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Dr Michael McBride

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HSS(MD) 9/2019

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*)

Your Ref:
Our Ref: HSS (MD) 9/2019
Date: 17 May 2019

Please see attached full addressee list

Dear Colleague

YELLOW FEVER VACCINE (STAMARIL) EXTREME CAUTION REQUIRED

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 an alert issued by the Medicines and Healthcare products Regulatory Agency (MHRA) in relation to the yellow fever vaccine (Stamaril).

2. **Extreme caution is needed when using this vaccine in people 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. In recent months, MHRA have been notified of 2 fatal adverse reactions to yellow fever vaccine. In one case, the vaccine was given to a person with a history of thymectomy following a thymoma (a contraindication in the product information). In another case, the vaccine was given to a 67-year-old with no other known risk factors. Both patients died shortly after vaccination due to suspected yellow fever vaccine-associated viscerotropic disease (YEL-AVD).

4. YEL-AVD is a recognised adverse reaction that resembles severe yellow fever infection. The global reporting rate is around 1 case in every 1 million people vaccinated, with thymus disease, immunosuppression, and an age of 60 years and older increasing the risk.[1] Another serious risk of vaccination is vaccine-associated neurotropic disease (YEL-AND), which can occur at a similar rate and with the same risk factors. YEL-AND can present with a variety of neurological manifestations.

Contraindications and warnings for the yellow fever vaccine

5. For full prescribing information and warnings, precautions, and risks, please refer to the Summary of Product Characteristics.

6. Yellow fever vaccine is contraindicated in any person who is immunosuppressed due to immunosuppressive therapy or congenital or idiopathic disease. This includes a history of thymus dysfunction (including myasthenia gravis and thymoma). A history of thymectomy is also a contraindication.

7. Due to a higher risk of severe and potentially fatal adverse reactions, yellow fever vaccine should only be given to people aged 60 years and older when it is considered that there is a significant and unavoidable risk of acquiring yellow fever infection.

8. Any healthcare professional prescribing or administering the vaccine must ensure they are fully familiar with the up-to-date Summary of Product Characteristics. More information and guidance on yellow fever vaccine can also be found in the Green Book and the National Travel Health Network and Centre (NaTHNaC) website.

9. The MHRA are in the process of reviewing the benefit-risk balance of yellow fever vaccine and measures to minimise risks in the light of these cases and the latest scientific data. The Commission on Human Medicines has convened an Expert Working Group, which will make recommendations. MHRA will update guidance, as necessary.

10. When a person presents for yellow fever immunisation, it is important that healthcare professionals clearly discuss with them the individual risks and benefits of the vaccine based on their specific travel itinerary. Sufficient time should be set aside to ensure that the person is immune competent and has no contraindications to the vaccine, including a review of full medical history and any available medical records. Any potential history of thymus disease

or thymus removal should be specifically queried. Any decision to administer the vaccine to a person aged 60 years and older must be based on a significant and unavoidable risk of acquiring yellow fever infection.

11. Provision of the Patient Information Leaflet would provide a helpful basis for this discussion with potential vaccinees. Risk assessment checklists should also be used to ensure checks have been completed and patients have been assessed for immunocompetence (in line with local and organisational requirements).

12. NaTHNaC recommends that health professionals use a travel risk assessment form to guide the travel health consultation and, where appropriate, seek specialist advice when a significant medical history is identified. More information on yellow fever, and the YF Vaccine Centre code of practice can be found on the NaTHNaC website.

Report suspected adverse reactions to vaccines or medicines

13. 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.

14. 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**	**Mrs Cathy Harrison** **Acting Chief Pharmaceutical Officer**	**Mrs Charlotte McArdle** **Chief Nursing officer**

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

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

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.