Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 10-12 September 2019

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Press release 13/09/2019

**CVMP recommends authorisation of two new vaccines**

[**CVMP**](https://www.ema.europa.eu/en/glossary/cvmp)**opinions on veterinary**[**medicinal products**](https://www.ema.europa.eu/en/glossary/medicinal-product)

The Committee adopted by majority a positive opinion for an initial [marketing authorisation application](https://www.ema.europa.eu/en/glossary/marketing-authorisation-application) for **Gumbohatch**, from Laboratorios Hipra, S.A., a new vaccine for the active immunisation of 1-day-old broiler chicks and embryonated broiler chicken eggs to reduce clinical signs and lesions of the bursa of Fabricius caused by very virulent avian infectious bursal disease virus infection.

The Committee adopted by consensus a positive opinion for an initial [marketing authorisation application](https://www.ema.europa.eu/en/glossary/marketing-authorisation-application) for **Nobivac Myxo RHD Plus**, from Intervet International B.V., a new vaccine for rabbits to reduce mortality and clinical signs of myxomatosis (caused by rabbit myxoma virus) and haemorrhagic disease (caused by classical rabbit haemorrhagic disease virus and RHD type 2 virus). The vaccine is  classified as Minor Use, Minor Species (MUMS)/ limited market.

The Committee adopted by consensus positive opinions for the following [type II variation](https://www.ema.europa.eu/en/glossary/type-ii-variation) applications for:

* **Bravecto**, concerning the addition of new therapeutic [indications](https://www.ema.europa.eu/en/glossary/indication);
* **Posatex** and **Rhiniseng**, concerning quality changes;
* **Quadrisol**, concerning a new [pharmacovigilance](https://www.ema.europa.eu/en/glossary/pharmacovigilance) system;
* **Vectra Felis,**concerning change of the legal status from prescription-only to non-prescription veterinary medicine.

The Committee adopted by consensus a negative opinion for a [type II variation](https://www.ema.europa.eu/en/glossary/type-ii-variation) application for **Velactis** to change the current conditions of use and provide further risk management measures to allow the safe use in the target species, and, consequently, the [marketing authorisation](https://www.ema.europa.eu/en/glossary/marketing-authorisation) remains suspended.

More information about the above-mentioned medicines, including their full [indications](https://www.ema.europa.eu/en/glossary/indication), will be published on the Agency’s website.

**Renewals of marketing authorisations**

The Committee adopted by consensus positive opinions for the [renewal](https://www.ema.europa.eu/en/glossary/renewal) of the [marketing authorisations](https://www.ema.europa.eu/en/glossary/marketing-authorisation) for **Bovela**, **Nexgard Spectra** and **Suvaxyn CSF Marker**. The Committee, having re-assessed the benefit-risk balance of these products, concluded that the quality, safety and [efficacy](https://www.ema.europa.eu/en/glossary/efficacy) continue to be appropriately demonstrated and, therefore, recommended the [renewal](https://www.ema.europa.eu/en/glossary/renewal) of the [marketing authorisations](https://www.ema.europa.eu/en/glossary/marketing-authorisation).

**Community referrals and related procedures**

The Committee started a procedure for **Ronaxan and its associated names** (doxycycline hyclate) from Boehringer Ingelheim. The matter was referred to the Committee by Germany under Article 34 of Directive 2001/82/EC due to divergent decisions taken by Member States resulting in differences in the [product information](https://www.ema.europa.eu/en/glossary/product-information).

The Committee started a procedure for **Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection, and associated names, and generic products thereof**(dinoprost tromethamine). The matter was referred to the Committee by France under Article 35 of Directive 2001/82/EC. This [referral](https://www.ema.europa.eu/en/glossary/referral) procedure concerns the appropriateness of the current [withdrawal periods](https://www.ema.europa.eu/en/glossary/withdrawal-period) (meat and offal) in cattle for the aforementioned veterinary [medicinal products](https://www.ema.europa.eu/en/glossary/medicinal-product).

**Scientific advice**

The Committee adopted two [scientific advice](https://www.ema.europa.eu/en/glossary/scientific-advice) reports further to requests for:

* Initial advice on quality and [efficacy](https://www.ema.europa.eu/en/glossary/efficacy) issues for a new immunological veterinary [medicinal product](https://www.ema.europa.eu/en/glossary/medicinal-product) for horses;
* Initial advice on quality issues for a new veterinary [medicinal product](https://www.ema.europa.eu/en/glossary/medicinal-product) for a dermatological [indication](https://www.ema.europa.eu/en/glossary/indication) in dogs.

**Minor use, minor species (MUMS)/limited market**

Following the Committee’s review of five requests for classification under the MUMS/limited market policy, the [CVMP](https://www.ema.europa.eu/en/glossary/cvmp) classified:

* A product (antineoplastic agent) for dogs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives as it is intended for use in non-food producing species;
* A product (sensory organ [indication](https://www.ema.europa.eu/en/glossary/indication)) for dogs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives as it is intended for use in non-food producing species;
* A product (immunological product) for horses as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. Although indicated for horses, the product is exceptionally considered eligible for financial incentives as it is intended for use in food producing animals;
* A product (dermatological) for horses as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives in line with the Guidance on the classification of veterinary [medicinal products](https://www.ema.europa.eu/en/glossary/medicinal-product) indicated for minor use minor species / limited market (EMA/[CVMP](https://www.ema.europa.eu/en/glossary/cvmp)/388694/2014) which indicates products for horses as generally not eligible;
* A product (immunological) for pigs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is eligible for financial incentives as it is intended for use in food producing species.

**Pharmacovigilance**

The Committee reviewed the PSURs for **Bravecto**, **Bravecto Plus**, **Coxevac**and **Osurnia**, and recommended changes to their [product information](https://www.ema.europa.eu/en/glossary/product-information).

The Committee also reviewed the PSURs for **Cytopoint** and**Vectormune ND**and concluded that no further action or changes to their [product information](https://www.ema.europa.eu/en/glossary/product-information) were required.

**Organisational matters**

The Committee adopted revised procedural advice on appointment and responsibilities of the [CVMP](https://www.ema.europa.eu/en/glossary/cvmp) [rapporteur](https://www.ema.europa.eu/en/glossary/rapporteur)and [co-rapporteur](https://www.ema.europa.eu/en/glossary/co-rapporteur) in accordance with Article 62 (1) of Regulation (EC) No 726/2004 (EMA/[CVMP](https://www.ema.europa.eu/en/glossary/cvmp)/468877/2009 - Rev.2).

The Committee finalised the preparation of the Presidency [CVMP](https://www.ema.europa.eu/en/glossary/cvmp) and joint [CVMP](https://www.ema.europa.eu/en/glossary/cvmp)/[CMDv](https://www.ema.europa.eu/en/glossary/cmdv) meetings to be held under the Finnish Presidency of the EU, on 25-27 September 2019. The meeting will be conducted under the theme ‘Responding to challenges for the veterinary medicines network 2019-2020: New veterinary legislation’ and the discussions will focus on:

* Promoting product availability with emphasis on the provisions concerning limited markets.
* Implementation of the Regulation 2019/6 with emphasis on the new role for the [Pharmacovigilance](https://www.ema.europa.eu/en/glossary/pharmacovigilance)[Working Party](https://www.ema.europa.eu/en/glossary/working-party) and the responsibilities of [CVMP](https://www.ema.europa.eu/en/glossary/cvmp) and [CMDv](https://www.ema.europa.eu/en/glossary/cmdv) including communication on issues of common interest.