# Private Clinic COVID-19 Vaccination Station (PCVS) administering mRNA vaccines for children (aged 6 months to 11 years)

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Dear Doctors,

Thank you for joining the COVID-19 Vaccination Programme – Private Clinic COVID-19 Vaccination Station (PCVS) and offering mRNA vaccines to clients aged 6 months to 11 years. We would like to highlight the following important points for providing vaccination service at your PCVS.

Please always refer to the Doctors' Guide for the latest information:

Doctors' Guide for mRNA vaccines:
 https://www.chp.gov.hk/files/pdf/vssdoctorsguide\_covid19\_bnt\_pilot.pdf

Thank you for your support to the Government's COVID-19 Vaccination Programme.

Programme Management and Vaccination Division
Emergency Response and Programme Management Branch
Centre for Health Protection
Department of Health

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#### 1/ Doctors' Guide

- The Doctors' Guide contains essential information for doctors providing COVID-19 vaccination services and will be updated regularly.
- Please click on the following links for the latest version:
   mRNA vaccines https://www.chp.gov.hk/files/pdf/vssdoctorsguide\_covid19\_bnt\_pilot.pdf
- Useful forms can be found in Annex of the Doctors' Guide:
  - Annex V Temperature Excursion Incident Report Form
  - Annex V Vaccine Report Form Relating to Discrepancy/Defective
  - Annex VIIIb Report on Cases Referred to Hospitals
  - Annex Xb Clinical Incident Notification Form and Investigation Report

#### 2/ Publicity, package inserts and other useful materials

- Fact sheet for mRNA vaccines: https://www.chp.gov.hk/files/pdf/factsheet\_covidvaccine\_mrna\_eng.pdf
- Package inserts :

For Comirnaty JN.1 vaccine - toddler formulation (3 mcg): https://www.chp.gov.hk/files/pdf/packageinsert\_jn1\_comirnaty\_3mcg.pdf

For Comirnaty JN.1 vaccine - paediatric formulation (10mcg): https://www.chp.gov.hk/files/pdf/packageinsert\_in1\_comirnaty\_10mcg.pdf

- Consent form [ applicable to all mRNA / inactivated COVID-19 vaccines under the Government COVID-19 Vaccination Programme]:

  https://www.chp.gov.hk/files/pdf/consent\_form\_for\_covid19\_vaccination\_eng.pdf
- "How many doses of COVID-19 vaccine are recommended for me?": https://www.chp.gov.hk/en/features/106951.html
- Factsheet on COVID-19 Vaccination for Persons with Prior COVID-19 Infection:
   <a href="https://www.chp.gov.hk/files/pdf/factsheet\_priorcovid19infection\_eng.pdf">https://www.chp.gov.hk/files/pdf/factsheet\_priorcovid19infection\_eng.pdf</a>

- Points to Note and Frequently Asked Questions on COVID-19 vaccination for Children and Adolescents:

https://www.chp.gov.hk/files/pdf/faq\_children\_adolescents\_eng.pdf

FAQs on immunocompromised persons:
 https://www.chp.gov.hk/files/pdf/faqs\_on\_immunocompromised\_persons.pdf

- User Manual of eHealth System (Subsidies) [eHS(S)] for COVID-19 Vaccination: https://www.ehealth.gov.hk/en/covidvaccine/ehs.html

#### 3/ Recommendations on COVID-19 vaccination schedule – the simplified regimen

- With respect to the JSC consensus interim recommendation on the use of COVID-19 vaccines, the simplified arrangement for initial doses and the additional booster for 2024/25 under the Government COVID-19 Vaccination Programme has been implemented since 19 August 2024.
- For details, please refer to

The Concensus Interim Recommendations on the Use of COVID-19 Vaccines by JSC updated on 17 July 2024:

https://www.chp.gov.hk/files/pdf/consensus interim recommendations on use of c ovid19 vaccines in hong kong 17jul.pdf

#### Press releases:

Latest COVID-19 vaccination arrangements announced ( 8 August 2024) <a href="https://www.info.gov.hk/gia/general/202408/08/P2024080800571.htm">https://www.info.gov.hk/gia/general/202408/08/P2024080800571.htm</a>
Scientific Committees under CHP discuss use of COVID-19 and measles vaccines (17 July 2024)

https://www.info.gov.hk/gia/general/202407/17/P2024071700598.htm

#### A. Initial vaccination schedule

#### For immunocompetent persons

Immunocompetent persons aged 6 months to 4 years old without prior COVID-19 infection need to receive 2 doses of Moderna mRNA vaccines / 3 doses of

BioNTech mRNA vaccines or 2 doses of inactivated vaccines for initial vaccination.

Immunocompetent persons aged 5 years or above need to receive 1 dose of mRNA vaccine or 2 doses of inactivated vaccines to complete the initial vaccination.

#### For immunocompetent persons with prior COVID-19 infection

- Immunocompetent persons aged 6 months or above with prior COVID-19 infection should follow the vaccination schedule as immunocompetent persons aged 5 years or above (i.e. 1 dose of mRNA vaccine or 2 doses of inactivated vaccines, regardless of history of infection)
- No delay for initial doses vaccination for recovered persons, as recommended by vaccine manufacturers
- For details, please refer to "Factsheet on COVID-19 Vaccination For Persons with Prior COVID-19 Infection" at <a href="https://www.chp.gov.hk/files/pdf/factsheet\_priorcovid19infection\_eng.pdf">https://www.chp.gov.hk/files/pdf/factsheet\_priorcovid19infection\_eng.pdf</a>

#### For immunocompromised person

- Persons with immunocompromising conditions need to receive more dose(s) for completing initial doses compared to immunocompetent persons.
   Immunocompromised persons should follow the same vaccination schedule to complete the initial vaccination regardless of history of infection.
- For details, please refer to "FAQs on Immunocompromised Persons: at: <a href="https://www.chp.gov.hk/files/pdf/faqs">https://www.chp.gov.hk/files/pdf/faqs</a> on immunocompromised persons.pdf

#### B. Additional booster vaccination schedule

- Eligible high-risk priority groups can receive booster dose 180 days after their COVID-19 infection instead of recovery

Please refer to "How many doses of COVID-19 vaccine are recommended for me" at: <a href="https://www.chp.gov.hk/en/features/106951.html">https://www.chp.gov.hk/en/features/106951.html</a> for the vaccination schedule of initial dose(s) and additional booster dose(s).

Please also refer to the Points to Note and Frequently Asked Questions on COVID-19 vaccination for Children and Adolescents at:

https://www.chp.gov.hk/files/pdf/faq\_children\_adolescents\_eng.pdf

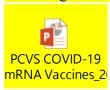
C. Transition vaccination arrangement for children aged 4 turning into 5

For children who have not yet completed the mRNA initial doses and transited from age 4 years to 5, they are allowed to continue receive the remaining initial doses as 4 years old persons, via walk-in at the vaccination venues providing COVID-19 vaccine for children.

4/ Vaccine Ordering and Training Material on Vaccine Management

(as of February 2025)

- For vaccine ordering, PCVS operators and related staff should go through the following training material:



For lost/ discrepancy / defective mRNA vaccines, please report to the Department of Health via the online Day End Report. After that, please complete the following form and return the following form to the CMT Pharmacist by email at pharm cmt@dh.gov.hk.



# 5/ Information related to Comirnaty JN.1 vaccine [paediatric and toddler formulations]

## A. Dosage and interval

- Comirnaty JN.1 vaccine [paediatric formulation] is available in multi-dose vial containing up to 6 doses and **NO DILUTION IS REQUIRED.**
- Comirnaty JN.1 vaccine [toddler formulation] is available in multi-dose vial containing up to 3 doses and requires dilution before use.

### B. Eligibility

PCVSs can provide JN.1 mRNA vaccine to eligible clients of age  $\geq 6$  months as the initial dose and to priority groups as the booster dose.

For further details, please refers to the poster: https://www.chp.gov.hk/en/features/106951.html

PCVSs should refer to the prevailing recommendation announced by the Government and offer JN.1 vaccines to clients belonging to announced priority group.

#### C. Route and site of administration

- The vaccine is administered intramuscularly in the deltoid muscle of non-dominant arm. Mid-anterolateral thigh injection **should** be offered to all adolescents, children and toddler (both male and female) aged 17 and below as the site of vaccination.
- The picture of proper position of holding a child during injection is recommended to display in the vaccination booths of PCVS for vaccinators' and accompanying adults' easy reference.



#### D. Ordering, delivery and storage

# (1) Comparison of shelf-life of different formulations of mRNA vaccines for person aged 6 months to 11 years

|                 | Comirnaty JN.1 - paediatric     | Comirnaty JN.1 - toddler formulation  |
|-----------------|---------------------------------|---------------------------------------|
|                 | formulation (10mcg/dose)        | (3mcg/dose)                           |
| Plastic cap     | Blue                            | Yellow                                |
| color           |                                 |                                       |
| <b>Dilution</b> | Not required                    | Required                              |
| Thawed vial     | 10 weeks (70 days)              | 10 weeks (70 days)                    |
|                 | (2 to 8°C)                      | (2 to 8°C)                            |
| Unopened vial   | 12 hours                        | 12 hours                              |
| prior to use    | (8°C to 30°C)                   | (8°C to 30°C)                         |
| Opened vial (2  | 12 hours (after first puncture) | 12 hours (after dilution with sodium  |
| to 30°C)        | (2°C to 30°C)                   | chloride 0.9% solution for injection) |
|                 |                                 | (2°C to 30°C)                         |

## (2) Wastage reduction

- Preventative measures should be in place to avoid unnecessary vaccine wastage.
- You are strongly recommended to avoid following scenarios that may lead to unnecessary vaccine wastage, including:
  - (a) High rate of absenteeism
  - (b) Substandard dilution technique
  - (c) Violation of vaccine storage condition
  - (d) Vaccine exposed to room temperature beyond allowed duration (please see above table for shelf life of different vaccines under various circumstances)
- Wastage rate will be reviewed by the PMVD periodically.

For further details, please refers to Section 4 "Vaccine ordering, delivery and storage" of Doctors' Guide for mRNA vaccines.

# E. Preparation procedure

Please note that dilution is **not** required for Comirnaty JN.1 vaccine [paediatric formulation]. Expiry of unopened vaccine at room temperature is 12 hours. After

- first puncture, the vaccine should be used within 12 hours.
- It is suggested that Comirnaty JN.1 vaccine [toddler formulation] should be diluted immediately after withdrawal from the refrigerator. Expiry of undiluted vaccine at room temperature is 12 hours. After dilution, the diluted vaccine should be used within 12 hours.
- Please see the procedure for the preparation of Comirnaty JN.1 vaccine [paediatric and toddler formulations].
  - (1) For **Comirnaty JN.1 vaccine [paediatric formulation]**, the procedure for vaccine preparation should be carried out according to the drug insert as illustrated below:

#### Preparation of 0.3 mL doses

- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a clear to slightly opalescent dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
- Multidose vials contain 6 doses of 0.3 mL each.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of Comirnaty JN.1 for children aged 5 to 11 years.
- Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Record the appropriate date/time on the vial. Discard any unused vaccine 12 hours after first puncture.
- (2) For **Comirnaty JN.1 vaccine [toddler formulation]**, the procedure for vaccine preparation should be carried out according to the drug insert as illustrated below:

# **Dilution**

- Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.
- Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.
- The thawed vaccine must be diluted in its original vial with 1.1 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.
- Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.1 mL air into the empty diluent syringe.
- Gently invert the diluted dispersion 10 times. Do not shake.
- The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.
- The diluted vials should be marked with the appropriate discard date and time.
- After dilution, store at 2 °C to 30 °C and use within 12 hours.
- Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

## Preparation of 0.3 mL doses

- After dilution, the vial contains 1.58 mL from which 3 doses of 0.3 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of Comirnaty JN.1 for infants and children aged 6 months to 4 years. Standard syringes and/or needles can be used in order to extract 3 doses from a single vial.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Discard any unused vaccine within 12 hours after dilution.

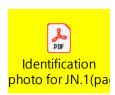
For further details, please refers to Section 6 "Vaccination procedures" of Doctors' Guide for mRNA vaccine.

# 6/ Recommendations on segregation

- For those venues providing more than one type of COVID-19 vaccines, there should be clear segregation for different type of vaccines at the venue. The logistics of storage and administration for each type of vaccine should be followed accordingly.

For details, please refers to section 6 of Doctors' guide.

- The identification photos of vaccines may be adopted to facilitate confirmation on choice of vaccine with the parents or guardians.



# ANNEX 1 – Useful Contacts

| Central Medical Team (CMT) - Medical issues (e.g. report of transfer to hospital, clinical incident) | Tel: 3975 4859  Fax: 2544 3908  Email: nurse_cmt@dh.gov.hk |
|--|--|
| CMT - Administrative support (e.g. report of non-medical incident)                                   | Tel: 3975 4860 Fax: 2544 3908 Email: adm_cmt@dh.gov.hk     |
| CMT Pharmacist (e.g. report of suspected temperature excursion)                                      | Tel: 5394 3508 Email: pharm_cmt@dh.gov.hk                  |
| PCVS Booking Related (e.g. quota amendment)  | Email: covid19_booking@dh.gov.hk                           |
| PCVS Vaccination Record rectification  | Email: vacs@dh.gov.hk                                      |

ANNEX 2 – Useful links of the document about the vaccination programme

| Document type                         | Document name   | QR code of the link<br>(can either click or scan) |     |      |
|---------------------------------------|---|---|-----|------|
|                                       |   | ENG   | СНІ | SChi |
| Webpage                               | COVID-19 Thematic website   |   |     |      |
|                                       | About the Vaccines  |   |     |      |
|                                       | About the Programme   |   |     |      |
|                                       | FAQs  |   |     |      |
| Eligibility for receiving vaccination | Persons eligible for receiving vaccination                              |   |     |      |
|                                       | Samples of identity documents (Annex A of "Quick Guide to joining RVP") |   |     |      |

| Package Insert of vaccines                     | BioNTech JN.1 ( Pediatrics formulation / 10mcg)   |  |  |
|--|---|--|--|
|  | BioNTech JN.1 ( Toddler formulation / 3 mcg)  |  |  |
| Vaccination fact sheet                         | mRNA COVID-19 vaccine   |  |  |
| Consent form                                   | Applicable to all mRNA / inactivated COVID-19 vaccines under the Government COVID-19 Vaccination Programme                              |  |  |
| Expert Opinion                                 | Expert Opinion  |  |  |
|  | Recommendations from the Scientific Committee on Emerging and Zoonotic Disease and Scientific Committee on Vaccine Preventable Diseases |  |  |
| Recommendation on number of doses and interval | How many doses of COVID-19 vaccine recommended for me?  |  |  |
| Information for children and adolescents       | COVID-19 Resources from<br>the Hong Kong Society for<br>Paediatric Immunology<br>Allergy and Infectious<br>Diseases                     |  |  |

|  | Referral letter for Paediatric<br>COVID-19 Vaccine Allergy<br>Safety Assessment                              |  |  |
|--|--|--|--|
|  | FAQ - children and adolescents   |  |  |
| Information for persons with diseases or allergy | Interim Guidance Notes On<br>Common Medical Diseases<br>and COVID-19 Vaccination<br>in Primary Care Settings |  |  |
|  | 3 Important Considerations for individuals with chronic diseases   |  |  |
|  | Examples of Chronic Diseases   |  |  |
|  | FAQ – Immunocompromised person   |  |  |
|  | Certification for<br>Immunocompromised<br>Persons  |  |  |
| Information for recovered persons                | Factsheet on COVID-19 Vaccination For Persons with Prior COVID-19 Infection                                  |  |  |
| eHealth  | User Manual of eHealth System (Subsidies) for COVID-19 Vaccination Programme                                 |  |  |

|                   | Quick Guide of Manual Input of Other Documents in the eHealth System (Subsidies) for COVID-19 Vaccination Programme  Consent form for eHealth |  |  |
|-------------------|---|--|--|
|                   | Consent form for enealth  | ■ 東京 ■<br>(6) (2) (4) (6) (7) (7) (7) (7) (7) (7) (7) (7) (7) (7 |  |
|                   | Register eHealth for your child   |  |  |
| Infection control | ICB Infection Control Guidelines  |  |  |
|                   | Recommendations on Hand<br>Hygiene and Use of Gloves<br>in Health Care Settings   |  |  |
|                   | Recommendations on the Management and Postexposure Prophylaxis of Needlestick Injury or Mucosal Contact to HBV, HCV and HIV                   |  |  |
|                   | Prevention of Sharps Injury and Mucocutaneous Exposure to Blood and Body Fluids in Healthcare Settings  |  |  |
|                   | Code of Practice for the<br>Management of Clinical<br>Waste   |  |  |

| Others | Reporting Adverse Drug Reactions |  |  |
|--------|----------------------------------|--|--|
|        |                                  |  |  |