

Brussels, February 2008

FECC position on Pharmaceutical Excipients

I) Introduction

The European Association of Chemical Distributors (FECC) represents around 1,200 European chemical distributors. FECC Members, many of them SMEs, create value in the supply chain meeting the demands of over one million downstream users. Many of them distribute excipients and Active Pharmaceuticals Ingredients to manufacturers of medicinal product throughout Europe. Chemical distributors are therefore a crucial part of the pharmaceutical supply chain.

FECC promotes the implementation of the WHO – Good Trade and Distribution Practices for Pharmaceutical Starting Materials (**GTDP**) for all excipients. This commitment to GTDP is the chemical distribution's contribution to reduce and manage the risks involved in supplying pharmaceutical starting materials to finished dosage form manufacturers.

Moreover, FECC believes that a Third Party Verification of the voluntary implementation of the GTDP principles among the Chemical Distributors increases the credibility of the chemical distribution companies' commitment to raise the Health, Safety and Environmental (HSE) standards in the pharmaceutical supply chain. In this context, CEFIC and FECC have jointly developed the European Single Assessment Document (**ESAD**). ESAD is a voluntary system for assessing the HSE standards of distributors' operations, whilst simultaneously providing a third party assessment system for the distributors' compliance to their Responsible Care programme. The sections F & G of ESAD provide a tool to carry out the Third Party Verification of the distribution of pharmaceutical excipients and to increase the transparency vis-à-vis the suppliers.

II) Future Directive on GMP for Excipients

In view of the possible legal proposal for a Commission Directive on excipients (Article 46 (f) of Directive 2001/83/EC), FECC would like to highlight the following:

- FECC Members have reservations regarding a defined list of excipients. FECC does not believe that only those excipients included in the list involve a risk.



- FECC believes that all excipients should be manufactured according to appropriate standards in order to maintain high quality standards in the supply chain, ensure full traceability and prevent contamination during all operations. The legislation should therefore focus on defining what 'appropriate' means for each group of excipients. Current systems such as the IPEC-PQG GMP Guide for Pharmaceutical Excipients or the HACCP code should be considered.
- The level of GMP for each group of excipients should be depending on the risk that the group of excipients imposes to the consumer/patient. In case excipients are used in different finished dosage forms with different levels of risk to the consumers/patients (e.g. oral vs injected vs topical), the level of GMP and QA measures required should also be different. This could be facilitated by definition of different excipients' grades.
- Furthermore, FECC strongly supports an integrated approach for quality assurance of pharmaceutical excipients. Regulation and quality systems should ensure that both the manufacturing process and the supply chain of pharmaceutical excipients are considered as a integrative process and are therefore handled with a consistent level of quality assurance and risk management on each step.

III) Future policies

FECC recognises that many producers and distributors of pharmaceutical excipients already proactively implement specific quality and safety measures in their quality systems to develop a higher level of excipient safety. FECC supports that future policies should aim at the creation of a level playing field in Europe and ensuring high quality standards in the pharmaceutical supply chain.

FECC will be pleased to provide further input on the above. For further information:

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