



CMD(h) SUB-GROUP ON HARMONISATION OF SPCs

BACKGROUND

According to the amending Directive 2004/27/EC the CMD is obliged to lay down a list of medicinal products for which a harmonised SPC 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 EMEA, refer these products to the CHMP. Before triggering a referral the views from interested parties should be taken into account.

MANDATE

The mandate of the CMD(h) Sub-group on Harmonisation of SPCs will be:

1. Advise Member States in choosing products suitable for harmonisation by giving examples of criteria to be used
2. Recommend to CMD which products, suggested by Member States, should be included in the list of medicinal products for which a harmonised SPC should be drawn up.
3. Have contact with interested parties, in an appropriate way and time, to ensure that their views will be considered.
4. Be a forum for discussions with the Commission on which party will make the referral for which product, the order and timing for referrals and the practical arrangements such as pre-referral meeting with MAH/EMEA etc.