



The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE
European Agency for the Evaluation of Medicinal Products:
Committee for Proprietary Medicinal Products
Meeting of 21 to 23 January 2003

No opinions were adopted on applications for marketing authorisation.

The CPMP concluded its Community-wide review for medicinal products containing a fixed combination of **salmeterol and fluticasone propionate** (Seretide Diskus, Viani Diskus and associated product names) following an arbitration referral by Ireland in April 2002. This fixed combination is currently authorised through the mutual recognition procedure for the treatment of asthma. The referral relates to applications for a new indication to include chronic obstructive pulmonary disease (COPD). Based on the currently available information, the Committee considered that there is a positive risk/benefit balance for a restricted indication for the symptomatic treatment of patients with severe COPD and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy.

The Committee began Community-wide reviews for:

- The generic product **Fluconazole Tiefenbacher** (fluconazole) from Tiefenbacher GmbH & Co. The arbitration referral by Germany relates to public health concerns over the use of the product in pregnancy and lactation and also to potential cardiac toxicity concerns. The application is currently under review in the mutual recognition procedure. The arbitration referral is made under Article 29 of the Community Code on human medicines.
- **Coversyl** (perindopril) and associated product names from Servier. The referral is part of the concerted action by EU regulatory authorities to harmonise the marketing conditions of a number of European brand leaders in major therapeutic areas. The referral is made by the European Commission under Article 30 of the Community Code on human medicines. The referral was not initiated as a result of any established safety or efficacy concern with this product.
- **Lopid** (gemfibrozil) and associated product names from Pfizer. The referral is part of the concerted action by EU regulatory authorities to harmonise the marketing conditions of a number of European brand leaders in major therapeutic areas. The referral is made by the European Commission under Article 30 of the Community Code on human medicines. The referral was not initiated as a result of any established safety or efficacy concern with this product.

A more detailed CPMP meeting report will be published shortly, including details from the MRFG meeting of 21 January 2003.

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