European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

European Medicines Agency holds Focus Group meeting on fibrosarcoma occurring at sites of injection of veterinary medicines in cats

The European Medicines Agency (EMEA) organised a focus group meeting with stakeholders on fibrosarcoma occurring at sites of injection (injection site sarcoma) of veterinary medicinal products in cats on 9 July 2007.

The development of fibrosarcoma in cats at the site normally used for injection of veterinary medicinal products is recognised as a rare but serious occurrence. Reports of such lesions are available both in the public literature and in the European pharmacovigilance system. The focus group meeting was held as part of the continued surveillance of injection site sarcoma in cats within the European Regulatory Network and is a follow-up measure to an advisory notice to veterinary surgeons regarding the same topic prepared by the EMEA Committee for Medicinal Products for Veterinary Use (CVMP) in 2003 (EMEA/CVMP/205/03-FINAL). This advisory note is available on the EMEA website http://www.emea.europa.eu/pdfs/vet/press/pp/020503en.pdf.

The meeting brought together 19 invited experts from clinical practice, industry and research, as well as from the CVMP Working Parties for Pharmacovigilance, Immunologicals and Efficacy to collect information and discuss current knowledge and developments in research and clinical practice, treatment options, and pharmacovigilance methods to monitor injection site sarcoma.

The group concluded that further research into injection site sarcoma and the suspected relationship to veterinary medicinal products is necessary. The group also supported joint efforts aimed at increasing the awareness among the veterinary profession, including veterinary pathologists, about the occurrence and nature of injection site sarcoma as well as efforts to promote reporting through the pharmacovigilance system. The group emphasised the need for a harmonised case definition as an essential first step in improving surveillance and reporting.

The conclusions and recommendations from the meeting will be passed to the CVMP and its Pharmacovigilance Working Party for consideration on further actions including the possible need for an appropriate update of the advisory notice on this topic published by the Committee in 2003.

This focus group meeting is also part of the continuing efforts at the EMEA to further strengthen veterinary pharmacovigilance.

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Notes:

1. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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