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

FAQ

Local Representative and Labelling

QUESTION:

For a centralised Marketing Authorisation is it compulsory to place the name and contact details of the Local Representative on the outer packing and/or package leaflet?

POSITION/ANALYSIS OF THE FRENCH NATIONAL ORDER OF PHARMACISTS:

- European Directive 2001/83/EC amended indicates in the English version of the text:

TITLE I DEFINITION

Article 1 – 18a
Representative of the marketing authorisation holder: The person, commonly known as local representative, designated by the marketing authorisation holder to represent him in the Member State concerned.

TITLE V LABELLING AND PACKAGE LEAFLET

Article 54
The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging: ….. (k) the name and address of the marketing authorisation holder and, where applicable, the name of the representative appointed by the holder to represent him;

Article 59
1. The package leaflet shall be drawn up in accordance with the summary of the product characteristics; it shall include, in the following order: ….

(vi) the name and address of the marketing authorisation holder and, where applicable, the name of his appointed representatives in the Member States;

- The enforceable French translation of Directive 2001/83 amended (Ref: 02001L0083 — FR — 26.07.2019 — 013.001):

TITRE I DEFINITION

Article 1 18bis

Représentant du titulaire de l'autorisation de mise sur le marché : personne communément appelée « représentant local », désignée par le titulaire de l'autorisation de mise sur le marché pour le représenter dans l'État membre concerné;

TITRE V ÉTIQUETAGE ET NOTICE

Article 54
L'emballage extérieur ou, à défaut d'emballage extérieur, le conditionnement primaire de tout médicament doit porter les mentions suivantes: …. k) le nom et l'adresse du titulaire de l'autorisation de mise sur le marché et, le cas échéant, le nom du représentant du titulaire désigné par ce dernier;

Article 59

1. La notice est établie en conformité avec le résumé des caractéristiques du produit; elle doit comporter, dans cet ordre: …

vi) le nom et l'adresse du titulaire de l'autorisation de mise sur le marché et, le cas échéant, le nom de ses représentants désignés dans les États membres.

In France, the “exploitation” (marketing) of medicinal products is restricted solely to "exploitant" establishments under the terms of Article R. 5124-2, paragraph 3, of the French Public Health Code.

Consequently, a reference to the local representative is provided for, both on the labelling of the outer packaging, or, where there is no outer packaging, on the immediate packaging and on the package leaflet.

Article R5121-138
While observing the wording required by other legislative and regulatory provisions, ***the labelling of the outer packaging, or, where there is no outer packaging, the labelling of the immediate packaging*** *of a medicinal product or of a product referred to under Article L. 5121-8 shall carry the following wording, inscribed in a manner as to be easily readable, clearly understandable and indelible : ……*
Paragraph 12: The name and address of the Marketing Authorisation Holder ***and, where required, the medicinal product’s or product’s "exploitant" company****.*

Article R5121-149
The ***package leaflet*** *shall be drawn up in compliance with the Summary of Product Characteristics. It shall contain the standard text, specifically asking patients to report any suspected side effects to their doctor, to their pharmacist, to any other healthcare professional or directly to their regional pharmacovigilance centre and giving details of the various methods of notification at their disposal. It shall also carry, in this order, the following indications: ….*

f) The name and address of the Marketing Authorisation Holder ***and, where required, the medicinal product’s or product’s "exploitant" company****.*

IN PRACTICE:

Insofar as the Marketing Authorisation Holder appoints a Local Representative (LR), this LR must appear on both the outer packaging (or where there is no outer packaging, on the immediate packaging) and on the package leaflet, as prescribed by the European provisions.

The Order believes that, for public health reasons, in addition to the name, the package leaflet must also carry the contact details to be used by both the patients themselves and the healthcare professionals.

The French Public Health Code provides that, *where required,* the "exploitant" appears on both items.

Or:

- A medicinal product's local representative and "exploitant" can be two different entities. European regulations provide that only the local representative, if he is designated by the Marketing Authorisation Holder, is indicated on the package leaflet and referred to in the "Blue Box" on the outer packaging.
- The concept of "exploitant" is a French one and cannot be imposed at the European level.

Consequently, if a medicinal product's "exploitant" is neither the Marketing Authorisation Holder nor his local representative, his contact details cannot appear on the box.

In all cases, if the establishment responsible for the "exploitation" is located in France ("exploitant" status in compliance with Article R 5124-2 of the French Public Health Code), whether the Holder designates him or not as local representative, a "pharmaceutical contract" giving details of the roles and responsibilities laid out in the French Public Health Code must be signed between the parties and by the Chief Pharmaceutical Officer.

In cases where the Holder does not appoint an "exploitant" located in France all the pharmaceutical operations are under the responsibility of the Holder based in the EU.

KEY WORDS: centralised Marketing Authorisation, Local Representative, "exploitant", package leaflet, labelling, packaging.

REFERENCE ARTICLES OF THE FRENCH PUBLIC HEALTH CODE: *Articles R 5121-138 and 149 - Article R 5124-2 – ANSM recommendation* (*the French National Agency for the Safety of Medicines and Healthcare Products) – Articles R 5124-34 to 36.*

European Directive 2001/83/EC on the Community code relating to medicinal products for human use