

Wednesday, 7<sup>th</sup> April 2004

**IRISH MEDICINES BOARD  
RABIES VACCINE BP– PRECAUTIONARY RECALL OF TWO BATCHES**

The Irish Medicines Board (IMB) stated today that it is in close consultation with the French regulatory authorities and Aventis Pasteur MSD Limited in relation to the worldwide recall of a rabies vaccine manufactured by the company's operations in France. This recall is as a precautionary measure following a recent test at the company, which revealed a low level of contamination with live weakened rabies virus in a single batch. **This batch was rejected by the company and never released to the market.** The IMB states that the company is carrying out a recall of all batches of rabies vaccine manufactured at that facility at that time as a maximum precautionary measure and that the risk of potential harm ranges somewhere between nil to negligible.

The IMB confirms that this rabies vaccine has been licensed for use in Ireland since 1994 and that two specific batches have been recalled from the Irish market. These two batches are numbered X0712-1 and X0071-6 and were marketed in Ireland between the 24<sup>th</sup> October 2003 and 2<sup>nd</sup> April 2004. These batches passed all European and US release procedures before being released onto the Irish market.

The IMB states that an alternative source for this vaccine is licensed in Ireland and sufficient supplies are being made available at this time in order to meet the demand. The IMB advises that they are in contact with the National Disease Surveillance Centre (NDSC), Department of Health and Children (DoHC) and relevant national and international experts in this area. Relevant healthcare professionals are also being advised on the situation.

Any person who received the rabies vaccine after October 24<sup>th</sup> 2003, should not be unduly concerned as this is a precautionary recall but are advised to contact the doctor/travel centre that administered their vaccine for further advice and to determine whether they may have received the vaccine from a recalled batch.

A question and answer document for the public and healthcare professionals is available on the IMB and NDSC websites @ [www.imb.ie](http://www.imb.ie) and [www.ndsc.ie](http://www.ndsc.ie)

**ENDS**

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