

Notice Information: Human Medicines - Recall
31 July 2002

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Authorisation Holder:

Part 2. Target Audience

- a) Target Audience:

Part 3. Problem/Issue

a) Problem/Issue:

The Irish Medicines Board (IMB) has today suspended the BCG vaccine licence held by Evans Vaccine Ltd UK and is reviewing all licences for products held by this company which are supplied to the Irish market. This action follows an on site investigation by the IMB, of the company's facility in the UK producing the BCG vaccine. The IMB was dissatisfied with the procedures adopted by the company in producing this vaccine. A detailed review of all data from the company with regard to the vaccines produced for the Irish market is now taking place, but the IMB believes that the licence for the BCG product should be suspended in the interim. The investigation by the IMB at the BCG vaccine manufacturing facilities was carried out following an incident earlier this month, in which one batch of this vaccine supplied by Evans Vaccines to the Irish market was recalled as a precautionary measure due to a potentially reduced effectiveness. This recall had no safety implications, the concern being that the vaccine could be less potent than that normally administered. The IMB Board today also directed that an additional team of IMB inspectors should immediately carry out detailed inspections of all facilities at the Evans Vaccine plant at Speke, Liverpool, UK. Under an EU Mutual Recognition System all inspections and investigations of manufacturers are carried out by the state agency responsible in each jurisdiction. In this case the Medicines Control Agency (MCA) in the UK is responsible for inspecting the facilities at Evans Vaccines Ltd UK. The IMB is formally expressing its disquiet to the MCA at aspects of this particular case. It has sought the co-operation of the MCA to immediately send an IMB team of inspectors to the plant to carry out more detailed investigations of relevant data, facilities and reporting mechanisms carried out by this company. According to Dr Frank Hallinan, Chief Executive, IMB a different manufacturer of BCG vaccines is now supplying the Irish market, and a continuing supply can be guaranteed. He confirmed that concerns raised with the recalled BCG vaccine in relation to the Evans Vaccines Ltd's manufacturing practices, calls for further investigations. The Minister for Health and Children has been informed of these developments.

Part 4. Background Information

a) Background Information:

NOTE: The BCG vaccine provides protection against tuberculosis (TB) and in Ireland is normally administered to new born babies, older children and adults who are considered to be at risk of developing tuberculosis, where potential contact with the disease could occur or has occurred.

Part 5. Keywords

a) Keywords:

BCG vaccine