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FDA, European Commission and EMA reinforce collaboration to advance medicine development and evaluation

US and EU regulators aim to enhance trust in quality, safety and efficacy of medicines

Senior leaders from the United States Food and Drug Administration (FDA), the European Commission and the European Medicines Agency (EMA) reviewed their ongoing cooperative activities and discussed strategic priorities for the next two years at their regular bilateral meeting held on 19 June 2015, at FDA Headquarters in Silver Spring, Maryland, USA.

Over the past years, EMA and FDA have significantly increased their level of collaboration and sharing of information to advance regulatory excellence worldwide. There are now daily interactions, most of them structured around scientific and regulatory working groups or "clusters". The focus of the cluster reviews during this bilateral was pharmacovigilance, biosimilars, pediatrics and veterinary medicines.

Strategic priorities

Looking ahead, EMA, European Commission and FDA decided to establish a new cluster on patient engagement to share experience and best practices regarding the involvement of patients in the development, evaluation and post-authorization activities related to medicines.

Participants also agreed that communication on the ongoing successful cooperation should be enhanced and that efforts to support communication activities and align core messages should be strengthened.

They also agreed to further strengthen their collaboration in inspections and data integrity, safety monitoring of medicines, biosimilars, pediatric medicines, rare diseases, timely access to new medicines and veterinary medicines. This will help EU regulators and FDA increase efficiency on a global level and avoid duplication.

Planned focus for each area includes:

Patient engagement: In the U.S. and in the EU, patients are well informed and expect that their voice is heard by regulators when it comes to the way studies are designed and the assessment of the benefits and risks of specific medicines. Involving patients in the evaluation discussions adds meaningful perspectives to the process. EMA and FDA aim to expand patient input during the regulatory process, for example to better understand how medicines and the availability of treatments affect patients and how patients approach quality, safety and efficacy of medicines.

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Safety of medicines: The long-term collaboration between EMA and FDA in pharmacovigilance has facilitated the exchange of critical information and the coordination of communication to patients and healthcare professionals in the U.S. and EU. The participants agreed to further strengthen collaboration in the International Pharmacovigilance cluster with a more strategic focus on, among others, the assessment of everyday use of medicines.

Biosimilars: Activities in this cluster will continue to support the global development of biosimilars. The agencies are interested in aligning their scientific approaches to biosimilars to avoid regulatory divergence that may delay patients' access to medicines.

Pediatric medicines: Regulatory collaboration is of vital importance for the development of pediatric medicines. Because the development of pediatric medicines is largely driven by legislation in the EU and the U.S., EMA and FDA will continue to align their scientific approaches including through "common commentaries" and development plans which help to achieve a rational approach to the conduct of the necessary clinical trials. A workshop to share EU and US experience under their respective regulatory frameworks may be organized in 2016 to further support these efforts, resources permitting.

Rare diseases: Collaboration in the area of rare diseases is of growing importance. Medicines developers can already use a common template to request orphan designation of their medicine in the EU and the US. Building on this success, and the Pediatric Cluster's work on rare diseases, EMA and FDA will establish a joint working group, the Team of International Global Rare Disease Experts (TIGRE), to better support the development of safe and effective medicines for children who suffer from rare diseases.

Timely access to new medicines: Improving timely access to new medicines to treat serious diseases has been at the core of the collaborative endeavours of EMA and FDA. By sharing information to facilitate joint approaches, e.g., in scientific advice or the evaluation of medicines, and by building on the best available regulatory practices the two regulators aim to minimize divergence and support patients' early access to new treatments.

Veterinary topics: Recognizing that the One Health concept is a worldwide strategy for expanding interdisciplinary collaboration in all aspects of healthcare for humans, animals and the environment, FDA and EMA continue pathways for effective communication and information sharing activities. Cooperation is particularly strong in the area of novel veterinary therapies such as stem cells, oncology products and cytokines. EMA and FDA are focusing their efforts to further encourage the development of novel veterinary medicines and to further reduce antibiotic resistance.

Inspections: Progress was also made for the mutual reliance on inspections of drug manufacturing sites. EU regulators and FDA are evaluating how their respective inspectorates, in addition to their regulatory and procedural frameworks to inspect manufacturers of human medicines compare. This is an essential prerequisite to relying on each other's inspection findings, avoiding duplication of efforts, and enabling wider inspection coverage. Both agencies are working expeditiously towards a plan for a final framework for an agreement and an implementation plan.

Data integrity: Both agencies stressed the importance of data integrity as a cornerstone to establishing and maintaining confidence in test results and agreed to work on communication and training to help increase the awareness of manufacturers.

The European Commission, EMA and FDA organize in-person bilateral meetings routinely to monitor progress and ensure that their collaboration delivers on agreed strategic priorities that promote the safety, efficacy and quality of medicines to the benefit of global public and animal health.