



A new regulatory setting for NPP

(Named Patient Product)



NEW DECREE FOR NPP*

Following legislation passed on June 7th 1960, laboratories in France received authorisation to manufacture and deliver NPP. The legislative framework has not developed much since then. Very recently, the AFSSAPS (the French local health authority) has published new regulations referring specifically to NPP. The document defines new conditions for funding and continued authorisation of the production and delivery of individual preparations and requirements to strengthen and guarantee the quality of NPP. The main changes that follow from this ruling are:

- **development of documentation compatible with the European pharmaceutical standards:** with technical documentation for each source preparation supplied (providing laboratory information on pharmacology, toxicology and clinic, stability, batch consistency...) and a document relating to each specific NPP (analysis and formulation, quality control and follow-up of allergens).
- **proof of 5-year authorisation:** note that there used to be no time limit.
- **renewal of authorisation under certain conditions:** in particular to provide all pharmacovigilance data.
- **development of information leaflets supplied with allergens,** information cards for health professionals and leaflets for the patients. It is also suggested that each patient should be given a desensitising logbook.
- **submission of promotional materials to the AFSSAPS.**

*OJ decree n°2004-188 of February 23, 2004

INTERVIEW... with M.C. Annequin (AFSSAPS)* - (France)

The essential point is the need for producing a precise description of the source preparations and procedures followed when preparing each NPP.

Expressions. New regulations have just been issued with regard to NPP; can you give us the background to this measure and explain its principal objectives?

M.C. Annequin. In 1998, the rules governing medicines intended for human use were changed to exclude autoserum and autogenous vaccines but remained unchanged for NPP. The intention was to focus on NPP products to guarantee quality level.

E. Which for you are the key points of this new ruling?

M. C. A. The essential point is the need for producing a precise description of the source preparations and procedures followed when preparing each NPP. The other very important point of this ruling is the limitation of the authorisation period to 5 years.

E. All these rules only apply nationally. What about the rest of Europe?

M. C. A. These are strictly national measures but we have had the opportunity to consult with our Italian colleagues, who are also working to produce new regulations on NPP.

E. What will be the impact for you at the AFSSAPS, in terms of organisation and workload?

M. C. A. We have already anticipated the consequences of this ruling, identifying one person especially in charge for the allergens; in addition, two working groups have been created, one for the pharmaceutical evaluation of these products and the other for their clinical evaluation.

*The French local health authority