EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2019)2998443

SUMMARY REPORT OF THE STANDING COMMITTEE ON VETERINARY MEDICINAL PRODUCTS HELD IN BRUSSELS ON 22 MARCH 2019

CIRCABC Link: *https://circabc.europa.eu/w/browse/675c58a7-8429-498b-ba34-69043a7cc198*

A.01 Opening and adoption of the agenda.

The agenda of the meeting was adopted.

A.02 HorStem – information about ongoing procedure for a marketing authorisation.

The Commission's services gave a presentation on this new advanced therapy veterinary medicinal product.

In its first vote on HorStem, the Committee Veterinary Medicinal Products (CVMP) did not reach the absolute majority position required in accordance with Article 8(5) of its Rules of Procedure (17 from 32 votes) thus recommending by default the refusal of the granting of the marketing authorisation for the above-mentioned veterinary medicinal product[1]. On 21st February 2019 the CVMP, having considered the grounds for the re-examination request[2] in accordance with Article 34(2) of Regulation (EC) No 726/2004, concluded, by a majority of 27 out of 30 votes, that its negative opinion of 11th October 2018 should be revised, and recommended the granting of a marketing authorisation[3]. In accordance with Article 31(1) of Regulation (EC) 726/2004, part of the European Public Assessment report[4] on the above mentioned veterinary medicinal product is a risk management plan (on quality) and a very comprehensive post-marketing surveillance study in 800 horses.

A.03 Implementation of the Regulation on veterinary medicinal products – update.

The Commission's services updated the Member States on the ongoing work for the implementation of the Regulation (EU) 2019/6.

7 mandates have been sent out to EMA in January 2019 asking for a scientific opinion that will inform the Commission while drafting the legal acts: (i) restructuring of Annex II; (ii) rules and methods of gathering data on antimicrobials; (iii) criteria for

1 EMA/CVMP/197477/2018 Opinion of the Committee for Medicinal Products for Veterinary Use on the granting of a marketing authorisation 11. Okt 2018
2 EMA/CVMP/870401/2018 Applicant's detailed grounds for requesting a re-examination - Rapp's assessment report
3 EMA/CVMP/120703/2019 Opinion of the Committee for Medicinal Products for Veterinary Use on the granting of a marketing authorisation
4 EMA/CVMP/114463/2019 CVMP final assessment report of an application for the granting of a community marketing authorisation for HorStem

antimicrobials reserved for human use; (iv) list of variations not requiring assessment; (v) good pharmacovigilance practice; (vi) content of pharmacovigilance master file and (vii) Union product database.

The Chair informed the Member States about next steps in the process:

- a dedicated webpage containing the latest updates on implementation will be created;

- drafting of 2nd package mandates will start soon.

The Chair informed also the Member States that in case there are mistakes in the translations into national languages of Regulation (EU) 2019/6, all errors spotted should be communicated to the Council secretariat

(email: dql.rectificatifs@consilium.europa.eu).

A template document should be used, which will be shared via CIRCABC after the meeting.

A.04 Update from the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) meeting of 24/2 – 1/03/2019.

The Commission's services informed the Member States about the latest guidelines adopted at the 37th meeting of the VICH Steering Committee that took place in South Africa February 2019.

New GL 57 Metabolism and Residue Kinetics: Residues in Fish. Studies to evaluate the Metabolism and Residue Kinetics of veterinary drugs in food-producing species: marker residue depletion studies to establish product withdrawal periods in aquatic species.
Revision of GL 36(R), Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish a microbiological ADI.

A.05 Update and information about the future inclusion of veterinary products in the scope of the Agreement on Mutual Recognition between the United States and the European Union for Good Manufacturing Practices (GMP).

The Commission's services explained the state of play of the implementation of the Agreement on Mutual Recognition between the United States and the European Union for GMP and the possibility of including veterinary products in the scope of the agreement.

The Member States were updated on the current audit schedule: what countries were planned for audit, when and whether the US will be observing the audits or not. It was emphasised that the schedule was often subject to change due to requests for postponing on the part of the competent authorities.

The specific cases of Italy and Czechia were mentioned, as there are no audits scheduled soon for either countries. The US has indicated that they may resort to desk-top audits, but no definitive conclusion on their part has reached the Commission.

The situation with the dual agencies was also touched upon. It remains unclear whether for the potential recognition of their veterinary activities the US will rely solely on the last two vet-specific questions from the pre-requisite checklists or may introduce additional ones.

As regards the audit of FDA-CVM, it was rescheduled to Week 24 due to the US federal government shutdown of last year. In view of the time required for the final audit results to be out, a recognition decision seems unlikely by 15 July 2019.

Most probably, that date will be used to decide on continuing the work on both sides of the Atlantic towards mutual recognition of the veterinary authorities' capabilities.

A.06 Any Other Business.

There were no other topics discussed.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Arti-Cell Forte - Chondrogenic induced equine allogeneic peripheral blood-derived mesenchymal stem cells", a veterinary medicinal product.

The Commission's services explained that the above draft decision was discussed in the Standing Committee meeting of 24 September 2018. However, at that time, the Member States decided that there were certain questions which were not sufficiently addressed in the CVMP assessment report of an application for the granting of a Union marketing authorisation for Arti-Cell Forte dated 21 June 2018. Additionally, the Standing Committee raised important new questions.

Therefore, the Standing Committee in September 2018 agreed that the adoption procedure for the product was suspended in line with Art. 35(4) of Regulation (EC) No 726/2004 and the CVMP opinion was sent back to EMA together with a set of questions raised by the MSs.

On 21 February 2019, EMA provided responses to the questions that were sent following the September 2018 Standing Committee. The document "EMA/CVMP/789792/2018 - Responses to questions from the European Commission for further clarification of CVMP opinion" was distributed to Member States prior to the meeting.

The representative of the European Medicines Agency gave a presentation on the CVMP document. A short discussion took place where the majority of the Member States expressed the view that they supported the conclusions of the CVMP/EMA.

Vote taken: Favourable opinion.