European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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Public Statement on Positive Opinion for Tuberculosis Vaccine

On 9 September 2005 the COMP adopted a positive Opinion recommending orphan designation of recombinant modified vaccinia virus Ankara expressing tuberculosis antigen 85A (MVA TB vaccine), a booster vaccine for prevention of tuberculosis disease. The opinion was given on the grounds that marketing of the medicinal product would be unlikely to generate sufficient return to justify the necessary investment.

The medicinal product that is the subject of this positive Opinion has a wide public health interest. Tuberculosis (TB) is one of the most serious and devastating problems threatening public health worldwide. As more than 30 years have passed since the introduction of a new medicinal product to prevent or treat TB, the need for new medicinal products cannot be overstated.

After the publication of the information on this opinion, several potential sponsors of vaccines for prevention of tuberculosis disease have expressed their concerns on the impact that the designation could have both on the development of other products for prevention and on the application of the incentives for Orphan Designated Products, and particularly on the market exclusivity.

One of the objectives of the orphan drugs Regulation 141/2000 is to stimulate research and development in the field of orphan and rare diseases. Therefore, in the EMEA's view the designation of a vaccine will trigger development for other vaccine candidates in the same field, and will also increase the interest from other potential sponsors to apply for Orphan Designation. Consequently, it will give them the opportunity to benefit from the incentives offered for these products, for instance free protocol assistance, which is given before marketing authorisation independently of the existence of similar designated products.

The EMEA would like to clarify that market exclusivity is applicable only after a product has reached the market, which means the medicinal product has received a positive opinion from the EMEA Committee for Medicinal Products for Human Use (CHMP) and has been granted marketing authorisation by the European Commission. As orphan designation does not confer any protection during the development of the drug it does not preclude developing a competitor product. Nothing prevents the designation for the same or similar products as orphan medicinal products. In addition, market exclusivity applies only to the same or similar products for the same therapeutic indication after autorisation of a first orphan product, as stated in Article 8(1) of Regulation 141/2000.

Further information on the definition of similarity and the elements to be considered for its evaluation are available in the European Commission guideline on aspects of the application of Article 8 of Regulation (EC) No. 141/2000, available from the European Commission website (http://pharmacos.eudra.org/F2/pharmacos/archives.htm#2004).

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