PRESS RELEASE

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EU Heads of Medicines Agencies (Human and Veterinary) meeting

The EU Heads of Medicines Agencies (Human and Veterinary) held the first of two meetings under the UK Presidency in Edinburgh, Scotland on 14 and 15 July 2005.

The HMA (Human) discussed proposals for the protection of public health in the areas of risk management and counterfeit medicines.

For further development of the European Risk Management Strategy (ERMS), they agreed to publish an overview of the pharmacovigilance resources available in the EU, compiled from a survey of national competent authorities, in the context of the Action Plan now underway. They will also formalise the ad hoc working group on ERMS and make it a permanent working group, with a revised remit to reflect its role in implementing the Action Plan, including publishing an annual status report and advising on further development of the strategy.

During 2005/6 work on the Action Plan will focus on implementing the new Community legislation, in particular implementing risk management plans, strengthening the adverse reaction notification system by enhanced electronic reporting and exploring further work sharing opportunities between national competent authorities.

Also considered were the growing concerns in the EU about counterfeit medicines. They agreed that using the existing EU group of national medicines enforcement officers, Member States should commission studies to identify the scale of medicines counterfeiting. The work of this group and the outcome of these studies will be closely reviewed by HMA with a view to consider ways of improving counterfeit detection techniques in the EU and develop an EU wide anti-counterfeiting strategy that includes use of current techniques and available tools to combat counterfeiting.

The HMA (Veterinary) reached a decision on the advancement of the Global Technology Platform. Established by the European Commission, the Technology Platform brings together companies, research institutions, the financial world and regulatory authorities to define a common research agenda for animal health.

The aim of the Technology Platform is to facilitate and accelerate the development and distribution of the most effective tools for controlling animal diseases globally, thereby improving human and animal health, food safety and quality, animal welfare, and market access, contributing to achieving the Millennium Development Goals. The group discussed and endorsed the vision document produced by the Platform and noted the plans for defining the future research agenda for veterinary medicines in Europe.

HMA (Veterinary) discussed and agreed a draft agenda for a meeting with the International Federation for Animal Health planned to be held prior to the next meeting of the HMA-V in

the UK in November. The proposed agenda includes a discussion on issues relating to the implementation of the new legislation and the topic of medicines availability.

ENDS

Notes to Editor:

1. The Action Plan to Further Progress the European Risk Management Strategy was published on HMA and EMEA websites on 11 May 2005.