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

Consultation item No 1: Do you agree with this appraisal and approach? Please comment.

Comment:

Active substances processed in an epicutaneous test allergen are normally small molecular compounds which may cause contact dermatitis.

Fundamentally, all substances occurring at the workplace or in the environment may act as contact allergens. Therefore these active substances are parts of e.g. mechanical rubber goods, of leather goods, fuel, lubricants and consumable technical supplies, are acrylates or part of adhesives, mechanical joining elements or any other technical substances which most commonly occur in the everyday working life.

None of these substances is manufactured in companies which neither are subject to GMP controls nor are they manufactured under GMP-conditions or can be compared with the quality of active ingredients used in "normal" drugs.

Moreover, active substances used for diagnosis of contact dermatitis should be applied in such a quality standard which relates to the normal quality of technical substances and which mirrors the normal situation at the working place or in everyday life.

As a consequence, the provisions in Directive 2003/94/EC should not apply to active substances used for the production of epicutaneous test allergens. This is consistent with the provisions of Commission Directive 2003/94/EC, Article 2, Point 6, referring to "Quality standards (which) are appropriate to their **intended use**".