EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

VETERINARY MEDICINES HIGHLIGHTS 2020

AUTHORISATION OF NEW MEDICINES

Overview of the European Medicines Agency's (EMA) recommendations for the authorisation of new veterinary medicines in 2020:

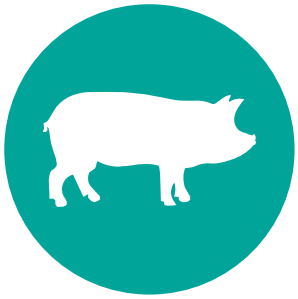
POSITIVE OPINIONS **20**

NEW ACTIVE SUBSTANCES **10**

NEGATIVE OPINIONS **0**

WITHDRAWN APPLICATION **1**

NEW VETERINARY MEDICINES



Pigs

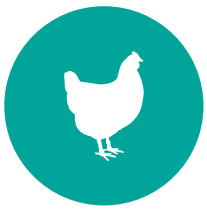
CircoMax Myco
Enteroporc Coli
Enteroporc Coli AC
Increxxa
Lydaxx
Mhyosphere PCV ID
OvuGel
Rexxolide
Tulaven
Tulinovet
Tulissin

Cattle

Increxxa
Lydaxx
Rexxolide
Tulaven
Tulinovet
Tulissin

Sheep

Increxxa
Lydaxx
Rexxolide
Tulaven
Tulinovet
Tulissin



Chickens

Innovax-ND-ILT
Prevexxion RN
Prevexxion RN+HVT+IBD
Vectormune FP ILT
Vectormune FP ILT+AE

Dogs

Librela
Nobivac DP Plus

Cats

NexGard Combo
Solensia

Medicines that contain a new active substance are highlighted in green

PARTICULARLY RELEVANT RECOMMENDATIONS*

Innovations advancing animal health

Pigs

CircoMax Myco ●

A new vaccine for the active immunisation of pigs against porcine circovirus 2 (subtypes 2a and 2b) to reduce viral load in blood and lymphoid tissues and faecal shedding caused by infection with PCV2. The vaccine is also intended to induce active immunisation against Mycoplasma hyopneumoniae and reduce lung lesions.

Dogs

Librela ●

A canine monoclonal antibody for alleviation of pain associated with osteoarthritis in dogs.

Cats

Solensia ●

A feline monoclonal antibody for the alleviation of pain associated with osteoarthritis in cats.

Chickens

Prevexxion RN ●

A new vaccine for the stimulation of active immunity of one-day-old chicks in order to prevent mortality and clinical signs of and reduce lesions caused by Marek's disease virus (including very virulent Marek's disease virus).

Prevexxion RN+HVT+IBD ●

A new vaccine for the stimulation of active immunity in one-day-old chicks in order to prevent mortality and clinical signs of and reduce lesions caused by Marek's disease virus (including very virulent Marek's disease virus); and to prevent mortality and clinical signs of and lesions caused by infectious bursal disease (Gumboro disease) virus.

● Biotech product

New uses for existing medicines

Pigs

Aivlosin

To be also used for the treatment and metaphylaxis of swine respiratory disease associated with Mycoplasma hyopneumoniae and Pasteurella multocida in pigs.

Dogs

Cytopoint

To be also used for the treatment of pruritus associated with allergic dermatitis in dogs.

New maximum residual limits (MRLs) recommended in 2020

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.

Positive opinions were adopted recommending the establishment of MRLs for the following active substances in 2020:

Pigs and cattle

Bupivacaine

Lidocaine

Fish

Imidacloprid

*The same veterinary product may appear in several categories.

Vaccines

Pigs

CircoMax Myco ●

For the active immunisation of pigs against porcine circovirus 2 (subtypes 2a and 2b) to reduce viral load in blood and lymphoid tissues and faecal shedding caused by infection with PCV2. The vaccine is also intended to induce active immunisation against Mycoplasma hyopneumoniae and reduce lung lesions.

Enteroporc Coli

For the active immunisation of pregnant gilts and sows to provide passive protection to piglets against porcine neonatal diarrhoea caused by *Escherichia coli* strains expressing the fimbrial adhesins F4ab, F4ac, F5 and F6.

Enteroporc Coli AC

For the active immunisation of pregnant gilts and sows to provide passive protection to piglets against porcine neonatal diarrhoea caused by *Escherichia coli* strains expressing the fimbrial adhesins F4ab, F4ac, F5 and F6 and enteric disease caused by toxins of *Clostridium perfringens* types A and C.

Mhyosphere PCV ID ●

For the active immunisation of pigs against porcine enzootic pneumonia and porcine circovirus type 2 related diseases.

Dogs

Nobivac DP Plus ●

For the active immunisation of puppies from four weeks of age to prevent clinical signs and mortality of canine distemper virus infection and canine parvovirus infection and to prevent viral excretion following canine distemper virus infection and following canine parvovirus infection.

Chickens

Innovax-ND-ILT ●

For the active immunisation of one-day-old chicks or embryonated chicken eggs against Newcastle disease, avian infectious laryngotracheitis and Marek's disease.

Prevexxion RN ●

For the active immunisation of one-day-old chicks to prevent mortality and clinical signs of and reduce lesions caused by Marek's disease virus (including very virulent Marek's disease virus).

Prevexxion RN+HVT+IBD ●

For the active immunisation of one-day-old chicks in order to prevent mortality and clinical signs of and reduce lesions caused by Marek's disease virus (including very virulent Marek's disease virus); and to prevent mortality and clinical signs of and lesions caused by infectious bursal disease (Gumboro disease) virus.

Vectormune FP ILT ●

For the active immunisation of chickens from 8 weeks of age in order to reduce the skin lesions due to fowlpox and to reduce the clinical signs and tracheal lesions due to avian infectious laryngotracheitis.

Vectormune FP ILT+AE ●

For the active immunisation of chickens to reduce skin lesions due to fowlpox, clinical signs and tracheal lesions resulting from avian infectious laryngotracheitis, and to prevent egg production losses due to avian encephalomyelitis.

● Biotech vaccine

Medicines for minor use minor species (MUMS)**

Cats

NexGard Combo

An antiparasitic veterinary medicinal product for the treatment of cats with, or at risk from mixed infections by cestodes, nematodes and ectoparasites.

** 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.

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 new safety advice issued in 2020:

Activyl Tick Plus	Addition of further information in the package leaflet for special precautions for use of Activyl Tick Plus in animals.
Advocate	Amendment to the product information in relation to the use during pregnancy and lactation and other special precautions for use of Advocate in animals.
Cardalis	Addition of further information in the package leaflet on potential side effects following administration of Cardalis, such as gastrointestinal signs and pruritus.
Convenia	Addition of further information in the package leaflet on potential side effects following administration of Convenia, such as haematological reactions, gastrointestinal signs, neurological signs and hypersensitivity reactions.
Credelio	Addition of further information in the package leaflet on potential side effects following administration of Credelio, such as neurological and gastrointestinal signs.
Galliprant	Clarification of the information in the package leaflet on potential side effects following administration of Galliprant in relation to gastrointestinal signs.
Metacam/Novem	Addition of special precautions to the product information for Metacam/Novem to ensure the safety of the person handling and administering the treatment.
Neptra	Amendment to the product information on potential side effects following administration of Neptra, to include eye disorders.
Onsior	Amendment to the product information on potential side effects following administration of Onsior, to include renal disorders.
Purevax FeLV	Amendment to the product information on potential side effects following administration of Purevax FeLV to include gastrointestinal signs and anaphylaxis. Update the frequency of the adverse reactions.
Vectra 3D	Amendment to the product information for Vectra 3D, to clarify the potential follow-up of rare application site reactions.

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