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

PHARM 273

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

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**Subject** : centralised procedure; different legal status for different pack sizes

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**Issue to be discussed:**

In particular cases there are reasons for submitting large packs of medicinal products to stricter restrictions (e.g.: hospital-use only) than small packs of the same product.

Article 13 (3) of Regulation 2309/93 foresees that “*some products may be authorized only for use in hospitals*”. It should be considered whether this sentence can be understood in a way to allow a differentiated approach with regard to different pack-sizes of the same product.

If considered acceptable, the special condition (hospital use) for the large pack size would be mentioned in Annex II of the Community MA Decision and may be mentioned in the blue box in accordance with section B of the “*Guideline on the packaging information of medicinal products for human use authorised by the Community*”.

**Action to be taken:**

For discussion.