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Dear Colleague,

7th February 2023

COVID-19 vaccination programme: Children aged 6 months to 4 years

From mid-February 2023 COVID-19 vaccines will be offered to children aged 6 months to 4 years. The COVID-19 vaccine will be available for this group in CVCs across the country.

COVID-19 vaccine for children aged 6 months to 4 years

In October 2022 the European Medicines Agency (EMA) approved formulations of Comirnaty and Spikevax mRNA vaccines for use in those aged 6 months to 4 years inclusive. Children aged 6 months to 4 years in Ireland will be offered the Comirnaty COVID-19 vaccine. Paediatric formulations of Spikevax are not available in Ireland.

A primary course of COVID-19 vaccination is recommended by the National Immunisation Advisory Committee (NIAC) for those aged 6 months to 4 years with underlying conditions that place them at higher risk of severe COVID-19. The presence of an underlying condition (as listed in appendix 1) significantly increase the risk of hospitalisation and severe disease.

NIAC have also advised that the COVID-19 vaccination should be offered to all children aged 6 months to 4 years because of:

- the protection provided against severe COVID-19 infection and Multisystem Inflammatory Syndrome in Children (MIS-C, further details below) and their late consequences
- the enhanced protection vaccination gives to those who have had COVID-19 infection
- the modest protection for immunocompromised and other household contacts who are too young to be vaccinated
- the safety profile of the vaccines
- similar vaccine immunogenicity to that in older children and adolescents.

Safety, efficacy and effectiveness of the vaccine

Clinical trials show this vaccine is highly effective at prevent COVID-19 in children, with the immune response of children aged 6 months to 4 years to the recommended lower doses of the vaccines comparable to that in adolescents and young adults who received higher doses.

Though serious illness from COVID-19 is rare in this age group, they are even less likely to become seriously ill with COVID-19 if they are vaccinated. Children with certain health conditions are at higher risk of severe illness and hospitalisation if they get COVID-19. Therefore, we would be grateful if parents and guardians of children in this cohort are signposted to trusted information on this vaccine from the HSE available at <a href="https://linear.ncbi.nlm.ncb

Dosage and administration of the vaccine

Comirnaty (3 micrograms/dose) requires dilution and is administered intramuscularly as a primary course of three 0.2ml doses with an interval of three weeks between dose one and two and at least eight weeks between dose two and three.

There is currently no recommendation for additional or boosters in this age group, including those with immunocompromise.



Health and care professionals are the most trusted source of vaccine information

It is important that parents and guardians get their information from a trusted source, such as <u>hse.ie</u> or a medical professional, when making the decision to vaccinate their child.

In Ireland, health and care professionals are the most trusted source of information about vaccines. We would greatly appreciate your support in providing information to parents and guardians about the COVID-19 vaccines and encouraging COVID-19 vaccination for children aged 6 months to 4 years.

COVID-19 vaccine is also still available in CVC's for children aged 5-11 years old, and so parents with children in this age group, particularly those who would be vulnerable to severe COVID-19 disease, can be reminded that it is not too late to be vaccinated.

We have developed a number of informational resources for health and care professionals.

We ask you to familiarise yourself with the clinical guidance and FAQs to help support your work and responding to queries or concerns parents and guardians may have.

Resources available for health and care professionals

- Clinical Guidelines V46 https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinical-guidance-for-covid-19-vaccination.pdf
- FAQs
 https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/faqscovidvacc/covid19faqhcps.
 html
- SOP https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/sopsc19vaccines.htmll
- Medicine Protocol
 https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/medicineprotocolsc19v.html
- Consent information https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/consenthcpc19v.html

The HSELand programme will be available later this week from www.hseland.ie

Yours sincerely,

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Appendix 1: List of underlying health conditions that increases the risk of severe COVID-19 Taken from NIAC Chapter 5a:

Underlying condition	Very high risk	High risk
Cancer	Receiving or within 6 weeks of receiving systemic cytotoxic chemotherapy, targeted therapy, monoclonal antibodies or immunotherapies Receiving treatment or pending treatment for a haematological cancer Undergoing or within 6 weeks of surgery or radical radiotherapy for lung or head and neck cancer Advanced/ metastatic cancer	Haematological ¹ - within 5 years of treatment
		Non haematological cancer within 1 year following immunomodulating treatment All other cancers being treated (excluding hormonal treatment)
Chronic heart and vascular disease		e.g., heart failure, hypertensive cardiac disease
Chronic kidney disease	On dialysis, or eGFR less than 15 ml/min	eGFR less than30ml/min
Chronic liver disease		e.g., cirrhosis or fibrosis
Chronic neurological disease or condition	With evolving respiratory failure requiring non-invasive ventilation e.g., motor neurone disease, spinal muscular atrophy	Significantly compromised respiratory function and/or the ability to clear secretions e.g., Parkinson's disease, cerebral palsy
Chronic respiratory disease	Severe e.g., severe cystic fibrosis, severe COPD, severe pulmonary fibrosis	Other conditions e.g., stable cystic fibrosis, severe asthma (continuous or repeated use of systemic corticosteroids), moderate COPD
Diabetes	HbA1c 58mmol/mol or greater	All other diabetes (Type 1 and 2)



Immunocompromise due to disease or treatment	Severe e.g., Transplantation: - Listed for solid organ or haematopoietic stem cell transplant (HSCT) - Post solid organ transplant at any time - Post HSCT within 12 months Genetic diseases: - APECED ² - Inborn errors in the interferon pathway - Some B and T cell deficiencies Treatment e.g., - Cyclophosphamide, Rituximab, Alemtuzumab, Cladribine or Ocrelizumab in the last 6 months	Other e.g., High dose systemic steroids ³ HIV, not on treatment or CD4 count less than 200 /10 ⁶ Lfor adults
Inherited metabolic diseases	Disorders of intermediary metabolism/at risk of acute decompensation e.g., Maple Syrup Urine Disease	Disorders of intermediary metabolism not fulfilling criteria for very high risk
Intellectual disability	Down Syndrome	Intellectual disability excluding Down Syndrome
Obesity	BMI >40 Kg/m ²	BMI >35 Kg/m ²
Severe mental illness		e.g., schizophrenia, bipolar disorder, severe depression
Sickle cell disease	Sickle cell disease	

¹ Including e.g., leukaemia, lymphomas, blood dyscrasias or other malignant neoplasms affecting the bone marrow or lymphatic systems

- Adults and children ≥10kg: ≥40mg/day for more than 1 week, or ≥20mg/day for 2 weeks or longer
- Children less than 10 kg: 2mg/kg/day for 2 weeks or longer

² APECED - autoimmune polyendocrinopathy candidiasis ectodermal dystrophy

³ The following doses of prednisolone (or equivalent dose of other glucocorticoid) are likely to be immunosuppressive: