

Grounds for refusal

The CHMP considered that the data submitted in support of this application failed to show therapeutic equivalence between the test and the reference product:

- the description of the pharmaceutical development was considered to be unsatisfactory and the deficiencies resulting from this, including the absence of skin permeation or similar *in vitro* studies, were considered to be critical;
- the data provided by the company was considered to be neither robust nor extensive enough to warrant waiving a clinical study, or other validated model, to show therapeutic equivalence.

Based on:

- the results from the studies provided by the MAH;
- the rapporteur's and co-rapporteur's assessment reports;
- and scientific discussion within the Committee,

the CHMP was of the opinion that the particulars submitted in support of the application do not comply with article 10 of Directive 2001/83/EC as amended. The Committee further considered that it is not possible, on the basis of the data submitted in support of this application, to establish a positive benefit-risk balance for this product and that, in these circumstances, the marketing of the product constitutes a risk to public health.

Therefore, the Committee adopted an opinion recommending the refusal of the marketing authorisation in the concerned member states and the suspension of the marketing authorisation in the reference member state, subject to the conditions outlined in annex III of the Opinion.

Annex III

Conditions for the lifting of the marketing authorisation suspension

Prior to the lifting of the suspension of the marketing authorisations, the national competent authorities, coordinated by the reference Member State, shall ensure that the following conditions are fulfilled by the marketing authorisation holder:

1. Therapeutic equivalence to the reference product, through an appropriate clinical study or other validated model is demonstrated.
2. Key pharmaceutical parameters of the drug product, manufacturing process and control are established .