STATEMENT FROM THE NATIONAL IMMUNISATION ADVISORY COMMITTEE
January 2014

Adverse local reactions to booster doses of Diphtheria, Tetanus and acellular Pertussis vaccine

There has been a recent increase in reports of adverse local reactions to 4 in 1 (diphtheria, tetanus, acellular pertussis, inactivated polio vaccine - DTaP/IPV) when given as a fourth dose (booster vaccine) to children aged 4-5 in Junior Infants as part of the school vaccination programme.

The reactions mainly consist of hot, swollen, red and tender arms from the shoulder to elbow. Some children have been given intravenous or oral antibiotics and /or anti-inflammatory medication. These adverse events have occurred with different batches of vaccine and additional information from the vaccine manufacturer did not show any evidence of quality issues.

The Irish Medicines Board (IMB) has reviewed the 123 reports associated with DTaP/IPV vaccine received in 2013 (an increase from the 45 reports in 2012). These reports have generally been consistent with what was expected with the most frequently reported reactions relating to the injection site.

The Summary of Product Characteristics for the vaccine states that booster doses of DTaP containing vaccines result in an increase in local reactogenicity and fever compared to the primary course. The most frequent reactions reported have been large, localised swelling (diameter > 50 mm) occurring around the injection site.

In general these reactions begin within 48 hours of vaccination and resolve spontaneously over an average of 4 days without sequelae. Such reactions do not contraindicate further doses of diphtheria, tetanus, or pertussis containing vaccines.

Investigation of the limb swelling has shown that these reactions result from angioedema as a cell-mediated immune response rather than inflammatory cellulitis. Antibiotic treatment or the use of anti-inflammatory medication does not reduce the duration or severity of such reactions.

Parents of children who receive the booster dose of a DTaP containing vaccine should be informed of the risk of extensive swelling, highlighting that this is not usually associated with significant pain or limitation of movement.

If a child presents with signs of extensive limb swelling following booster vaccination, the presumptive diagnosis should be of a recognised non-infective injection site reaction and parents should be reassured, unless there is fever or the situation worsens.

Please continue to report any adverse reactions observed to the IMB to facilitate ongoing monitoring of national experience with the use of the vaccine.

References

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