EUROPEAN COMMISSION
DIRECTORATE-GENERAL III
INDUSTRY
Industrial affairs III: Consumer goods industries
Pharmaceuticals and Cosmetics

PHARM 272

48th PHARMACEUTICAL COMMITTEE
27. - 28. 9. 1999

Subject : centralised procedure, labelling; indication of additional items on the outer packaging

Issue to be discussed:

Indication of additional items on the outer packaging of centrally authorised medicinal products

Interested parties have suggested that the indication of the following items on the outer packaging of a medicinal product should be acceptable:

1. The company-logo of the MAH
The main argument supporting this request is that the logo would be an additional element which helps patients and doctors to identify a given product. Further arguments supporting this request will be presented in a paper from EFPIA which will be circulated to the Committee shortly.
2. The trade mark ownership
The argument supporting this request will be presented in a paper from EFPIA which will be circulated to the Committee shortly.
3. The name of a co-promotor
The argument supporting this request will be presented in a paper from EFPIA which will be circulated to the Committee shortly.

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Article 2 paragraph 1 of Directive 92/27/EEC contains an exhaustive list of the particulars that shall appear on the outer packaging of a medicinal product. According to Article 2 paragraph 2 of Directive 92/27, the outer packaging may also include symbols or pictograms designed to clarify certain information concerning the list mentioned above and "*other information compatible with the SPC which is useful for health education to the exclusion of any element of a promotional nature*".

The particulars mentioned above (company-logo, trade mark ownership, name of a co-promotor) are not mentioned in Article 2 paragraph 1 of Directive 92/27/EEC and their possible inclusion on the outer packaging must therefore be justified under Article 2 paragraph 2.

Taking into account the limited size of the outer packaging, the possibility to mention other particulars than those explicitly provided by the legislation must be very carefully evaluated. The possibility to mention a *local representative* for each MS on the "blue box" of the outer packaging of centrally authorised products has already been agreed as acceptable under Article 2 paragraph 2 of Directive 92/27 in order to have a contact point for patients and doctors in each MS.

Action to be taken:

The Pharmaceutical Committee is asked to consider and express its view on the acceptability of the three suggestions made by interested parties.