EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31st December 2011

Submission of comments on the Revised Commission guidelines on Good Distribution Practice of Medicinal Products for Human Use (SANCO/C8/AM/an D(2010) 380358)

Comments from:

Name of organisation or individual

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
5.30 The containers in which medicinal products are shipped should be sealed.		Comment: This paragraph could be interpreted as also being applicable to shipping containers used for air and sea distribution. Pharmaceuticals shipped by air might be subjected to security checks during which shipping containers (such as Envirotainer or Opticooler) are opened for inspection. This is similarly applicable for clinical trial supplies packed in VIP boxes. Proposed change (if any): we suggest to add…" **The containers in which medicinal products are shipped should be sealed** whenever or where practically possible".	

Please add more rows if needed.