EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 October 2023
EMA/CVMP/416566/2023
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Bovilis Cryptium

Common name: Bovine *Cryptosporidium parvum* vaccine

On 5 October 2023, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Bovilis Cryptium emulsion for injection for cattle. The applicant for this veterinary medicinal product is Intervet International B.V.

Bovilis Cryptium is an immunological veterinary medicinal product containing glycoprotein Gp40 of *Cryptosporidium parvum* (ATCvet code QI02AO02) as active substance, which acts by stimulating active immunity against glycoprotein Gp40 in pregnant heifers. When the colostrum of such heifers, which contains antibodies against glycoprotein Gp40, is ingested by calves, it passively immunises the calves against *C. parvum*.

The benefits of Bovilis Cryptium are its ability to passively immunise calves against *C. parvum* and to decrease the associated morbidity caused by diarrhoea. The most common side effects are elevated temperature and the effects related to the injection site: swelling, pain, warmth, and granuloma.

The full indication is:

"For active immunisation of pregnant heifers and cows to raise antibodies in their colostrum against Gp40 of *Cryptosporidium parvum*, intended for passive immunisation of calves to reduce clinical signs (i.e. diarrhoea) caused by *C. parvum*.

Newborn calves:

Onset of immunity: Passive immunity commences from the start of colostrum feeding.
Duration of immunity: In calves that receive colostrum and transition milk as indicated and which were challenged at birth, passive immunity has been demonstrated until 2 weeks of age."

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC) which will be published in the Union Product Database (UPD) and will be available in all official

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Bovilis Cryptium and therefore recommends the granting of the marketing authorisation.