Establishment of Recombinant Major Allergens Bet v 1 and Phl p 5a as European Pharmacopoeia BRPs and Validation of ELISA Methods for their Measurement (BSP090)

In the field of allergic diseases, data reported in several papers have shown that allergen extracts to be used for in vivo diagnosis and immunotherapy represent a lot of problems linked to the standardization and the poor quality of the extracts themselves. Consequently appropriateness of diagnosis and immunotherapy can be strongly affected by these problems. Therefore, collaborative studies to establish methods and international reference materials for the measurement of individual major allergens are of primary importance for improving allergen extract standardization and quality.

The EU-funded a multidisciplinary research project CREATE (Development of Certified Reference Materials for Allergenic Products and Validation of Methods for their Quantification) that finished in April 2005. The major aim of this project was to introduce the measurement of individual major allergens for allergen extract standardization and to identify appropriate reference materials for this approach. It was attempted to achieve this through validation of ELISA systems for the quantification of major allergens in extracts, using defined reference materials as standards. However, the ELISA validation was not completed during the CREATE project. Furthermore, the establishment of a large batch of reference material was outside the scope of the CREATE project. During a meeting of the International Union of Immunological Societies (IUIS), Allergen Standardization Subcommittee, it was agreed that, based on the CREATE project, two major allergens from birch pollen (Bet v 1) and timothy grass pollen (Phl p 5a) and the corresponding ELISA systems from Allergopharma (Phl p 5 a), ALK-Abelló (Bet v 1 and Phl p 5a) and Stallergènes (Bet v 1) appeared to be the most promising systems for further validation. A project proposal was accepted by the Steering Committee of the Biological Standardisation Programme (BSP) at its meeting in January 2006 and the BSP090 project was started. (Project Leader: Dr. Stefan Vieths, Paul Ehrlich Institut, Germany).

This project (BSP090), sponsored by the Biological Standardisation Programme of the EDQM (European Directorate for the Quality of Medicines & HealthCare), is intended to establish on a large scale Ph. Eur. Biological Reference Preparations (BRPs) for two recombinant major allergens from birch pollen (Bet v 1) and from timothy grass pollen (Phl p 4) as well as to validate reference ELISA methods for their quantification. The project will be run in 3 phases: an initial feasibility evaluation (phase 1) was done in the laboratory of the project leader, an extended feasibility study with 3 participating laboratories (phase 2) and an international collaborative study (phase 3). The results obtained by this study will be important to establish on a large scale Ph. Eur. Biological Reference Preparations (BRPs) for two recombinant major allergens from birch pollen (Bet v 1) and from timothy grass pollen (Phl p 4) as well as to validate reference ELISA methods for their quantification.