

"Translation of the above letter in French"

**To the attention of Chairmen, Managing Directors,
Chief Pharmaceutical Officers and Legal Directors of
pharmaceutical companies**

Subject: Position of the Chief Pharmaceutical Officer (*Pharmacien responsable*) within a pharmaceutical company

Dear Sir or Madam,

The French legislator decided that the pharmaceutical responsibility should lie with a nominally designated person, known as the Chief Pharmaceutical Officer. It is therefore crucial that this person is given the actual capacity to fully exercise this responsibility.

In a context of globalisation and growing fragmentation of the pharmaceutical chain, the Chief Pharmaceutical Officer stands as a pillar of the French health system which ensures that necessary medicines of the required quality are made available to the patients.

The attention of both the French National Agency for Medicines and Health Products Safety (*Agence nationale de sécurité du médicament et des produits de santé – ANSM*) and the French Chamber of pharmacists (*Ordre National des Pharmaciens*) is being increasingly drawn to the position actually allotted to the Chief Pharmaceutical Officer within pharmaceutical companies and the effects thereof, including effects on the quality of medicines.

Therefore, we feel that it is essential to call onto your contribution so that the responsibility of Chief Pharmaceutical Officers can be fully exercised.

The Public Health Law (*Code de la santé publique*) sets out the position, missions and responsibilities of the Chief Pharmaceutical Officer. He/She must be a Corporate Officer / Company Representative (*art. R. 5124-34 of the Public Health Law*) and, as such, he/she shall hold the appropriate powers pertaining to the pharmaceutical activities of the company. His/Her missions are set by law (*art R. 5124-36*) and must be stated *in extenso* in his/her statement of appointment.

With respects to general and professional ethics, and in the best interest of public health and patients, the Chief Pharmaceutical Officer shall especially be able to independently take any decision regarding the pharmaceutical products and activities of the company, in accordance with the requirements of the Public Health Law and of the applicable Good Practices,.

The Chief Pharmaceutical Officer is the ultimate decision maker on the national territory according to the aforementioned missions set by law. As such, he must be able to play his full role in relation with the operating conditions of all the company's departments undertaking pharmaceutical activities.

It is important for this responsibility to be made clear. The position of the Chief Pharmaceutical Officer must be clearly specified in the organisation chart of the company, especially in terms of hierarchical links, delegation of tasks to departments in charge of pharmaceutical activities, and functional links with these departments.

Without prejudice to the joint and several liability of the company, the Chief Pharmaceutical Officer is personally liable under both civil and criminal law for the fulfilment of his pharmaceutical missions, and can also be subject to disciplinary actions.

We know that we can rely on your commitment to make sure that the particular position held by the Chief Pharmaceutical Officer in guaranteeing medicines quality and patients safety is maintained both in your company and within European and international network.

Yours faithfully,

Frédéric BASSI
Ordre national des pharmaciens

Head of the division of
industrial pharmacists

Philippe GODON
Ordre national des pharmaciens

Head of the division of
wholesale pharmacists

Dominique MARTIN
Agence nationale de sécurité du médicament
et des produits de santé

Director General