

Dr Stefan Führung
European Commission
Directorate for Health and Consumers
B-1049 Brussels

Ref: VD 65.975

23 March 2012

Dear Dr Führung,

Subject: Concept Paper for an Implementing Act on the Requirements for the Assessment of the Regulatory Framework Applicable to the Manufacturing of Active Substances of Medicinal Products for Human Use

Further to your request for comments issued 07 December 2011, we would like to thank the European Commission for the opportunity to provide an input to the above-mentioned Concept Paper, and are sending you today the Efpia's response.

We remain at your disposal, should you have any further question.
With best regards,

Véronique Davoust
Manager, Technical Development & Operations Committee

Encl.: 65.975a1_EFPIA Comments on Concept Paper 1438409.doc
65975a2_EFPIA TDOC Position Paper API Importation 2011 11.docx