



EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Industrial affairs: Consumer goods industries
Pharmaceuticals and cosmetics

PHARM 293a

49th PHARMACEUTICAL COMMITTEE
22. - 23. 3. 2000

Subject : Indication of additional items at the packaging of medicinal products;

Background:

According to Article 2 (2) and Article 7 (3) of Directive 92/27/EEC, the outer packaging and the package leaflet “*may include symbols or pictograms designed to clarify certain information mentioned in paragraph 1 and other information compatible with the summary of the product characteristics which is useful for health education, to the exclusion of any element of a promotional nature.*”

EFPIA has asked the Pharmaceutical Committee to consider whether the following items on the packaging might be acceptable:

1. The manufacturer’s name :

EFPIA gave the following reasons for this request: “*The object is to enable the patient to know at first sight, from the outer package, who to call in case of need. He should have a clear option to call the MA holder or the manufacturer.*”

2. Pictograms or symbols showing the therapeutic indication and/or the pharmaceutical form and/or method/route of administration :

EFPIA gave the following reasons for this request: “*The mention of these on the outer package would aim to “clarify certain information mentioned in §1 which is useful for health education” as expressly permitted by Article 2.2 of Directive 92/27/EC. These pictograms, such as for example the picture of a heart (for a cardio-vascular disease) and the picture of a spoon (for a syrup), would increase the safety of elderly patients who often consume several medicinal products per day for different diseases and whose eyesight is usually impaired. It is not uncommon to hear about an elderly person who has taken the pill for the heart instead of the pill for the stomach or who has put in his eyes drops for the nose....These pictograms could contribute to diminishing this type of risk which can have serious health consequences.*”

Action to be taken:

The Committee is requested to express its view on the proposals from EFPIA

