News story: Veterinary medicines containing zinc oxide: European referral process

The European Medicines Agency's (EMA) Committee for Medicinal Products for Veterinary Use (CVMP) has reached a final conclusion that the benefit-risk for veterinary medicines containing zinc oxide is negative and that this class of products should be withdrawn.

The European Commission will now make the final decision on these products. It will consider the CVMP's recommendation and the evidence submitted by Member States. The Commission's decision is expected some time after June this year.

The VMD, in consultation with stakeholders, has submitted evidence to support a proposal for a 10 year transition period if medicines containing zinc oxide are to be withdrawn.

The background to the referral of these products and the developments since our last announcement on GOV.UK on 6 February are set out below.

In February 2016 the Netherlands and France submitted a referral to the EMA for all veterinary medicines containing zinc oxide administered orally to food producing animals. The grounds for the referral were concerns regarding the potential risk that zinc oxide presents to the environment and the risk for co-selection of antimicrobial resistance. In order to evaluate the overall benefit:risk balance for the products, consideration was also to be given to the authorised treatment benefits.

In December 2016, the CVMP concluded that the treatment benefits of zinc oxide for the prevention of diarrhoea in pigs did not outweigh the environmental risk associated with their use. Based on its scientific conclusions, the CVMP recommended withdrawal of the marketing authorisations for these products. The committee's conclusion was challenged by the marketing authorisation holders of the affected products earlier this year. The CVMP undertook a re-examination of the opinion and concluded at its meeting in March 2017 that the benefit-risk balance for the products remains negative and the opinion should be upheld. The press release summary can be found on the EMA website.

The initial conclusions of the CVMP were forwarded to Member States and the European Commission as it is the Commission that decides if and when a CVMP recommendation is adopted. Prior to adopting a final Decision, the Commission invited Member States to a meeting of its 'Standing Committee'.

At this meeting in January 2017, the potential impact that a withdrawal of these medicines would have on the pig industry was discussed. All Member States requested a transition period, if the medicines were to be withdrawn,

but the requested length of such a period varied. The Commission representative invited Member States to submit evidence to support their proposed transition period by mid-March 2017.

The VMD, in consultation with stakeholders, has submitted evidence to support a request for a 10 year transition period if the medicines are to be withdrawn. This will allow for changes in pig farming practices to avoid increases in the occurrence of diarrhoea at weaning, to ensure animal welfare and prevent increases in the use of antibiotics.

Once the Commission has considered the evidence from all Member States, there will be a further meeting of the Standing Committee. This is expected to be in June (date to be confirmed). The Commission will then issue its Decision on the products.

The detailed grounds for the CVMP's opinion will be published on the EMA's website after the Commission adopts its final Decision.

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