



EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Industrial affairs: Consumer goods industries
Pharmaceuticals and cosmetics

PHARM 304

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

Subject : Borderline medicinal products and biocides

Summary:

In April 1999, at the 47th Pharmaceutical Committee, a questionnaire was distributed concerning the classification in the different Member States of antiseptics, these products being the main issue concerning the borderline between medicinal products and biocidal products.

Following the answers received it seems that for antiseptics applied on wounded skin there is a harmonised position: they are considered as medicinal products in all Member States. For antiseptics applied on intact skin, the positions are not harmonised. In certain Member States these products are considered as medicinal products and in other as biocidal products. This issue has also been discussed with representatives of the Member States invited by the DG in charge of the Biocidal products (DG ENV).

The main difficulty in finding a straightforward classification of antiseptics applied on intact skin is that these antiseptics can be used on intact skin in other areas than the medicines area like for instance in the food industry or other areas where it is needed to use this sort of products in order to protect the final consumer from the transmission of microbes.

One way forward could be to propose to have regulated as medicinal products:
- antiseptics applied on intact skin when they are used by health professionals in hospitals, surgery or other medical premises on patients before an injection or an operation,

or

- antiseptics applied on intact skin for medical purposes.

Nota bene: repellents are considered as biocidal products.

Action to be taken :

For discussion and agreement

