1. **Purpose**

This SOP describes the process for preparation of **ready to administer** 0.3mL syringes of Comirnaty Original/Omicron BA.1 COVID-19 mRNA Vaccine 15micrograms/15micrograms/0.3ml dose dispersion for injection (**Comirnaty** **Bivalent)** prior to immediate administration.

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| Different strengths / formulations of Comirnaty vaccine are available. Ensure the correct procedure is selected for the strength / formulation required. This SOP is for use with **Comirnaty Bivalent** with the following label format:        The supply of Comirnaty Bivalent Original / Omicron BA. 1 in the UK will have different carton and vial labels to the licensed product, and will carry the description “tozinameran / riltozinameran" on the carton artwork and vial label. |

1. **Scope**

This procedure covers the process from the removal of vials of thawed vaccine from the outer carton in the refrigerator, or removal of individual vials from a cool box, up until the point of administration. This includes assigning an expiry date and time after the first dose withdrawal and the preparation of syringes for administration.

This procedure may be adapted to suit either of the following models:

* One person to both draw up individual doses into syringes and administer the vaccine.
* One person to draw up individual doses into syringes and pass the syringe to a vaccinator. This model requires additional local risk assessment, and the introduction of local controls to reduce the risk of needle stick injuries on transfer between individuals.

1. **Responsibility**

Staff performing any stage of the preparation of the vaccine are responsible for following this procedure.

The responsible Pharmacist must ensure that appropriate and formal authorisation for vaccine administration is in place such as a Patient Group Direction (PGD), National Protocol, Patient Specific Direction (PSD) or other appropriate legal mechanism. In addition, the responsible Pharmacist must ensure that the staff groups who are undertaking the processes are those defined as eligible to do so.

1. **Procedure**
   1. Prepare the workstation for use:
      * + ensure the preparation workstation is clear and free from any other vials of vaccine.
        + ensure a yellow lidded sharps bin with sufficient free capacity and an indelible pen are available
        + clean workstation with a disinfectant wipe and discard into a clinical waste bin.
   2. [Insert statement on local practice for wearing of aprons and other PPE / sanitising hands / donning gloves for preparing injectable medicines]
   3. When ready to begin preparation select one vial of Comirnaty **Bivalent** vaccine.
      1. If working with vials stored in a refrigerator:

* If there is more than one batch of vaccine vials, use the one with the shortest expiry
* Check the post thaw expiry date on the carton has not been exceeded.
* Remove a single vial and close the carton.

N.B It is permissible to remove multiple vials from the refrigerator if local systems are in place to ensure segregation of punctured and unpunctured vials.

* + 1. If working with vials from a cool box at 2-8OC:
       - Check the vial is within the post-thaw expiry date by checking the label on the vial transport container. Refer to SOP HCV 6: *Use of cool boxes to transport Covid-19 vaccines to end user locations.*
       - Remove a single vial and close the lid of the cool box.
    2. Check the identity of the vial. This procedure is intended for use with the Comirnaty **Bivalent** vaccine.
       - Check the vial has a grey cap
       - Check label format on the vial selected matches the image below:

Vial label



* + 1. Assemble the following materials required to prepare syringes:
       - Comirnaty **Bivalent** vial X 1
       - 1mL syringe with integrated 23g (or finer) x 25mm needle X 6
       - Sterile single use 70% alcohol swab x 6
    2. Gently mix by inverting the vial 10 times, DO NOT shake. One inversion requires the vial to be fully rotated back to an upright position. Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
    3. Inspect the vial visually for foreign particulate matter and/or discoloration prior to administration. If particulate matter or discolouration are present, the vaccine should not be administered.

N.B. After mixing the vaccine should present as a white to off-white dispersion with no particulates visible.

* + 1. Confirm the **0.3mL** booster course dose of Comirnaty **Bivalent** is required by the patient
    2. Remove the grey vial dust cover and cleanse the vial stopper with a single use 70% alcohol swab, and discard swab in a clinical waste bin.
    3. Using aseptic technique, draw up **0.3mL** of the vaccine using a new 1mL syringe with integrated 23g or finer x 25mm needle.

N.B.

* A 21g or finer x 38mm needle and 1mL syringe should be used for administering the vaccine to morbidly obese patients.
* If using a syringe with an auto retracting needle depressing the plunger will cause the needle to retract prematurely.
  + 1. Adjust to remove air bubbles with the needle still in the vial to avoid loss of vaccine.
    2. Check volume withdrawn is **0.3mL. [May require independent 2nd check depending on local policy]**
    3. Visually inspect the syringes for foreign particulate matter and leaks. Discard if these are observed.
    4. The newly filled syringe must be used for immediate administration. **[Local risk assessment may be required to manage risk of needle stick injury when handling unsheathed needles]**
    5. After first dose withdrawal, use the vial as soon as practically possible and within 12 hours (stored at 20C to 300C). Document the expiry date and time (24-hour format, e.g. 14:00) on the vial after first use.
    6. Repeat steps 4.3.6 to 4.3.13 a further five times to produce a total of six syringes from each vial. Each time the vial bung is punctured, this should be in a different location to previous points of puncture on the bung.
    7. 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. Do not pool excess vaccine from multiple vials.
    8. Once empty, or no longer needed, immediately discard the used vaccine vial into a yellow lidded sharps bin.
  1. At the end of the session, discard any punctured vials. Punctured vials must not be stored between sessions or returned to the refrigerator.
  2. Dispose of outer cartons by defacing using permanent black marker pens, and placing in the confidential waste stream. Note: the packaging can be flattened easily. For mass vaccination centres packaging must be stored in a secure container(s) and shredded on-site.

1. **Document history**

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| **Date** | **Version** | **Section** | **Details** |
| 07/09/2022 | 1.0 | All | This is the first version published. |
| 08/09/2022 | 1.1 | 4.4  4.3.14  4.3.15 | Removed reference to lidded box  Amended temperature from 25C to 30C  Amended maximum doses to be removed from 5 to 6 |
| 20.09.2022 | 1.2 | 4.4  4.3.15 | Clarified statement relates to punctured vials  ‘Steps to be repeated’ amended as it is not necessary to invert vial between doses |
| 27.09.2022 | 1.3 | 4.3.1 | Added statement regarding removal of multiple vials from refrigerator |

1. **References**

[Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection](https://www.medicines.org.uk/emc/product/13978/smpc)

1. **Supporting Documents**

SOP HCV 6: Use of cool boxes to transport Covid-19 vaccines to end user locations.