European Commission

European Agency for the
Evaluation of Medicinal Products

September 12, 2003

Dear Dr McClellan,

The Food and Drug Administration (FDA) of the United States of America (US) on the one side and European Commission's Directorate General Enterprise and the European Agency for the Evaluation of Medicinal Products (EMEA) (collectively "the Participants") on the other side have recognised the need to further improve their relationship and in particular, in the Transatlantic Economic Partnership Action Plan, the need for increased co-operation as a means to address technical barriers to trade in goods. This view was later reflected in the Guidelines on regulatory co-operation and transparency between the US Government and the European Commission. In particular these Guidelines encourage the identification of areas where regulatory co-operation could be established.

One of the specific aims mentioned in the guidelines is to obtain from each other and interested parties the benefit of the expertise, perspectives and ideas for alternative approaches to regulation. In addition the idea of harmonisation of regulatory requirements *ex novo* is specifically highlighted.

There is already considerable experience in the field of regulatory co-operation between the FDA and European Commission administrations responsible for regulation in the pharmaceutical sector. To date, this has been in the context of regular bilateral meetings between representatives of DG Enterprise (since 1989) and representatives of the FDA.

The success of existing regulatory co-operative measures on harmonisation of technical requirements and an agreement on a common format for the submission of certain regulatory information to the respective pharmaceutical regulatory authorities has led to the desire from both sides to increase the range of information that can be shared in the interests of better regulatory co-operation.

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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

Good Manufacturing Practices (GMP), GMP Inspection reports and product sample results available to the EMEA or the European Commission.

6. Good Clinical Practices (GCP) inspections for specific products and GCP Inspection reports available to the EMEA or the European Commission.

7. Information Technology systems supporting regulatory processes.

At the EMEA, the information may be shared with national experts on secondment from the EU Member States, EEA countries, or EU candidate countries. These individuals will be required to sign a confidentiality undertaking with the EMEA (form to be annexed). This form will also be completed by each FDA staff member visiting the EMEA.

The Participants reserve the right to limit the scope of the above information should its dissemination or exchange undermine specific interests, including commercial, industrial or professional secrecy, the protection of the individual and of privacy, the public interests of the EU or the protection of the EMEA or the European Commission's interests in the confidentiality of its proceedings. In some cases, exchange of information under this arrangement may be subject to prior authorisation from the companies concerned.

Participants note that it is an essential element of this international arrangement on regulatory cooperation that confidential information emanating from the other Participant will be treated as such.

On each occasion where there is a request for disclosure to third parties of non-public information received from EMEA or the European Commission, FDA shall consult with the EMEA or the European Commission. Likewise, on each occasion where there is a request for disclosure of non-public information received from FDA, the EMEA or the European Commission shall consult with the FDA.

The EMEA and the European Commission affirm that they have the authority to protect non-public information, including confidential commercial information, provided to their officials or representatives by the FDA, and will protect such information as information not to be disclosed under Article 4.1(a) of Regulation (EC) No 1049/2001. The EMEA and the European Commission understand that the FDA considers it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the international relations between the Participants. The EMEA and the European Commission agree that "confidential commercial information" includes information referred to in the US Freedom of Information Act, 5 U.S.C. § 552(b)(4), and in Regulation (EC) No. 1049/2001

Similarly, the FDA affirms that it has the authority to protect non-public information, including confidential commercial information, provided to its officials or representatives by the EMEA or the European Commission, and will protect such information as information not to be disclosed under the US Freedom of Information Act. The FDA understands that the EMEA and the European Commission consider it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the international relations between the Participants. The FDA agrees that "confidential commercial information" includes information referred to in the US Freedom of Information Act, 5 U.S.C. § 552(b)(4), and in Regulation (EC) No. 1049/2001.

This arrangement is concluded for a period of two years after which we will assess at least annually its effectiveness.

The European Commission and the EMEA should be obliged if FDA would acknowledge receipt of this letter and confirm that this letter and your reply constitute the arrangement set out above between our services.

We look forward to implementing this arrangement allowing for the sharing of non-public information and to continuing cooperative activities to further enhance the relationship between the FDA, the EMEA, and the European Commission, in the best interests of public and animal health.

Paul Weissenberg

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Products