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Committee for Medicinal Products for Veterinary Use

Public statement on the evaluation of the compliance of marketing authorisation holders with CVMP Risk Management Strategy with respect to potential presence of RD114 in feline and canine vaccines

The Committee for Medicinal Products for Veterinary Use (CVMP) adopted the evaluation of the compliance of marketing authorisation holders with CVMP Risk Management Strategy with respect to potential presence of replication competent endogenous retrovirus RD114 in starting materials and final products of feline and canine vaccines (EMA/CVMP/IWP/592652/2014), following the risk management strategies submitted by marketing authorisation holders.

The CVMP Risk Management Strategy was adopted by the Committee in February 2017 and subsequently the holders of centrally authorised marketing authorisations were asked to advise how they intend to implement this strategy with respect to their centrally and nationally authorised products. The strategy was developed to provide direction for risk management with regard to the potential presence of replication competent RD114 in feline and canine vaccines. This strategy responds to the CVMP opinion from 2010 pursuant to Article 30(3) (EMA/CVMP/433418/2010) concerning RD114.

The Committee concluded that the risk assessment and the risk management strategy provided by applicants are compliant with the CVMP strategy and no further information or action is required with respect to the vaccines covered by this plan. The risk linked to the presence of replication-competent RD114 retrovirus in the existing canine and feline vaccines is considered negligible.

The benefit-risk balance of the affected vaccines remains unchanged and the Committee strongly favours continued use of these vaccines. No evidence of an actual risk has been identified for this quality issue. Canine and feline vaccines are considered safe for cats and dogs and consequently no additional risk management measures are deemed necessary.

The evaluation of compliance thereby closing the outstanding issue of compliance of existing vaccines with the CVMP Risk Management strategy as initiated by the Art 30 (3) referral on RD114 in live attenuated vaccines in 2010.

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