

Mr Stefan Fuehring Unit D6 Pharmaceuticals DG Health and Consumers European Commission B-1049 Brussels

Ref: VD 65.992

20 April 2012

Dear Mr Fuehring,

Subject: Concept Paper on Delegated Act on the principles and guideline of good manufacturing practice for active substance in medicinal products for human use (Sanco.ddg1.d.6(2012)73176)

Further to your request for comments issued 20 January 2012, we would like to thank the European Commission for the opportunity to provide an input to the Concept Paper on Delegated Act on the principles and guideline of good manufacturing practice for active substance in medicinal products for human use, and are sending you today the EFPIA's response.

EFPIA would welcome the opportunity to further discuss with the Commission services the implementing measures of the Falsified Medicines Directive to ensure smooth implementation by the pharmaceutical industry.

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

Best regards,

Véronique Davoust

Manager, Technical Development & Operations Committee

Cc: Fabio Datri (EC) Agnès Mathieu (EC)

