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| **CRITERIA FOR SELECTION OF PRODUCTS FOR SmPC HARMONISATION** |

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According to the amending Directive 2004/27/EC the CMDh is obliged to lay down a list of medicinal products for which a harmonised SmPC 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 SmPC HARMONISATION

The CMDh has endorsed, at its January 2006 CMDh meeting, the following criteria for selection of products for which a harmonised SmPC should be drawn up:

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