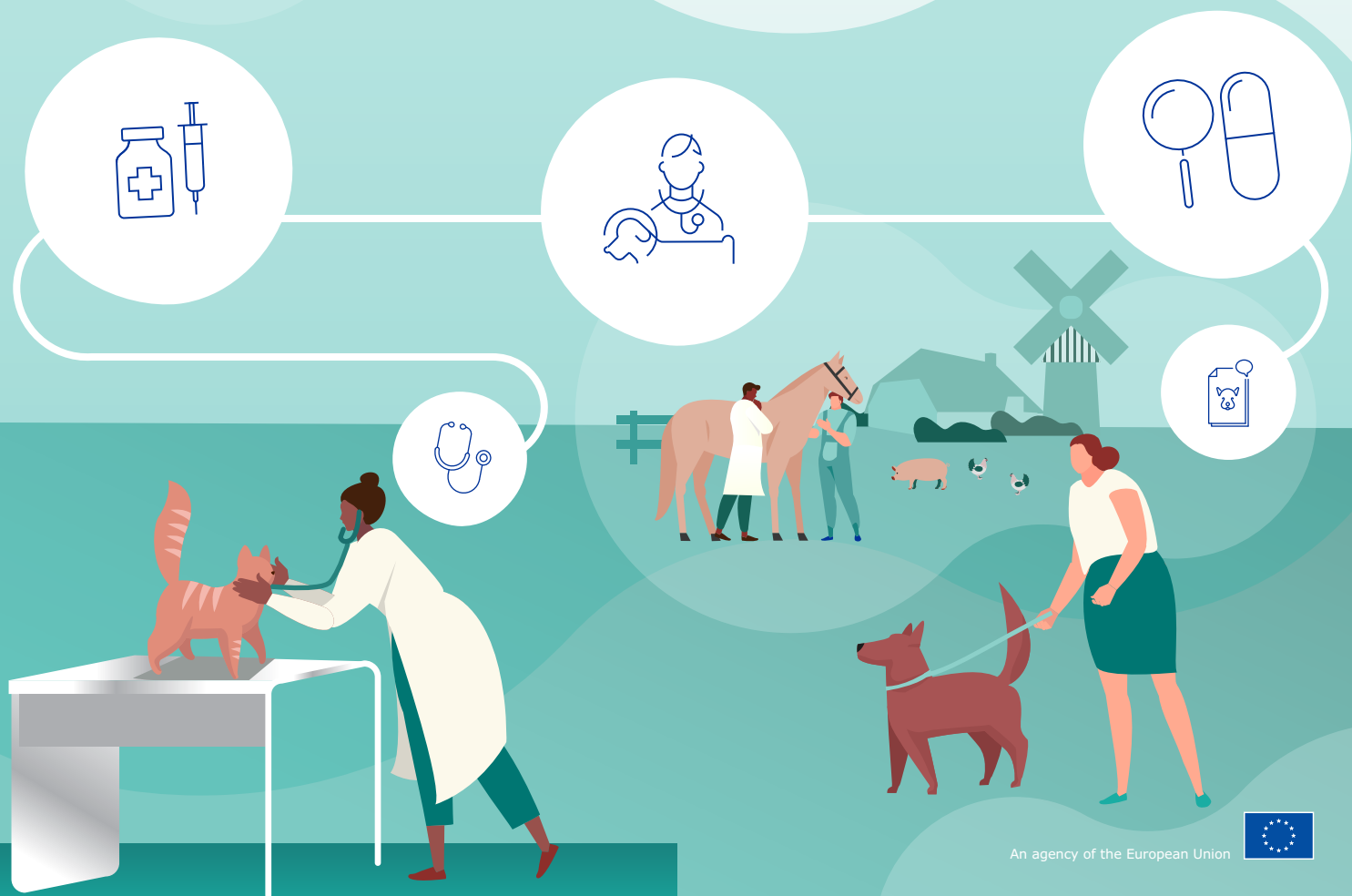




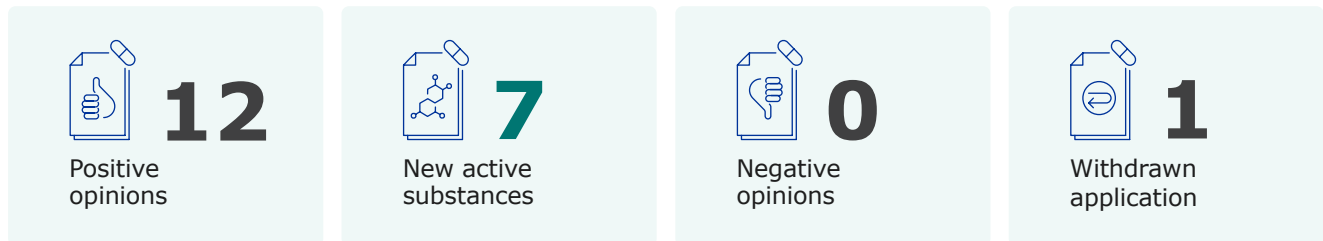
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Veterinary Medicines Highlights 2021



AUTHORISATION OF NEW MEDICINES

Recommendations for the authorisation of new veterinary medicines in 2021 at a glance:



New veterinary medicines



Dogs

Credelio Plus
Daxocox
Imoxat
Tessie
Zenalpha



Chickens

Ultifend ND IBD



Cats

Bonqat
Felpreva
Imoxat



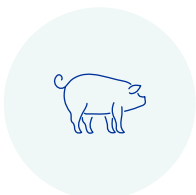
Ferrets

Imoxat



Horses

Strangvac



Pigs

CircoMax
Suiseng Diff/A



Rabbits

Fatrovax RHD

Medicines that contain a new active substance are highlighted in green

INNOVATIVE MEDICINES AND VACCINES*

Vaccines



Chickens

Ultifend ND IBD ●

A new vaccine for the active immunisation of chickens or chicken embryonated eggs to reduce mortality, clinical signs and lesions caused by Newcastle disease virus and to reduce virus shedding; to reduce mortality, clinical signs and bursa lesions caused by very virulent infectious bursal disease virus (IBDV); to reduce mortality, clinical signs and lesions caused by classical Marek's disease virus.



Pigs

Suiseng Diff/A ●

A new vaccine for the passive immunisation of neonatal piglets by means of the active immunisation of breeding sows and gilts to prevent mortality and reduce clinical signs and macroscopic lesions caused by *Clostridioides difficile*, toxins A and B and to reduce clinical signs and macroscopic lesions caused by *Clostridium perfringens* Type A, alpha-toxin.



Horses

Strangvac ●

A new vaccine for the active immunisation of horses from 8 months of age to reduce clinical signs of disease in the acute stage of infection with *Streptococcus equi* and reduction in number of abscesses within submandibular and retropharyngeal lymph nodes.



Rabbits

Fatrovax RHD

A new vaccine for the active immunisation of rabbits from 28 days of age against rabbit haemorrhagic disease caused by rabbit haemorrhagic disease virus 1 (RHDV1) and rabbit haemorrhagic disease virus 2 (RHDV2).

Fatrovax RHD is used to reduce mortality, infection, clinical signs and organ lesions of rabbit haemorrhagic disease, which causes high death rates in young and adult rabbits.

Fatrovax RHD increases the range of available treatments for a minor species. The active substances are obtained by means of biotechnology using *Trichoplusia ni* pupae, avoiding the use of rabbits in the production of the vaccine. This is in line with the so-called 3R principles (replace, reduce and refine animal use for the development, manufacturing and testing of medicines).



Pigs

CircoMax ●

A new vaccine for the active immunisation of pigs against Porcine Circovirus type 2 (PCV2) to reduce viral load in blood and lymphoid tissues, virus faecal shedding and the lesions in lymphoid tissues associated with PCV2 infection.

● Biotech vaccine

*The same veterinary product may appear in several categories.

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 5 known products was expanded in 2021:



Cats

NexGard Combo

To be also used for the treatment of notoedric mange (caused by *Notoedres cati*), the treatment of infections with *Aelurostrongylus abstrusus* (L3, L4 larvae and adults) and prevention of aelurostrongylosis in cats.



Dogs

Bravecto

To be also used for reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for up to 12 weeks in dogs.

Cortavance

To be also used for alleviation of clinical signs associated with atopic dermatitis in dogs.



Pigs

Improvac

To be also used for suppression of oestrus in female pigs.

Suvaxyn CSF marker

To be also used for active immunisation of breeding sows in order to reduce infection of their unborn piglets by classical swine fever virus (CSFV).

Medicines for minor use minor species (MUMS)**



Cats

Felpreva

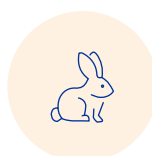
A new veterinary medicine for cats with, or at risk from, mixed parasitic infestations.



Horses

Strangvac

A new vaccine for the active immunisation of horses from 8 months of age to reduce clinical signs of disease in the acute stage of infection with *Streptococcus equi* and reduction in number of abscesses within submandibular and retropharyngeal lymph nodes.



Rabbits

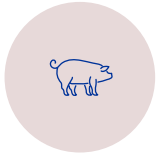
Fatrovax RHD

A new vaccine for the active immunisation of rabbits from 28 days of age against rabbit haemorrhagic disease caused by RHDV1 and RHDV2.

** Minor use veterinary medicines are intended for use in major species such as cattle, sheep, pigs, chickens, 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 medicines that might help reduce the need for antimicrobials in animals

By protecting animals against diseases, which might have needed treatment with antimicrobials, this new vaccine may help reduce the use of antimicrobials:



Pigs

Suiseng Diff/A

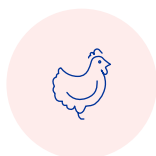
A new vaccine for the passive immunisation of neonatal piglets by means of the active immunisation of breeding sows and gilts to prevent mortality and reduce clinical signs and macroscopic lesions caused by *Clostridioides difficile*, toxins A and B and to reduce clinical signs and macroscopic lesions caused by *Clostridium perfringens* Type A, alpha-toxin.

New Maximum Residual Limits (MRLs) introduced in 2021

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 European Union (EU).

Positive opinions were adopted recommending the establishment of MRLs for the following active substances in 2021:



Chickens

Bambermycin

in poultry tissues

Toltrazuril

in poultry eggs

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 safety procedures in 2021 included:



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

Advocate spot-on solution for dogs	Ataxia (inability to co-ordinate muscle movements); muscle tremor (shaking)
Bravecto spot-on solution for cats	Convulsions
Bravecto Plus	Ataxia
Cerenia tablets for dogs	Lethargy (lack of energy)
Cerenia injection for solution for dogs and cats	Lethargy
Comfortis	Ataxia in cats; muscle tremor in cats
Cytopoint	Injection site pain; injection site swelling; immune-mediated diseases, such as haemolytic anaemia (excessive breakdown of red blood cells) or thrombocytopenia (low blood platelet counts, which can lead to bleeding and bruising)
Felisecto Plus	Convulsions; ataxia; emesis (vomiting); diarrhoea
Fevaxyn Pentofel	Haematemesis (vomiting of blood); diarrhoea with bleeding
Galliprant	Elevated liver enzymes; elevated blood urea nitrogen (a marker for liver and kidney problems); elevated creatinine
Kriptazen	Diarrhoea (change of frequency from "very rare" to "rare")

Letifend	Hypersensitivity reactions, such as anaphylaxis and skin manifestations, including oedema (swelling), urticaria (itchy rash), pruritus (itching)
Librela	Allergic reactions
Osurnia	Application site reactions, such as erythema (reddening of the skin), pain, pruritus, oedema and ulcer; hypersensitivity reactions, including facial oedema, urticaria and shock
Prevomax	Lethargy
Purevax RC	Emesis
Purevax RCP	Emesis
Purevax RCP FeLV	Emesis
Purevax RCPCh	Emesis
Purevax RCPCh FeLV	Emesis
Simparica Trio	Vomiting; diarrhoea; lethargy, anorexia/inappetence; tremor; ataxia; convulsion
Stronghold Plus	Convulsions; ataxia; emesis; diarrhoea
Ubac	Anaphylactic-type reactions (sudden, severe allergic reactions), such as oedema
Vectra Felis	Muscle tremors; lethargy
Vectra 3D	Convulsions
Vepured	Emesis; recumbency (inability to stand due to loss of consciousness, pain or inability to control the body); convulsions; lethargy; loss of consciousness



Addition of new special precautions to be taken by the person administering the following veterinary medicines to animals:

Draxxin	Reddening of the skin (erythema) and/or dermatitis as a result of contact with the medicine. If there is suspicion of an allergic reaction following accidental exposure (recognised by itching, difficulty in breathing, hives, swelling on the face, nausea, vomiting, etc.), appropriate treatment should be administered. Seek medical advice immediately and show the package leaflet or the label to the physician.
Kexxtone	Keep dogs away from treated animals. Accidental ingestion of active ingredient by dogs has resulted in fatal consequences. In case of suspected ingestion by dogs, seek veterinary advice immediately.
Vectra 3D	Pregnant women and women suspected of being pregnant should not administer the product and should avoid direct contact with the application site until the application site is no longer noticeable.

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

www.ema.europa.eu

Veterinary Medicines Highlights 2021