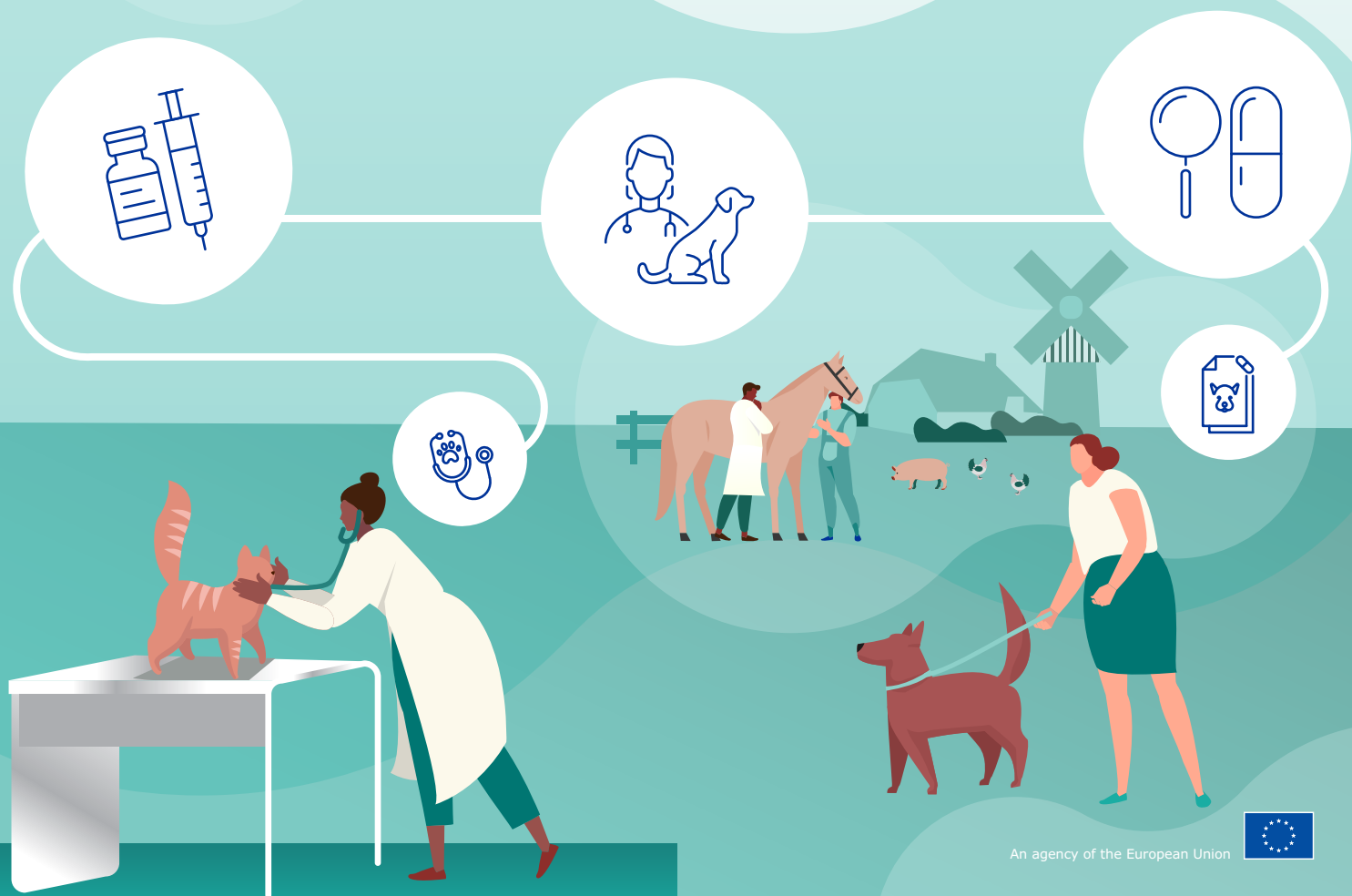




EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Veterinary Medicines Highlights 2022



# AUTHORISATION OF NEW MEDICINES

Recommendations for the authorisation of new veterinary medicines in 2022 at a glance:



## New veterinary medicines



### Dogs

DogStem  
Cortaderm  
Coxatab  
Lotilaner Elanco  
Mometamax Ultra  
**Neoleish**



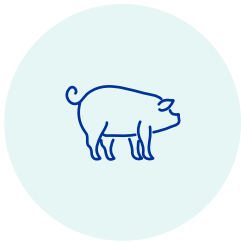
### Cattle

Chanaxin



### Chickens

Evanovo



### Pigs

Chanaxin  
**Brucellin Aquilon**



### Horses

**RenuTend**



### Cats

Lotilaner Elanco



### Sheep

Chanaxin

# PARTICULARLY RELEVANT RECOMMENDATIONS\*

## Innovations advancing animal health



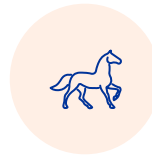
### Dogs

#### DogStem

A new veterinary medicine for reduction of pain and lameness associated with osteoarthritis in dogs.

#### Neoleish

A plasmid DNA vaccine for the active immunisation of Leishmania-negative dogs from 6 months of age to reduce the risk of developing an active infection and/or clinical disease after exposure to *Leishmania infantum*.



### Horses

#### RenuTend

A new veterinary medicine to improve healing of injuries of tendons and suspensory ligaments in horses.

## Vaccines



### Chickens

#### Evanovo

A new vaccine for the active immunisation of chickens to reduce clinical signs (diarrhoea), intestinal lesions and oocysts output associated with coccidiosis caused by *Eimeria acervulina*, *Eimeria maxima* and *Eimeria praecox*, and for the reduction of clinical signs, intestinal lesions and oocysts output associated with coccidiosis caused by *Eimeria tenella*.



### Dogs

#### Neoleish ●

A plasmid DNA vaccine for the active immunisation of Leishmania-negative dogs from 6 months of age to reduce the risk of developing an active infection and/or clinical disease after exposure to *Leishmania infantum*.

● Biotech vaccine

\*The same veterinary product may appear in several categories.

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## 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 2022:



### Dogs

#### Bravecto

Chewable tablets for dogs to be also used for persistent tick killing activity from 7 days to 12 weeks after treatment for *Ixodes hexagonus* and for reduction of the risk of infection with *Dipylidium caninum* via transmission by *Ctenocephalides felis* for up to 12 weeks.

#### Credelio

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

#### Nexgard and Nexgard Spectra

To be also used for the treatment of tick infestations with *Hyalomma marginatum* and for the treatment of ear mite infestations (caused by *Otodectes cynotis*). The product information was also amended to allow the use of these veterinary medicines in breeding, pregnant and lactating female dogs.



### Dogs

#### Simparica and MiPet Easecto

To be also used for reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for 28 days after treatment.

#### Suprelorin

To be also used in female dogs.



### Cats

#### Advocate

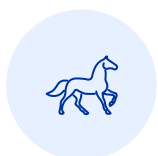
To be also used for the treatment of the lungworm *Troglostrongylus brevior* (adults) in cats.

#### Suprelorin

To be also used in male cats.

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## Medicines for minor use minor species (MUMS)\*\*



### Horses

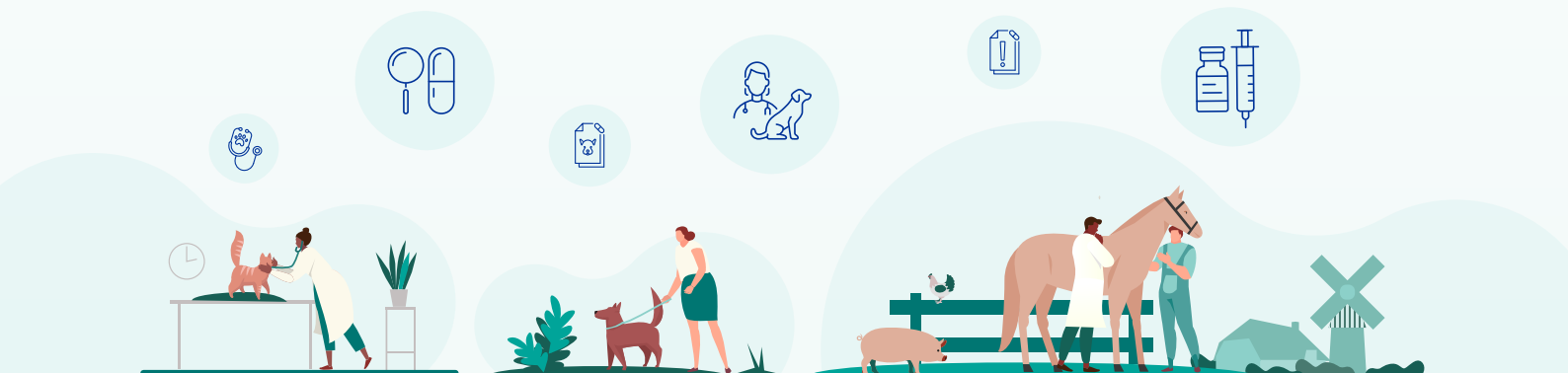
#### RenuTend

A new product to improve healing of injuries of tendons and suspensory ligaments in horses.

\*\* 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.

## KEEPING MEDICINES SAFE

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



### Important safety procedures in 2022 included:



Addition of further information in the package leaflet on potential side effects following the administration of:

**Bravecto spot-on solution for dogs**

Muscle tremor (shaking); ataxia (incoordination); convulsion

**BTVPUR**

Hypersensitivity reactions

**Cardalis**

Lethargy (lack of energy); anorexia (loss of appetite); ataxia; incoordination or signs of fatigue. In dogs with chronic kidney disease, benazepril<sup>1</sup> may increase plasma creatinine concentrations at the start of therapy very rarely

**Cerenia**

Neurological disorders, such as ataxia, convulsion/seizure, or muscle tremor

**Equilis Prequenza**

Hypersensitivity reaction, including anaphylaxis (sometimes fatal)

**Equilis Prequenza Te**

Hypersensitivity reaction, including anaphylaxis (sometimes fatal)

**Equilis Te**

Hypersensitivity reaction, including anaphylaxis (sometimes fatal)

**Felpreva**

Neurological disorders, such as ataxia (incoordination) and tremor

**Hiprabovis IBR Marker Live**

Hypersensitivity reactions, including anaphylaxis (sometimes fatal) (change of frequency from "very rare" to "rare" and addition of anaphylaxis)

**Librela**

Polydipsia; polyuria (increase in urine production); addition of anaphylaxis, pruritus (itching) and facial swelling under hypersensitivity reactions; clinical signs of immune-mediated diseases, such as haemolytic anaemia or thrombocytopenia (low blood platelet counts, which can lead to bleeding and bruising)

<sup>1</sup> Benazepril hydrochloride and Spironolactone are the active substances of Cardalis.

<b>Mhyosphere PCV ID</b>	Anaphylactic-type reactions (e.g. vomiting, circulatory disorders, dyspnoea), which might be life-threatening
<b>Nasym</b>	Anaphylactic-type reactions, which may be serious (including fatal)
<b>Neptra</b>	Deafness or impaired hearing, mainly in elderly animals (dogs)
<b>Nobivac DP Plus</b>	Hypersensitivity reaction, including anaphylaxis (sometimes fatal)
<b>Nobivac Myxo-RHD Plus</b>	Anorexia; lethargy
<b>Procox</b>	Lethargy; muscle tremor; ataxia (incoordination); convulsion
<b>Proteq West Nile</b>	Injection site abscess
<b>Solensia</b>	Mild reactions at the injection site (e.g. pain and alopecia (hair loss))
<b>Stelfonta</b>	Compromised circulation; loss of essential tissue
<b>Suprelorin</b>	Epileptic seizures
<b>Zuprevo</b>	Anaphylaxis (may be fatal)



Addition of new special precautions for use of:

<b>Aservo EquiHaler</b>	A European survey showed that 16 out of 84 horses could not be treated according to the product information due to horses not co-operating. In case a horse has a tendency towards defensive behavioural reactions, additional safety precautions could be considered (e.g. employ a second person to handle the horse). Acclimatising the horse with a training device prior to treatment start has in some cases shown to ease the administration of the veterinary medicine.
<b>Improvac</b>	The safety and efficacy of the veterinary medicine in non-target species, such as horses, has not been evaluated. Adverse events have been observed in horses, including serious anaphylactic-type reactions, which have led to fatalities.
<b>Librela</b>	Where a dog has not been able to properly exercise prior to treatment due to its clinical condition, it is recommended that the dog is gradually (over a few weeks) allowed to increase the amount of exercise they take (to prevent overexercise by some dogs).
<b>Stelfonta</b>	Treating tumours at extremities may result in localised impairment of circulation due to a local inflammatory response at the treatment site leading to tissue loss and possible requirement for amputation. Ingestion of tumour remnants should be prevented.
<b>Suvaxyn Circo</b>	In case of accidental self-injection, the person administering the veterinary medicine should seek medical advice immediately and show the package leaflet or the label to the physician.



Addition of new advice on correct administration of:

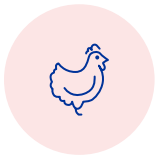
<b>Stelfonta</b>	The site of application should be covered for the first day after treatment in order to prevent licking of residual or leaking product (in addition to the prevention of direct contact with the residual or leaking product).
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## **NEW MAXIMUM RESIDUAL LIMITS (MRLs) INTRODUCED IN 2022**

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](#).

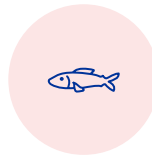
Positive opinions were adopted recommending the extension of MRLs for the following active substances in 2022:



### **Chickens**

#### **Ketoprofen**

extension to chickens; this conclusion was extrapolated to poultry.



### **Fish**

#### **Praziquantel**

extension to fin fish; the entry for ovine species was extrapolated to all ruminants except cattle.

**European Medicines Agency**

Domenico Scarlattilaan 6  
1083 HS Amsterdam  
The Netherlands

**Telephone** +31 (0)88 781 6000

**Send a question:** [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

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