



Veterinary medicines highlights 2016

11 Positive opinions

6 New active substances

1 Negative opinion

1 Withdrawn application

New veterinary medicines

Pigs	Chicken	Newborn calves	Atlantic salmon	Rabbits	Honey bees	Dogs	Cats
Coliprotec F4/F18	Evalon	HALAGON	CLYNAV	Eravac	VarroMed	Cepedex Letifend Sedadex Sevohale	Cepedex Sedadex Stronghold plus

Medicines that contain a new active substance are highlighted in blue

Innovations advancing animal health

Protecting honey bees



Honey Bees

VarroMed

is an antiparasitic medicine that treats the Varroa mite infestation in honey-bee colonies, which is considered to be the most significant parasitic health concern affecting honey bees worldwide. The decline of these pollinators could lead to serious biological, agricultural, environmental and economic difficulties.

Vaccines against emerging diseases



Rabbits

Eravac

is a vaccine for the protection of rabbits against a new variant of rabbit haemorrhagic disease virus, called RHDV2, for which all current vaccines are ineffective.

Vaccines



Chicken

Evalon

a vaccine that protects chicken against coccidiosis, a parasitic disease of the intestinal tract



Dogs

Letifend

a biotechnological vaccine based on a recombinant protein for dogs to protect them against leishmaniasis, a disease transmitted by sand flies



Atlantic salmon

CLYNAV

a biotechnological vaccine based on a DNA plasmid that protects Atlantic salmon against pancreas disease caused by infection with salmonid alphavirus subtype 3



Rabbits

Eravac

a vaccine that protects rabbits against a new variant of rabbit haemorrhagic disease virus, called RHDV2



Pigs

Coliprotec F4/F18

a vaccine that protects against porcine post-weaning diarrhoea caused by *Escherichia coli* in pigs

Medicines for minor use minor species (MUMS)*



Rabbits
Eravac



Atlantic salmon
CLYNAV



Dogs
Letifend



Honey bees
VarroMed

Medicines against infectious diseases that could reduce the use of antimicrobials in animals



Chicken
Evalon

a vaccine that protects chicken against coccidiosis, a disease of the gut. Coccidial infections are widely treated with anticoccidial medicines which can have a potential risk of inducing resistance. The use of this vaccine to enhance resistance to infection might therefore have an indirect benefit in reducing the use of anticoccidial medicines***.



Pigs
Coliprotec F18/F4

a vaccine that protects pigs against post-weaning diarrhoea caused by toxic *Escherichia coli*. This has the potential to change the current practice to give antibiotics to control infection in pig herds.

Antimicrobial resistance: EMA's recommendation on colistin

Colistin should only be used as a second-line treatment in animals and sales should be minimised across all European Union (EU) Member States. If use in animals is cut to 5mg colistin/ population correction unit**, an overall reduction of around 65% in the current sales of colistin for veterinary use at EU level could be achieved.

Important CVMP safety recommendations in 2016

- Increase the withdrawal period of medicines containing **gentamicin** in cattle and pigs to enhance consumer safety; avoid administering gentamicin subcutaneously.
- Take environment protection measures to make sure that **altrenogest**, a steroidal hormone for young female pigs and mares, has no adverse effects on the reproduction of aquatic organisms.
- Refuse the marketing authorisations and withdraw currently authorised **zinc oxide**-containing medicines, used in medicated feeding stuff for piglets, as these products increase soil zinc concentrations to levels considered harmful for the environment.
- Suspend **Velactis** after serious adverse events were reported in cattle, including recumbency (lying down or inability to stand up) and death.
- Withdraw all marketing authorisations for veterinary medicines containing **colistin** in combination with other antibiotics that are administered orally throughout the EU.

New uses for existing medicines

The use of **4** known substances has been expanded in 2016:

DRAXXIN to be also used against swine respiratory disease (SRD)

Profender to be also used as a spot-on solution for cats

Poulvac E. coli to be also used in turkeys

Trifexis to be also used to treat and prevent flea infestations in dogs

*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.

**Clarified by replacing 'by' with 'to' on 26/01/2017.

***Amended on 08/03/2017 to better reflect the risk of inducing antimicrobial resistance.



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