EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2018)6174647

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 24 SEPTEMBER 2018

(Section *Veterinary Medicinal Products*)

CIRCABC Link: *https://circabc.europa.eu/w/browse/9a6fc441-0460-43d8-98ac-784374aa941a*

A.01 Opening and adoption of the agenda.

The agenda of the meeting was adopted.

A.02 Follow-up to the discussion on diclofenac - Member State's update on the measures taken at national level, including in particular information on reported vulture deaths in the Member States that have diclofenac authorised and potential new authorisation given at national level.

The Commission's services reminded that in the Standing Committee meeting of 9 February 2015 and following the EMA's Committee for Medicinal Products for Veterinary Use ('CVMP') advice and extensive discussion on the potential risk of diclofenac to vultures, the Member States were requested to set in an action plan appropriate measures to address the issue. Since 2015, the Commission's services regularly ask the Member States for an update regarding the situation in their countries regarding veterinary medicines containing diclofenac.

Member States were requested to answer the following questions :

- if any new marketing authorisations containing diclofenac had been issued in the last year;
- if there were any new measures adopted to mitigate the risk; and
- if there were any reported vulture deaths in their territory.

No new marketing authorisations were issued by the Member States, neither any new risk mitigation measures were adopted. Also, no deaths of vultures were reported for the past year.

A.03 Member State's update on the measures taken at national level, in particular suspension of the marketing authorisations of products for food-producing animals following a procedure under Article 30(3) of Directive 2001/82/EC for diethanolamine.

The EMA has recently taken diethanolamine out of the list of "substances considered as not falling within the scope of Regulation (EC) No. 470/2009 with regard to residues of veterinary medicinal products in foodstuffs of animal origin". As a consequence, certain veterinary medicinal products for food producing animals on the EU market are affected, because there is no MRL for diethanolamine.

The Commission's services asked the Member States to give update on the marketing authorisations for veterinary medicinal products intended for food-producing animals containing diethanolamine as excipient.

Most Member States have already suspended the MAs for veterinary medicinal products intended for food-producing animals containing diethanolamine as excipient or are in the process of suspending them. Some of those Member States expect shortcomings for treatments of special diseases, especially for colic in horses, while others have veterinary medicinal products authorised which can be used as alternative treatment. Some Member States have temporarily restricted the marketing authorisations to horses exempted from the food chain in their horse passports. Some Member States have recalled batches already on the market, but that possibility was not exploited by all Member States suspending the MA. Few Member States have announced that there will be no suspension of concerned products in their country, due to the already stressed situation with the availability of veterinary medicinal products to treat special diseases. One marketing authorisation holder has announced to change the excipient in his products in the near future and the assessment of this variation will have top priority in the concerned Member States.

A.04 Maximum Residue Limits (MRLs) – update on implementing measures to the Regulation (EC) No 470/2009.

The Commission's services gave an update on the implementing measures to Regulation (EC) 470/2009.

In 2017 and 2018, the Commission adopted 3 implementing measures to the Regulation (EC) No 470/2009 (MRL Regulation) :

- on the form and content of the applications and requests - Commission Implementing Regulation (EU) 2017/12, OJ L 4, 7.1.2017;
- on the rules for extrapolation - Commission Regulation (EU) 2017/880, OJ L 135, 24.5.2017; and
- on the methodological principles for the risk assessment and risk management recommendations - Commission Regulation (EU) 2018/782, OJ L 132, 30.5.2018.

A.05 Update and information about International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) topics.

The Commission's services informed the Member States about the latest guideline adopted at the VICH meeting in June, GL 56 on “Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Species: Study Design Recommendations for Residue Studies in Honey for establishing MRLs and Withdrawal Periods” and about the prospective change in the meeting cycle from November 2019 on.

Furthermore, the outcome of the Workshop on enhanced international cooperation amongst veterinary medicines regulatory bodies, taking place in the margins of the VICH meeting with around 25 persons from 20 different countries and organisations, was shortly presented to the Member States.

A.06 Stand of play and information about the revision of Directive 2001/82/EC.

The Commission's services informed the Member States about the latest developments in the process of revising the current legal framework on veterinary medicines.

The Chair informed the Member States that the co-legislators of the EU - the European Parliament and the Council - reached a political agreement on the text of the new Regulation on veterinary medicines in June 2018.The work with jurist-linguist is nearing the end. Text context changes were not allowed during this work, only the check of legal coherence and correctness. Until now the 3 texts were kept together and they are at the same step.

The final adoption, publication and entry into force of this Regulation are expected in autumn 2018 while it should start to apply three years later, towards the end of 2021.

Implementation work : quite broad and substantial coverage, 25 DA and IA. Around 12 or 13 acts must be in place at the date of implementation. Member States will be informed and consulted in line with the rules on DA and IA.

A.07 AOB

The Commission's services asked the Member States to have a look at the contacts' list table that was provided to check if the email addresses, to which the invitations to Standing Committees are normally sent, are correct. If not, the Member States were asked to provide correct email addresses.

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 draft Implementing Decision deals with granting of the marketing authorisation for a stem cell product. It is the first veterinary stem cell-based medicine in the EU.

The chair explained and summarised the background information. In June 2018, the CVMP adopted a positive opinion for granting of a marketing authorisation by a majority of 19 out of 28 votes. There were 2 divergent positions to the CVMP opinion.

Presentations were given by the European Medicine Agency 'EMA' (on the scientific opinion) and one Member State (on the outstanding concerns regarding the product).

The chair did not call for a vote because it emerged from the discussion with the Member States that despite an in-depth discussion that took place during the EMA's Committee for Medicinal Products for Veterinary Use ('CVMP') meeting, there were certain questions which were not sufficiently addressed in the CVMP assessment report of an application for the granting of a community marketing authorisation for Arti-Cell Forte dated 21 June 2018. Additionally, important new questions were raised by the Standing Committee.

The Standing Committee agreed that the adoption procedure for the product is suspended in line with Art. 35(4) of Regulation (EC) No 726/2004.

The Standing Committee agreed that the assessment report on the authorisation for Arti-Cell Forte is sent back to EMA for further consideration, together with the new questions formulated by the Member States.

Vote Postponed