

Briefing to Doctors

Key points for the use of Comirnaty JN.1
COVID-19 vaccines under the Residential Care Home
Vaccination Programme

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Clinical Incidents related to COVID-19 vaccination at RVP

- All 3 recent serious clinical incidents at RCH settings all related administering COVID-19 vaccines beyond recommended use-by date

Comirnaty XBB COVID-19 vaccine

- 31 December 2024 <https://www.info.gov.hk/gia/general/202412/31/P2024123100510.htm>

Spikevax JN.1 COVID-19 vaccine

- 23 July 2025 <https://www.info.gov.hk/gia/general/202507/23/P2025072300686.htm>
- 12 August 2025 <https://www.info.gov.hk/gia/general/202508/12/P2025081200622.htm>

Press Releases

DH investigates incident of RCHE administering COVID-19 vaccines beyond recommended use-by date

The Department of Health (DH) said today (December 31) that a review of the vaccine orders and vaccination records found that

Clinical Incidents related to COVID-19 vaccination at RVP

1. "Preliminary investigations revealed that, on December 18, healthcare workers from the medical organisation concerned visited an RCHE ...and administered the **Comirnaty XBB COVID-19 vaccines**, which were **12 days beyond the recommended use-by date**, to two residents. According to the vaccine manufacturer's recommendation, the Comirnaty XBB COVID-19 vaccine should be **stored at 2 to 8 degrees Celsius after thawing and should be used within 70 days**,"
2. "Upon reviewing the vaccine orders and vaccination records, the DH found that the doctor concerned visited ..., an RCHE in..., ...to provide vaccination services. During these visits, he administered **Spikevax JN.1 COVID-19 vaccines** that were **beyond the recommended use-by date** to 18 residents. According to the manufacturer's recommendation, the vaccine should be **stored at 2 to 8 degrees Celsius after thawing and should be used within 30 days**.
3. "Upon reviewing the vaccine orders and vaccination records, the DH found that the doctor concerned administered **Spikevax JN.1 COVID-19 vaccines** that were **beyond the recommended use-by date** to seven residents at ..., an RCHD in ..., on May 22. While the COVID-19 vaccines concerned have not exceeded their expiry dates, they should be **stored at 2 to 8 degrees Celsius after thawing and used within 30 days**, according to the manufacturer's recommendation."

Availability of JN.1 mRNA vaccines for adult

- Current **Spikevax JN.1 vaccines with batch number 3048234 will expire on 5 Nov 2025**, when stored frozen at -50°C to -15°C. This batch of vaccines will continue to be distributed **until late Oct 2025**.
- After that, Comirnaty JN.1 vaccines in multidose vial will be distributed for use.
- **Comirnaty JN.1 vaccine in multidose vials will replace the current Spikevax JN.1 for ordering via the COVID-19 Vaccines Ordering System starting from 21 Oct 2025 11:00 am.**

Comparison of JN.1 COVID-19 Vaccines (for aged ≥ 12 years)



	Comirnaty JN.1 dispersion for injection COVID-19 mRNA Vaccine 30 micrograms/dose	Spikevax JN.1 dispersion for injection in pre-filled syringe COVID-19 mRNA Vaccine 50 micrograms/dose 0.5 mL
Presentation	Multi-dose vial (Grey cap)	Pre-filled syringe (without needle)
Fill volume	2.25mL	0.5mL
Volume of each dose	<u>0.3mL</u> [30 micrograms of bretovameran]	<u>0.5mL</u> [50 micrograms of SARS-CoV-2 JN.1 mRNA]
Number of doses per unit	<u>6</u> doses*	<u>1</u> dose
Pack size available	1 or 10 vials per box	10 pre-filled syringes per box
Consumables available for ordering	1ml LDV syringe with 25G x 1" fixed needle (100 pcs/box)	25G x 1" luer-lock needle (100 pcs/box)

*Low-dead volume (LDV) syringes should be used in order to extract 6 doses from a single vial.

Shelf Life of JN.1 COVID-19 Vaccines (for aged ≥ 12 years)

	Comirnaty JN.1 dispersion for injection COVID-19 mRNA Vaccine 30 micrograms/dose (Package Insert: https://www.chp.gov.hk/files/pdf/packageinsert_jn1_comirnaty.pdf)	Spikevax JN.1 dispersion for injection in pre-filled syringe COVID-19 mRNA Vaccine 50 micrograms/dose 0.5 mL (Package Insert: https://www.chp.gov.hk/files/pdf/packageinsert_jn1_spikevax.pdf)
Frozen	18 months (-90°C to -60°C)	9 months (-50°C to -15°C)
Thawed	<u>10 weeks</u> (2°C to 8°C)	<u>30 days</u> (2°C to 8°C)
Unopened prior to use	<u>12 hours</u> (8°C to 30°C)	<u>24 hours</u> (8°C to 25°C)
Opened vial (after first puncture)	<u>12 hours</u> (2°C to 30°C)	

Labelling of JN.1 COVID-19 Vaccines (for aged ≥ 12 years)

	Comirnaty JN.1 dispersion for injection COVID-19 mRNA Vaccine 30 micrograms/dose (HK-68417)	Spikevax JN.1 dispersion for injection in pre-filled syringe COVID-19 mRNA Vaccine 50 micrograms/dose 0.5 mL (HK-68388)
Outer Box		
Single Unit (Vial / Syringe)	COMIRNATY JN.1 30 mcg injection brevovameran IM 6 doses Do not dilute Discard time:	spikevax™ JN.1 50 mcg dispersion for injection IM COVID-19 mRNA Vaccine 0.5 mL
Tips	<ol style="list-style-type: none"> 1) Verify vaccine name and HK registration number before preparation and administration 2) LDV syringe order quantity will be automatically calculated by the system based on order history, please retain the remaining syringes for future use 	<ol style="list-style-type: none"> 1) Require more storage space 2) Shorter shelf life after thawing (30 days) 3) Needle order quantity will be automatically calculated by the system based on order history, please retain the remaining needles for future use

New labelling for Comirnaty JN.1 vaccine

Use by Date (at 2°C to 8°C) :	14 OCT 2025
接種使用期限 :	
Thawed Date 2-8°C 冷藏起始日 :	06 AUG 2025
BPR No. :	PBPR10J022
Lot No. :	24MI003
Expiry Date (at -90°C to -60°C) :	28 FEB 2026
GTIN :	04260703261146

Major updates:

- Repositioning of “Use by Date” to the top row
- Clearer date format in DD MMM YYYY for improved clarity
- Omission of time to minimize distractions
- Bilingual text for “Use by Date” & “Thawed Date”
- Removal of 2D barcode
- Increased label and font size for better readability

Reminder:

- For daily operation, please refer to **“Use by Date”** on the outer box on a regular basis and prior to vaccine administration, as the information is not shown on the label of individual vials
- Vaccine can be used **until the end of the labelled “Use by Date”**.
- For example, if the “Use by Date” on the label is “14 OCT 2025”, it means the vaccine can be used **until 11:59 pm** on that date.
- Vaccines that are beyond the “Use by Date” should not be used.

Important Points to Note

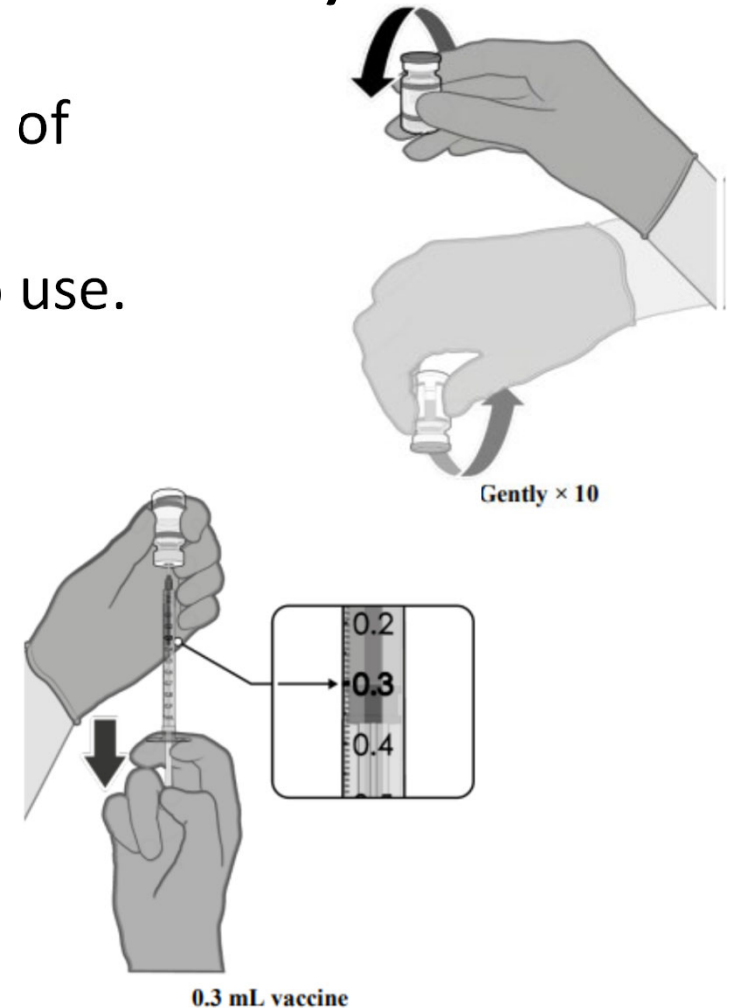
- Comirnaty JN.1 vaccines will be thawed prior to delivery. Thawed vaccines can be stored at **2°C to 8°C for up to 10 weeks**. For daily operation, please **refer to “Use by Date” on the outer box** on a regular basis and prior to vaccine administration, as the information is not shown on the label of individual vials. **Vaccines that are beyond the "Use by Date" should not be used.**
- According to the package insert, **the unopened vials can be stored for up to 12 hours at temperature between 8°C and 30°C.**
- Multidose vials contain **6 doses of 0.3mL each**. **No dilution** is required.
- **Discard any unused vaccine 12 hours after first puncture.**
- Please note that ALL Spikevax vaccines with **batch number 3048234** will expire on **5 Nov 2025**. Any remaining vaccines should be **removed from the medical fridge, quarantined in a lockable cabinet and marked "Do Not Use" on the outer packaging** according to established procedure. Please report the remaining quantity of expired vaccines to RVP team, and DH will collect these vaccines asap.

Vaccine Ordering

- Same as current practice for vaccine ordering via COVID-19 Vaccines Ordering System: https://covid_vac.chp.gov.hk/
- Order made after 21 Oct 2025 11:00am will be supplied with **Comirnaty JN.1** vaccine
- Different from **Spikevax JN.1** used before, **LDV syringes (instead of needles)** are required for administration of **Comirnaty JN.1**
- LDV syringe order quantity will be automatically calculated by the system based on order history, please retain the remaining syringes for future use.
- Please place vaccine orders **at least 10 calendar days** before the vaccination date.
- Vaccine will be delivered within 1 week prior to the vaccination date as far as possible
- LDV syringes will be delivered separately

Comirnaty JN.1 multidose vial (2.25 mL)

- One multidose vial (2.25 mL) contains 6 doses of **0.3 mL**
- Gently mix by **inverting vials 10 times** prior to use. Do not shake.
- Appearance after mixing: white to off-white dispersion with **no particulates** visible
- Withdraw **0.3mL** of Comirnaty JN.1 using low dead-volume (LDV) syringe
- Record appropriate date/time on the vial
- **Discard 12 hours after first puncture**

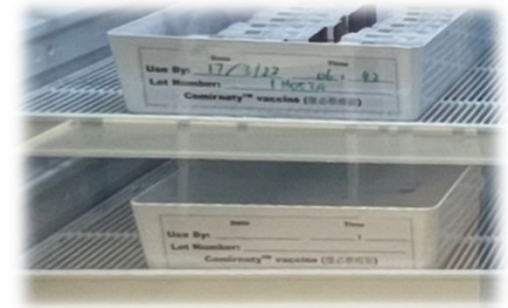


Vaccine Management – Cold Chain

- Data logger
 - Check **current, max. and min.** temperature of the refrigerator by generating a temperature log from data logger daily
- Maximum-minimum thermometer
 - record current, max. and min. temperature in the “Daily Fridge Temperature Chart” manually **3 times daily each working day**, preferably in the morning, at noon and in the afternoon
 - **Reset after each recording**
- **Min. Temperature \leq Current Temperature \leq Max. Temperature**
- Contingency plan should be in place for vaccine storage in the event of PBVR/ medical fridge storing vaccines malfunction or electricity disruptions
- Please quarantine the affected vaccines and report to PMVD immediately in case of temperature excursion (outside the recommended range of +2°C to +8°C)

Vaccine Management – Labelling

- Vaccine tray in PBVR/ Medical Fridge storing vaccine
 - Vaccine name
 - Strength (only 1 strength for RVP)
 - **Use-by date**
 - Lot number
- Vaccine vials and syringe [For multi-dose vials]
 - Vaccine name
 - **Use before date & time**
 - Lot number



Wastage reduction

- Please ensure your venue have preventive measures in place to **avoid unnecessary vaccine wastage**
 - Eg. only sufficient but not excess stocks of vaccine should be stored at your venue.
- Please only take out the required quantity of vaccines from refrigerator for preparation when required.
- The unused vial / pre-filled syringe should continue to be kept in the outer box and stored in a refrigerator (2°C to 8°C).
- PMVD will review wastage rate on various venues from time to time.

Report & collection of remaining COVID-19 vaccines

Please remind the RCH under your purview to report the remaining quantity of expired vaccines to RVP team, and DH will collect these vaccines asap.

衛生署 院舍防疫注射計劃 2019 冠狀病毒病疫苗接種計劃（新冠疫苗） 院舍庫存疫苗報告表		新冠疫苗 庫存 疫苗報告表
備註： 1. 請院舍／宿舍／學校或服務機構於 2025 年 10 月 15 日前 ，填妥並交回至衛生署項目管理及疫苗計劃科。 （傳真號碼：2713 6916（安老院舍）／2544 3922（殘疾人士院舍）；電郵地址： rvp@dh.gov.hk ） 2. 接種使用期限須參閱疫苗外盒的標籤填寫。 3. 遞交表格後，如再有改動，請即時將已更新的表格傳真或電郵至衛生署。		
甲部 院舍／宿舍／學校或服務機構資料		
名稱：_____		
編號：_____		聯絡電話：_____
乙部 可使用之新冠疫苗數量（尚未超過接種使用期限）		
疫苗名稱	莫德納 JN.1 疫苗 (預充式注射器)	
現時貯存於雪櫃的新冠疫苗數量	____ 針；批次編號：_____	____ 針；批次編號：_____
	解凍後的接種使用期限：	解凍後的接種使用期限：
	20____年____月____日	20____年____月____日
如將在 2025 年 10 月 15 日 至 11 月 5 日期間舉行疫苗接種活動		預定接種日期：2025 年____月____日

丙部 院舍庫存之新冠疫苗		
疫苗名稱	_____	_____
疫苗的「接種使用期限」	批次編號：_____ 解凍後的接種使用期限： 20____年____月____日 （____時____分）	批次編號：_____ 解凍後的接種使用期限： 20____年____月____日 （____時____分）
疫苗數量	_____針；	_____針；

本人謹此聲明，本院舍所存有的新冠疫苗（政府疫苗注射計劃提供）均已於上述表格填報。

負責院舍／宿舍／學校／服務機構的職員資料		
姓名：	職位：	院舍／宿舍／學校／服務機構蓋章
簽署：		
日期：		

End