EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 November 2016
EMA/CVMP/713330/2016
Committee for Medicinal Products for Veterinary Use

**Summary of opinion[1] (post-authorisation)**

# Trifexis

## International non-proprietary name (INN): spinosad / milbemycin oxime

On 10 November 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Trifexis. The marketing authorisation holder for this veterinary medicinal product is Eli Lilly and Company Limited.

Trifexis is currently authorised as chewable tablets. The new indication, prevention of angiostrongylosis (immature adult stages (L5) of *Angiostrongylus vasorum*) has been sufficiently proven by data, with a treatment restricted to 6 months in any one year.

Detailed conditions for the use of this product are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.



[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
**Send a question via our website** www.ema.europa.eu/contact