ROYAL COLLEGE OF PHYSICIANS OF IRELAND

Professor Breda Smyth
Chief Medical Officer
Department of Health
Block 1, Miesian Plaza
50 – 58, Lower Baggot Street
D02 XW14

15 November 2023

cc Dr Colette Bonner DCMO
Ms Richael Duffy Principal Officer
Ms Pauline Brady CMO Office

**Re: Recommendations for adapted Nuvaxovid vaccine: Nuvaxovid XBB.1.5**

Dear Professor Smyth,

The European Medicines Agency (EMA) has recommended authorising an adapted Nuvaxovid vaccine targeting Omicron XBB.1.5 subvariant of the SARS-CoV-2 virus on 31/10/2023. The vaccine, known as Nuvaxovid XBB.1.5, manufactured by Novavax, is authorised in adults and children aged 12 years and over.

NIAC recommends that Nuvaxovid XBB.1.5 may be offered to those aged 12 years and over with a contraindication to an mRNA vaccine, or who have chosen not to receive an mRNA vaccine. Nuvaxovid XBB.1.5 can be offered regardless of previous types of COVID-19 vaccines received. Administration in pregnancy can be considered when the benefits of vaccination outweigh the potential risks to the mother or the fetus, or when an mRNA vaccine is contraindicated or declined. [1] As per prior NIAC recommendations regarding the original Nuvaxovid vaccine, mRNA vaccines remain the preferred choice for primary and booster vaccines because of the extensive safety data and effectiveness against COVID-19. Safety and effectiveness data is more limited for Nuvaxovid due to fewer doses given. It is anticipated that the safety profile of Nuvaxovid XBB.1.5 will be similar to Nuvaxovid. Post marketing safety data for Nuvaxovid has demonstrated an acceptable safety profile, like that seen in the original clinical trials.

The original Nuvaxovid vaccine has been shown to boost SARS-CoV-2 antibody responses following primary vaccination with either Vaxzevria or Comirnaty. Additionally, data from a study in previously vaccinated adults showed that when Nuvaxovid was adapted to target another related strain, Omicron BA.5, it was able to trigger a strong immune response against this strain. While boosting

[1] https://www.rcpi.ie/Healthcare-Leadership/NIAC/Hot-topics-and-resources/Hot-topics-and-general-resources

with an XBB.1.5 adapted mRNA vaccine remains the preferred option, Nuvaxovid XBB.1.5 may be considered for those aged 12 years and over with a contraindication to an mRNA vaccine, or who have chosen not to receive another COVID-19 vaccine.

These recommendations reflect current available evidence and will be reviewed if more information becomes available.

Yours Sincerely,

**Dr Edina Moylett**
**NIAC Chair**

**Dr Sarah Geoghegan**
**NIAC Clinical Lead**

Frederick House, 19 South Frederick Street, Dublin 2, D02 X266, Ireland
t: +353 1 863 9700 f: +353 1 672 4707 e: college@rcpi.ie w: rcpi.ie

Charities Regulatory Authority Number: 20002718