



# Quality rules in Europe and France

Regulations concerning allergens used in immunotherapy have changed a great deal in France over recent months.

**INTERVIEW...** with **Mr Cheron** Responsible for Quality within the pharmaceutical working group on Allergens for the AFSSAPS\* and Vice-President of the products of biological origin group (France).

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**Expressions.** : What is the aim of the working group of the AFSSAPS to which you belong?

**Mr Cheron.** The AFSSAPS has various commissions. Because allergens are a distinct entity, it was decided to set up a specific working group with a clinical department and a pharmaceutical department, in which I work. This department is responsible for examining aspects such as the origin of products, the manufacturing process and quality control for a given allergen and its excipients. We also look at stability of raw materials and the final product as well as batch consistency.

**E.** How has pharmaceutical legislation changed in recent years?

**Mr Cheron.** In 1992, all types of medicine were redefined by European directive.

Allergens were reclassified as drugs. In France a marketing authorization approval is now required for specialities, and each Named Patient Product must be declared once to the AFSSAPS. For

mother preparations, a scientific dossier must be presented within months. Countries such as Germany, Italy and Spain are likely to adopt a similar approach. Each mother preparation dossier has both clinical and pharmaceutical components with a comprehensive study of the allergen representative of the family and more concise information about the other allergens.

**E.** Are there specific recommendations regarding allergen contaminants?

**Mr Cheron.** The absence of contaminants or pollutants is of special importance to us and we insist that laboratories describe exactly the measures they take to eliminate them from their products. There are three types of risk:

- With chemical contaminants (pesticides, solvents and metals), there is a risk of accumulation to toxic levels within the body.
- With bacteria and viruses, there is a risk of infection - at an individual or an epidemic level.
- Finally, contaminants may themselves be allergenic and so compromise diagnosis and treatment. Each risk should be considered separately. We have, for example a specialist virus group whose work is particularly pertinent to the production of allergens of animal origin.

**E.** What in your opinion would be the next steps towards improved production and quality control?

**Mr Cheron.** The next step will probably relate to allergens that are purified or produced using genetic recombination. Currently, there are no pan-European regulations but recommendations that are being applied country by country.

It is likely that a European agency will take responsibility for processing allergen files in the future and for issuing Europe-wide endorsement.



\* The french local health authority