



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

PHARM 274

48th PHARMACEUTICAL COMMITTEE
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Subject : medicinal products and driving

Background:

- The Commission Services in the Directorate General responsible for transport (DG VII) are working on the general issue on driving: driving and alcohol, accidents, etc. Of course one of the topics is driving and medicinal products. They have been informed on the warnings which are mentioned on the SPC and leaflet and made the suggestion that these warnings should be more detailed and contain substantive information;
- Certain Member States have nationally imposed a symbol on the labelling in order to reinforce the information;

Legal issues:

- Article 2 of Directive 92/27 provides for the possibility that “the outer packaging may include symbols or pictograms designed to clarify certain information mentioned in paragraph 1 and other information compatible with the SPC which is useful for health education....”
- Article 12 of the same Directive mentions the possibility to publish guidelines, elaborating on the detailed implementation of the Directive.

Proposed action:

- a harmonised symbol (same symbol in all Member States) could be imposed for all cases where a medicinal product has an effect on the ability to drive vehicles or to operate machinery.
- detailed information should be provided in the package leaflet and in the SPC

- a specific guideline could be prepared in the NTA-WP or – alternatively - the “guideline on the readability of the label and package leaflet of medicinal products for human use” could be amended in order to substantiate this proposal;
- attention should be paid to the fact that the warning should be detailed and contain substantive information (following an evaluation of the risks) and not just global standard sentences.

Action to be taken:

For discussion.