

12 October 2018
EMA/CVMP/197495/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (initial authorisation)

HorStem

Equine umbilical cord mesenchymal stem cells

On 11 October 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a negative opinion², recommending the refusal of the granting of a marketing authorisation for the veterinary medicinal product HorStem, a stem-cell based product presented as a suspension for injection.

HorStem was proposed for the treatment of lameness and other clinical symptoms associated with mild to moderate degenerative joint disease (osteoarthritis) in horses.

The applicant for this veterinary medicinal product is EquiCord-Ymas S.L.

The active substance of HorStem is equine umbilical cord mesenchymal stem cells, a biological product. Mesenchymal stem cells have immunomodulatory and anti-inflammatory properties and can possess regenerative properties.

The grounds for the negative opinion relate to quality and efficacy.

The CVMP, on the basis of the quality, safety and efficacy data submitted considers that it is not possible to conclude that the overall benefit to risk balance for HorStem is favourable and therefore cannot recommend the granting of the marketing authorisation.

¹ Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the opinion.

² Applicants may request a re-examination of any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to request re-examination thereof within 15 days of receipt of the opinion.
