Hampshire International Business Park
Basingstoke, Hampshire RG24 8EP
United Kingdom
Tel +44 (0)1256 894000
Fax +44 (0)1256 894709
www.shire.com

22nd December 2011

To: European Commission
SANCO
SANCO-gmp@ec.europa.eu and ADM-GMDP@ema.europa.eu

SHIRE'S RESPONSE TO SANCO'S CONSULTATION ON COMMISSION GUIDELINES ON GOOD DISTRIBUTION PRACTICE OF MEDICINAL PRODUCTS FOR HUMAN USE

SANCO/C8/AM/an D (2010) 380358

Shire welcomes the opportunity to submit the following questions and comments, in response to the consultative document on Good Distribution Practice.

1) In reference to section 3.4: Why should medicinal products not intended for the union market be kept segregated from union market products when standard warehouse controls are sufficient to prevent mix up of products for different markets?

2) In reference to section 5.10: More specificity and clarity on the meaning of "irregularity in sales patterns" would be beneficial for wholesalers.

3) In reference to section 6.10: The term packaging in Section 6.10 should be clearly defined to prevent confusion between secondary packaging and shipping boxes.

4) In reference to section 9.19: Whilst it is acknowledged that all products should be temperature monitored during shipping, validation of temperature controlling systems for distribution of ambient products will be a significant cost to the industry and is currently a long way from industry practice. Please clarify if this is expected for ambient as well as cold-chain products.

Sincerely,

Mr Steve Parker
Associate Director Global Affiliate
Responsible Person
+44 1256 894124
sparker@shire.com

Dr Kerry Hawitt PhD
Associate Director Quality Compliance
+44 1256 894219
khawitt@shire.com

Shire Pharmaceuticals,
Hampshire International Business Park
Chineham
Basinstoke
RG24 8EP