EUROPEAN MEDICINES AGENCY
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Press Office

Press release

European Medicines Agency and FDA announce launch of generic medicines application inspections initiative

Collaborative effort builds upon 2009 Good Clinical Practices Initiative

The European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA) today announced the launch of a joint initiative to share information on inspections of bioequivalence studies submitted to the EMA, the FDA and/or to the regulatory authorities in some EU Member States in support of marketing-authorisation applications for generic medicines. The joint initiative also introduces a mechanism to conduct joint inspections of facilities where these bioequivalence studies are conducted.

Successful demonstration of bioequivalence is the basis for the approval of generic medicines. Studies submitted in support of generic medicines applications must demonstrate scientifically that the generic medicine is "bioequivalent", or performs in the same manner as the innovator medicine. Regulatory authorities inspect facilities that conduct these studies to ensure data submitted to the agencies are reliable and of high quality.

This initiative will be carried out in the framework of the confidentiality arrangements established between the European Commission, the EMA, interested EU Members States and the FDA.

The EU Member States initially involved in this initiative are France, Germany, Italy, the Netherlands and the United Kingdom. Additional Member States are expected to join the initiative in the future.

Welcoming the initiative, Fergus Sweeney, Head of the EMA's Inspections and Human Medicines Pharmacovigilance Division, said: "The progress of this initiative is testimony to increased cooperation and the hard teamwork of the inspection staff of all our agencies, helping us to better leverage our respective inspection resources. Globalisation of clinical trials means that we all rely on each other to assure the quality of bioequivalence clinical trials, and data from these, on which the approval of generic medicines, and therefore the health of EU and American patients, rely."

The bilateral inspection initiative includes an 18-month pilot phase, and builds on the successful 2009 EMA-FDA Good Clinical Practice (GCP) Initiative, designed to ensure that clinical trials submitted in marketing applications for medicines in the United States and Europe are conducted ethically and that the data generated by these trials are reliable.

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Key objectives of the initiative are:

- To streamline information sharing on inspections of bioequivalence studies conducted and planned for generic medicines marketing authorisation applications. These include clinical facilities, analytical facilities or both;
- To share information on negative inspection outcomes, which reveal system problems of these facilities, and with potential impact on the acceptability/reliability of the data obtained from other studies conducted in the same facility;
- To conduct joint inspections of clinical trial sites all over the world;
- To provide training opportunities to improve bioequivalence inspections.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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