sanofi pasteur MSD
vaccines for life

Batch Recall

Typhim Vi®,Solution for Injection, (Typhoid Polysaccharide Vaccine), 0.5 ml single dose, PA 544/7/1

Batch Number	Expiry Date
G0069-1	31/01/2013
G0327-1	30/06/2013
H0048-1	31/01/2014
H0048-6	31/01/2014
H0473-5	30/09/2014

15th October 2012

Dear Healthcare Professional,

In consultation with Regulatory and Health Authorities, Sanofi Pasteur MSD has voluntarily taken the decision to recall the 5 above referenced batches of Typhim Vi® Solution for Injection, (Typhoid Polysaccharide Vaccine), PA 544/007/001, with immediate effect.

This recall is going to GP/ Pharmacy/Clinic level.

This action has been agreed with the Irish Medicines Board.

These batches are being recalled as they are at risk of lower polysaccharide content and therefore potentially lower than expected antigen content. The results of recent investigations suggest heterogeneity in the content of the active component (polysaccharide) in some syringes of these batches.

- There is no safety concern for individuals who have received a Typhim Vi® vaccine dose from a recalled batch.
- Individuals who received a Typhim Vi® vaccination from a recalled batch may have received less than the intended amount of antigen. Although no clinical trial data on the immunogenicity and efficacy of Typhim Vi® with antigen content below specification is available, Sanofi Pasteur MSD does not recommend revaccination earlier than otherwise indicated.
- Typhim Vi® vaccines from batches not listed above can continue to be administered.

Immediate actions to be taken by Pharmacists and any GP or Clinic holding stock:

- Please immediately quarantine any units of these batches which you have in your possession
- Hospital/Clinic pharmacists: please ensure this covers all units that may be at different locations in your hospital/clinic
- Please pass the below information to relevant Healthcare Professionals within your facility
- Please indicate to Sanofi Pasteur MSD the details of the Typhim Vi®, Solution for Injection, (Typhoid Polysaccharide Vaccine), stock you have in quarantine by faxing the attached form to (01) 420 35 88
- Please hold quarantined stock for collection by Movianto and include the original fax-back form. Credit will be provided for stock returned within 2 weeks of receipt of this notice
- Replacement unaffected stock is available

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Advice for administering Healthcare Professionals:

- for an individual vaccinated with Typhim Vi® less than 3 years ago and living in, or planning to visit, an endemic area
    - it is not feasible to measure the immunological status and hence level of protection against typhoid fever since these are not easily measurable and difficult to interpret
    - a reminder of the classical avoidance of risky food and drink and all hygienic recommendations should be provided
    - according to Typhim Vi® prescribing information, there is no recommendation for revaccination before 3 years after the primary dose. There are limited data available on the immune response of revaccination if administered less than 2 years after the initial vaccination.

- for an individual vaccinated with Typhim Vi® more than 3 years ago and living in, or planning to visit, an endemic area
    - a reminder of the classical avoidance of risky food and drink and all hygienic recommendations should be provided
    - re-vaccination with a Vi polysaccharide typhoid vaccine is recommended
    - there are no data available on the immune response or efficacy of an oral attenuated *S. typhi* vaccine administered after a previous vaccination with a Vi polysaccharide typhoid vaccine.

In all cases, Sanofi Pasteur MSD recommends that the decision to vaccinate and re-vaccinate an individual is taken when the benefit of vaccination outweighs the risk of non-vaccination according to the level of exposure to typhoid fever.

Sanofi Pasteur MSD apologizes for any inconvenience this action may cause. Should you have any medical queries, please contact Medical Information on telephone number + 44 1628 587 693 or any other queries please contact Frances Hayes, Customer Service Manager, or Paul Waldron, Senior manager, Operations on telephone number (01) 468 56 00 or fax (01) 420 3588.

You can report any suspected adverse event associated with the use of Sanofi Pasteur MSD products by calling +44 1628 587 693. Information about adverse event reporting can be found at www.imb.ie.

Yours sincerely,

Martin Dempsey
Country Manager
Contact: 01 46 856 00

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