Mpox Vaccine JYNNEOS® Information Sheet for Immunization

I. Vaccine Brand, Components, and Characteristics

The Danish company Bavarian Nordic A/S developed the first ever live-attenuated, non-replicating vaccine, which was the Mpox vaccine stocked by the Taiwan Centers for Disease Control. This vaccine is permitted for special import by the Food and Drug Administration, Ministry of Health and Welfare, Taiwan, after receiving authorization from the United States, Canada, and the European Union.

- Principal components:
  Each dose (0.5 mL) contains between 0.5 x 10^8 IU and 3.95 x 10^8 IU of non-replicating, live Modified Vaccinia Virus Ankara - Bavarian Nordic, MVA-BN®.
- Other components:
  Host-cell DNA, protein, benzonase, gentamicin, ciprofloxacin.
- According to the previous clinical studies, both intradermal and subcutaneous vaccinations are equally effective at eliciting an immune response, and both carry an extremely low risk of serious adverse events.

II. Inoculation Site: The deltoid muscle in the upper arm is the recommended inoculation site. If the deltoid is not the option, (for instance, if local side effects from the first dose continue to cause discomfort at the time of administering the second dose), the provider may choose a different site for injection (e.g. The volar surface of the forearm).

III. Vaccination Scheduling:

(I) Pre-exposure prophylaxis (PrEP): Those who meet the criteria and exhibit no symptoms of suspected Mpox are eligible for vaccination. If you have high-risk contact with a confirmed case of Mpox and have not received the post-exposure prophylaxis (PEP) vaccine, you can get vaccinated if you have no symptoms of suspected monkeypox infection.

(II) Post-exposure prophylaxis (PEP): High-risk contacts should get vaccinated as soon as possible, preferably within four days of their last exposure, for the best possible preventive outcomes. If vaccinated between 4 and 14 days after exposure, it may not prevent disease but may lessen its severity. Vaccination is not advised if Mpox symptoms have already appeared.

IV. Inoculation Technique, Dosage, and Interval:

(I) Intradermal injection*, two doses, 0.1mL per dose, at least four weeks apart; or

(II) Subcutaneous injection, two doses, 0.5 mL per dose, at least four weeks apart; (In the event of limited vaccine supplies, PrEP and PEP vaccination subjects over the age of 18 are given preference for intradermal vaccination; in general, PrEP subjects receive their first dose first.)

*Precautions: Individuals under 18 years of age, with a family history of keloids, or with severe immunodeficiency** should not undergo intradermal injection, but rather a subcutaneous inoculation.

**Those with severe immunodeficiency, including those with advanced or poorly controlled HIV infection (CD4<200 cells /mm^3), leukemia, lymphoma, systemic malignancy, radiotherapy, organ transplantation; use of alkylating agents, antimetabolites, tumor necrosis factor inhibitors, or high-dose corticosteroids; recipients of hematopoietic stem cell transplantation within 24 months, or those with graft-versus-host (GVHD) or recurrence of illness more than 24 months after trasnplantation; those with autoimmune disorders with immunodeficiency.

V. Adverse Reactions

(I) The following symptoms may occur among those who have not received the first-generation smallpox vaccine:

- Injection site reactions: pain (85%), redness (61%), swelling (52%), lumps (45%), itching (43%), etc.
- Systematic reactions: muscle pain (43%), headaches (35%), fatigue (30%), nausea (17%), chills (10%), etc.

(II) Possible reactions for those who have been inoculated with the first-generation smallpox vaccine are as follows:

- Injection site reactions: redness (81%), pain (80%), lumps (70%), swelling (67%), itching (32%), etc.
- Systematic reactions: fatigue (34%), headaches (28%), muscle pain (22%), etc.

VI. Contraindications and Precautions

(I) Those who are allergic to vaccine components.

(II) Note possible anaphylactic shock following injection.

(III) Those with compromised immune systems or those taking immunosuppressants may not mount a full immune response to the vaccine.

(IV) The Mpox vaccine is a live-attenuated vaccine that does not replicate. Theoretically, it is an inactivated vaccine that can be administered concurrently with other inactivated or live vaccines or at any time interval. In addition, before receiving a second COVID-19 vaccination, males between the ages of 12 and 39 who are at an increased risk of myocarditis due to their COVID-19 vaccination must wait four weeks. In the event that there is an imminent need for

post-exposure prophylaxis (PEP), it is advised that delaying the Mpox vaccination is unnecessary.

VII. After Vaccination: precautions and possible adverse reactions

(I) To prevent and immediately manage the extremely rare severe immediate allergic reaction after vaccination, you should take a brief rest for at least 15 minutes at or near the vaccination unit after vaccination.

(II) After vaccination, you should seek immediate medical attention if you experience persistent fever, severe reactions such as dyspnea, wheezing, dizziness, or rapid heartbeat. Please inform your doctor of your history of Mpox vaccine, vaccination date, and associated symptoms you experienced.Clinicians in the medical care facility or the Public Health Bureau can provide assistance with reporting to the Vaccine Adverse Event Reporting System (VAERS) (https://vaers.cdc.gov.tw/).

Mpox Vaccine JYNNEOS® Vaccination Consent Form

1.Basic information of vaccine recipient:

(1) Name: _____

(2) Sex: ☐Male ☐Female

(3) I.D./ Alien Residence Certificate: _____

(4) Date of birth: _____ (YYYY/MM/DD)

(5) Mobile phone: (___)_____

(6) Address:_____,

_____Township/District, _____ County (City)

(7) Have you received smallpox vaccine? (After 1979, Taiwan ceased administering vaccinia vaccine.)

☐No; ☐Yes，year of vaccination_____; ☐unsure

(8) Have you received Mpox vaccine?

☐No; ☐Yes，date of vaccination_____; ☐unsure

2.Vaccinee are required to read the Mpox vaccine Information Sheet for Immunization carefully. Please verify and tick:

Assessment content	No	Yes	Unsure
1. Are you experiencing suspected symptoms of Mpox?			
2. Have you experienced severe allergic reactions to vaccines or medications in the past?			
3. Are you allergic to other components of the vaccine?			
4. Do you have a weakened immune system, for instance, because you’ re on an immunsuppressive therapy?			
5. Are you currently pregnant or breastfeeding?			
6. Body temperature: _____℃			

I have fully understood the vaccine's protective effects, adverse reactions, contraindications, inoculation procedures, and post-inoculation precautions, and I hereby consent to:

☐ **I consent to receiving immunization of Mpox vaccine.**

☐ **First dose**

☐ **Second dose, date of first dose inoculation**_____ (YYYY/MM/DD)

☐ **I do not consent to receiving immunization of Mpox vaccine.**

Signature of vaccine recipient: _____

Date: _____(YYYY/MM/DD)

Signature of legal representative: _____

Date: _____(YYYY/MM/DD)

***After filling out this information sheet, hand it over to the health care providers for evaluation.**

***Physician Assessment Box (To be filled out by the physician)**

☐ Pre-exposure prophylaxis (PrEP)

☐ Post-exposure prophylaxis (PEP)

Vaccine	Dose	If inoculation is allowed		Signature of physician	Other remarks
Monkey pox vaccine JYNNEOS®	0.5ml/ subcutaneous injection	Yes	No		
	0.1ml/ intradermal injection	Yes	No		

Vaccination medical institution: _____

VARCHAR(10) of medical institution: _____