



7th December 2021

Mr Stephen Donnelly TD
Minister for Health
Department of Health
Block 1, Miesian Plaza
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Dublin 2

Via email to Private Secretary to the Minister for Health

Dear Minister

As you will be aware, on November 25th, the European Medicines Agency (EMA) recommended granting an extension of indication for the COVID-19 vaccine Comirnaty® to include its use in children aged 5 to 11 years old. The human medicines committee of the EMA concluded that the benefits of Comirnaty® in this age group outweigh the risks, particularly in those children with conditions that increase the risk of severe COVID-19. The EMA is currently conducting an evaluation of an application to extend the use of Spikevax® to children aged six to 11 years. It is anticipated a decision will be forthcoming in the next month.

I have today received advice from the National Immunisation Advisory Committee (NIAC) **strongly recommending COVID-19 vaccination for children aged 5-11 years (i) with underlying conditions (ii) living with a younger child with complex medical needs (iii) living with an immunocompromised adult.** Children who fall into these categories should receive the same priority as booster doses for those aged 16-49 years who have an underlying condition. Further, **NIAC has recommended that COVID-19 vaccination should be offered to all other children aged 5-11 years to protect them from severe disease, short and long-term consequences of infection (e.g. multisystem inflammatory syndrome in children, long COVID), as well as potential negative psychosocial and developmental impacts.** Given that this is a primary vaccination course, NIAC has advised that children aged 5-11 years should be offered vaccination with the same priority as booster doses for those aged under 40 years.

The COVID-19 vaccine Comirnaty® has been recommended by NIAC for children aged 5-11 years at a dose of 10 µg (as compared with 30 µg in those aged over 12 years) to be given as a two-dose schedule, three weeks apart. Vaccination should be deferred for a period of at least four weeks after infection with SARS-CoV-2 in children of this age group. Given the lack of data in respect of co-administration of other childhood vaccinations with the paediatric formulation of Comirnaty®, NIAC has advised, on a precautionary basis, that COVID-19 vaccine administration in this age group should be separated from other vaccines by a period of 14 days. **A third dose of Comirnaty® may be administered at least 28 days after the second dose to children aged 5-11 who are severely immunocompromised, as part of an extended vaccination schedule.**

In coming to these recommendations, NIAC considered the potential risks and benefits of vaccination, including the direct and indirect effects on health and wellbeing in this age group. Cognisance was also taken of the current epidemiological situation and the recent sharp increase in the case rates amongst children aged 5-11 years. Between November 18th and December 1st, those aged 5-12 years accounted for 20% of COVID-19 cases. Consideration was also given to global vaccine equity, and recommendations were informed by the guiding ethical principles set out in the Allocation Framework for Equitable Access to COVID-19 vaccines.



As pointed out by NIAC, the potential benefits of vaccination are most obvious for children with underlying conditions. The presence of an underlying condition in children aged 5-11 years is associated with approximately 12 times higher odds of hospitalisation and a 19 times higher odds of ICU admission. In those aged under 18 years, having multiple underlying conditions is an independent risk factor for severe COVID-19. It should be noted however, that European data indicates that 78% of hospitalised children in this age group with COVID-19 had no reported underlying medical condition. Irish data reports a broadly similar finding.

For the vast majority of children, COVID-19 is a mild self-limiting illness. As observed by NIAC, rates of hospitalisation and ICU admission are very low in children aged 5-11 years and, thankfully to date, no deaths have been recorded in this age group in Ireland. In the period November 18th to December 2nd 2021, there were 12,304 COVID-19 cases recorded in children aged 5-11 years, with 18 children (0.15%) being hospitalised. Data from ten EU/EEA countries collected during the Delta period recorded that 0.61% of children aged 5-11 years infected with SARS-CoV-2 were hospitalised. Multi-Inflammatory Syndrome in Children (MIS-C) and long-COVID are also cited as concerns by NIAC. A rare but serious disorder temporally associated with SARS-CoV-2, MIS-C has been estimated to affect 0.5%-3.1% of all paediatric patients with COVID-19. Most children affected are generally previously healthy and will recover, but 60% of children with MIS-C require ICU admission. For the majority of children who develop COVID-19, their symptoms will resolve in days or weeks but, in some, symptoms can persist for months. There is a good deal of uncertainty regarding the prevalence of long-COVID in children, and symptoms of long-COVID can be difficult to distinguish from those attributable to the indirect effects of the pandemic e.g. social isolation, school closures. UK data estimates the prevalence of long-COVID for those aged 2-11 years to be 0.2%.

As NIAC note, vaccination against COVID-19 in all children aged 5-11 years, irrespective of health status, could reduce the burden of the disease in this age group. Moreover, ensuring that adults are fully vaccinated will also serve to protect unvaccinated younger children from SARS-CoV-2 infection. As recommended by NIAC, efforts will need to be made to minimise any adverse impact of offering COVID-19 vaccination to children on routine primary childhood and school immunisation programmes. While not the primary consideration for NIAC in coming to these recommendations, it is noted that modelling data from the European Centre for Disease Prevention and Control (ECDC) indicates that vaccinating children aged 5-11 years could reduce the effective reproduction number by approximately 15% at most in a scenario where adult and child vaccination coverage were above 85% and 50-70% respectively.

In the current advice, NIAC detail the safety, immunogenicity and efficacy of lower dose Comirnaty®. The safety of the vaccine was studied in approximately 3,100 children aged 5-11 years. The safety profile was similar to that documented in older age groups who received the higher dose. The majority of side effects experienced by children were mild or moderate and resolved within one to three days of vaccination. More than four million first doses and approximately 450,000 second doses of Comirnaty® have been administered to 5-11-year-olds in the US with no immediate safety issues being identified, although the period of follow up has been limited. No cases of myocarditis or pericarditis were observed in the clinical trial in children aged 5-11 years, however due to the number of trial participants, very rare side effects may not have been detected. Cases of myocarditis/pericarditis following vaccination with COVID-19 mRNA vaccines occur most commonly in adolescents and young adults (12-30 years), more often after the second dose, more often in males than females and more often with Spikevax® than Comirnaty®. The EMA has evaluated the occurrence of vaccine associated myocarditis as very rare, i.e. up to ten in 10,000 vaccinated people may be affected. Preliminary data from the US and Israel where limited numbers of 5-11-year-olds have already received Comirnaty® indicate the incidence of myocarditis may be lower in this age group as compared to those aged 12-15 years. Available data indicate most individuals affected have responded well to conservative treatment and have recovered quickly.



Clinical trial data demonstrate a comparable immune response to Comirnaty© given at a lower dose in 5-11-year-olds to that seen with the higher dose in 16- to 25-year-olds (as measured by the level of antibodies against SARS-CoV-2). The efficacy of Comirnaty© was calculated in almost 2,000 children from 5 to 11 years of age who had no sign of previous infection and vaccine efficacy against symptomatic disease was 90.7%. It should be noted that the safety and efficacy of COVID-19 vaccines in both children and adults continues to be monitored closely through the EU pharmacovigilance system.

As recommended by NIAC, it is essential that parents/guardians are informed of the benefits and risks of COVID-19 vaccination in this age group and are made aware of the current knowledge gaps in order to assist them to make a decision in the best interests of their child. In line with the Convention on the Rights of the Child, children should be involved in the decision-making process in a manner commensurate with their age and level of maturity and understanding. There will be a requirement for the HSE to prepare age-appropriate information to assist parents and guardians in coming to an informed decision as part of the consent process for receiving a COVID-19 vaccine.

I am endorsing the NIAC recommendations and note that they are in conformity with the recommendations made by the ECDC in the technical report published on December 1st in respect of COVID-19 vaccination of children aged 5-11 years. Notwithstanding the very low individual risk for children aged 5-11 years of developing severe COVID-19, given the current epidemiological situation increasing case numbers in this age group will likely lead to an increase in absolute numbers of children who will experience severe disease and longer-term sequelae. This is particularly concerning in light of the emergence of the Omicron variant which carries mutations similar to changes seen in previous variants of concern associated with enhanced transmissibility. As for those children and young persons aged 12-15 years, every effort should be made to support parents and children aged 4-15 in coming forward for vaccination such that uptake in this group can be maximised.

Yours sincerely

Dr Tony Holohan
Chief Medical Officer

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