IRISH MEDICINES BOARD

Notice Information: Human Medicines - 3rd Party Publications 30 March 2007

Part 1. Product Information

a)	Title:	BCG Vaccine SSI
b)	Product Name/Type:	BCG Vaccine SSI - Update
c)	Reference:	MIMS Publication March 2007
d)	Prescription Required:	Yes

Part 2. Target Audience

a)	Target Audience:	Healthcare Professionals

Part 3. Problem/Issue

a) Problem/Issue:

BCG Vaccine SSI – Update 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 overview of the numbers and types of suspected adverse reactions occurring in Ireland and reported to the IMB in association with use of BCG Vaccine SSI. 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 above, a significant increase in the number of suspected adverse reaction reports notified to the IMB was observed between 2002 and 2004 and a retrospective review of these reports carried out by paediatric experts and IMB staff suggested that the increased reporting rate, although within the expected frequency of adverse reactions 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 a more potent than the previously approved Copenhagen 1077 strain] and administration errors due to incorrect dose or route of administration. In 2005, 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 of adverse reactions associated with BCG Vaccine SSI to the IMB decreased significantly, with a similar number of reports submitted in 2006 [54 case reports]. The majority of reports received during 2006 continued to involve local reactions, some of which were considered serious as they involved abscess formation, lymphadenopathy and/or secondary infection and some of which also required medical or surgical intervention (i.e. excision/drainage), or treatment with intravenous or oral antibiotics. The IMB would like to take this opportunity 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 are encouraged to continue to report suspected adverse reactions associated with the vaccine to the IMB where such reactions occur. The IMB would like to thank those healthcare professionals who have submitted reports of suspected adverse reactions associated with BCG Vaccine 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. 2- IMB Drug Safety Newsletter Editions 17 and 21. Adverse reaction reports BCG vaccine 2000 - 2006 0 10 20 30 40 50 60 70 80 90 100 2000 2001 2002 2003 2004 2005 2006 New Clinical March07 14/2/07 4:57 pm Page xx

Part 4. Action to be taken

a)	Action to be taken:	Prescribers are reminded of the importance of administering this vaccine intradermally in order to minimise the occurrence of severe local reactions and are encouraged to continue to report suspected adverse reactions associated with the vaccine to the IMB where such reactions occur.

Part 5. Enquiries

a)	All enquiries should be made to:	References: 1- MIMS Ireland, April 2003, September 2004, February 2005, March 2006. 2- IMB Drug Safety Newsletter Editions 17 and 21.

Part 6. Keywords

a)	Keywords:	BCG