



Veterinary medicines highlights 2015

New veterinary medicines

In 2015, the European Medicines Agency (EMA) recommended for marketing authorisation a total of 14 new medicines for veterinary use of which one is for minor use minor species (MUMS)/limited market. Eight are medicines for food-producing animals, of which five are vaccines.

14 positive opinions

7 new active substances

1 negative opinion

0 withdrawn applications

Of the 14 new medicines recommended for veterinary use in 2015, seven medicines contain new active substances. These medicines were recommended for use in cattle, chicken, dogs, horses and pigs.

Dogs

Canigen L4
Fortekor Plus
Sileo
Simparica
UpCard
Zycortal

Pigs

Coliprotec F4
Porcilis PCV ID
Suvaxyn Circo+MH
RTU

Horses

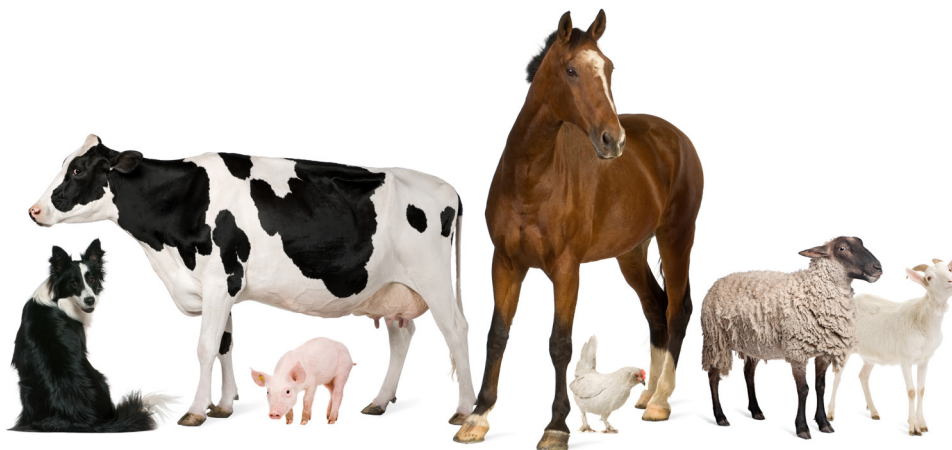
Novaquin

Chicken

Innovax-ILT
Vectormune ND

Dairy cattle

Imrestor
Velactis



EMA's recommendations are sent to the European Commission for the adoption of an EU-wide marketing authorisation decision.



Vaccines protecting food-producing animals from infectious diseases

In 2015, a total of five vaccines were recommended for marketing authorisation to prevent viral or bacterial infections in food-producing animals.

Four of these are biotechnology products (Porcilis PCV ID, Vectormune ND, Innovax-ILT, Suvaxyn Circo+MH RTU). This reflects the shift currently seen in manufacturing of veterinary vaccines from traditional methods towards biotechnology.

Two of the vaccines (Vectormune ND, innovax-ILT) use a single vaccine organism to protect against two diseases, reducing the number of live organisms to which chicken are exposed through vaccination.

Coliprotec F4 - a live vaccine to protect against porcine post-weaning diarrhoea caused by enterotoxigenic *Escherichia coli* in pigs.

Porcilis PCV ID - an inactivated vaccine to protect against porcine circovirus in pigs.

Vectormune ND - a live vaccine to protect against Newcastle disease and Marek's disease in chicken.

Innovax-ILT - a live vaccine to protect against both infectious laryngotracheitis and Marek's disease in chicken.

Suvaxyn Circo+MH RTU - a combination vaccine against both porcine circovirus and *Mycoplasma hyopneumoniae*, infections commonly occurring together in pigs.



5 vaccines in total

4 biotechnological vaccines

Medicines for minor use minor species (MUMS)/limited market

EMA's Committee for Medicinal Products for Veterinary Use (CVMP) also recommended authorisation of one product for minor use minor species (MUMS)/limited market. A more flexible approach is applied in terms of data requirements for medicines that are classified as MUMS.

Zycortal to treat mineralocorticoid deficiency (Addison's disease) in dogs. If untreated the deficiency may cause cardiovascular emergency in dogs.

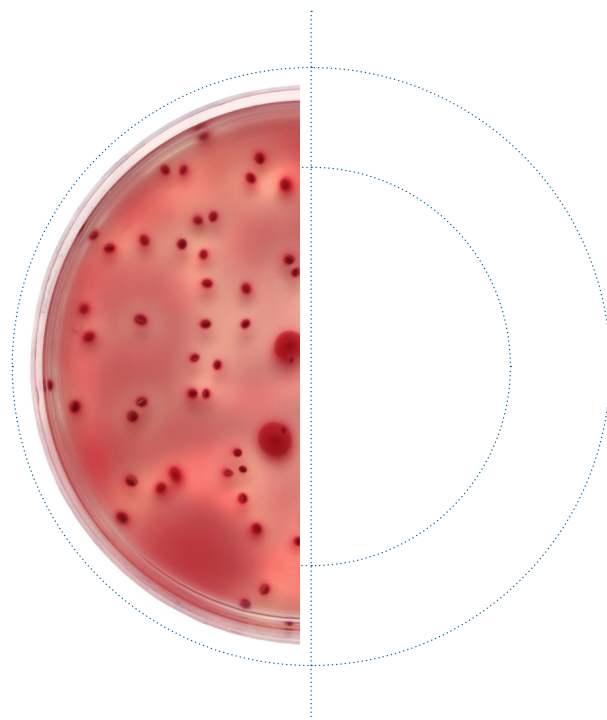


New medicines to reduce the need for antimicrobials in animals

The CVMP recommended two medicines for approval that have the potential to reduce the need for antimicrobial treatment in dairy cattle. Both are intended for the prevention of mastitis, a painful inflammation of the udder tissue that is a severe welfare issue if left untreated.

Velactis to reduce milk production during the dry-off period in dairy cows, reducing the risk of udder infections.

Imrestor to reduce the risk of clinical mastitis in dairy cows during the 30 days following calving.



New uses for existing medicines

Among the pharmaceutical products recommended in 2015, one known active substance was authorised for a new indication.

Sileo to alleviate acute anxiety and fear associated with noise in dogs.

Extension of indication

The use of an already-authorized medicine in a new species or a new indication offers new treatment opportunities.

Zactran to extend its use in pigs to treat swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, and *Haemophilus parasuis*.



Monitoring in real life – Optimising safe and effective use

Once a veterinary medicine has been put on the market, EMA and European Union (EU) Member States continuously monitor the benefits and risks associated with this medicine in real life for human and animal health and for the environment. This is to ensure that the medicine is used in the best possible way by practitioners in the EU. The use of veterinary medicines in food-producing animals may result in the presence of residues in foodstuffs obtained from treated animals. The Agency assesses and recommends maximum residue limits (MRLs) for pharmacologically-active substances in veterinary medicinal products used to treat animals, to provide for the safe use of food-stuffs of animal origin, including meat, fish, milk, eggs and honey.

Important procedures on safety in 2015

Closamectin Pour-On Solution and associated names (closantel and ivermectin): a review was started following suspension of marketing authorisation in France. CVMP recommended that the medicine should remain available, but that changes should be made to the product information and conditions concerning risk mitigation and surveillance measures.

Lidocaine: The CVMP reviewed the risk to consumers from the use of lidocaine in food-producing species. The Agency issued regulatory recommendations to ensure a negligible risk to consumer safety from residues that may occur in milk following off-label use in cattle. The Agency recommended communication with veterinarians in order to ensure that an adequate interval of time is allowed to elapse between the administration of lidocaine and the taking of milk for human consumption.



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