

In this context, and within the scope of the guidelines on regulatory co-operation, the European Commission together with the EMEA and the FDA see value in establishing an arrangement to exchange more regulatory information including advance drafts of legislation and/or regulatory guidance documents as well as information related to the authorisation and supervision of medicinal products. Because this type of information may include information of a non-public nature, both sides agree, to the extent permitted by their respective laws, to keep the information exchanged confidential.

The potential benefits of this exercise are expected to include accelerated access of patients to new and innovative medicines; resource savings due to reduced duplication of assessment and improved performance and safety as a result of the involvement of the best regulatory expertise from both sides. This co-operation shall not compromise each Participant's ability to carry out its responsibilities and shall not create any kind of legal obligation on the part of the FDA, the European Commission, or the EMEA.

Therefore the European Commission and the EMEA are pleased to cooperate with the FDA to facilitate the sharing of documents and/or information related to ensuring the safety, quality, and efficacy of medicinal products for human and veterinary use, including orphan medicinal products, authorised or under review both in the US and in the European Union (EU). This is also intended to include information on maximum residue limits.

In this context, the term 'medicinal products authorised in the European Union' refers to products subject to evaluation or authorised under the centralised procedure as well as medicinal products authorised at national level by the EU Member States that are subject to official European Community arbitration and referrals.

This cooperation activity will strengthen communication between public authorities involved in these activities and reinforce public health protection.

The type of information that may be shared includes, but is not limited to:

1. All legislation and guidance documents available under the rules and regulations governing medicinal products in the EU (<http://dg3.eudra.org/F2/eudralex/index.htm>). This also includes all position papers, notes for guidance and any other guidance documents either in draft, finalised or released for consultation.
2. Post-authorisation pharmacovigilance data, particularly those of urgent nature related to EU or non-EU originating adverse drug reactions as well as safety concerns arising from periodic safety update reports and post-authorisation obligations and commitments.
3. Information on quality defect or product recalls for medicinal products known to the EMEA or to the European Commission to have been manufactured or distributed in the US.
4. Information contained in applications for scientific advice, orphan medicine designation, marketing authorisation or post-authorisation activities of significant public health interest, and maximum residue limits.
5. Without prejudice to arrangements set out in the framework of the US-EC Mutual Recognition Agreement in particular its Sectorial Annex on Pharmaceutical