AUTHORISATION OF NEW MEDICINES

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

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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
- Prevexxon RN
- Prevexxon 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.

**Chickens**

**Prevxexion 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).

**Prevxexion 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.

**Dogs**

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

**Cats**

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

**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.

**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.

**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.

**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.

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

**Biotech vaccine**
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.