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DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

COMIRNATY® KP.2, 30 micrograms/dose dispersion for injection in pre-filled syringe (glass) ▼
PLGB 53632/0062

Supply of Refrigerated Stock in EU approved artwork for Private Market.

Dear Healthcare Professional,

Summary: Supply to the United Kingdom of refrigerated packs of COMIRNATY® KP.2 30 mcg/dose dispersion for injection in pre-filled syringe (glass) in EU approved artwork (Cartons and syringe labels).

To ensure continuity of supply the marketing authorisation holder, BioNTech Manufacturing GmbH, has obtained approval from the MHRA to supply EU approved artwork with an EU printed package insert leaflet (PIL) to the United Kingdom (UK). This stock is expected to be on the UK market from January 2025 for private sale until depletion.

Please note: COMIRNATY® KP.2 30 mcg/dose dispersion for injection in pre-filled syringes (glass) **are delivered refrigerated at 2 °C to 8 °C, and must be stored at 2 °C to 8 °C.**

Please also note the following:

- This product is considered licensed in the United Kingdom.
- The product from the EU has the same formulation as the United Kingdom product.
- The product from the EU is manufactured according to the same manufacturing process and quality controls as the United Kingdom product.
- Please refer to the UK approved PIL supplied separately with the EU packs.

For product information please refer to https://www.medicines.org.uk/emc/product/100164

The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of COMIRNATY® KP.2 30 mcg/dose dispersion for injection in pre-filled syringe (glass) ▼.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Reporting of suspected adverse reactions

COMIRNATY® KP.2 30 mcg/dose dispersion for injection in pre-filled syringe (glass)▼ is subject to additional monitoring. This will allow quick identification of new safety information.

Please report ANY suspected adverse drug reactions (ADRs) to drugs and vaccines identified by the black triangle▼ to the MHRA through the Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason,
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle▼

Reporting forms and information can be found at https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm or via some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals. When reporting please include the vaccine brand and batch/Lot number if available.

Adverse events of concern in association with Comirnaty can also be reported to Pfizer Medical Information on 01304 616161 or via www.pfizersafetyreporting.com. Please do not report the same adverse event(s) to both systems as all reports will be shared between Pfizer and MHRA (in an anonymized form) and dual reporting will create unnecessary duplicates.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

Company contact point

If you have any questions about this letter or for more information about COMIRNATY® KP.2 30 mcg/dose dispersion for injection in pre-filled syringe (glass) ▼, please contact Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or Telephone: 01304 616161, or https://www.pfizermedicalinformation.co.uk/.

Yours faithfully,

[Signature]

Pawel Widomski
Senior Director Global Regulatory Affairs CMC
BioNTech Manufacturing GmbH