*From the Chief Medical Officer*
Dr Michael McBride

**HSS(MD)38/2019**

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Your Ref:
Our Ref: HSS(MD)38/2019
Date: 5 December 2019

For Action:
Chief Executives, Public Health Agency/Health and Social Care Board/HSC Trusts/NIAS
GP Medical Advisers, Health and Social Care Board
All General Practitioners and GP Locums (*for onward distribution to practice staff)*
RQIA (*for onward transmission to all independent providers including independent hospitals and travel clinics*)

**Please see attached full addressee list**

Dear Colleague

**NEW RECOMMENDATIONS AND EXTREME CAUTION REQUIRED IN RELATION TO YELLOW FEVER VACCINE (STAMARIL)**

**ACTION REQUIRED**

**Chief Executives must ensure that this letter and the information in Annex A is drawn to the attention of all staff involved in prescribing or administering the yellow fever vaccine.**

**The HSCB must ensure that this information is cascaded to all General Practitioners.**

**The RQIA must ensure that this information is passed to all independent providers including 'Travel clinics'.**

## Introduction

1. The purpose of this letter is to draw your attention to a series of new recommendations issued by the Commission on Human Medicines (CHM) on the yellow fever vaccine (Stamaril). This follows on from HSS(MD) 9/2019 issued on the 17 May - https://www.health-ni.gov.uk/sites/default/files/publications/health/hss-md-09-2019.pdf

2. Extreme caution is needed when using this vaccine for the following people:

   - **anyone who may be immunosuppressed, including a history of thymus dysfunction or thymectomy, and**

   - **those aged 60 years or older.**

   A reminder to healthcare professionals is attached at Annex A.

3. This follows a review of rare, but serious and fatal reactions following the vaccine. Recommendations include strengthened measures to minimise risk in those with weakened immune systems, and in particular those aged 60 years or older and anyone who has had their thymus removed.

4. Yellow fever is a life-threatening viral condition and vaccination against the disease is highly effective and is the best way to protect those at risk of disease during travel. Revaccination is generally not recommended as the duration of protection following administration of 1 dose of yellow fever vaccine is expected to be lifelong.

5. For most people, the balance between the benefits and possible side effects of the vaccine remains overwhelmingly favourable for most travellers when used as indicated. However, because the vaccine contains a live, weakened strain of the yellow fever virus, **strict adherence to contraindications and precautions is essential to reduce the risk of serious side effects in those who may have a weaker immune system.**

6. Yellow fever associated viscerotropic disease (YEL-AVD) and yellow fever vaccine associated neurotrophic disease (YEL-AND) both resemble yellow fever infection and are rare, but can be a fatal side-effect of the vaccine. These are more likely to occur in certain groups including those aged 60 years and older and those with weakened immunity. The risks are estimated to be up to 1 per 100,000 primary vaccinees, although this could be more than four times greater in those aged 60 years and older.

7. Recommendations by the CHM Yellow Fever Vaccine Expert Working Group for certain people receiving the vaccine have been developed to minimise risks. The recommendations are in addition to the full list of contraindications and precautions described in the current Summary of Product Characteristics and Patient Information Leaflet, which will be updated.

8. Recommendations from the Commission on Human Medicines (CHM) include:

   - In people aged 60 years or older, due to a higher risk of life-threatening side effects, the vaccine should be given only when there is a significant and unavoidable risk of acquiring yellow fever infection, such as travel to an area where there is a current or periodic risk of yellow fever

transmission - this would exclude travel to areas in which vaccination is 'generally not recommended' by WHO;

- Only healthcare professionals specifically trained in benefit-risk evaluation of yellow fever vaccine should administer the vaccine, following their individualised assessment of a person's travel itinerary and suitability to receive the vaccine;

- Do not administer the vaccine to people:

    - who have had their thymus gland removed for any reason;

    - who are taking biological drugs that are immunosuppressive or immunomodulating;

    - who have a first-degree family history of YEL-AVD or YEL-AND following vaccination that was not related to a known medical risk factor (i.e. in case of an unidentified genetic predisposition).

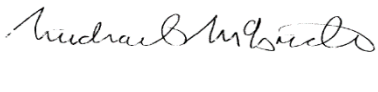
- Thoroughly inform vaccinees about the early signs and symptoms of these side-effects and to urgently seek medical attention if these side effects are suspected – this will support rapid identification and referral for treatment of YEL-AND and YEL-AVD. The manufacturer's patient information leaflet should be given to everyone receiving a yellow fever vaccine as part of the travel consultation.

9. **The above recommendations are in addition to the full list of contraindications and precautions described in the current Summary of Product Characteristics and patient information leaflet,** which will be updated in due course. Standardised pre-vaccination screening checklists are also being produced, along with a patient group direction (PGD) template. A further communication will be issued when these are ready to ensure they are implemented in clinical practice.

10. Please continue to report suspected adverse reactions to vaccines and other medicines to the MHRA Yellow Card Scheme at https://yellowcard.mhra.gov.uk/ when reporting a suspected reaction to a vaccine please provide the brand name (or product licence number and manufacturer) and the specific batch number.

11. Any medication related incident that could have or did lead to patient harm, loss or damage (for example, vaccination of a contraindicated patient) should continue to be reported through local reporting systems such as Datixweb in HSC Trusts, or submission of an AIF1 form to the HSCB in primary care settings. Independent providers should report medication related incidents to RQIA through their usual processes.

Yours sincerely



**Dr Michael McBride**
**Chief Medical Officer**

**Professor Charlotte McArdle**
**Chief Nursing Officer**

**Mrs Cathy Harrison**
**Acting Chief Pharmaceutical Officer**

This letter is available on the Department of Health website at https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications

**CIRCULATION LIST**

Director of Public Health/Executive Medical Director, Public Health Agency (*for onward distribution to all relevant health protection staff and education providers of vaccination training courses*)
Assistant Director Public Health (Health Protection), Public Health Agency
Director of Nursing, Public Health Agency
Assistant Director of Pharmacy and Medicines Management, Health and Social Care Board, *(for onward distribution to all Community Pharmacies)*
Directors of Pharmacy HSC Trusts
Director of Social Care and Children, HSCB
Family Practitioner Service Leads, Health and Social Care Board *(for cascade to GP Out of Hours services)*
Medical Directors, HSC Trusts *(for onward distribution to all Consultant Obstetricians, Paediatricians and other relevant staff)*
Directors of Nursing, HSC Trusts *(for onward distribution to all Community Nurses, and Midwives)*
Directors of Children's Services, HSC Trusts
Regional Medicines Information Service, Belfast HSC Trust
Regional Pharmaceutical Procurement Service, Northern HSC Trust
University Health Contacts

**ANNEX A**

## REMINDER FOR HEALTHCARE PROFESSIONALS

- As with any live attenuated vaccine, yellow fever vaccine must not be given to people who may be immunosuppressed.

- Yellow fever vaccine is contraindicated in people with a history of thymus dysfunction (including myasthenia gravis and thymoma)

- Yellow fever vaccine is contraindicated in people who have had their thymus gland removed (thymectomy)

- In people aged 60 years and older, the vaccine should only be given when it is considered that there is a significant and unavoidable risk of acquiring yellow fever infection.

- Professionals who administer yellow fever vaccine must be familiar with any contraindications and special precautions before proceeding with immunisation.

- If there is any doubt as to whether a person who is due to receive yellow fever vaccine may be immunosuppressed, immunisation should be deferred until specialist advice has been sought.

- Protocols and checklists should be strengthened to avoid inappropriate administration that can lead to severe and possibly fatal adverse effects; those administering the vaccine should also be familiar with the YF Vaccine Centre code of practice.

- Any suspected adverse reactions during immunisations should be reported on a Yellow Card