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Medical Directors Directors of Pharmacy Directors of Nursing COVID-19 Vaccination leads Health Board Immunisation Co-ordinators

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Dear colleague,

Pfizer BioNTech COVID-19 Vaccine – Doses per Vial

Pfizer-BioNTech's approved <u>product literature</u> for the COVID vaccine states: "This (the vaccine) is a multidose vial and must be diluted before use. 1 vial (0.45 mL) contains 5 doses of 30 micrograms of BNT162b2 RNA (embedded in lipid nanoparticles)." Once diluted with 1.8 mL of saline, one vial should contain 2.0 to 2.25 mL of diluted vaccine.

However, you will be aware of the potential for a sixth full dose to be drawn. On 24 December 2020, the Medicines and Healthcare Products Regulatory Agency (MHRA) updated their published information to <u>Healthcare Professionals</u> to indicate that there may be sufficient vaccine remaining for a sixth dose in some circumstances.

The updated extract states:

'After dilution, the vial contains 5 doses of 0.3 mL. Withdraw the required 0.3 mL dose of diluted vaccine using a sterile needle and syringe and administer. Vial volume was optimized to reliably obtain 5 doses regardless of syringe type used as most syringe and needle combinations require withdrawal of excess volume in order to ensure the full 0.3 mL dose of vaccine can be administered. When low dead-volume syringes and/or needles are used, the amount remaining in the vial after 5 doses have been extracted may be sufficient for an additional (sixth) dose. Care should be taken to ensure a full 0.3 mL will be administered to the subject and that all doses from a single prepared vial are administered within 6 hours of the time of dilution. Where a full 0.3 mL dose cannot be extracted the contents should be discarded. Any unused vaccine should be discarded 6 hours after dilution.'

Drawing a sixth dose should be subject to an individual healthcare professional's judgement, on a case-by-case basis.







The manufacturer has stressed care should be taken to ensure a full 0.3 mL dose will be administered to the patient **from the same vial**. Where a full 0.3 mL dose cannot be extracted the contents should be discarded.

The vaccine does not contain a preservative so should be used as soon as practically possible, and all doses must be administered within 6 hours of the time of dilution.

Public Health England (PHE) has recently increased the volume of combined needles and syringes supplied with the vaccine to accommodate the potential for a sixth dose. 1200 combined needles and syringes will be supplied with every 975 dose pack of the Pfizer vaccine. Stocks of consumables at vaccination centres should be monitored to assure sufficient quantities remain available.

I hope this is a helpful update.

Yours sincerely,

Alison Strath Interim Chief Pharmaceutical Officer





