

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



FAQ

Continuing “exploitant” activity during a health crisis



QUESTION:

Can pharmaceutical activity be discontinued in the event of exceptional circumstances?

The French Public Health Code gives details of the operations performed by an establishment authorised for “exploitant” activities (Art R 5124-2): *« Exploitation » includes the operations of wholesale or provision free of charge, advertising, information, pharmacovigilance, batch monitoring, and, where applicable, batch withdrawal, in addition to, if necessary, the corresponding storage operations.*



THE POSITION OF THE FRENCH NATIONAL ORDER OF PHARMACISTS:

An « exploitant » establishment marketing medicines cannot be « closed » as long as there are medicines in the distribution channels which are available to healthcare professionals for patients.

In this way, in exceptional circumstances, the physical site can be closed but not the legal entity, nor its activity, nor its responsibility.

Pharmaceutical operations, and all related tasks, must be kept under pharmaceutical responsibility even if, in a crisis situation, they can be organised in a scaled manner, at a distance.



IN PRACTICE:

The Chief Pharmaceutical Officer must take all necessary steps in order to have at his/her disposal teams ensuring that these operations are performed and, even more so, to provide for his/her own availability. It must be possible to contact the CPO, including at night-time and on public holidays.

It is the responsibility of the Chief Pharmaceutical Officer, or of the Acting CPO replacing him/her, to ensure the company’s pharmaceutical continuity, regardless of the circumstances, including during periods of “lockdown” or quarantine.

The ANSM (the French National Agency for the Safety of Medicines and Healthcare Products) must be informed of any difficulty in the performance of professional duties which could jeopardise the continuity of pharmaceutical activity: ipplf@ansm.sante.fr.



KEY WORDS: Chief Pharmaceutical Officer, continuing activity, health crisis.



REFERENCE ARTICLES OF THE FRENCH PUBLIC HEALTH CODE: *Article R 5124-2*