To: Fabio D'Atri and Caroline Attard, SANTE, European Commission

23 November 2015

Response to the public consultation of **Commission Delegated Act on Principles and guidelines on good manufacturing practice for investigational medicinal products for human use and inspection procedures**, pursuant to the first subparagraph of Article 63(1) of Regulation (EU) No 536/2014.

In response to the questions in the proposed Delegated Act, MPA has the following opinions:

Question 1a:
Yes. The term is widely used and it would add to clarity.

Question 1b:
Yes, in our experience this is the present standard.

Question 2:
MPA proposes alternative b), as this documentation is to be considered part of the clinical trial documentation.

Question 3:
Yes. The Certificate of Analysis is normally included in the package of documents which the QP should have for certification.

Question 4a:
Yes.

Question 5:
In our experience this represents a very unusal situation. MPA does not have any statistics to present.

On behalf of MPA, Sweden

Helena Lindberg
GCP inspector

Ann Marie Janson Lang
Ad-hoc CT deleagate