USE OF MVA-BN VACCINE IN RESPONSE TO MPOX (MONKEYPOX)

Supporting Information
for healthcare workers

This document has been created and updated
by the HSE National Immunisation Office
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Contents

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Version Updates

Date of revision	**13/9/2022**
Additional information	Update: “Vaccine Preparation and Administration.”
	24/6/2022
Timing of vaccination calculated from **last** exposure	Update: “ Recommended Groups for Vaccination”
	29/7/2022
NIAC updated recommendation	Update: Background New: MVA-BN Vaccines Update: “Recommended Groups for Vaccination” Update: “Contraindications and precautions” Update: “Post Vaccination Advice” New Appendix 2 and 3
	25/8/2022
NIAC updated recommendation:	Route of administration
	31/03/2023
NIAC updated recommendation:	Site of vaccination
	08/09/2023
Additional Information	The HSE MPOX Clinical Advisory Group (CAG) update Advice on Boosters

Background

Human monkeypox was given its name in 1970 (after the virus that causes the disease was discovered in captive monkeys in 1958). On 28 November 2022 the WHO recommended using a new preferred term “mpox” as a synonym for monkeypox. Both names may be used simultaneously for one year while “monkeypox” is phased out.

MPOX (Monkeypox) is a zoonotic disease caused by the MPOX (Monkeypox) virus of which there are two different clades: Clade I (formerly the Central African or Congo Basin clade), and Clade II (formerly the West African clade) with sub-clades IIa and IIb. MPOX (Monkeypox) virus can spread between people in a number of ways including: though large respiratory droplets which can be transferred during face-to-face or close physical contact, direct contact with infectious lesions, touching clothing, bedding or towels used by someone with the MPOX (Monkeypox) rash or scabs. Vertical transmission can also occur from mother to foetus. Incubation period can range between 5-21 days.

Since May 2022 there has been a rise in MPOX (Monkeypox) cases in a number of countries worldwide without an established epidemiological travel link to area where MPOX (Monkeypox) is endemic. The current outbreak is primarily (but not exclusively) linked with men who have sex with men including gay and bisexual men. Cases in the 2022/2023 global outbreak have mostly been Clade IIb [1].

At the start of this current outbreak in 2022 there was no MPOX (Monkeypox) vaccine licensed for use in Europe. However, previous smallpox vaccination has shown to offer cross-productivity against MPOX (Monkeypox) as the MPOX (Monkeypox) virus is closely related to the virus that causes smallpox. Smallpox vaccination offers protection that is expected to last over 20 years based on current data. Smallpox vaccination in Ireland stopped in 1972. Therefore, there is likely to be little immunity within the community in Ireland in amongst younger cohorts.

The World Health Organisation also released interim guidance on vaccination for MPOX (Monkeypox) [2]. Regionally the European Centre for Disease Control has updated its risk assessment on MPOX (Monkeypox) supporting the use of the smallpox vaccine in pre and post exposure contexts [3]. Lastly, the National Immunisation Advisory Committee has recently published guidance on this topic too for Ireland [4].

MVA-BN Vaccine

Imvanex (Modified Vaccinia Ankara- manufactured by Bavarian Nordic) was originally intended as a smallpox vaccine and was licensed by the European Medicines Agency (EMA)

since 2013. The efficacy of the vaccine against smallpox has not been established. However, the vaccine has been found to be effective at producing antibodies against smallpox therefore this was authorised under exceptional circumstances- which means it was not possible to obtain complete information on the vaccine due to the rarity of smallpox and any new information is reviewed as obtained [2].

On 22nd July 2022 the European Medicines Agency announced that it recommended an extension to use of the Imvanex vaccine for the prevention of MPOX (Monkeypox) disease and disease caused by vaccinia virus [5]. Their decision was based on data from animal studies where protection was found against MPOX (Monkeypox) disease and the similarities between the MPOX (Monkeypox) and smallpox viruses.

Imvanex contains a live attenuated vaccinia virus (Modified Vaccina Ankara Bavarian Nordic Live virus; MVA-BN) which is related to the smallpox virus. It is a third generation non-replicating smallpox vaccine. The MVA-BN is unable to replicate in human cells therefore unable to cause disease in humans, may cause fewer side effects than conventional smallpox vaccines and be maybe used in a population such as the immunocompromised. Due to its similarity to smallpox the antibodies produced in response to this vaccine also offers protection against MPOX (Monkeypox) [6].

Imvanex is currently licensed in the United States (trade name Jynneos) and Canada (trade name Imvamune) for use to prevent smallpox and also MPOX (Monkeypox) in adults [7]. Due to limited stocks of Imvanex, the EMA's Emergency Task Force has recommended the Jynneos vaccine can be used in the European Union in response to MPOX (Monkeypox) disease. Furthermore the EMA has also recommended the EU storage conditions for Imvanex can be applied to Jynneos.

In Ireland, the MVA-BN vaccine (Imvanex or Jynneos) is being used in response to MPOX (Monkeypox).

Many countries are using these vaccines in response to MPOX (Monkeypox) in the context of pre and post exposure prophylaxis.

On 19th August the EMA's Emergency Task Force reviewed the evidence for the administration of MVA-BN via the intradermal route. It concluded that national authorities may decide as a temporary measure to use Imvanex as an intradermal injection at a lower dose to protect at-risk individuals during the current MPOX (Monkeypox) outbreak while supply of the vaccine remains limited. [8]

NIAC have recommended that those aged 18 years and over may receive the vaccine via the intradermal route. [9]

Factors for consideration before vaccination (as part of informed consent).

The vaccine is licensed for use in adults aged 18 years and over [10].

Data to support the use of the MVA-BN vaccine in response to MPOX (Monkeypox) includes:

- Previous observational data suggests the smallpox vaccine is 85% effective against MPOX (Monkeypox).
- MVA-BN vaccine is effective at producing antibodies against smallpox – therefore cross protection is expected against MPOX (Monkeypox) virus too.
- In primates studies protection was conferred against severe disease after vaccination with MVA-BN vaccine when exposed to a lethal dose of the MPOX (Monkeypox).
- MVA-BN vaccine is recommended by the European Medicines Agency (EMA) for use against MPOX (Monkeypox).

The following risks of vaccination and risks of MPOX (Monkeypox) should be considered prior to vaccination including (but not limited to):

- MPOX (Monkeypox) can cause serious illness. However, in most people the illness is usually mild and self-limiting (recovery in 2-4 weeks). MPOX (Monkeypox) may cause severe illness in pregnant women, children, older adults and immunocompromised individuals.
- Case fatality rates can vary depending on the MPOX (Monkeypox) clade and ranges from 1-10%. However it should be noted that majority of this data is from settings where access to healthcare services may be limited.
- The individuals risk of contracting the disease - classified as high, intermediate or low risk contact as per HPSC guidance [11].
- Data so far from the MVA-BN vaccine has shown that most adverse reactions are mild to moderate and self-limiting. Serious reactions can occur but these are rare.
- The data regarding effectiveness of this vaccine against MPOX (Monkeypox) is not available and safety data regarding the use of this vaccine in immunocompromised persons is limited.

- For post-exposure prophylaxis if given within 4 days of exposure the vaccine may prevent disease but if given between day 5-14 after date of exposure may reduce symptoms but may not prevent disease.

Recommended groups for vaccination

The National Immunisation Advisory Committee (NIAC) has made recommendations for vaccination with MVA-BN vaccine in response to MPOX (Monkeypox) in two contexts: Pre-Exposure Prophylaxis (PrEP) and Post Exposure Prophylaxis (PEP) [4]

Each dose of MVA-BN vaccine is 0.5ml given subcutaneously in the deltoid region.

Alternatively, if vaccine supplies are limited, those aged 18 years and over may receive each dose of MVA-BN as 0.1ml given intradermally in the volar aspect of the forearm. If the volar (palmar) side of the forearm is not an option (e.g., scarring or patient preference), the vaccine may be administered ID into the deltoid area.

If a second dose is required a dose interval of less than 4 weeks should be avoided.

NIAC advise the SC route is preferred as the technique is familiar and adverse reactions are significantly less.

It takes two weeks after the vaccination course is completed to be fully immunised. The vaccination course required for individuals eligible for vaccination is outlined in Table 1.

Table 1: Vaccination course for pre and post exposure prophylaxis with MVA-BN vaccine in response to MPOX (Monkeypox).

Group	No previous smallpox vaccination	Previous Smallpox vaccination
PrEP	Two doses 28 days apart.	One dose *
PEP: High and intermediate risk contacts (as defined by HPSC guidance on management of contacts [11])	One dose. If there is a likelihood of on-going exposure give second doses 28 days after the first dose.	One dose *

* For immunocompromised individuals who have previously received smallpox vaccination will require two doses.

If vaccine availability if restricted. The following prioritisation should be considered:

1. High risk contacts within 4 days of last exposure
2. Intermediate risk contacts within 4 days of last exposure
3. High and intermediate risk contacts between 5 and 14 days of last exposure
4. Pre-exposure prophylaxis following individual risk assessment

Prior to vaccination in the context of PEP please review the latest HPSC guidance on management of contacts [11].The current guidance documents enabled you to identify and classify contacts into: zero, low, intermediate or high risk, depending on nature, proximity of contact and if they are a healthcare worker. Their management (including recommendation for vaccination) varies on this risk categorisation.

Extension of PrEP for health workers such as designated healthcare and laboratory staff (including domestic staff etc.) who will be involved in the management of MPOX (Monkeypox) cases or their samples is currently not being offered. This is based on the current epidemiological data, low vaccine supplies, availability of PEP for exposed HCWs, and the overall risk for HCWs with appropriate procedures and PPE is considered low (see table below).

Table2: ECDC risk categorisation for various cohorts. Taken from [3].

	Persons with multiple sexual partners, including some MSM	Broader population	Health professionals			
			HCWs		Laboratory personnel	
			Proper PPE	Unprotected exposure	Proper procedure and PPE	Unprotected exposure
Probability	High	Very low	Very low	High	Very low	High
Impact	Low	Low	Low	Low	Low	Moderate
Overall risk	**Moderate**	**Low**	**Low**	**Moderate**	**Low**	**High**

The risk may be higher for certain people in some of the above categories, particularly very young children, pregnant women, elderly, or immunocompromised persons.

On 22nd July NIAC made further recommendations to the Department of Health in view of the current epidemiology that “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.”

The HSE MPOX Clinical Advisory Group (CAG) updated its recommendation on the eligible populations advised to consider MPOX PrEP vaccination.

MPOX Primary Prevention Vaccination CAG Recommendations April 2023

These recommendations relate to individuals who have not completed full MPOX vaccination course, or had infection, within the last two years and who fall in to the below risk group for infection.

Men who have sex with men or transgender women who have sex with men who are: sexually active with likelihood of remaining sexually active in the next 3 months

AND one of the following:

reported condomless anal sex with at least two partners over the last 6 months

likely to engage in condomless anal sex in the next 3 months

episode of documented or reported acute STI over the last 12 months

documented or reported use of HIV post-exposure prophylaxis following sexual exposure (PEPSE) over the last 12 months

reported engagement in chemsex over the last 6 months.

Advice on Boosters

In April 2023, the Department of Health have communicated that NIAC have advised that a recommendation for a booster dose of mpox vaccine may need to be considered at 2 years following primary immunisation for those at ongoing risk of exposure following a risk assessment. This would be a clinical decision for the prescribing doctor.

This recommendation was also considered by the CAG who provided further advise for the HSE on this matter: "The group advised that a decision on providing Mpox boosters will be contingent on the evolving epidemiology of the infectious disease, and the level of protection offered by the Jynneos/Imvanex vaccine and natural infection. The earlier need for booster vaccines should be kept under review.

Contraindications and precautions

MVA-BN vaccine should not be given to individuals who have had:

- anaphylaxis to any of the vaccine constituents (these include chicken protein, benzonase, gentamicin, ciprofloxacin and Trometamol).

Precautions:

- If the patient has an acute febrile illness defer vaccination until recovery unless the risks of deferral outweigh the low risks of vaccination.
- Anyone with a history of keloid scar formation should not be given the vaccine by the intradermal route but may receive the vaccine subcutaneously.
- No interval is required between a COVID-19 vaccine and a subsequent MVA-BN vaccine. However there should be an interval of four weeks between the MVA-BN vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis.

In certain risk cohorts there is limited data and additional information should be considered prior to vaccination as summarised in table 3. It should be noted MPOX (Monkeypox) may cause severe illness in pregnant women, children, older adults and immunocompromised individuals.

Table3: Factors when considering vaccination in certain population groups [4] [12]

Population Group	**Available information**	**NIAC recommendation** [12]
Immunocompromised	Data on the use of this vaccine is available on patients with HIV (CD4 count 100-750 cells/µl)- there appears to be a lower immune response than usual. The response in other immunocompromised conditions is not available.	Can be used in individuals with certain immune deficiencies or conditions, such as HIV or atopic dermatitis but note that the immune response may be lower.
Pregnancy	Limited data available in less than 300 pregnant women who have previously receive this vaccine.	Vaccination can be considered for those at increased risk following an individual benefit-risk assessment.

	Data from animal studies does not support a negative impact on reproductive toxicity. As it's a non-replicating vaccine there is no theoretical issues regarding its use in pregnancy Profile of adverse reactions expected to be similar to general population.	
Breastfeeding	This is a non-replicating vaccine. Unknown if the vaccine is excreted in breast milk. Use of vaccine in breastfeeding is not contraindicated.	Vaccination can be considered for those at increased risk following an individual benefit-risk assessment.
Children	The vaccine is not authorised in children under the age of 18. The safety and efficacy of this vaccine has not be established in children. Similar vaccine platform has been used in clinical trials for other vaccines involving children (including those as young as 5months old). Therefore the side effect profile is expected to be similar to adults.	Vaccination can be considered in children at increased risk following an individual benefit-risk assessment

The intradermal route may be used in those aged 18 years and over, including those who are immunocompromised and those living with HIV.

Only the subcutaneous route should be used in those under the age of 18 years.

Those who turn 18 years between their first and second dose may receive the second dose intra dermally.

Vaccine Constituents

- Modified Vaccinia Ankara – Bavarian Nordic Live virus
- Trometamol
- Sodium chloride
- Water for injections
- This vaccine contains trace residues of chicken protein, benzonase, gentamicin and ciprofloxacin

Vaccine storage

- The vaccine is delivered from the manufacturer to the National Cold Chain Service (NCCS) frozen and is stored in a frozen state in NCCS. The expiry of the vaccine is dependent on temperature at which it is maintained. The Expiry date is only applicable to the vials if they remain frozen at -80°C.
- The vaccine is delivered in its thawed state at temperatures between +2°C and +8°C.
- The USE BEFORE date will be printed on the label that has been affixed to the box by the NCCS.
- The USE BEFORE Date reflects an 8 week shelf-life after thaw (i.e. removal from the freezer in NCCS) when vaccine is stored at 2°C - 8°C **in the dark** determines the timelines within which the vaccine should be administered. Vaccine should not be administered after the USE BEFORE date, irrespective of the expiry date.
- Store in the original package to maintain the vial in the dark.
- The vaccine comes in glass vials that contains 0.5 ml. It will be delivered in their original boxes of 20 vials or in smaller amounts depending on requirements.
- Do not re-freeze a vial once it has been thawed

Vaccine Preparation and Administration Subcutaneously

Prior to administration the patient should be provided with the manufacturers Patient Information Leaflet and the HSE information leaflet. After counselling for the risk, benefits and potential side effects of receiving the vaccine, a consent form should be signed by the

patient and a prescription written by a doctor for the supply and administration of the vaccine. Leaflets and consent forms can be found at https://www.hpsc.ie/a-z/zoonotic/monkeypox/mpoxvaccinationinformation/

Step 1: The vaccine should be allowed to reach room temperature before use.

Step 2: Swirl the vial gently before use for at least 30 seconds.

Step 3: Inspect the vial. The SmPC states: "The suspension should be visually inspected for particulate matter and discoloration before use. In the event of any damage to the vial, foreign particulate matter and/or variation of physical aspect being observed, discard the vaccine". If this situation arises please see appendix 1 for actions. [10]

Step 4: Withdraw 0.5ml (one dose) from the vial (using a 1ml graduated syringe and 38mm long, 21 gauge needle).

Step 5. Replace the needle on the syringe with one suitable for subcutaneous administration (16mm long, 23- to 25-gauge needle). The vaccine should be administered subcutaneously into the deltoid region

Note: Any leftover vaccine in the vial and clinical waste should be discarded appropriately. The vaccine is not to be co-administered or mixed with other vaccines.

Administration (adapted from chapter 2 NIAC immunisation guidelines)

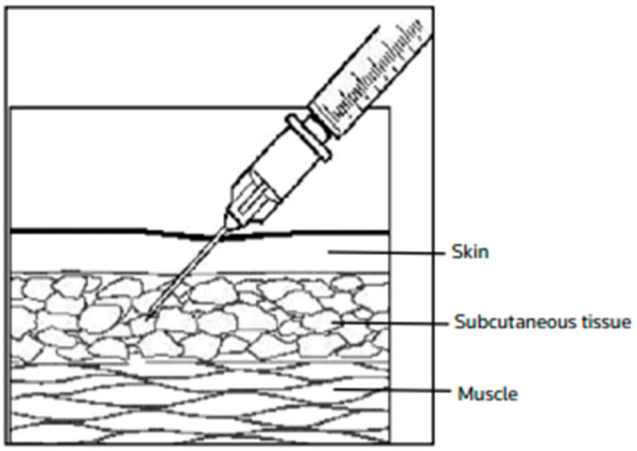
All vaccinators must be appropriately trained to administer vaccines via the subcutaneous route and should be up to date with basic life support and anaphylaxis training, with an anaphylaxis kit available in the event of anaphylaxis.

The vaccine is administered subcutaneously in the deltoid region. A 16mm, 23 to 25-gauge needle is used.

Technique:

- Insert needle at 45^{o} angle to the skin (figure 1)
- Gently pinch up subcutaneous tissue to prevent injecting into muscle.
- Aspiration prior to injection is not required.

Figure 1: Subcutaneous injection-correct angle and depth of insertion (taken from [13])



Vaccine Preparation and Administration via the Intradermal route

Prior to administration the patient should be provided with the manufacturers Patient Information Leaflet and the HSE information leaflet. After counselling for the risk, benefits and potential side effects of receiving the vaccine, a consent form should be signed by the patient and a prescription written by a doctor for the supply and administration of the vaccine. Leaflets and consent forms can be found at https://www.hpsc.ie/a-z/zoonotic/monkeypox/mpoxvaccinationinformation/

All vaccinators must be appropriately trained to administer vaccines via the intradermal route and should be up to date with basic life support and anaphylaxis training, with an anaphylaxis kit available in the event of anaphylaxis.

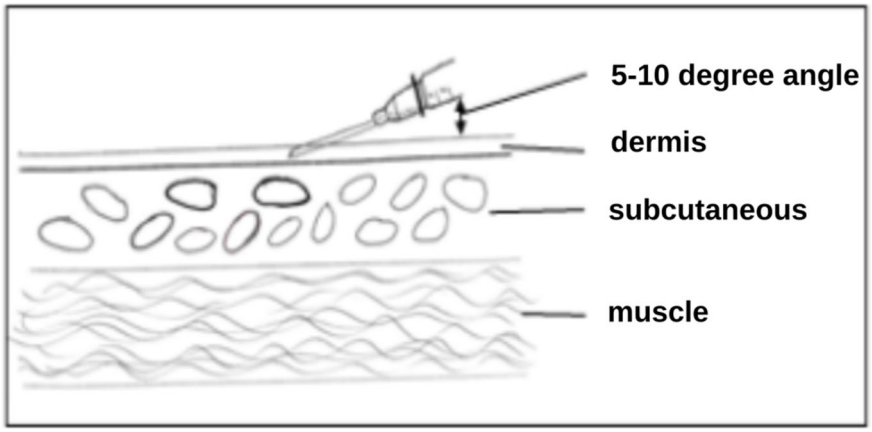
When possible, low dead volume syringes and/or needles should be used to extract up to five doses (0.1 mL each) from a single vial. If standard syringes and needles are used, there may not be sufficient volume to obtain five doses from a single vial.

- The vaccine should be allowed to reach room temperature before use.
- Hold the vaccine vial upright and swirl gently for at least 30 seconds before each use.
- The suspension should be visually inspected for particulate matter and discoloration before each use. In the event of any damage to the vial, foreign particulate matter and/or variation of physical aspect being observed, discard the vaccine.
- Clean the vaccine vial stopper with a single-use antiseptic swab before each use.
- Using a 1ml syringe and a 25-27G, 10-16mm needle carefully withdraw 0.1 ml of vaccine.
- Do **NOT** combine residual vaccine from multiple vials.

Extreme care must be taken during repeated puncture of the bung to withdraw doses as the stability of the bung is unknown. If the bung becomes damaged, discard the vial.

- Administer the vaccine by ID injection into the volar aspect (inner side) of the forearm.
- Using the finger and thumb of the non dominant hand, stretch the skin at the mid point of the volar (palmar) side of the forearm.
- Insert the needle into the dermis with the bevel facing upwards, at an angle of 5-10 degrees, to a distance of 2-3 mm. The bevel should be covered by skin and visible through the epidermis.
- Slowly inject 0.1ml. When given correctly, an ID injection should raise a blanched bleb or wheal.

Figure 2: Intradermal injection-correct angle and depth of insertion (taken from [13])



If no resistance is felt when the needle is inserted, the needle may be in SC tissue.

In this case, withdraw the needle and repeat the injection at a new site.

- Once the vial is punctured and all the contents are not used, the vial should be stored at +2°C to +8°C and used as soon as possible and within eight hours of the first puncture.
- A person who presents for their second ID vaccine dose who is still experiencing erythema or induration at the site of first dose intradermal vaccine administration may have the second dose administered intradermally in the contralateral forearm.

It may be helpful to view the CDC video 'How to administer a JYNNEOS vaccine intradermally'. https://www.cdc.gov/poxvirus/mpox/video/administer-jynneos-vaccine-intradermally/intradermal-JYNNEOS.html

Infection Prevention and Control for the administration of the MVA-BN vaccine in the context of MPOX (Monkeypox)

Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the “WHO five moments of hand hygiene” with emphasis on:

- Before vaccine preparation
- Before drawing up and administering the vaccine
- Before and after each recipient contact

PPE should be worn as per HPSC guidance for healthcare staff doing any care for potential contacts- this will require a risk assessment for PPE and precautions. Also a risk assessment is required to identify cleaning and decontamination of surfaces and environment following vaccination (if the vaccine is given outside the home). Check HPSC website for latest guidance on infection prevention and control for healthcare workers. [14]

Adverse events

Like all medicines, this vaccine may cause side effects. Most of these are mild to moderate, short-term, and not everyone gets them [10]. The patient should be informed of the possible side effects prior to vaccination.

More than 1 in 10 people will have these very common side effects: headache, muscle aches, nausea, tiredness, side effects where the vaccine was administered (pain, redness, swelling, hardness or itching).

Up to 1 in 10 people will have these common side effects: fever and chills, joint pain, pain in hand and feet, loss of appetite, side effects where the vaccine was administered (lump, discolouration, bruising or warmth)

Up to 1 in 100 people will have these uncommon side effects: nose and throat infection, upper respiratory tract infection, swollen lymph nodes, abnormal sleep, dizziness, abnormal skin sensations, muscle stiffness, sore throat, runny nose, cough, diarrhoea, vomiting, rash, itch, skin inflammation, bleeding, irritation, underarm swelling, feeling unwell, flushing, chest pain, pain in the armpit, increase of cardiac laboratory values (like Troponin I), liver enzyme increased, white blood cell count decreased, mean platelet volume decreased.

Up to 1 in 1,000 people will have these rare side effects: sinus infection, influenza, conjunctivitis, hives, skin discolouration, sweating, skin bruising, night sweats, lump in skin, back pain, neck pain, muscle cramps, muscle pain, muscle weakness, swelling of the ankles, feet or fingers, faster heartbeat, ear and throat ache, abdominal pain, dry mouth, vertigo, migraine, nerve disorder causing weakness, tingling or numbness, drowsiness, scaling, inflammation, abnormal skin sensation, reaction at the injection site, rash, numbness, dryness, movement impairment, vesicles at the injection site, weakness, influenza like illness, swelling of the face, mouth and throat, white blood cell count increased, bruising.

Note:

Atopic dermatitis: more adverse reactions may occur post vaccination and 7 in 100 people with the condition who receive the vaccine may experience a flare-up of their condition.

Frequency of side effects similar after dose 1 or dose 2

Adverse Events after Intradermal administration

A safety study was carried out in the US with Jynneos vaccine, randomising participants to receive two doses of vaccine four weeks apart either subcutaneously or intradermally.

The frequencies of systemic and local adverse reactions reported in this study in greater than 10% of subjects within 15 days of vaccination are shown in the table. Erythema at the injection site was reported by 81.4% and 99.5% of participants in the SC and ID groups, respectively. In the SC group this was reported as resolved within 14 days following the second vaccine dose in all individuals, whereas in the ID arm 44% still had erythema at the end of this period. At six months, more than a third of subjects in the ID group continued to have minimal induration or erythema at the injection site. Additionally, a few patients who received the vaccine intradermally developed small nodules or discoloration at the injection site.

Reactogenicity event	SC (%) N=166	ID (%) N=190
Feeling Tired	49.7	51.3
Muscle Aches	41.3	30.4
Headache	43.1	41.4
Nausea	21.6	23.0
Change in Appetite	15.0	20.4
Chills	12.6	14.7
Joint Pain	9.0	17.8
Pain at injection site	91.0	65.4
Erythema at injection site	81.4	99.5
Induration at injection site	69.5	99.5
Itchiness	48.5	89.0
Underarm pain	18.0	20.9
Underarm swelling	6.0	10.5

Data were not available for one individual in each of the two groups

Post Vaccination Advice

NIAC advises that “Vaccine providers should consider observing patients (seated or supine) for 15 minutes following administration of any vaccine to decrease the risk for injury should syncope occur.” [13]

Vaccine recipients should be informed that they may experience prodromal symptoms of MPOX (Monkeypox) in the two days (48hours) after vaccination.

The administration of the vaccine including patient details, batch number and use before date and route of administration should be recorded on the Mpox Vaccination System (managed by SwiftQueue).

Any paper consent forms should be kept locally in line with policies on storage of immunisation records. Any immediate adverse events should also be recorded on the patient immunisation records.

The Post Vaccination leaflet should be completed and given to the patient.

Vaccine recipients should be informed it is recommended by NIAC there should be an interval of four weeks between the MVA-BN vaccines and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis.

The company that markets the vaccine will provide data on the vaccine’s benefits and risks for patients who are given the vaccine.

The Health Products Regulatory Authority (HPRA) is responsible for managing the national pharmacovigilance system. The HPRA reports nationally occurring adverse reactions to the EMA.

Healthcare professionals and members of the public are encouraged to report any suspected adverse reactions (including known side effects) to the HPRA following the

instructions available on the HPRA website www.hpra.ie. As much information as is known should be provided, and where possible, the vaccine batch number should be included.

Appendix 1: Steps to be undertaken when a vaccinator is concerned regarding quality defects or particulates in a vial.

When a vaccinator is concerned regarding quality defects or particulates in a vial the following steps should be followed:

- The vaccinator should contact another healthcare professional (HCP) and ask for a second opinion
- The affected vial should be returned to the fridge and kept there in Quarantine (between +2˚C and +8˚C)
- The vial in quarantine should be placed in a clearly marked area in the fridge "Quarantine - do not use"
- The vaccinator and senior experienced HCP should check the other vials in this batch in their fridge by removing one vial at a time and ensuring that the duration out of the fridge is kept to a minimum (less than 2 minutes) and the vial is kept in the dark except when being inspected.
- If more vials are considered defective, they should calculate the impact of placing vials into quarantine and arrange for additional deliveries if required.
- The HPRA, and National Immunisation Office (NIO) should be emailed with details of the issue and with a photograph of vial identifying the defect (if possible).
- The NIO will follow up and contact other locations where this batch has been delivered if necessary.

Please ensure vaccines are stored between +2°C and +8°C and in the dark.

Should vaccines be exposed to temperatures outside of these parameters please contact the NIO immediately.

Contacts for National Immunisation Office Pharmacists include:

Cliona Kiersey: mobile 087 9915452

Achal Gupta: mobile 087 4064810

Email the pharmacists inbox: pharmacynio@hse.ie

Appendix 2: Resources to support vaccination

The National immunisation office has produced the following documents (and approved by the MPOX (Monkeypox) IMT) to support vaccinators.

- Supporting Information for healthcare workers: Use of MVA-BN vaccine in response to MPOX (Monkeypox).
- HSE Patient information leaflet
- Consent forms (children and adults)
- Post Vaccination leaflet (which includes a vaccination record card)
- Link to SmPC on EMA website

These documents (and translations where required) are available on the HPSC MPOX (Monkeypox) vaccination pages: https://www.hpsc.ie/a-z/zoonotic/monkeypox/mpoxvaccinationinformation/

The NIAC immunisation guidelines on MPOX (Monkeypox) is available here: https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland [4]

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