



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:

Positive opinion:

New active substances

Negopin W a<sub>l</sub>

Withdrawn applications

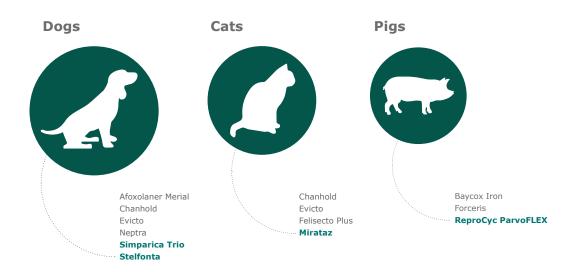
# **Authorisation of new medicines in 2019**

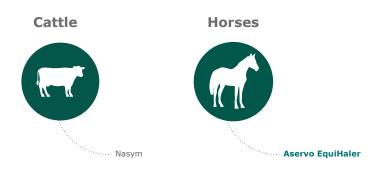
Positive opinions

New active substances

Negativ opinion Withdrawn application

## **New veterinary medicines**







## 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, nonmetastatic 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 parvovirosis 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.



### 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, nonmetastatic cutaneous and subcutaneous mast cell tumours in dogs.

<sup>\*</sup>The same veterinary product may appear in several categories.

<sup>\*</sup> 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.

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.



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

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