



~~CMD(H) sub-group on harmonisation of SPCs~~ **CMDh SUB-GROUP ON
HARMONISATION OF SmPCs**

*Doc. Ref.: CMDh/061/2005/Rev1
May 2011*

BACKGROUND

According to the amending Directive 2004/27/EC the CMD(h) is obliged to lay down a list of medicinal products for which a harmonised SPCSmPC should be drawn up.

This list shall take into account proposals from Member States and the list shall be forwarded to the Commission once a year. The Commission or a Member State could, in agreement with the EMA, refer these products to the CHMP. Before triggering a referral the views from interested parties should be taken into account.

CRITERIA FOR SELECTION OF PRODUCTS FOR SPCSmPC HARMONISATION

The CMD(h) has endorsed, at its January 2006 CMD(h) meeting, the following criteria for selection of products for which a harmonised SPC should be drawn up:

- Significant differences in Core parts of the SPCSmPC (Sections 4.1 – 4.4).
- Exclusivity/patent expiry dates.
- Extent of the use of the product.
- Number of MS where the product is authorised.