MOH OI V1.1/2024

OPERATIONS INSTRUCTION TO VACCINATION PROVIDERS FOR THE CONDUCT OF COVID-19 PFIZER-BIONTECH/COMIRNATY OMICRON XBB.1.5 MONOVALENT VACCINE – mRNA VACCINATION FOR INDIVIDUALS AGED 12 YEARS OLD AND ABOVE

# Documentation Record

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| S/N | Version No. | Date | Description | Author | Approving Authority | Remarks |
| Name, Designation |
| 1 | 1.0 | 24 Oct 2023 | First Version | Dom Choong  M, OPB | D(P&P) |  |
| 2 | 1.1 | 27 Feb 2024 | Para 6:  Updated Clinical Guidance on two-dose baseline, step-down measures for strenuous activity, vaccine co-administration, observation, Anaphylaxis management, revised Guidance Document  Para 7.2:  Updated Parent Consent Table  Para 7.8 b:  Amended 14 days interval between vaccines to can be administered concurrently  Para 7.9:  Updated documents attachments  Para 7.13 to 7.17:  Deleted Incident Reporting | Tay Lee Hwa  M, VOTG | D(VOTG) |  |

**Purpose**

1. This Operations Instruction seeks to inform Vaccination Providers on the instructions to operationalise the COVID-19 Pfizer-BioNTech/Comirnaty XBB.1.5 monovalent vaccination for individuals aged 12 years old and above.

# Principal Considerations

1. The principal considerations are as follows:
2. **Client Safety**
3. Suitable age of client to receive the mRNA COVID-19 vaccination should be calculated based on the date of birth, not just the birth year, and adhering to the minimum age of 12 years and above.
4. For clients who are receiving the vaccines for the first time, the second dose could be offered to be received at the same venue as the first dose, and the vaccine should be from the same manufacturer as the first dose. Vaccination Providers should pay attention to the minimum and maximum interval between the first and second doses according to the vaccine manufacturers’ specifications.
5. **Minimise Vaccine Supplies Wastage**
6. Due to the short shelf-life of the thawed vaccines, Vaccination Providers should avoid holding on to excess vaccine supplies and should trigger re-supply only when necessary.
7. Due to the short shelf-life of the vaccines after opening of vials, Vaccination Providers should plan and schedule the client’s vaccination in batches to reduce vaccine wastage.

# Concept of Operations

1. Vaccinations will be administered to individuals at designated vaccination sites, such as, Joint Testing and Vaccination Centres (JTVCs), Public Health Preparedness Clinics (PHPCs), Polyclinics, Private Vaccination Programme (PVP), etc.
2. Leverage on MVTs And HVTs

Mobile Vaccination Teams (MVTs) and Home Vaccination Teams (HVTs) will be deployed to conduct onsite vaccinations at designated locations and according to schedules confirmed by MOH and site providers. This includes aged care facilities, nursing homes, etc.

Home Vaccination Teams (HVTs) may be deployed to conduct vaccinations at individual’s residential home upon request (if client has mobility issues).

# Operating Parameters

1. Vaccination Providers will continue to achieve throughput as per MOH’s latest instructions.

# Updates to Clinical Guidance

* 1. Individuals who have not been vaccinated against COVID-19 with effect from 1 March 2024 are now recommended to receive two initial vaccine doses.

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| **Vaccine** | **Age** | **Dose(s) and Recommended Intervals** |
| Pfizer-BioNTech/Comirnaty XBB.1.5 monovalent COVID-19 Vaccine[[1]](#footnote-1) | ≥ 12 years | Primary series vaccination   * 2 doses of 30mcg (0.3mL) * 8 weeks apart |
| 2023/2024 booster vaccination   * 1 dose of 30 mcg (0.3mL) * 1 year after last dose received |

* 1. The advice to avoid strenuous physical activity after vaccination is updated to apply to only male vaccinees aged 12-29 years, for a duration of 1 week.
  2. COVID-19 vaccines can now be administered concurrently with other non-COVID-19 vaccines across all ages eligible for the vaccine.
  3. There is no longer stipulated period of observation after COVID-19 vaccination, other than for persons at increased risk of anaphylaxis who should be observed for 30 minutes. These individuals include those who had a past history of:

1) Allergic reactions (that is, immediate hypersensitivity reactions) to other COVID-19 vaccines, OR,

2) Any anaphylaxis

* 1. Emergency drugs / equipment requirements for COVID-19 vaccine providers is now aligned to that required under prevailing regulatory requirements relevant to the licensable healthcare service which the licensee is licensed for and is stipulated in the "Licence Conditions for Providing or Intending to Provide Emergency Life Saving Measures".
  2. There is no more restriction of nonsteroidal anti-inflammatory drugs (NSAIDs) use after COVID-19 vaccine administration.
  3. Information on dosage, administration, storage, and handling are included in the vaccine package insert below. Vaccination Providers staff should ensure that they are familiar with the materials before carrying out vaccinations.

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| **Document** | **Purpose of Document** | **Pfizer-BioNTech/Comirnaty XBB.1.5 Monovalent** |
| Vaccine Package Insert | Information to vaccination clinics and vaccinators on dosage, administration, storage, and handling |  |

* 1. MOH has provided clinical guidance materials to support personnel who are carrying out the vaccinations. Personnel who are carrying out vaccinations should ensure that they are familiar with the materials before carrying out vaccinations.

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| **Document** | **Purpose of document** | **Attachment** |
| Guidance for Vaccination Providers  (Annex A) | Guidance to vaccination providers and vaccinators |  |

# Operations

**Parent Consent for Vaccination for Persons below 18 Years Old**

* 1. Persons below 18 years old are required to have the consent of their parent or legal guardian in order to be administered with the vaccine.
  2. The table below states the requirements for parent’s / legal guardian’s consent, and the in-person presence of the parent / legal guardian during vaccination.

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| Age of Person being Vaccinated (X) | Parent / Legal Guardian  Consent? | Parent / Legal Guardian Presence? |
| 6 ≤ X <13 | Consent Required. MSP to verify consent onsite with accompanying parent / legal guardian / authorized proxy | Presence Required |
| 13 ≤ X <18 | Consent Required. MSP to verify consent onsite | Presence Not Required |

**Requirements on Granting of Consent and Consent Verification (including in person parent/guardian presence)**

* 1. The Vaccination Providers will verify the following before administering the vaccine to the client:

1. **HAS Appointment**. Verify the HAS appointment status of the client to ensure that he/she has a valid appointment booked for the timeslot when present. If there is a valid HAS appointment, consent was given at the point the appointment was made and there is no need for written consent. If the client does not have any valid appointments, Vaccination Providers shall facilitate the client’s vaccination on site and ensure that consent has been obtained.
2. Verify the identification document of the client to ensure that he/she is the correct person for whom the parent/legal guardian had booked the vaccination appointment.
3. Clients who present the MOE EZ-link as their form of identification document shall be recognized as MOE students. Vaccination Providers shall record the accompanying adult’s relationship with the client in GPConnect-lite.

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| Specimen screenshot of MOE EZ-link card |  |

1. If the client presents other forms of identification documents (e.g., birth certificate or other valid identification cards), Vaccination Providers shall verify the parent’s/legal guardian’s signed letter of consent either in hardcopy or softcopy form (Annex B) which is produced by the client. If the client is unable to produce the signed letter of consent either in hardcopy or softcopy form, the Vaccination Providers will verbally verify consent with the parent / legal guardian whose presence is required in-person and record the consent in GPConnect-lite. Consent for this group is sought at the point when appointment was made.

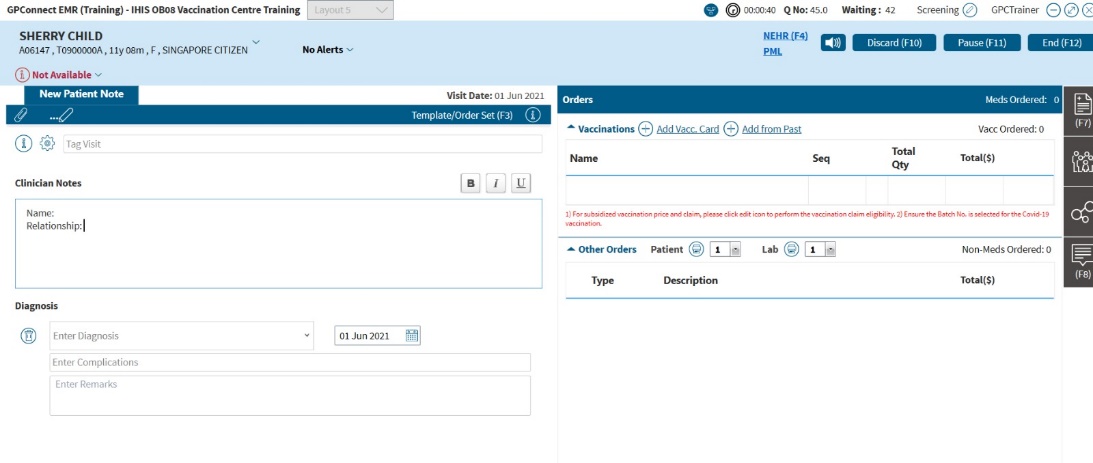
For foreign clients with foreign identification documents or whose birth certificates indicate they were not Singaporean at birth, Vaccination Providers shall register the clients with their FIN number.

Vaccination Providers are not required to retain the hardcopy of the signed letter of consent, either at the first, second or additional dose appointment. However, the Vaccination Providers should document the parent’s/legal guardian’s consent in GPConnect-lite by capturing the following details for every client whose parent/legal guardian consent needs to be verified:

1. Name of the parent/legal guardian
2. Contact number of the parent/legal guardian
3. Consent obtained from parent/legal guardian
4. <Mode of consent obtained> from parent/legal guardian
5. Relationship between parent/legal guardian and client

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| Annex B – Letter of Consent and Authorisation |  |

1. For the second and additional dose appointments, the Vaccination Providers onsite will again verify that the client has the required parent consent and capture the same details in GPConnect-lite for each appointment, before administering the second and additional dose.
2. The Vaccination Providers will capture the required data under the “Clinical Notes” area and in accordance with the template shown below.



* 1. Hospitals and other healthcare institutions that provide vaccination services to their existing clients should obtain consent from a parent/legal guardian for their clients who are below 18 years old, using the hospital/institution’s existing processes. Hospitals/institutions should document the parent/legal guardian’s consent obtained in an appropriate EMR system/IT System.

**Consent for Vaccination**

* 1. Consent for vaccination is implied when a person registers for vaccination, shows up for vaccination, offers medical information to the Nurse/vaccinator if asked, and presents his/her arm to receive the vaccine without raising any verbal objection. Sector Leads/Agencies may choose to adopt a higher standard of consent-taking (e.g., written consent) in line with the agency’s existing processes. As part of the process in booking a vaccination appointment via the Health Appointment Booking System (HAS), the person will be asked for his/her consent to be vaccinated.
  2. For persons who may be unable to provide consent for vaccination (including persons with dementia or others lacking mental capacity), consent from next-of-kin (NOK)/ donee/deputy if no NOK is available, is required.

**Consent for Vaccination of Persons Lacking in Mental Capabilities with/without Next-Of-Kin (NOK)**

* 1. The following section will cover the requirement for consent for persons with lacking mental capabilities with/without NOK.

1. Those with mental capacity: Clients’ consent needs to be obtained and documented.
2. Those with no mental capacity: To obtain consent from the donee/deputy, if there is one, or the NOK who makes decisions on behalf of the clients.
3. Those with no mental capacity and no donee/deputy/NOK: The doctor may proceed with the vaccination according to his/her best judgment of the resident’s best interest.
   1. The vaccination will generally follow the processes below:
4. Pre-vaccination – Clients will make appointment for vaccination.
5. On-Site Registration and Triaging – Upon the client’s arrival at the vaccination site, the client will be triaged and screened based on the client’s updated information and age. For organisations with access to NEHR, the Doctor/Nurse shall also access the client’s NEHR via GPConnect Lite/Staff Surveillance System (S3)/Electronic Medical Record (EMR) to verify the client’s medical history. COVID-19 vaccines can now be administered concurrently with other non-COVID-19 vaccines across all ages eligible for the vaccine. The Doctor/Nurse shall also check the client’s COVID-19 vaccination records, if any, via GPConnect Lite/S3/EMR.
6. Vaccination – Vaccination and data capture.
7. Post-vaccination – Monitoring and reporting of adverse effects, if necessary.
   1. The following documents are required during the vaccination process:

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| **Document** | **Purpose of Document** | **Pfizer-BioNTech/Comirnaty XBB.1.5 Monovalent** |
| Vaccination Information Sheet  (Annex C) | Vaccine information and post-vaccination advice for client, if necessary |  |
| Vaccination Screening Form  (Annex D) | Reference of the minimum dataset for various uses, including registration, declaration of contraindications, indication of consent, medical record documentation, and vaccination procedure medical record documentation |  |
| Vaccination Card  (Annex E) | Vaccination record for client and appointment reminder for subsequent doses, if necessary  To be issued to client after the vaccination is administered, if required. Vaccination Card is not meant to be used for travel purposes/proof of vaccination; client may request for a digital vaccination certificate from the Notαrise website (<https://www.notarise.gov.sg>) |  |

**Vaccination Screening Form**

* 1. If a client has been assessed to be ineligible or has to be deferred for vaccination, the screening Doctor/Nurse should reflect the associated reason/medical conditions on the GPConnect Lite/S3/EMR system as follows:

1. The reasons/medical conditions[[2]](#footnote-2) should be aligned to the latest “Definition of medical ineligibility for all COVID-19 vaccines under NVP” in MOH Circulars, last updated circular no. 183/2021



1. The screening Doctor/Nurse should clearly communicate the said reasons to the client.
   1. Clients undergoing the second/additional dose do not need to fill up a new Vaccination Screening Form. Vaccination Providers should continue to exercise due diligence to assess clients during screening/triaging. This includes questioning clients as to whether they experienced anaphylaxis after the first/second dose. The Vaccination Batch Number should continue to be recorded, as new batches will be distributed to institutions in future.

**Daily Reporting Requirements**

* 1. Vaccination Providers are required to submit daily reports to MOH. The reporting requirements are as follows:

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| **Document** | **Attachment** |
| Daily Reporting Requirements  (Annex F) |  |

# Logistics

**Vaccine Handling and Storage**

* 1. Vaccination Providers shall adhere to the following vaccine storage guidelines.

1. Unused vaccines vials should be stored in the refrigerator with a temperature maintained at between 2°C and 8°C and must be monitored. For refrigerators that do not have a temperature data logger, the internal temperature of the refrigerator where unopened vaccines are stored at should be recorded twice daily e.g. in the morning and evening.
2. Care should be taken to protect the vaccine vials from light if the refrigerator door/window panel is transparent.
3. Adopt first-expire-first-out system when retrieving vaccine vials from the refrigerator.
   1. Vaccination Providers shall adhere to the following vaccine handling guidelines.
4. Vaccines vials must always be protected from light when not being handled. Unopened vaccine should be kept within the outer box to protect from light. Handling refers to the process of preparation (pre-filling the syringe) and administration of the vaccine.
5. Vaccine vials should be visually inspected for discolouration, or particulates and before each syringe is filled up.
6. When filling up the syringes, the dose in each syringe should be visually inspected by lifting up each syringe to check for (i) the correct final dosing volume, (ii) no discolouration and no particulates, and (iii) no air bubbles

**Disposal of Used/Empty Vaccine Vials, Syringes and Needles**

* 1. Used/empty vaccines vials are considered pharmaceutical waste. They should be collected in containers that are non-reactive, tamper-proof and designed to resist impact rupture and labelled with the proper colour code and symbol before disposal by a licensed biohazard waste collector.
  2. As COVID-19 vaccines delivered to vaccination sites are considered controlled consumables, used/empty vials should be properly accounted for and stored in a controlled environment before disposal to prevent unauthorised possession.

(Reference:<https://www.straitstimes.com/singapore/consumer/surgical-masks-vaccines-among-counterfeit-goods-on-the-rise-online>)

* 1. Vaccination Providers should adhere to the following guidelines to prevent needle-stick injuries.

1. Used needles and syringes should be disposed as one single unit into a Sharps Disposal Container immediately after they have been used.
2. Used needles should not be removed from the syringe, bent or broken by hand manipulation/removal device/port to prevent accidental needle sticks which may cause serious infections.
3. Used needles and syringes should not be left protruding from Sharps Disposal Containers, and Sharps Disposal Containers should not be more than full.
4. Sharps Disposal Containers should be located in a safe and secure position such that they cannot be easily tipped over. Sharps Disposal Containers should not be stored on the floor or above shoulder level.
5. There should not be any form of crossing over of hands/clients when disposing used needles and syringes into Sharps Disposal Containers.
6. When Sharps Disposal Containers are not in use, the temporary closure mechanism must be used.
7. If recapping of needles is necessary or required as part of the vaccine preparation workflow, the needle should be recapped with the aid of a pair of forceps, using a cap-holding device, or using a “one-handed scoop” technique to scoop the cap.
   1. Vaccination Providers should ensure that Sharps Disposal Containers used are properly, securely, and safely stored in a controlled area that is not accessible by any unauthorised personnel. Proper storage and handling of Sharps Disposal Containers before disposal **must be adhered to** as part of workplace safety management (i.e. Sharps Disposal Containers must not be stacked hazardously.)
   2. Please refer to the National Infection Prevention and Control Guidelines for more information:



**Inventory Management**

* 1. Vaccination Providers need to have a system to account for the vaccines issued. Proper recording of vaccine inventory and stock movement (e.g. stock balance/usage/ received/transferred/wastage/disposed) should be maintained. Vaccination service providers are recommended to adopt the good practice of counting empty/used/ damaged vaccine vials before disposal, to ensure that the quantity discarded tallies with that taken out of the fridge.
  2. Vaccination Providers must have a system to monitor the stock expiry and transfer any excess stock to fellow Vaccination Providers at the first instance, to reduce wastage. If necessary, Vaccination Providers may seek assistance from your operations lead[[3]](#footnote-3) at least 2 weeks before expiry for MOH redistribution of the excess stock, subject to availability of vaccination sites that are able to consume it before expiry.
  3. Vaccination Providers are recommended to hold sufficient supply for 5 to 7 days to keep the vaccine fresh, and to manage the supply and re-supply properly to keep wastage to a minimum.

**Pfizer-BioNTech/Comirnaty XBB.1.5 Monovalent (12 years and above)**

* 1. The Pfizer-BioNTech/Comirnaty XBB.1.5 monovalent vaccines will be thawed by MOH’s vaccine distributors and will be delivered to Vaccination Providers at the temperature range of 2°C to 8°C. The shelf-life of the vaccine is **10 weeks** once removed from the freezer at the central warehouse. The expiry date of the vaccine at 2°C to 8°C will be labelled on the vaccine vial.
  2. Each vial of Pfizer-BioNTech/Comirnaty XBB.1.5 Monovalent (12 years and above) is a multi-dose vial sufficient for **six** clients to be vaccinated. Similar to Moderna/Spikevax, this Pfizer-BioNTech/Comirnaty XBB.1.5 Monovalent vaccine **does not require dilution** and must be used **within 12 (twelve) hours** from the time of first puncture of vial.
  3. Vaccination Providers are required to submit vaccine orders via Zuellig Pharma’s Online Ordering Portal, **eZRx (**[**https://ezrx.com**](https://ezrx.com/)**)**. Public healthcare institutions without eZRx access are required to submit vaccine orders via email.
  4. Vaccination Providers should note the order cut-off time, and the expected delivery when requesting for top-up of vaccines.

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| **Order Placed on Working Day** | **Vaccines Delivery** |
| Day 1; Before 10am | By Day 4; Within 3 working days |
| Day 1; After 10am  (Processed as next working day; Day 2) | By Day 5; Within 4 working days |
| Orders placed on Friday and eve of public holiday (By 10am) | Within next 3 working days |
| *Note: No order processing on weekends and public holidays.* | |

* 1. Please refer to Annex J and K for the detailed work instructions for the request of vaccine and medical supplies.

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| **Document** | **Site Provider** | **Attachment** |
| Work instructions for the requisition of vaccine and medical supplies  (Annex J- Pfizer-BioNTech/Comirnaty XBB.1.5 Monovalent; 12yr & above) | PHPCs, JTVCs and Hospitals |  |
| Detailed work instructions for the requisition of vaccine and medical supplies  (Annex K- Pfizer-BioNTech/Comirnaty XBB.1.5 Monovalent; 12yr & above) | Public Healthcare Institutions without eZRx access |  |

* 1. Medical supplies such as needles and syringes may also be ordered from MOH via MOH-appointed logistics partners if the medical service provider is unable to get from their usual sources.

**Low Dead Volume (LDV) Needles & Syringes**

* 1. Vaccination sites can order the **MICSAFE NIPRO Slip Tip 1cc LDS** syringe and **NIPRO Hypodermic 25G needle** (as a set). Users should attempt to extract six doses from the Pfizer-BioNTech/Comirnaty XBB.1.5 Monovalent (12 years and above) vial.

# IT Systems

* 1. The broad approach for IT systems is to provide a unified and integrated system to complement MOH vaccination sites with administrative and clinical functions to handle operational requirements.

**Health Appointment Booking System (HAS)**

* 1. The COVID-19 vaccination appointment booking function had been incorporated into the HAS to enable MOPs to book their COVID-19 vaccination appointments at the respective vaccination sites. This system will enable notifications and reminder functions to facilitate appointment attendance.

**Vaccination Operations EMR System**

* 1. GP Connect Lite (GPC Lite), Vaccination Care System (VCS) and Patient Risk Profile Portal (PRPP) have been identified to be the EMR Systems to manage the vaccination sites’ operations. Deployment of GPC Lite, VCS or PRPP to specific vaccination sites is at MOH’s discretion.

**Updating of COVID-19 Vaccination Records into National Immunisation Registry (NIR)**

* 1. Updating of vaccination records into NIR will be done via GPC Lite/VCS/PRPP automatically. Vaccination sites are to ensure that all clients’ vaccination records accumulated within each operational day are entered into GPC Lite/VCS/PRPP by **2200H** on the same day.

**Manual Updating of Vaccination Records into NIR**

* 1. There are currently 2 main methods to manually update vaccination records into the NIR Web Portal. Operators performing the updating of vaccination records via this route are to login using their CorpPass account using this internet link: <https://www.nir.hpb.gov.sg/nird/ens/enslogin>.
  2. *Data Entry Method*: Operators may choose one of the following relevant modes to perform the data entry function on the NIR Web Portal. ‘*Individual Record Entry (12 Years Old and Above)*’, ‘*Individual Record Entry (Below 12 Years Old)*’ and “*Multiple Record Entry*”.
  3. *Batch (Excel) Upload Method*: Operators may choose to batch vaccination records and pre-populate them into the .xls excel template provided on the NIR Web Portal. The completed templates are to be uploaded into the NIR Web Portal within the daily stipulated timing. **Operators should adhere to this template and not develop one of their own.**
  4. To perform the operations specified in this section efficiently, operators are advised to apply for an appropriate number of NIR “User” accounts within their respective organisations to assist with the updating requirements.
  5. The collective instructions for manual updating of vaccination records into NIR are prescribed in the following document.

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| **Document** | **Attachment** |
| NIR User Guide for COVID Notification  (Annex K) |  |

# Conclusion

1. MOH seeks Vaccination Providers’ adherence to the requirements stipulated in this Operations Instruction when carrying out vaccination service for their clients.

# MOH Contact Information

1. MOH Vaccination Operations Centre (VOC): [COVID\_Vaccination\_Ops@moh.gov.sg](mailto:COVID_Vaccination_Ops@moh.gov.sg)

**Issued by:**

**S. Vijakumar**

**Director, Vaccination Operations Task Group**

**Ministry of Health**

# On behalf of:

## Group Director, Crisis Strategy and Operations Group

## Ministry of Health

Dated: 27 Feb 2024

1. Vaccine dose of the Pfizer-BioNTech/Comirnaty XBB.1.5 monovalent vaccine to be used for primary series vaccination in individuals aged 12 years and older is 30 mcg (0.3 mL), the same as that used for the booster dose. [↑](#footnote-ref-1)
2. The reasons/medical conditions are codified in GPC as: fever, acute respiratory infections, general unwell, immunosuppression, platelet count abnormality, allergy to vaccine product, history of drug-induced anaphylaxis, others, cancer treatment. [↑](#footnote-ref-2)
3. PHPC should contact your AIC account manager. [↑](#footnote-ref-3)