IRISH MEDICINES BOARD

Notice Information: Human Medicines - 3rd Party Publications 03 April 2008

Part 1. Product Information

a)	Title:	BCG Vaccine SSI – Update
b)	Product Name/Type:	BCG Vaccine SSI
c)	Reference:	MIMS April 2008

Part 2. Problem/Issue

a)	Problem/Issue:	Further to previous articles on BCG Vaccine SSI1, including the outcome of a retrospective review of suspected adverse reactions associated with its use, this month's article provides an update on experience of adverse reactions reported during 2007, in the context of overall reporting rates for the preceeding years. BCG Vaccine SSI [Danish 1331 strain] was first authorised in Ireland in 2001 for immunisation against tuberculosis and has been used in the immunisation programme since the withdrawal of the Evans BCG vaccine from the market in July 2002. As detailed in the graph below, a significant increase in the number of suspected adverse reaction reports notified to the IMB was observed between 2002 and 2004. A retrospective review of these reports and follow-up questionnaires carried out by paediatric experts and IMB staff suggested that the increased reporting rate, although within the expected frequency of adverse reactions expected for the product, appeared to be associated with a combination of factors including heightened awareness surrounding use of the newly available BCG Vaccine SSI following 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 more potent than the previously approved Copenhagen 1077 strain] and administration errors due to incorrect dose or route of administration. Following publication of a series of articles in MIMS Ireland1 and in the IMB's Drug Safety Newsletter2 highlighting the issues identified above, the rate of reporting to the IMB decreased significantly in 2005. While the figure was consistent in 2006, there was a further decline in the number of reports submitted to the IMB during 2007, with a total of 36 cases reported. The majority of these cases continued to involve severe local reactions, some of which involved abscess formation, lymphadenopathy and/or secondary infection and some of which also required treatment with antibiotics or referral to paediatric experts for further evaluation and/or surgical intervention (i.e. excision/drainage). While the overall rate of reported adverse reactions is consistent with the expected incidence of reactions, because of the severity of some cases and the issues associated with follow up, referral and further intervention, when necessary, the IMB wishes to again highlight the potential for serious adverse reactions associated with BCG Vaccine SSI e.g. lymphadenopathy, abscess formation etc., particularly if the vaccine is inadvertently given subcutaneously or intramuscularly rather than intradermally. As such, prescribers are reminded of the importance of administering this vaccine intradermally in order to minimise the occurrence of severe local reactions and to continue to report suspected adverse reactions to the IMB. The IMB would like to thank those healthcare professionals who have submitted reports of suspected adverse reactions associated with BCG SSI. The important contribution of busy healthcare professionals to the continued surveillance of the safety of medicines through the spontaneous reporting system is greatly appreciated. References: 1. MIMS Ireland, April 2003, September 2004, February 2005, March 2006 & March 2007. 2. IMB Drug Safety Newsletter Editions 17, 21 & 24.