EMA Says Reporting Of Suspected Side Effects Of Veterinary Medicines Helps To Protect Animal, Human Health (26-03-2018)

United Kingdom, 26 March 2018: The European Medicines Agency (EMA) has published its annual bulletin on the veterinary pharmacovigilance activities carried out to monitor medicines in practice and to ensure their safe and effective use. The activities use reports from the field related to unwanted medical events that have been observed following the use of a medicine and that may or may not have been caused by the medicine.

In 2017, the monitoring of centrally authorised veterinary medicinal products was further strengthened thanks to an overall increase in the electronic reporting of adverse events to EudraVigilance Veterinary (EVVet), the European Economic Area database of suspected adverse reaction reports. A more comprehensive dataset is important as it enhances regulators' ability to analyse the data effectively, to identify any emerging issue with a medicine and to initiate regulatory actions, as necessary.

Over 50.000 new reports were submitted to EVVet in 2017, bringing the total number of reports in the database to approximately 253.000 reports. This is an increase of almost 25% over the last year alone and represents a significant increase in reporting to the database which has been operational since 2005. While overall there is still suspected underreporting, one reason for this significant rise may be due to increased media attention in 2017, including on social media, regarding adverse events related to anti-parasitic products used in companion animals.

This bulletin provides a detailed overview of all the regulatory actions taken for centrally authorised products following pharmacovigilance activities. It also includes details on ongoing discussions related to observations in the field which have not yet been concluded but may raise the awareness of veterinarians, who remain the primary source of adverse event reporting.

Veterinarians are encouraged to report any suspected side effects directly to their national competent authority or to the marketing authorisation holder. In addition, animal owners, animal handlers and farmers can also contribute to this reporting.