

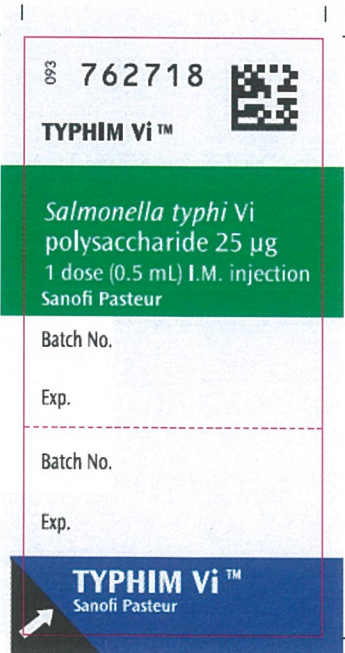
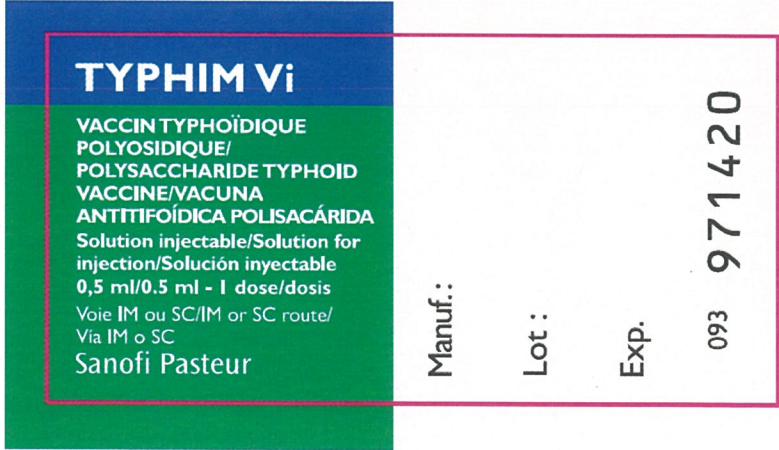
01 April 2020

Dear Healthcare Professional

Supply of Typhim Vi under labelling exemption

Sanofi is currently faced with supply shortage of Typhim Vi (*Salmonella typhi* vi polysaccharide vaccine) packaged in the Medsafe approved labelling. To address this issue, Sanofi has imported additional doses of Typhim Vi packaged using the Standard International syringe label that does not comply with New Zealand labelling requirements. It is important to note that the product, carton and package leaflet are identical to those currently supplied, including in terms of strength and volume (25 µg/mL *Salmonella typhi* vi polysaccharide in 0.5 mL). The differences only pertain to the syringe labelling and we are writing to you to ensure that you are aware of these differences.

The Standard International labelling is intended for the global market and hence is different to the labelling used in New Zealand.

New Zealand labelling Typhim Vi 0.5 mL English	Standard International labelling Typhim Vi 0.5 mL French, English and Spanish
<p>Syringe Label</p>  <p>The New Zealand syringe label features a white background with a blue header and footer. At the top, it displays the product number '093 762718' and a QR code. Below this, the product name 'TYPHIM Vi™' is printed. A prominent green box contains the text: 'Salmonella typhi Vi polysaccharide 25 µg', '1 dose (0.5 mL) I.M. injection', and 'Sanofi Pasteur'. Below the green box, there are two sets of fields for 'Batch No.' and 'Exp.'. The bottom blue section contains 'TYPHIM Vi™' and 'Sanofi Pasteur'.</p>	<p>Syringe Label</p>  <p>The Standard International syringe label has a blue and green background. The top blue section contains 'TYPHIM Vi' in white. The green section contains the following text: 'VACCIN TYPHOÏDIQUE POLYOSIDIQUE/ POLYSACCHARIDE TYPHOÏD VACCINE/VACUNA ANTTIFÓIDICA POLISACÁRIDA', 'Solution injectable/Solution for injection/Solución inyectable', '0,5 ml/0.5 ml - 1 dose/dosis', 'Voie IM ou SC/IM or SC route/ Via IM o SC', and 'Sanofi Pasteur'. To the right of the green section, there are three vertical labels: 'Manuf.:', 'Lot:', and 'Exp.', with the number '093 971420' printed vertically next to them.</p>

In particular, the syringe label states that Typhim is approved for intramuscular (IM) or subcutaneous (SC) route (as is the case in some international markets). You should note that in New Zealand, Typhim Vi is approved for IM injection only. Consequently, the Typhim batch should not be used for SC administration in accordance with information currently registered in New Zealand.

Should you have any questions relating to this product, please call Sanofi Pasteur Medical Information at 0800 283 684.

Thank you for your understanding.

Regards,

A handwritten signature in black ink, appearing to read 'CTF', with a horizontal line extending to the right from the end of the signature.

Dr. Christian T. Felter, MD
Head of Medical, Sanofi Pasteur Australia and New Zealand