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cc Dr Colette Bonner DCMO
Dr Siobhán O’Sullivan Chief Bioethicist
Ms Pauline Brady CMO Office

Re: Recommendations for the use of smallpox (vaccinia) vaccine as pre and post exposure prophylaxis against monkeypox

Dear Professor Smyth,

Thank you for your letter of 12 July 2022 requesting NIAC to review the recent epidemiology in Ireland in relation to the ongoing monkeypox outbreak and to assess whether any change is required to the existing recommendations relating to the use of monkeypox vaccine that already include pre- and post-exposure prophylactic vaccination.

Between 3 April and 19 July 2022, [9,281 cases had been reported](#) from 31 countries and areas to the European Centre for Disease Control (ECDC) and the World Health Organization (WHO) Regional Office for Europe, were laboratory confirmed. Almost all were male (9,149/9,197 - 99.5%) and 42% were aged between 31-40 years. Among cases with known HIV status, 38% (923/2,403) were HIV-positive. Less than 10% were hospitalised and one case was admitted to ICU. No cases were reported to have died. Some (31) cases were reported to be health workers, however no occupational exposure has been reported.

In Ireland, [69 cases have been reported](#) and laboratory confirmed. All are male with a median age of 36 years (range 19-65 years). Sexual orientation is known for 58, all of whom self-identified as gay, bisexual or other men who have sex with men (gbMSM). Nine cases (13%) have been hospitalised; two for clinical care related to monkeypox infection, three for isolation purposes only and information on the reason for admission for the other four is awaited. The epidemiological picture to date in Ireland is similar to that seen in other countries, where cases are primarily in gbMSM.

Smallpox vaccination is effective against monkeypox. Smallpox Modified Vaccinia Ankara – Bavarian Nordic (MVA-BN) is currently distributed in the EU under two brand names:

- Imvanex – approved by the European Medicines Agency (EMA) for the prevention of smallpox. Although this vaccine is not licensed for the prevention of monkeypox in Europe, it has been used in the UK in response to the current and previous incidents

- Jynneos – approved by the Food and Drug Administration (FDA) in the US for the prevention of smallpox and monkeypox

The EMA Emergency Task Force together with the CHMP Biologics Working Party and the European Directorate for the Quality of Medicines & HealthCare (EDQM) have evaluated the specificities of the FDA-approved Jynneos, in case it is used as a replacement of Imvanex. The [EMA has stated that](#) Imvanex and its FDA authorised equivalent, Jynneos, are considered the most suitable vaccines against monkeypox.

The recent ECDC risk assessment states that targeted pre-exposure prophylaxis (PrEP) vaccination of smaller groups of individuals may have a high efficiency in outbreak control and the prioritisation of individuals at substantially higher risk of exposure can be considered.


NIAC has reviewed the current evidence and, in addition to [recommendations issued on 27 May 2022](#), now recommends the following:

1. Pre-exposure prophylactic (PrEP) vaccination should be offered to those at high risk of infection e.g., gay, bisexual, men who have sex with men (gbMSM) and others at high risk of unprotected exposure. They could be identified from attendance at sexual health clinics with a recent history of multiple partners, attending commercial venues expressly for engaging in public sex (sex on premises venues) or using a proxy marker such as bacterial sexually transmitted infection in the past year. These are risk factors similar to those used to assess eligibility for HIV PrEP and should be applied regardless of HIV status.
2. Two doses of smallpox vaccine should be administered **subcutaneously** 28 days apart to as many high risk individuals as soon as practicable.

NIAC strongly supports all measures that increase equitable access to vaccines.

NIAC will closely monitor the epidemiology of infection in Ireland and vaccination recommendations may be updated to include other groups in the future.

Yours sincerely,



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Karina Butler
Chair NIAC