IRISH MEDICINES BOARD

Notice Information: Human Medicines - 3rd Party Publications 31 March 2006

Part 1. Product Information

a)	Title:	BCG VACCINE SSI
b)	Product Name/Type:	BCG VACCINE SSI- MIMS Advisory
c)	Reference:	MIMS Publication March 2006
d)	Prescription Required:	No

Part 2. Problem/Issue

a)	Problem/Issue:	Further to previous articles on BCG Vaccine SSI (April 2003, September 2004 and February 2005), this month's item describes the outcome of a retrospective review of suspected adverse reaction reports associated with use of BCG vaccine and possible reasons for an observed increase in the rate of adverse reaction reporting between 2002 and 2004. BCG Vaccine SSI [Danish 1331 strain] was first authorised in Ireland in 2001 and became the only available BCG vaccine in 2002 following withdrawal of the previously used Evans BCG vaccine [Copenhagen 1077 strain] from the Irish market due to concerns regarding the possible sub-potency of some batches. Following the introduction of BCG Vaccine SSI in 2002, a significant increase in the number of suspected adverse reaction reports notified to the IMB was observed. A detailed retrospective review of cases classified as "serious" within the agreed regulatory definition of the term was initiated, which included distribution of a questionnaire to the original reporters over a two-year period from August 2002 to the end of July 2004. IMB staff together with paediatric experts evaluated the original reports and the responses to the questionnaires. A total of 121 adverse reactions were reported during the study period; 59 cases of regional lymphadenopathy, 58 cases of local reactions exceeding 10 mm in diameter and 4 cases of generalised rash. Interestingly, administration of an incorrect dose or administrations by an incorrect route were reported factors in 10 of the adverse reaction reports. Evaluation of the data suggested that the observed increase in the notification of adverse reactions during the two-year period between 2002 and 2004 may have been due to a number of factors. These included heightened awareness surrounding the use of the newly available BCG SSI vaccine following the publicity associated with the withdrawal of the previously used product, a change in vaccine potency and reactogenicity [the Danish 1331 strain is known to be a more potent than the Copenhagen 1077 strain] and administration errors due to incorrect dose or route of administration. Overall there was a significant increase in the notification of suspected adverse reactions following introduction of the Danish 1331 BCG strain in Ireland, however, the reporting rate remained within the frequency of adverse reactions expected for the product and the Irish experience was consistent with what has been observed in other countries following the introduction of the Danish 1331 strain. The IMB would like to sincerely thank those healthcare professionals who contributed to this review by submission of reports and provision of responses to questionnaires. As always, the important contribution of busy healthcare professionals to the continued surveillance of the safety of medicines through the spontaneous reporting systems is greatly appreciated. Finally we would take this opportunity to encourage continued reporting of any suspected adverse reactions to the IMB in the usual way. References: 1- MIMS Ireland, April 2003, September 2004, February 2005.

Part 3. Keywords

a)	Keywords:	BCG VACCINE SSI