

European Commission Health and Consumers Directorate-General Unit SANCO/D/6. DM24/028, BE-1049 **Brussels**

12th April 2012

Dear Sirs,

DELEGATED ACT ON THE PRINCIPLES AND GUIDELINES OF GOOD MANUFACTURING PRACTICE FOR ACTIVE SUBSTANCES IN MEDICINAL PRODUCTS FOR HUMAN USE CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION

Regarding the above subject, EIGA is pleased to submit comments to the concept paper, and these are attached.

EIGA is the industry association that represents virtually all European companies manufacturing and distributing medical, industrial and food grade gases. Our member companies work together in safety, quality and technical matters with the objective of ensuring the highest level of patient safety for the gases that are supplied for medicinal use.

EIGA supports the principles of the concept paper, though we consider medicinal gases to be a specific part of the medicinal products industry that should be excluded and this is reflected in our comments to the concept paper.

We trust that we have provided sufficient information for you to evaluate our position, and we would be happy to discuss with yourselves in more detail any points you may require clarification.

Yours Sincerely

Andrew Webb

Deputy General Secretary

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