ROYAL COLLEGE OF PHYSICIANS OF IRELAND

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4th September 2023

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

Re: Comirnaty Omicron XBB.1.5 COVID-19 vaccine

Dear Breda,

Thank you for your letter of 31 August 2023 regarding the EMA authorisation and the European Commission approval of the newly adapted Comirnaty Omicron XBB.1.5 vaccine.

As you are aware NIAC provided a detailed evidence review of COVID-19 epidemiology and scientific data on 17 Aug 2023 in support of a recommendation for the preferential use use of newly adapted monovalent vaccine, Comirnaty Omicron XBB.1.5 in the Autumn/Winter booster campaign.[1]

Further to the preclinical data summarised in our correspondence of 17 Aug 2023, Pfizer have released some additional pre-clinical data. It has been reported that Comirnaty Omicron XBB.1.5 generates a substantially improved antibody response against XBB related sublineages XBB.1.5, XBB.1.16 and XBB.2.3 compared to Comirnaty Omicron BA.4/BA.5 bivalent vaccine.[4] Since mid June 2023, a new SARS-CoV-2 variant, EG.5 which is of XBB descendent lineage has been increasing in predominance in Ireland. EG.5 has a growth advantage over other currently circulating variants globally. This is thought to be due to a combination of immune escape associated with a new mutation (F456L) and wanning population immunity. There is no evidence to date to suggest this variant is associated with increased disease severity compared to other currently circulating variants.[2] EG.5 has accounted for 30% of SARS-CoV-2 sequences in Ireland in the last five weeks (week 29 to 33, 2023).[3] There has been an increase in both COVID-19 case numbers and hospitalisations over this time period, however numbers still remain considerably lower than was observed in winter 2022/2023.[4] Preclinical data demonstrates that serum antibodies induced by Comirnaty Omicron XBB.1.5 vaccine also effectively neutralised EG.5.1.[5]

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A new SARS-CoV-2 variant, BA.2.86 is being tracked by the CDC and UKHSA. BA.2.86 was first identified in Israel and has since been detected in the UK, US, Denmark, Norway, Sweden, Switzerland, Thailand, Canada and South Africa.[2 6] It has not been detected in Ireland to date.[3] It is notable due to a high number of mutations. It is distinct from both its descendant BA.2 lineage, and from XBB.1.5 by 34 and 36 mutations respectively.[7] At this time there is no evidence to suggest it has been responsible for an increase in transmissions or disease severity, however as a precautionary measure, following detection of BA.2.86 in the community, the UK have brought their Autumn vaccination programme forward.[8] The CDC in their risk assessment for SARS-CoV-2 sublineage BA.2.86 opined that the newly adapted XBB-targeted vaccine will be effective at reducing severe disease and hospitalisation.[2]

In line with our correspondence dated 17 Aug 2023, NIAC continues to recommend the preferential use of newly adapted monovalent vaccine, Comirnaty Omicron XBB.1.5 when it becomes available in Ireland.[1] In the interim, bivalent mRNA COVID-19 vaccines should continue to be used. It is important to note that currently approved COVID-19 vaccines continue to provide protection against severe disease and death.[1 9] In the event of supply constraints of Comirnaty Omicron XBB.1.5, the highest-risk groups, particularly those of advanced age, should be prioritised for receipt of Comirnaty Omicron XBB.1.5 vaccine.

A clinical trial investigating the tolerability, safety and immunogenicity of Comirnaty Omicron XBB.1.5 is underway.[10] When results are available NIAC will review these clinical data and update recommendations if appropriate.

The National Immunisation Guidelines Chapter 5a will be updated to include the new recommendation regarding Comirnaty Omicron XBB.1.5 vaccine after the EMA publishes the updated Summary of Product Characteristics.

NIAC will continue to review COVID-19 epidemiology and scientific data on an ongoing basis and may update recommendations as new information becomes available.

Yours Sincerely,

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