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Refusal of the marketing authorisation for Horse Allo 20 (allogeneic equine mesenchymal stem cells)

On 21 June 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product Horse Allo 20, intended for the treatment of lameness in adult horses with osteoarthritis.

On 24 January 2019, the CVMP revised part of its opinion but confirmed its recommendation to refuse the marketing authorisation.

The company that applied for authorisation is Centauri Biotech SL.

What is Horse Allo 20?

Horse Allo 20 is a veterinary medicine that contains allogeneic equine mesenchymal stem cells as active substance. It was to be available as a suspension for injection into a joint.

Horse Allo 20 was developed as a novel therapy medicine containing cells that have been manipulated so that they can be used to repair, regenerate or replace tissue.

What was Horse Allo 20 expected to be used for?

Horse Allo 20 was expected to be used to treat lameness in adult horses with osteoarthritis. Osteoarthritis is a condition that causes swelling and pain in the joints and which is often associated with lameness.

How does Horse Allo 20 work?

The way that mesenchymal stem cells work has not been clearly established but published studies indicate that they have an anti-inflammatory action and may have an effect in regenerating tissue. This was expected to help control the inflammation and joint damage associated with osteoarthritis in horses, and so reduce lameness.

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What did the company present to support its application?

The applicant presented data from a field study involving horses from 2 years of age with osteoarthritis, where 37 horses were treated with Horse Allo 20 while 33 horses received a dummy treatment. The main measure of effectiveness was a reduction in 1 or more grades of lameness using a scoring system that runs from 1 to 5.

What were the CVMP's main concerns that led to the refusal?

The CVMP noted that there were problems with the way the main study was designed and carried out, and concluded that the effectiveness of the medicine had not been sufficiently demonstrated. The CVMP was also concerned about the high number of side effects reported in the field study. Finally, the Committee had concerns about the way the medicine was manufactured and its quality ensured.

Following a request from the European Commission, the CVMP revised part of its opinion concerning compliance with Good Manufacturing Practice (GMP). The Committee removed its previous objection that the company did not comply with GMP but all other concerns remained. The CVMP was therefore of the opinion that the benefits of Horse Allo 20 did not outweigh its risks and recommended that it be refused marketing authorisation.