to look at its quality and benefit-risk balance.

Important new safety advice issued in 2019:

Bravecto	Add further information in the package leaflet on potential side effects following administration of Bravecto , such as further neurological signs.
Bravecto Plus	Add special precautions and warnings to the product information for Bravecto Plus to ensure the safety of the person handling and administering the treatment, as well as include information on potential side effects following administration, such as neurological signs.
Broadline	Amend the product information on potential side effects affecting vision following administration of Broadline .
Coxevac	Add further information in the package leaflet on potential side effects following administration of Coxevac , such as systemic reactions.
Credelio	Add further information in the package leaflet on potential side effects following administration of Credelio , such as neurological reactions.
Cytopoint	Add further information in the package leaflet on potential side effects following administration of Cytopoint , such as neurological reactions.
Draxxin	Amend the product information for Draxxin , to include additional special precautions for use in animals.
Eravac	Amend the product information on potential side effects following administration of Eravac to include lethargy and/or inappetence.
Letifend	Amend the product information on potential side effects following administration of Letifend , such as lethargy, vomiting, diarrhoea and hyperthermia.
Nexgard Spectra	Add further information in the package leaflet on potential side effects following administration of Nexgard Spectra , such as erythema and neurological signs.
Osurnia	Amend the product information for Osurnia to include special precautions relating to off-label use of the product in cats.
Simparica/ Mipet Easecto	Clarify further the information in the package leaflet on potential side effects following administration of Simparica and MiPet Easecto in relation to neurological signs.
Suprelorin	Amend the product information on potential side effects following administration of Suprelorin , in relation to weight gain and neurological signs.
Zycortal	Add further information in the package leaflet on potential side effects following administration of Zycortal , such as injection site reactions.

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