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11th March 2022

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION
STAMARIL, powder and solvent for suspension for injection in pre-filled syringe – Yellow fever vaccine (Live) PL 46602/0007
Interim Supply of EU Stock in Standard Export Packaging (Standard Export Packs) to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: SANOFI is currently experiencing supply disruption with STAMARIL, powder and solvent for suspension for injection in pre-filled syringe – Yellow fever vaccine (Live) in the UK.

To ensure continuity in supply during the current Covid-19 situation, Sanofi has obtained approval from the MHRA to supply Standard Export Packs (Batch T3J781V; Expiry 08/2022; 6000 packs), which is expected to be on the UK market from March-April 2022.

Please note the following:

- This product is considered licensed in the UK.
- The Standard Export Packs have the same formulation as the UK product
- The Standard Export Packs are manufactured according to the same manufacturing process and quality controls as the UK product.
- There are differences between the Standard Export Pack and UK product information. Key differences are listed below-
    - **The Product Information Leaflet (PIL) contained in the Standard Export Pack is not the same as the current approved UK PIL and so does not have the latest product information. A copy of the approved UK PIL will be provided with each dose of vaccine supplied.**
    - **The UK pack is supplied as one pre-filled syringe with 2 separate needles, while the Standard Export Pack is supplied as one pre-filled syringe with attached needle.**

- Text in three languages (English, French and Spanish) is included on each component of the Standard Export Pack: carton, vial label, solvent label and leaflet. Please note that while the pack size remains the same, the pack design is a little different. Images of the UK approved packaging and the Standard Export Pack are provided below for comparative purposes.

- Please refer to the UK approved PIL supplied with each order of the Standard Export Packs. **Discard the PIL in the Standard Export Pack.**

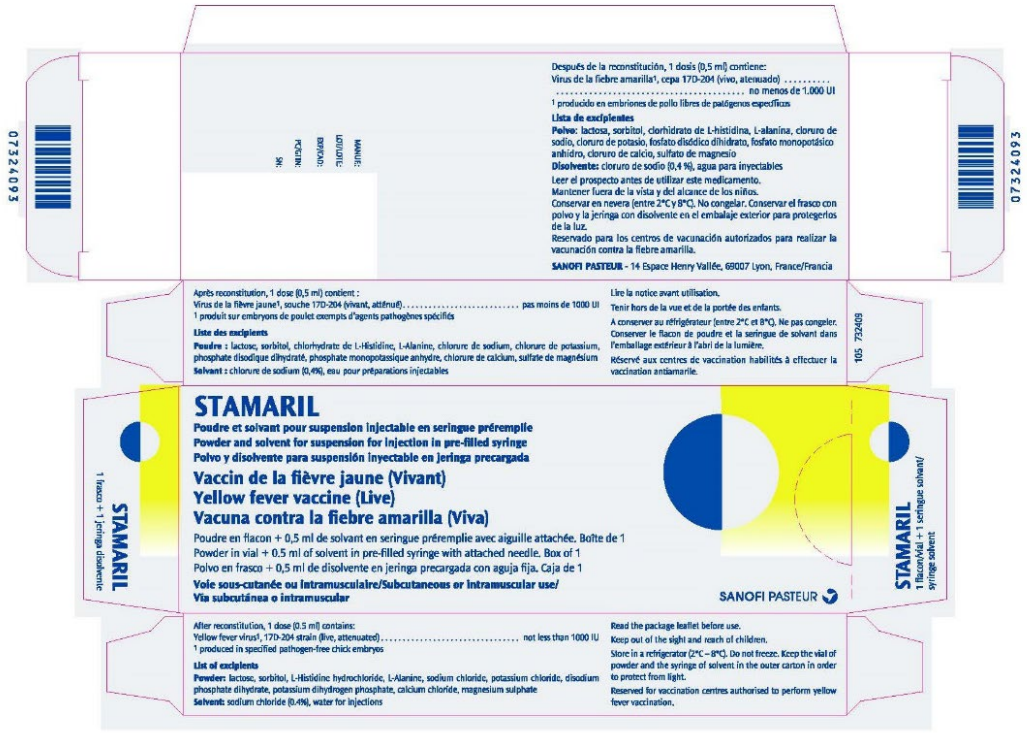
- For additional copies of the PIL, please refer to https://www.medicines.org.uk/emc/ or contact the company contact point (see below).

- The MHRA has approved this product under a batch specific variation to the marketing authorisation.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

United Kingdom Packaging

Standard Export Packaging



Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Adverse events should also be reported to Sanofi telephone number 0800 0902314.

Company contact point

If you have any questions about this letter or would like more information about STAMARIL, please contact Sanofi Medical Information Department on 0800 035 2525 or email **uk-medicalinformation@sanofi.com**.

Yours faithfully,

Susan Farrow

Dr Susan Farrow
Interim Head of Medical (Vaccines)