

COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

**PUBLIC SUMMARY OF
NEGATIVE OPINION FOR ORPHAN DESIGNATION
OF
mycobacterial cell wall complex
for Superficial bladder cancer**

On 12 September 2002, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on orphan designation for Mycobacterial cell wall complex in the treatment of superficial bladder cancer. A negative decision was granted by the European Commission on 18 December 2002.

The sponsor, Bioniche Teoranta Ireland, applied for orphan designation of mycobacterial cell wall complex for treatment of carcinoma in situ of the urinary bladder. This application was based on the severity and rarity of the condition, as well as an assumption of potential benefit despite currently available methods of treatment.

The negative opinion is based on the following grounds:

- for the purpose of designation as orphan medicinal product, limiting the indication to the proposed subset of carcinoma in situ of the urinary bladder was not acceptable as an effect in the broader population of superficial bladder cancer had not been excluded;
- it had not been established that superficial bladder cancer affects not more than 5 in 10,000 persons in the Community at the time the application was made;

Requests for designation as orphan medicinal products are made for investigational products. Absence of orphan designation does not preclude the development of this product, in particular through clinical trials, and subsequently the possibility of obtaining a marketing authorisation if quality, safety and efficacy are demonstrated.

For more information:

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