



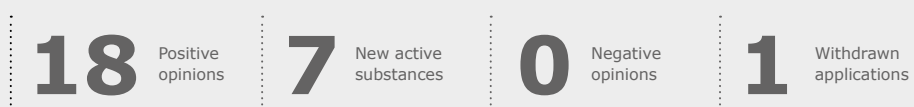
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Veterinary medicines highlights 2017



Authorisation of new medicines

Overview of the key figures on the European Medicines Agency's (EMA) recommendations for the authorisation of new veterinary medicines in 2017:



New veterinary medicines



Medicines that contain a new active substance are highlighted in green

Innovations advancing animal health



Dogs **Cytopoint**

The first monoclonal antibody in a veterinary medicine. Intended for the treatment of dogs with atopic dermatitis, a common allergic skin disease. It is a solution for injection containing the new active substance lokivetmab.

Medicines for minor use minor species (MUMS)*



Honey bees **Oxybee**

A powder and solution intended for the treatment of honey bees in hives infested with Varroa destructor.



Foxes and raccoon dogs **Rabitec**

A vaccine for the immunisation of foxes and raccoon dogs against rabies.

*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.

Vaccines



Cattle and sheep

Bovilis Blue-8

A vaccine used in cattle and sheep to protect them against bluetongue disease, an infection caused by the bluetongue virus, which is transmitted by midges.



Pigs

Ingelvac PCV FLEX ●

Suvaxyn Circo ●

Two vaccines that protect pigs against porcine circovirus type 2 (PCV2), a widespread DNA virus that can cause weight loss, enlarged lymph nodes, difficulty breathing, pale skin and yellowing of the skin in pigs.



Cats

Nobivac LeuFel

A vaccine used in cats to protect them against feline leukaemia, an infectious disease caused by the feline leukaemia virus (FeLV).



Chicken

Innovax-ND-IBD ●

A vaccine used to protect chicken against three different kinds of viral infections: Newcastle disease (ND), infectious bursal disease (IBD) and Marek's disease (MD).

Respiorc FLUpan H1N1 ●

A vaccine used to protect pigs against swine influenza caused by pandemic subtype H1N1. Swine influenza or swine flu is a disease of the lungs and airways in pigs. People with regular exposure to pigs may be at increased risk of swine flu infection.

Suvaxyn PRRS MLV ●

A vaccine that protects pigs against porcine reproductive and respiratory syndrome virus, a disease causing reproductive failure in breeding animals and respiratory tract illness in young pigs.

Vepured ●●

A vaccine used to protect piglets against oedema disease and to reduce the associated loss of daily weight gain until slaughter. Oedema disease is caused by a substance known as verotoxin 2e that is produced by certain strains of *Escherichia coli*.



Foxes and raccoon dogs

Rabitec ●●

A bait vaccine used to protect wild foxes and raccoon dogs against rabies. This life-threatening viral disease causes inflammation in the brain and can be transmitted to people by bites or saliva from an infected animal.



Sheep

Zulvac BTV Ovis

A vaccine used in sheep to protect them against bluetongue disease, an infection caused by the bluetongue virus, which is transmitted by midges.

- biotech vaccines
- vaccines against diseases that can be transmitted from animals to people
- new medicines to reduce the need for antimicrobials in animals

New uses for existing medicines

The use of six known substances was expanded in 2017:



SevoFlo

To be also used as anaesthetic for cats.



Activyl Tick Plus, Broadline and Nexgard Spectra

To be also used for the treatment of, and protection against, further parasite species.



Simparica

To be also used in dogs for the treatment of ear mites and demodicosis, an inflammatory disease caused by various types of the Demodex mite.



Zactran

To be also used in sheep and against a new pathogen in pigs causing swine respiratory disease.



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 new safety advice issued in 2017 included:

- Veterinary medicines containing **methylprednisolone hydrogen succinate** should no longer be used for the treatment of inflammatory or allergic conditions and for the treatment and prevention of shock conditions in cattle, to ensure consumer safety of the withdrawal periods**.

- **Zinc oxide**-containing veterinary medicines should no longer be used in medicated feeding stuff for piglets, as these products increase soil zinc concentrations to levels considered harmful for the environment.

- New risk mitigation measures and warnings in the product information of **moxidectin**-containing veterinary medicines used in cattle, sheep and horses, as these medicines might have a negative long-term impact on the environment.

- Amend withdrawal periods for cattle, sheep and goats for **Zanil** and associated names and generics, to ensure consumer safety.

- Include further information on potential side effects and additional precautions for the administration of **Broadline** in cats.

- Add instructions in the product information of **Equisolon** to ensure the safety of the person handling and administering the treatment to horses.

- Amend the information on potential side effects of **Simparica** to include mild and short-term gastrointestinal and neurological reactions in dogs.

- Add precautions to be taken by people with known hypersensitivity to the active substance of **Cerenia** when administering the product in dogs and cats.

- For **Bovela**, add further information on the diagnosis of persistent infection under special warnings for the target species.

- Include hypersensitivity reactions in the information on potential side effects of two vaccines for dogs, **Versican Plus DHPPi** and **Versican Plus Pi**.

- Include further information on potential side effects following administration of **Bravecto** chewable tablets for dogs, as well as special precautions for the use in dogs with pre-existing epilepsy.

**The minimum period of time between the administration of a medicine to an animal and the production of meat or other derived products for food (i.e. milk, eggs) from that animal, in order to keep the consumer safe.



- Include neurological signs in the information on potential side effects of **NexGard**.
- Add febrile limping syndrome in the information on potential side effects of **Leucofeligen FeLV RCP**.
- In the product information for **Improvac**, add instructions to be followed in case of accidental self-injection by the person administering the product, as well as for the physician treating that person subsequently.
- Include clearer instructions in the product information for **Metacam** to prevent accidental overdose in very small animals.



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:

- **Alarelin** - in medicines for all food-producing species
- **Bromelain** - in medicines for pigs
- **Porcine prolactin** - in medicines for pigs
- **Solvent naphtha, light aromatic** - in medicines for all food-producing species.

MRLs were extended to further species for the following active substances:

- **Fluazuron and Eprinomectin** - also for use in medicines for finfish.

