

Notice Information: - Advisory

21 April 2011

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Manufacturer/Supplier:

Part 2. Target Audience

- a) Target Audience:

Part 3. Problem/Issue

- a) Problem/Issue:
- Further to the ongoing investigation into the association between Bovine Neonatal Pancytopenia (BNP) in calves and the use of PregSure BVD vaccine in dams, the IMB wishes to update users of the vaccine with the following information.

 - A total of 13 reports in Ireland, involving 16 calves, have been notified to the IMB up to 15 April 2011 where there is a suspected link between use of the vaccine and the occurrence of BNP.
 - BNP is a complex disease and is, as yet, not fully understood. The disease has been identified in herds and in countries where the vaccine has not been used, as well as in situations where it is used. The disease has not been identified in some countries outside Europe where the vaccine continues to be used. Research into BNP is ongoing.
 - Recent research indicates that BNP may be transmitted to calves via colostrum.

Part 4. Background Information

a) Background Information:

The Irish marketing authorisation for PregSure BVD was suspended by the IMB on 1 September 2010, consequent to a decision of the European Commission that the benefit/risk balance had changed, with a possible association between use of the vaccine and the presence of BNP in calves. The marketing authorisation was subsequently withdrawn by the Marketing Authorisation Holder on 7 September 2011. Accordingly, the product is no longer available in Ireland.

Further information about this issue is contained in the IMB Notice of Suspension of the Marketing Authorisation and Recall (01/09/2010).

See also the relevant section of the EMA website

Part 5. Action to be taken

a) Action to be taken:

- Based on current knowledge and following communication with the marketing authorisation holder, Pfizer Animal Health, the IMB recommends the following precautionary measures:

- o Newborn calves that are born to cows that have previously produced a BNP calf should not receive colostrum from that cow. Rather, these calves should receive colostrum from another cow which has not produced BNP calves.

- o Pooled colostrum containing colostrum from a cow which has produced a BNP calf should not be used.

- Suspected adverse reactions to veterinary medicines should be reported either to the company involved (which will in turn report them to the IMB) or directly to the IMB (using the on-line reporting form).

Part 6. Enquiries

a) All enquiries should be made to:

Commensurate with its role in the protection of animal health, the IMB will continue to monitor developments in this area and to provide further advice as necessary.