September 2021

**Direct Healthcare Professional Communication**

**Stamaril® (live attenuated yellow fever vaccine): reminder of the indication, contraindications, recommendations and warnings for use to ensure appropriate evaluation of risk-benefit before vaccination – Yellow Fever vaccine checklist to be completed prior to administration of each traveller.**

Dear Healthcare professional,

This letter is sent in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) to remind you of the following:

***Summary***

**Appropriate evaluation of risk-benefit for individual travellers must systematically be done before vaccination, based on the Summary of Product Characteristics (SmPC) and recommendation for travelling in endemic countries.**

**A new checklist has been introduced to ensure vaccination is indicated for intended destination and to identify contraindications or precautions; this checklist is not a replacement for the full travel health risk assessment by a qualified practitioner and additional checklists or materials (e.g. patient information leaflet) should be used prior to vaccination, depending on clinical guidance. A copy of the checklist is included with this letter.**

**Before vaccination, vaccinator(s) must ensure, in accordance with SmPC, that:**

- **Yellow fever vaccination is recommended for the intended destination(s) of your patient, based on yellow fever endemic status at the time of the travel and / or if an International Certificate of Vaccination is required. You can check the countries with risk of YF transmission and countries requiring YF vaccination on the WHO website https://www.who.int/ith/ith_country_list.pdf or on the websites of National Travel Health Network and Centre https://travelhealthpro.org.uk/countries or Public Health Scotland https://www.travax.nhs.uk/.**

- **The traveller has no contraindication for vaccination (e.g. acquired or congenital immunosuppression including thymus disorders or thymectomy in past medical history and known immunosuppressive therapies, infants younger than 6 months). Please refer to the SmPC for a full list of contraindications.**

- **Risk factors and precautions as listed in the section "Special warnings and precautions for use" of the SmPC (e.g. persons 60 years of age or older, infants aged 6 months up to 9 months, and pregnant or breastfeeding women) have been explored and thoroughly assessed.**

- **The traveller is informed of risks associated with vaccination or non-vaccination, following the full risk assessment.**



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A copy of the SmPC and the pre-vaccination checklist is available electronically on the Electronic Medicines Compendium (eMC) website: www.medicines.org.uk/emc in the UK.

Vaccinators should also inform travellers about the early signs and symptoms of serious adverse reactions to yellow fever vaccine and advise them to seek urgent medical attention if they occur. A copy of the patient information leaflet should be provided to each traveller prior to vaccination.

***Background of safety concern***

In 2018-2019, two adverse events of Yellow Fever Vaccine-Associated Viscerotropic Disease (YEL-AVD) with fatal outcome were reported after Stamaril® vaccination in United Kingdom travellers for whom the vaccine was used outside of the guidance in the approved product information. Therefore, Sanofi Pasteur is reminding vaccinators of the indication, contraindications, warnings and precautions for Stamaril, and the importance of performing an individual risk-benefit assessment before administering the vaccine.

Stamaril® is authorised in the United Kingdom for active immunisation against yellow fever disease in persons 9 months of age and older. The product information has recently been updated to detail the consideration of risk-benefit balance for individual travellers.

Yellow Fever Vaccine-Associated Viscerotropic Disease (YEL-AVD) and Yellow Fever Vaccine-Associated Neurotropic Disease (YEL-AND) are important identified risks for Stamaril®. The occurrence of YEL-AVD/YEL-AND are very rare and have occurred at a relatively stable rate over time. An age of over 60 years and immunosuppression, including a medical history of thymus disorders or thymectomy, are identified as risk factors. These are included in the current SmPC as precautions for travellers over 60 years of age and as a contraindication for immunocompromised travellers.

The balance of benefits and risks of Stamaril® remains favourable for most travellers when used in accordance with the current authorised indications in the SmPC.

***Call for reporting***

Reporting suspected adverse drug reactions (ADR) after authorisation of the product is important. It allows continued monitoring of the benefit/risk balance of the product.

You can report adverse drug reactions online via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store

You can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk



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- at the back of the British National Formulary (BNF)
- by telephoning the Yellow Card scheme free phone line: 0800 731 6789
- by downloading and printing a form from the Yellow Card website (see link above)

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number. Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card Scheme.

Suspected adverse reactions should also be reported to Sanofi Tel: 0800 0902314. Email: uk-drugsafety@sanofi.com

***Company contact point***

Should you have any questions or require additional information, please contact:
**Medical Information** at Sanofi Tel: 0800 035 2525 Email: uk-medicalinformation@sanofi.com.

Yours faithfully,

Ian Gray
Sanofi UK & Ireland Country Medical Director and Head of Medical Sanofi Pasteur