Conseil central de la Section B
Fabricants, Importateurs, Exploitants

Paris, 16th February 2018

Dear colleague,

The *Lactalis* crisis has reminded us, as if it were necessary, of the importance of immediately taking into account the anomalies and non-compliances detected during production which are likely to create risks.

The prevention and management of these incidents require the implication of competent executives who have been trained to manage the crisis and to provide the most suitable sanitary measures guaranteeing the safety of users. The definition of these measures requires discussion both outside the company with the competent authorities and, where necessary, with specialised structures, and inside the company with the persons having the best expertise for quality investigation.

Confident in the ability of the industrial pharmacists, and more especially the Chief Pharmaceutical Officers (Articles R5124-36 and R5124-19), the CCB highlights the importance of their role and of their independence when taking decisions.

The Public Health Code makes specific reference to this manufacturing requirement in its Article R 5124-55: "When the Chief Pharmaceutical Officer of a manufacturer, an importer or an *exploitant* of medicinal products is aware, after a batch of medicinal products or products has been marketed, of an incident or an accident which occurred during the manufacturing or distribution of this batch and likely to create a risk for public health, he shall notify it without delay to the French National Agency for Medicines and Health Products Safety". Furthermore, the Good Manufacturing Practice currently in force (Chapter 8) indicates that "All concerned competent authorities should be informed in a timely manner in case of a confirmed quality defect (faulty manufacture, product deterioration, ……. non-compliance……., or any other serious quality problems) with a medicinal product ……which may result in the recall of the product ……".

It is also the responsibility of an *exploitant* Chief Pharmaceutical Officer to ensure that reliable recall information is provided rapidly to the distributors and dispensers and to check it with an exhaustive recall report. In addition, where medicinal products are concerned, the Chief Pharmaceutical Officer can use the *DP Rappels* portal for recall management.

Section B should like to remind you that it is the responsibility of each company and its Chief Pharmaceutical Officer to rigorously test with regular and extensive simulations the in-house quality procedures which guarantee product quality with the aim of ensuring public health, while observing deontology and professional ethics.

To its credit, the French pharmaceutical system has a responsible, central interlocutor capable of taking the necessary decisions completely independently in the interests of public health.

It is up to us, the industrial pharmacists, to ensure that the system works and to demonstrate its effectiveness.

Best regards,

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