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Press Office

Press release

European Medicines Agency and its international partners complete successful inspection pilots

International collaboration on drug quality and safety to continue

Two pilot programmes of collaboration on inspections between the European Medicines Agency (EMA) and its international partners in the United States and Australia have concluded successfully, according to two reports published today. The two programmes focus on increasing international regulatory collaboration among the regulatory agencies so that drug quality and safety can be enhanced globally.

The report on the joint good clinical practice (GCP) inspection pilot programme details the success of information-sharing and collaboration on inspections relating to clinical trials. Under the joint GCP inspection pilot, the EMA and the US Food and Drug Administration (FDA) exchanged more than 250 documents relating to 54 different medicines and, in conjunction with the GCP inspectors of the EU Member States, organised 13 collaborative inspections of clinical trials. This lays the foundation for a more efficient use of limited resources, improved inspectional coverage and better understanding of each agency's inspection procedures. It demonstrates how the agencies can work together to improve the protection of participants in clinical trials and better ensure the integrity of data submitted as the basis for drug approvals.

The report on the joint active pharmaceutical ingredients (API) inspections pilot programme details the success of information-sharing and collaboration on API inspections among the participating authorities (EMA, France, Germany, Ireland, Italy, United Kingdom, EDQM, FDA and Australia's Therapeutic Goods Administration (TGA)). Over the course of the 24-month pilot phase, the participants shared their surveillance lists and found 97 sites common to all three regions, resulting in the exchange of nearly 100 inspection reports and in nine joint inspections.

Both pilots involved the exchange of considerable amounts of information and the establishment of inspections carried out jointly by the agencies. This led to increased levels of understanding between the agencies, and a greater number of inspections of value to more than one authority.

Based on the positive experience in the two pilots, the agencies have agreed to continue with their collaboration on inspections, taking into account the experiences and lessons learned during the pilot phases.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The International API Inspection Pilot Programme started in December 2008 and ran for two years.
3. The Pilot EMA/FDA Good Clinical Practice Initiative ran from September 2009 to March 2011.
4. More information on these joint programmes can be found at:

   For GCP
   http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000072.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800268ad

   For GMP

   http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000171.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580029751
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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