Question for written answer E-001013/2012
to the Commission
Rule 117
Liam Aylward (ALDE), Pat the Cope Gallagher (ALDE) and Brian Crowley (ALDE)

Subject: Proposed revision of the European Good Distribution Practice Guidelines

The recent Commission proposal concerning revision of the European Good Distribution Practice Guidelines states that:

'The wholesale distribution of medicinal products is an important activity in the integrated supply chain management. Today's distribution network for medicinal products is increasingly complex and involves many players. The quality and the integrity of medicinal products can be affected by a lack of adequate control over the numerous activities, which occur during distribution and it is also necessary to address the threat that falsified medicinal products pose to the distribution channel. It is necessary to exercise control over the entire chain of distribution objectives by observing good manufacturing practice of medicinal products. This policy ensures that products manufactured in, or imported into the European Union are of the appropriate quality. This level of quality should be maintained throughout the distribution network without any alteration.'

1. Could the Commission clarify its procedure as regards the process of consulting the relevant stakeholders concerning the revision of these guidelines?

2. How does it plan to implement further guidelines concerning the storage and transportation of essential medicinal products?

3. Has it carried out extensive feasibility studies regarding the proposed changes to the transportation and storage of medicinal products?

4. Does it plan to provide any assistance to wholesale distributors and pharmaceutical companies in connection with the proposed revision of these guidelines?