

23 September 2012

Dear Doctor/Nurse,

**Subject: Recall of the polysaccharide immunization for paratyphoid,
manufactured by Sanofi Pasteur – "Typhium VI ®", due to low level of antigen**

According to the attached letter from Sanofi Pasteur, these are the main points:

In consultation with regulatory and health authorities, Sanofi Pasteur has decided to recall, of its own initiative, a number of lots of the the polysaccharide immunization for paratyphoid (Typhium VI ®). There is a possibility that these batches may contain a lower than necessary level of antigen.

These are the relevant lots:

H0101-2	H0078-5	G0461-2	E1293-1	E1246-1
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- There is no safety issue for anyone who has received this immunization from the above lots.
- Anyone who received an immunization from the above lots, may potentially have been administered a lower than necessary dosage of the antigen. Sanofi Pasteur does not, however, recommend repeat immunization.
- There is nothing to prevent using the Typhium VI ® immunization from lots other than those listed above.
- A shortage of the immunization is possible.

Typhium VI ® is given as an active immunization against paratyphoid caused by Salmonella enteric serovar typhi (S. typhi) starting from two years of age.

The vaccine is given in addition to avoidance of food and drink which carry a hygienic risk.

Precautions:

- A patient who received a Typhium VI ® immunization less than 3 years ago and who lives in or plans to visit endemic regions
 - There is no way of estimating or predicting the level of immunization and protection against the paratyphoid.
 - Patients should be warned against exposure to foods and drinks originating in locations in which the hygienic standards are low.
 - According to the Typhium VI ® doctor's leaflet, there is no recommendation for repeat immunization prior to the expiry of two or three years from the first dose. There is limited information on the immunization level of the repeat immunization if it is given before two or three years have passed from the initial immunization.
- A patient who received a Typhium VI ® immunization 3 years after the initial immunization, and who lives in or plans to visit endemic regions

- Patients should be warned against exposure to foods and drinks originating in locations in which the hygienic standards are low.
 - Repeat vaccination is required using VI Polysaccharide typhoid vaccine
 - There is no information regarding the immune reaction or the efficacy of the orally administered Attenuated S.Typhi vaccine after a polysaccharide paratyphoid immunization.
- A patient being immunized with Typhium VI® and who lives in or plans to visit endemic regions but has not yet been immunized
 - Patients should be warned against exposure to foods and drinks originating in locations in which the hygienic standards are low.
 - It is recommended that the patient be vaccinated with an approved anti-paratyphoid vaccine

In any case, Sanofi Pasteur recommends that the decision whether to re-immunize be taken where the advantages of the vaccination exceed the risk of non-vaccination according to the level of exposure to paratyphoid.

Asnat Tal

Pharmacist in charge

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