

# Medical Material Quality Control Message

## MMQC-23-1261

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**Message Number:** MMQC-23-1261  
**Released On:** 27 October 2023  
**Message Class:** Informational  
**Material Type:** Vaccine  
**MMQC\MMI Reference:** MMQC-23-1255  
**FDA Recall Reference:**  
**ECRI Reference:**  
**DLA Reference:**  
**MFG Release Date:**

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### Subject:

UPDATE / Ordering Guidance for Fall 2023-2024 COVID-19 vaccines (Moderna, Pfizer, Novavax)

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### Reason / Information:

The US Army Medical Materiel Agency Distribution Operations Center (USAMMA DOC) in conjunction with Defense Health Agency (DHA) are providing additional ordering guidance to the previous published MMQC-23-1255, for 2023-2024 COVID vaccines, Pfizer, Moderna, and Novavax. **REASON: On 3 October 2023, the U.S. Food and Drug Administration (FDA) amended the emergency use authorization (EUA) of Novavax COVID-19 Vaccine, Adjuvanted to include the 2023-2024 formula. Defense Logistics Agency (DLA) has provided additional ordering guidance for Pfizer Pre-Filled Syringes (PFS).**

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### Disposition / Instructions:

**BACKGROUND:** On 11 September 2023, the FDA approved and authorized for EUA updated mRNA COVID-19 vaccines (2023-2024 formula) that include a monovalent (single) component that corresponds to the omicron variant XBB.1.5 of SARS-CoV-2.

On 3 October 2023, the FDA amended the EUA of Novavax COVID-19 Vaccine, Adjuvanted to include the 2023-2024 formula. The Novavax COVID-19 Vaccine, Adjuvanted, a monovalent vaccine, has been updated to include the spike protein from the SARS-CoV-2 Omicron variant lineage XBB.1.5 (2023-2024 formula). The Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) is no longer authorized for use in the United States.

Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) is authorized for use in individuals 12 years of age and older as follows:

Individuals previously vaccinated with any COVID-19 vaccine: one dose of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) is administered at least 2 months after receipt of the last previous dose of an original monovalent (Original) or bivalent (Original and Omicron BA.4/BA.5) COVID-19 vaccine.

Individuals not previously vaccinated with any COVID-19 vaccine: two doses of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) are administered three weeks apart.

Immunocompromised individuals: an additional dose of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) may be administered at least 2 months following the last dose of a COVID-19 vaccine (2023-2024 Formula). Additional doses of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances. The timing of the additional doses may be based on

the individual's clinical circumstances.

**ACTIONS NEEDED:**

- 1) Medical Treatment Facilities (MTFs) shall remove Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) Vaccine from their inventory. To minimize the risk of vaccine administration errors, MTFs shall:
  - a. Remove all the original monovalent Novavax COVID-19 Vaccine, Adjuvanted vaccines from storage units immediately, even if they are not expired.
  - b. Once all inventory is fully accounted for, delete the Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) vaccine listings from the available vaccine inventory in their Defense Medical Logistics Standard Support (DMLSS) system.
  - c. Dispose of all the Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) vaccine vials in accordance with local, state, and federal regulations.
- 2) Pfizer and Moderna Ordering: MTFs will continue to submit "HOLDING ORDERS" for Pfizer and Moderna COVID Vaccines with the Pharmacy Prime Vendor (PVP) Cencora using their normal Defense Logistics Medical Standard Support (DMLSS)/Theater Enterprise-Wide Logistics System (TEWLS) ordering process for Prime Vendor (PV) ordering by setting the source of supply (SOS) to PVP for any of the National Drug Codes (NDC) listed below.
  - a. Holding Orders shall be placed electronically, as an off-line (SUBMIT).
  - b. During product non-availability the holding orders will prevent transactions from being cancelled due to a "Fill or Kill" requirement.
  - c. Credit balances cannot be used to place Holding Orders.
  - d. DLA recommends placing Holding Order for a few more weeks until PVP stock availability is increased, and DHA Medical Logistics provides guidance to discontinue this process.
  - e. COVID-19 Vaccines are no longer be a free issue item. Please work with your financial team to ensure funding is available for the purchasing of the vaccines.
  - f. COVID-19 vaccines will not be tracked within the DMLSS Assemblage Management module.

**NOTE: MTF's should only order single dose vials (SDV) NDC 00069-2362-10, due to limited availability for PFS. If ordering PFS NDC 00069-2392-10 / Pfizer COVID vaccines via PVP your order may be rejected.**

- 3) Novavax Ordering: MTFs can place a regular routine order via the PVP. No Holding Orders required.
  - a. Vaccine will ship at 2C to 8C.
  - b. Do not freeze.
- 4) **Continental United States (CONUS) PVP Customers** will notice the following changes when ordering/receiving COVID-19 vaccines.
  - a. **MODERNA VACCINES:**
    - i. PVP will ship Moderna vaccines frozen at -20C.
    - ii. PVP will not have temperature monitoring devices in their shippers, they will be using a pre-qualified frozen (-20C) shipper.
    - iii. Store vaccine at -20C to obtain full shelf-life or store at 2C to 8C for 30 days.
    - iv. Redistributions are only recommended in a frozen/solid (-20C).

v. Minimum ordering quantity: 60 doses.

**b. PFIZER VACCINES:**

- i. PVP will ship Pfizer vaccines at refrigerated temp of 2C-8C.
- ii. When ordering note the reduced shelf-life of 10 weeks from the initial 2C-8C packaging which will be indicated by a By Use Date (BUD) Label that the PVP will adhere to the material.
- iii. No re-freezing is authorized by the customer post-receipt.
- iv. Minimum ordering quantity: Adult -10 doses / Pediatric – 30 doses presentations.

**c. NOVAVAX VACCINES:**

- i. Standard refrigerated product will move through the existing regional Distribution Centers (DCs), following the current CONUS Cold Chain Management (CCM) order and delivery process.
- ii. Standard systematic order confirmation and scheduled delivery at appropriate time.
- iii. Product will be packaged in existing Cencora reusable tote containers, utilizing the standard tote reclamation process.
- iv. Delivery will be made with existing regional contract couriers.
- v. Minimum ordering quantity will be 10 doses for PVP/Cencora orders.

5) **Outside the Continental United States (OCONUS)** PVP Customers will notice the following changes when ordering/receiving COVID-19 vaccines.

**a. SHIPPING GUIDANCE:** Cencora will be using their standard FedEx Priority Alert contract, shipping schedules, and transit times:

- i. Germany will ship on Mondays and will continue to distribute out of the supporting distribution center, Cencora Bethlehem – EUCOM OCONUS.
- ii. South Korea will ship on Fridays and will continue to distribute out of the supporting distribution, Cencora Sacramento – PACOM.
- iii. All other locations will ship on Mondays and Fridays.

**b. MODERNA VACCINES:**

- i. Product will ship in DLA's (PVP) "new" frozen (-20C) packaging, utilizing their standard shipper, with modified Utek coolant materials, and will include a Purple-labeled Sensitech TempTale (at full shelf life).
- ii. Customers will follow the same standard receiving process as all other Pharm PV Cold Chain Management (CCM) shipments.
- iii. DLA Troop Support CCM will continue to send pre-alerts emails for the first year; after that, customers will receive the PV's standard automated shipping alerts.
- iv. Minimum ordering quantity: 60 doses.

**c. PFIZER VACCINES:**

- i. Product will ship in DLA's (PVP's) standard refrigerated (2-8C) shipper, to include an Orange-labeled Sensitech TempTale (at full shelf life).
- ii. Product will be identified with a By Use Date (BUD) label affixed to the material reflecting the new 10-week shelf life (initiated at 2-8C repackaging).
- iii. Customers will follow the same standard receiving process as all other Pharm PV CCM shipments.
- iv. DLA Troop Support – CCM will continue to send pre-alerts emails for the first year; after that, customers will receive the PV's standard automated shipping alerts.
- v. Minimum ordering quantity: Adult -10 doses / Pediatric – 30 doses presentations.

**d. NOVAVAX VACCINES:**

- i. Product will ship in DLA's (PVP's) standard refrigerated (2-8C) shipper, to include an Orange-labeled Sensitech TempTale (at full shelf life)
- ii. Customers will follow the same standard receiving process as all other Pharm PV CCM shipments.
- iii. DLA Troop Support CCM will continue to send pre-alerts emails for the first year; after that, customers will receive the PV's standard automated shipping alerts

(which are in the process of being updated/streamlined).  
iv. Minimum ordering quantity: 10 doses.

- 6) Navy Fleet assets will order by placing MilStrip orders directly with DLA to utilize the Direct Vendor Delivery (DVD) program, as currently done for all other non-DLA depot stocked vaccines. The Fleet Prime Vendor program will not support COVID vaccine requirements.
- 7) Non-Pharm PV customers will be expected to order through their Theater Lead Agent for Medical Materiel (TLAMM), which is the standard SOS for most vaccines, or they may also utilize the DLA DVD program.
- 8) MTF's with questions or concerns related to the PVP Cold Chain program and/or product quality should continue to contact DLA Troop Support Cold Chain Management (CCM) program office, per the terms of the PVP contract.

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### **Item Information:**

**NSN (FSC-NIIN):** 6505-01-714-2907

**NDC:** 80777-0102-95

**Nomenclature:** COVID-19 VACCINE MRNA (MODERNA) (PF) 50MCG/0.5ML INJ,VIAL  
**UI:** CA

**Manufacturer:** MODERNA

**LOT / SN:** ALL LOTS

**NOTE:** SPIKEVAX / CARTON, 10 SINGLE-DOSE VIALS / \$863.42 per carton

**NSN (FSC-NIIN):** 6505-01-714-2889

**NDC:** 80777-0102-96

**Nomenclature:** COVID-19 VACCINE MRNA (MODERNA) (PF) 50MCG/0.5ML INJ,SYR  
**UI:** CA

**Manufacturer:** MODERNA

**LOT / SN:** ALL LOTS

**NOTE:** SPIKEVAX / CARTON, 10 PRE-FILLED SYRINGES / \$883.52 per carton

**NSN (FSC-NIIN):** 6505-01-714-2879

**NDC:** 80777-0102-93

**Nomenclature:** COVID-19 VACCINE MRNA (MODERNA) (PF) 50MCG/0.5ML INJ,SYR  
**UI:** CA

**Manufacturer:** MODERNA

**LOT / SN:** ALL LOTS

**NOTE:** SPIKEVAX / CARTON, 10 BLISTER-SEALED PRE-FILLED SYRINGES / \$883.52 per carton

**NSN (FSC-NIIN):** 6505-01-714-2852

**NDC:** 80777-0287-92

**Nomenclature:** COVID-19 VACCINE MRNA (MODERNA) (PF) 25MCG/0.25ML INJ,VI  
**UI:** CA

**Manufacturer:** MODERNA

**LOT / SN:** ALL LOTS

**NOTE:** CARTON, 10 SINGLE-DOSE VIALS / \$863.42 per carton

**NSN (FSC-NIIN):** 6505-01-714-2755

**NDC:** 00069-2362-10

**Nomenclature:** COVID-19 VACCINE MRNA (PFIZER) (PF) 30MCG/0.3ML INJ,VIL  
**UI:** CA  
**Manufacturer:** PFIZER-BIONTECH

**LOT / SN:** ALL LOTS

**NOTE 1:** COMIRNATY (COVID-19 Vaccine, mRNA, 2023-2024 Formula)

**NOTE 2:** CARTON, 10 SINGLE-DOSE VIALS / \$860.82 per carton

**NSN (FSC-NIIN):** 6505 – NS1

**NDC:** 00069-2392-10

**Nomenclature:** COVID-19 VACCINE MRNA (PFIZER) (PF) 30MCG/0.3ML INJ,VIL  
**UI:** CA

**Manufacturer:** PFIZER-BIONTECH

**LOT / SN:** ALL LOTS

**NOTE 1:** COMIRNATY (COVID-19 Vaccine, mRNA, 2023-2024 Formula)

**NOTE 2:** CARTON, 10 PRE-FILLED SYRINGES / \$898.25 per carton

**NSN (FSC-NIIN):** 6505-01-714-2782

**NDC:** 59267-4331-02

**Nomenclature:** PFIZER C19VACCINE 5YR-12YR 10X.48ML SDV  
**UI:** CA

**Manufacturer:** PFIZER-BIONTECH

**LOT / SN:** ALL LOTS

**NOTE:** CARTON, 10 SINGLE-DOSE VIALS / \$576.38 per carton

**NSN (FSC-NIIN):** 6505-01-714-2774

**NDC:** 59267-4315-02

**Nomenclature:** PFIZER C19 VACCINE 6M-<5YR 10X.48ML MDV  
**UI:** CA

**Manufacturer:** PFIZER-BIONTECH

**LOT / SN:** ALL LOTS

**NOTE:** CARTON, 10 MULTI-DOSE VIALS / \$1291.24 per carton

**NSN (FSC-NIIN):** 6505 – NS2

**NDC:** 80631-0105-02

**Nomenclature:** NOVAVAX COVID 2023-24 VL (EUA) 2.5ML  
**UI:** CA

**Manufacturer:** NOVAVAX

**LOT / SN:** ALL LOTS

**NOTE:** CARTON, 2 MULTI-DOSE VIALS / \$582.91 per carton

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### **Service/Additional Instructions:**

Screening Forms and Standing Orders are being updated.

Updated guidance for COVID-19 vaccination and myocarditis or pericarditis can be found at

<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#myocarditis-pericarditis>

Reorganization and consolidation of sections on contraindications and precautions, including allergic reactions to COVID-19 vaccines can be found at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications>

Interim Clinical Guidance can be found at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>

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## **POC Contact Information:**

### **Air Force**

**Email:** [usaf.detrick.afmoa.mbx.sgm-readiness-vaccines@mail.mil](mailto:usaf.detrick.afmoa.mbx.sgm-readiness-vaccines@mail.mil)  
**Phone (COMM):** 301-619-4183  
**Phone (DSN):** 312-343-4183  
**Fax:**

### **Army - USAMMA DOC Vaccines**

**Email:** [usarmy.detrick.usamma.mbx.vaccines@army.mil](mailto:usarmy.detrick.usamma.mbx.vaccines@army.mil)  
**Phone (COMM):** 301 619-4128/4318  
**Phone (DSN):** 343-4128/4318  
**Fax:** 301-619-4468

### **DHA 24/7 Immunization Healthcare Support Center**

**Email:** [DoDvaccines@mail.mil](mailto:DoDvaccines@mail.mil)  
**Phone (COMM):** 877-438-8222  
**Phone (DSN):** 312-761-4245  
**Fax:**

### **NAVY OR MARINES**

**Email:** [usn.detrick.navmedlogcomftdmd.list.vialhelp@mail.mil](mailto:usn.detrick.navmedlogcomftdmd.list.vialhelp@mail.mil)  
**Phone (COMM):** 301-619-8054  
**Phone (DSN):** 343-8054  
**Fax:** 301-619-2473

### **USAMMC-E**

**Email:** [usarmy.rheinland-pfalz.medcom-usammce.list.dtd-quality-assurance@mail.mil](mailto:usarmy.rheinland-pfalz.medcom-usammce.list.dtd-quality-assurance@mail.mil)  
**Phone (COMM):** 011-49-6331-86-7118/7181  
**Phone (DSN):** 495-6265  
**Fax:** 6218

### **USAMMC-K**

**Email:** [usarmy.carroll.usammc-k.list.usammc-k-customer-support@mail.mil](mailto:usarmy.carroll.usammc-k.list.usammc-k-customer-support@mail.mil)  
**Phone (COMM):** 05033374490/+821092328897  
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**Fax:** 315-737-4490

### **USCG**

**Email:** [D05-DG-HSWLSC-USCG-Pharmacy-Logs@uscg.mil](mailto:D05-DG-HSWLSC-USCG-Pharmacy-Logs@uscg.mil)  
**Phone (COMM):**  
**Phone (DSN):**  
**Fax:** 757-628-433

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## **Additional Message Recipients:**

**Please ensure dissemination of this information to the following:**

Command  
Channels  
Immunization  
Clinics Medical  
Log Officers  
Medical Staff  
Pharmacy Officers

**Message Dissemination Authorization**

AF Activities will take action as prescribed in AFMAN41-209, Medical Logistics Support, Chapter 7. For MAJCOMS & NGB – This Msg has been transmitted to all designated subordinate medical activities.

See Army Regulation (AR) 40-61, 28 January 2005, Chapter 4, and The Department of The Army Supply Bulletin (SB 8-75-11) For Applicable Policies and Procedures.

DODD 5105.22 and DODD 6025.13

COMNAVSURFPAC/COMNAVSURFLANT INSTRUCTION 6000.1. SECTION 12. Procedures for Quality Control Surveillance of the Medical Material, g. The SMDR and Pharmacy technician shall subscribe to MMQC messages to ensure all drug recall, extensions and suspensions are addressed in an expeditious manner.

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\*\*\* END OF MESSAGE \*\*\*