



## French National Order of Pharmacists – Central Council of Section B – Industrial Pharmacists

### FAQ

# Organisational and hierarchical relationships in a department responsible for controlling advertising within a pharmaceutical establishment



### QUESTION:

**Organisation and hierarchy in the department responsible for controlling advertising and pharmaceutical responsibility?**



### POSITION OF THE FRENCH NATIONAL ORDER OF PHARMACISTS:

Amended directive 2001/83 EC indicates (Article 98) 1 "*The marketing authorization holder shall establish, within his undertaking, a scientific service in charge of information about the medicinal products which he places on the market.*" In France, only an "exploitant" company can be responsible for the marketing of medicinal products involving several pharmaceutical operations including advertising and information (Article R 5124-2, paragraph 3 of the French Public Health Code), furthermore declared in the annual inventory drawn up by "exploitant" companies (Sheet B4: number of persons employed, per pharmaceutical operation, in the establishment and the equivalent in full-time employment posts).

In addition, the transposition into the French Public Health Code (Article R 5122-2) confirms the obligation placed on the company to equip itself with a department responsible for advertising, placed under the control of the Chief Pharmaceutical Officer who must ensure that the provisions in respect of advertising are observed. On this subject it should be noted that the ANSM (the French National Agency for the Safety of Medicines and Healthcare Products) takes decisions on the approval of all promotional documents.

This is also to be found in the "CERTIFICATION REFERENCE DOCUMENT concerning the information activity by canvassing or prospection aimed at the promotion of medicinal products" (HAS – French Higher Authority for Health - March 2017) within the framework of the Charter on promotional information which indicates (criterion E6): "*The Chief Pharmaceutical Officer shall exercise his responsibility in respect of the promotional qualification of all information concerning medicinal products and its accuracy. In order to exercise his responsibility in respect of the promotional qualification of all information concerning medicinal products and its accuracy, the Chief Pharmaceutical Officer shall be involved in the monitoring of the medical information activity in order to guarantee its non-promotional nature. The Charter also indicates in respect of the methodology of*

*certification: "Guaranteeing the promotional qualification of all information concerning medicinal products is under the effective responsibility of the Chief Pharmaceutical Officer: formalising the responsibilities of the Chief Pharmaceutical Officer in respect of advertising and non-promotional information, deployment of necessary resources, performance of controls".*

This Chief Pharmaceutical Officer (Article R 5124-36, paragraph 1 of the French Public Health Code) shall be responsible for *organising and monitoring all the pharmaceutical operations of the company...and particularly, .....advertising, information and* (Article R 4235-69 of the French Public Health Code) *the CPO is obliged to monitor the accuracy of scientific, medical and pharmaceutical information and of advertising, in addition to their proper use.....*

Consequently, a pharmaceutical qualification/validation of all documents is a pharmaceutical act placed under the effective control of the Chief Pharmaceutical Officer.



#### **EN PRACTICE / POSITION OF THE FRENCH NATIONAL ORDER OF PHARMACISTS**

The control (validation) of all the promotional documents is a pharmaceutical operation under the regulations in force. The department responsible for controlling advertising is placed under the control of the Chief Pharmaceutical Officer which means the authority and/or organisational control (in the sense of mastery) including the number of people, the qualifications and the lines of hierarchy in compliance with the pharmaceutical organizational chart declared every year.

An outsourcing in whole and in part of the operations constituting advertising or medical information to a third party is allowed (Article R 5124-47, paragraph 6 of the French Public Health Code) within the framework of a written contract but the “exploitant” (Chief Pharmaceutical Officer) retains control and responsibility and must consequently set up quality management for these operations.



**KEY WORDS:** Chief Pharmaceutical Officer, advertising, promotion, organisation.



**REFERENCE ARTICLES OF THE FRENCH PUBLIC HEALTH CODE:** *Articles R 5122-2 – R 5124-2, R 5124-36 - R 5124-47 - R 4235-69*



**OTHER REFERENCE ARTICLES:** *Directive EU 2001/83EC – Article 98, HAS (French Higher Authority for Health) Reference document for promotional information – March 2017 – Criterion E6*