SUBMISSION OF COMMENTS ON: Public Consultation in Preparation of a Legal Proposal to Combat counterfeit Medicines for Human Use

Key Ideas for Better Protection of Patients Against the Risk of Counterfeit Medicines

COMMENTS FROM: Schering-Plough	**CONTACT PERSON: Siska De Moor**

GENERAL COMMENTS
We welcome the opportunity to provide input on this important consultation. We support the comments submitted on behalf of the European Federation of Pharmaceutical Industries and Associations, but also wanted to provide these additional comments.
A general comment on the document is that the same obligations as for wholesalers and all other parties in the distribution chain should be applied onto Internet pharmacies directly shipping products to patients. We also believe that it is important that this document apply to Over-the-Counter products in addition to prescription products.

SPECIFIC COMMENTS ON TEXT

GUIDELINE SECTION TITLE

Page/Section	**Comment and Rationale**	**Proposed change (if applicable)**
Page 6 4.1.1	It is important that rules for receiving a brokers, wholesalers, etc. license should be harmonized within the EU. There should be minimum requirements for licensing.	
Pages 11-12 4.3	The same rules as for API's should also apply for excipients (e.g. if magnesium stearate would be contaminated with BSE if stearate is made of animal origin or vegetable stearate is mixed with animal stearate, this could have a tremendous negative health effect).	

Please feel free to add more rows if needed.

These comments and the identity of the sender will be published on the EMEA website unless a specific justified objection was received by EMEA.

Public

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 95
E-mail: mail@emea.eu.int http://www.emea.eu.int