

COVID-19 VACCINE BULLETIN 1

Welcome to the first bulletin from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme.

Bulletins will be published every week or more frequently, if required.

6th dose from ONE vial



The National Immunisation Advisory Committee (NIAC) has recommended that, when a vaccinator can withdraw a **sixth** 0.3ml dose of Comirnaty® Pfizer/ BioNTech from a single diluted vial, this dose can be used as a viable dose in the vaccination programme.

The vial should be discarded if a full 0.3ml dose cannot be withdrawn as a 6th dose. There should be no pooling of vaccine from different vials. The Summary of Product Characteristics (SmPC) for Comirnaty® Pfizer/ BioNTech states that “one vial contains 5 doses of 0.3mL after dilution” and “After dilution the vial contains 2.25mL”.

Pfizer/BioNTech has applied to the European Medicines Agency (EMA) for an updated recommendation to approve the use of six doses per vial. This is consistent with current UK and US recommendations. NIAC understands that the EMA opinion is expected soon.

The label on the box of vaccine (the original tray or prepacked white box) will continue to have printed on it 5 doses per vial. This cannot be changed until the EMA updates the SmPC.

NIAC is currently adding this recommendation to the COVID-19 Chapter of the Immunisation Guidelines. The implementation of a 6th dose from each vial is effective from 6th January 2021.

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COVID-19 Vaccine & Pregnancy

A letter from an obstetric care giver (obstetrician or GP) is no longer required for pregnant women who are between 14 and 33 completed weeks of pregnancy who wish to receive Comirnaty® Pfizer/ BioNTech vaccine.

Pregnant women will be asked to confirm that they have consulted their obstetric care giver at the consent stage.

The Institute of Obstetrician and Gynaecologists together with the National immunisation Advisory Committee have prepared a Questions and Answers for pregnant or breastfeeding women and their doctors about COVID- 19 vaccination



[Read More](#)

Clinical Guidance Updated

A second version of the Clinical Guidance for COVID-19 Vaccination has been published to include the updates about the 6th dose and the vaccine and pregnancy, as well as additional questions on the vaccine and interactions with DNA and the vaccine and fertility.



[Read It Here](#)

Training

Over 1,800 people attended training sessions on 29th December 2020 and 6th January 2021.

At the end of this week, training modules will be available from HSELand.



Keep Up To Date

Recommendations about COVID-19 vaccine are changing as more information becomes available so please check our [website](#) for the most up to date information.

