

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

19 December 2022

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

Re: Use of Comirnaty Original/Omicron BA.4-5 bivalent vaccine in those aged 5-11 years

Dear Professor Smyth,

On 22 July 2022 NIAC [recommended a first mRNA COVID-19 booster](#) for those aged 5-11 years with immunocompromise associated with a sub optimal response to vaccines at the time of their primary or additional vaccination.

On 10 November 2022 the European Medicines Agency's Committee for Medicinal Products for Human Use extended the use of Comirnaty Original/Comirnaty Omicron BA.4-5 to children aged 5 to 11 years.

In authorising Comirnaty Original/Omicron BA.4-5 for those aged 5-11 years the vaccine safety was based on the data for a booster dose of an Omicron BA.1 adapted vaccine in individuals 18 years of age and older, as well as for a booster dose of the initially approved Comirnaty vaccine in individuals 5 years of age and older. This is acceptable as the vaccines are manufactured by the same process and contain the same total mRNA content as the monovalent paediatric formulation.

At NIAC's COVID-19 working group meeting today it was agreed that Comirnaty Original/Omicron BA.4-5 10 microgram may be used as a booster COVID-19 vaccine in those aged 5-11 years who are eligible for a booster dose.

Bivalent mRNA booster vaccines should be given to those eligible as follows:

	Age 5-11 years	Age 12-29 years	Aged 30 years and older
Bivalent BA.1 vaccines		Comirnaty Original/ Omicron BA.1 (0.3ml/30 mcg)	Comirnaty Original/ Omicron BA.1 (0.3ml/30 mcg) or Spikevax bivalent Original/Omicron BA.1 (0.5ml/50 mcg)
Bivalent BA.4-5 vaccines	Comirnaty Original/Omicron BA.4-5 (0.2ml/10mcg)	Comirnaty Original/ Omicron BA.4-5 (0.3ml/30mcg)	Comirnaty/ Omicron BA.4-5 (0.3/30mcg) or Spikevax bivalent Original/Omicron BA.4-5 (0.5ml/50mcg)

Yours sincerely,

Karina Butler
Imc 03054

Professor Karina Butler
Chair/Interim Clinical Lead NIAC