

Safeguarding public health  
Defective Medicines Report Centre  
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MHRA

## DRUG ALERT

### CLASS 2 MEDICINES RECALL

#### Action Within 48 Hours PHARMACY AND EQUIVALENT LEVEL RECALL

Date: 08 October 2012

EL (12)A/33

Our Ref: MDR 42-09/12

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Dear Healthcare Professional,

### Sanofi Pasteur MSD Limited

#### Typhim Vi

PL 06745/0039

(Typhoid Polysaccharide Vaccine)

Sanofi Pasteur MSD is recalling 16 batches of the above product because the results of recent investigations have indicated that some syringes within them may potentially have antigen levels which are below the required specification. This means that some individuals who have been vaccinated with Typhim Vi since 07 January 2011 may be insufficiently protected against typhoid. Not all doses in these batches are affected but it is not possible to predict who may have received the affected doses. We understand that there are no additional safety concerns associated with affected batches.

The recall will result in this product being out of stock by the end of October so revaccination is not practical. At this time, Sanofi Pasteur MSD is unable to confirm when normal supply of the vaccine will resume. There is a licensed oral typhoid vaccine available on the UK market but stocks of this are also limited. All travellers should, in any case, be advised of the importance of exercising scrupulous food and water hygiene precautions when visiting areas where typhoid is prevalent.

Batch details are presented on page 2 of this notification. Remaining stocks of the affected batches should be quarantined and returned to the original supplier for credit. For enquiries relating to stock returns please contact Sanofi Pasteur MSD Customer Services on 0800 0855511 or by fax on 0800 0858958

For medical information enquiries, please telephone 0800 7311654 or fax to 01628 635072.

#### MHRA Distribution:

Regional Contacts for NHS Trusts and Provider Units  
Chief Pharmacists: England, Scotland, Wales, Northern Ireland  
Prison Health Policy Unit (DH)  
Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar  
Special Hospitals  
Healthcare Commission for distribution to Independent Health Care Establishments  
Primary Care Trusts (England)

Medicines and Healthcare products Regulatory Agency (MHRA)  
151 Buckingham Palace Road London SW1W 9SZ UK  
T 020 3080 6000 www.mhra.gov.uk

An executive agency of the Department of Health

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Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Primary Care Trusts are asked to forward this to relevant clinics and to General Practitioners and Community Pharmacists for information

Yours faithfully

Alison Bunce

Pharmaceutical Assessor, DMRC

**Typhim Vi batches being recalled**

Batch Number	Expiry date	Pack size	Date of first distribution
G0069-1	31 Jan 2013	1 x 0.5ml pre-filled syringe	07/03/2011
G0069-2	31 Jan 2013	10 x 0.5ml pre-filled syringe	07/01/2011
G0069-3	31 Jan 2013	10 x 0.5ml pre-filled syringe	08/02/2011
G0327-3	30 Jun 2013	1 x 0.5ml pre-filled syringe	11/04/2011
G0327-4	30 Jun 2013	10 x 0.5ml pre-filled syringe	28/04/2011
G0529-2	30 Sep 2013	1 x 0.5ml pre-filled syringe	19/06/2012
G0530-1	30 Sep 2013	10 x 0.5ml pre-filled syringes	28/03/2012
G0563-1	30 Sep 2013	10 x 0.5ml pre-filled syringes	21/07/2011
G0574-1	31 Oct 2013	10 x 0.5ml pre-filled syringes	03/08/2011
G0574-6	31 Oct 2013	10 x 0.5ml pre-filled syringes	18/10/2011
H0048-1	31 Jan 2014	1 x 0.5ml pre-filled syringe	04/10/2011
H0048-6	31 Jan 2014	1 x 0.5ml pre-filled syringe	01/12/2011
H0473-1	30 Sep 2014	10 x 0.5ml pre-filled syringes	13/07/2012
H0473-5	30 Sep 2014	1 x 0.5ml pre-filled syringe	Released 25/07/2012 *
H0473-6	30 Sep 2014	10 x 0.5ml pre-filled syringes	03/09/2012
H0539-3	31 Oct 2014	10 x 0.5ml pre-filled syringes	05/09/2012

\* This batch has not been distributed in the UK by Sanofi Pasteur MSD. It is included in the listing, however, as it is possible that it may have been imported into the UK by a European wholesaler.