An Roinn Sláinte
Department of Health
Office of the Chief Medical Officer

18th February 2022

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 July 26th, 2021 I received advice from the National Immunisation Advisory Committee (NIAC) recommending primary vaccination of children and young people (CYP) aged 12-15 years. The programme commenced in August 2021 and, to date, 71% of this age group have received two doses of the mRNA vaccine Comirnaty®. In the interim, evidence of waning of vaccine-induced immunity, as well as the emergence of the highly transmissible, more immune evasive variant Omicron, has eroded some of the benefits afforded by primary vaccination.

I have today received further advice from NIAC in respect of booster doses for this age group (see enclosed). In order to mitigate any potential loss in the level of vaccine-induced protection due to immune escape, and to reduce the risk of infection with its direct and indirect consequences, **NIAC has recommended a booster dose for those aged 12-15 years who have underlying medical conditions, those living with a younger child with complex medical needs, or with an immunocompromised adult**. While recognising that the evidence for the need for a booster for protection against severe disease is less compelling in respect of healthy CYPs, **NIAC has recommended that a booster dose should be offered to all CYP aged 12-15 years** on the basis of the favourable risk-benefit profile of the vaccine; waning immunity conferred by primary vaccination; reduction of risk of infection and its consequences including illness and psycho-social impacts. It is also noted by NIAC that reduction of overall infection rates could impact on the emergence of new variants of concern. A booster dose of the mRNA vaccine Comirnaty® (30µg) should be given at an interval of six months or longer since completion of the primary vaccine series. For those CYP who have experienced a breakthrough infection, the booster dose should be deferred for at least six months following the onset of infection.

In coming to its recommendations, NIAC considered several factors, including the direct and indirect benefits and risks of booster vaccination for those aged 12-15 years, the risks of breakthrough infection, the short- and long-term side effects of infection, as well as broader population benefits and the principle of equity. For most, CYP (breakthrough) infection with SARS-CoV-2 results in mild disease but it can be more severe in those with an underlying condition. Data from the US indicates that of those aged 12-17 years hospitalised as a result of COVID-19, 71% had at least one underlying health condition, with the number of conditions being associated with an increased risk of ICU admission and death. While Omicron infection appears to result in less severe disease than that elicited by the Delta variant, there have been 260 CYP aged 12-15 years hospitalised, six admitted to ICU and, thankfully, no deaths in this age group during the period 19th December 2021 to 9th February 2022, when Omicron was the predominant variant circulating. It is worth noting that of the 20 admissions to ICU of young people aged under 18 years between 1st January and 16th February 2022, 17 were unvaccinated. Additional data are needly to fully determine the disease severity caused by infection with Omicron in CYP.

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Children and adolescents infected with SARS-CoV-2 are at risk of multisystem inflammatory syndrome in children (MIS-C), a rare but serious condition that can occur in the weeks following infection. There have been 15 such admissions to ICU of CYP aged 10-15 years in Ireland during the period January 2020 to February 2022. There is insufficient evidence at the current time to estimate the risk of MIS-C following breakthrough infection with micron. Vaccination has been shown to have a significant protective effect against MIS-C; surveillance data from the US reported a vaccine effectiveness (VE) of 91% Comirnaty® in adolescents aged 12-18 years against MIS-C. While evidence is limited in CYP, SARS-CoV-2 infection may also lead to long-COVID, albeit evidence suggests the risk is lower in CYP compared to older age groups, and available data pre-date the emergence of Omicron. In a recent review by the UK Health Security Agency, it was reported that adults who were fully vaccinated were less likely to develop long-COVID compared to those who remained unvaccinated, and that vaccination of those with long-COVID reduced COVID symptoms. There are also preliminary reports from the US that those aged 18 years and younger are up to 2.5 times more likely to be diagnosed with diabetes 30 days or more following SARS-CoV-2 infection. In its advice, NIAC also note that CYP are also at risk of collateral harm from infection due to educational and social disruption which can negatively impact on the mental and physical well-being of this group.

Data regarding duration of protection provided by vaccination against SARS-CoV-2 infection in CYP has recently emerged, indicating waning similar to that seen in adults, albeit that they are starting from a higher baseline as mRNA vaccines are generally more immunogenic in adolescents than in adults. An Israeli study has documented VE of 85% and 90% against infection and symptomatic disease respectively in 12–16-year-olds up to three months after vaccination. This decreases to 75% (infection) 78% (symptomatic disease) 3-5 months after vaccination and further declines to 58% and 65% respectively after five months. There is very little evidence on the duration of protection in CYP against severe outcomes e.g. hospitalisation, however, it is reasonable to assume that as observed for adults, it will be more durable than against infection. Real-world data from the US indicates vaccination of those aged 12 to 18 years reduces the risk of hospitalisation from COVID by 94%, while unvaccinated CYP aged 12-17 years have a 10-fold higher risk of being hospitalised than those who are vaccinated. As NIAC note, these data relate largely to the Delta period and VE against symptomatic disease and, to a lesser extent against severe disease, is reduced against Omicron, compared to previous variants of concern. Moreover, there is limited data available on VE against Omicron for those aged 12-15 years, but it is reasonable to infer from the adult data that it is reduced compared to Delta.

In adults, a booster dose with an mRNA vaccine significantly improves protection against severe outcomes, symptomatic diseases and infection from Omicron, although this increase in protection is less than that observed against Delta. In the US, three doses of an mRNA vaccine were necessary to achieve the same level of VE against Omicron as that seen after two doses against Delta and Alpha infection. Notwithstanding that, NIAC observe that VE against symptomatic infection and hospitalisation was restored to 60-75% and 90% respectively, two to four weeks after administration of a booster in the adult population. Data from Denmark also indicates that those who had received a booster were less likely to transmit the virus (both Delta and Omicron) than those who had received two doses of vaccine. It remains unclear how long this protection will persist, and emerging evidence suggests a waning in the effectiveness of the booster dose after three months, at least in respect of infection and possibly also symptomatic disease.

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Evidence from Israel's booster programme with Comirnaty® shows a significant reduction in the confirmed rate of infection in CYP aged 12-15 years following the booster dose compared to those of the same age who were vaccinated with the primary series five to six months earlier. There are currently no data available on the effectiveness of booster doses against severe outcomes in CYP, however NIAC consider it reasonable to assume that prevention of infection, which has been documented will, in turn, mitigate the immediate and more long-term negative effects of COVID-19.

No safety concerns have been noted following booster doses in the adult population beyond those documented after the primary series. In Israel and the US, the rates of myocarditis/pericarditis following a booster dose are generally lower than post dose two of the primary vaccination series. Safety data on COVID-19 booster doses for CYP are much more limited. For the primary series, adolescents aged 12-17 years of age are among the age groups with the highest risk for the very rare event of myocarditis/pericarditis, although it does appear that risk is lower in 12–15-year-olds compared to older adolescents. Most cases are of short duration and resolve with treatment. In the US, approximately 2.8 million CYP aged 12-17 years have received a booster dose of Comirnaty® with no new safety signals emerging. In data reported by the Centers for Disease Control in the US, boosters were associated with self-limiting side effects which were generally mild to moderate. In young adults aged 16-24 years, side effects were more commonly reported after the second dose compared to the first and were less common after a booster dose than a second dose.

As noted by NIAC, a number of other countries including Austria, France, Germany, Hungary, Italy, Lichtenstein, Luxembourg, Romania and the US have recommended boosters for CYP aged 12-17 years. Canada and the UK have recommended boosters only for those aged 12-17 years in a risk group, while Denmark has recently announced that it will not offer boosters to this age group due to the high levels of vaccine and infection-acquired immunity in the population.

I am endorsing the NIAC recommendations as detailed above. I would note that while primary vaccination with the mRNA vaccines has been authorised by the European Medicines Agency, no such authorisation exists for this age group in respect of a booster dose. An application to authorise Comirnaty® as a booster for adolescents from 12 years of age is currently being assessed by the EMA. In the context of such off-label use, special attention needs to be paid to the provision of supporting information as part of the informed consent process for CYP and their parents/guardians.

The recommendations will be updated as required, based on any further NIAC advice.

Yours sincerely

Dr Tony Holohan
Chief Medical Officer

Designated Public Official under Regulation of Lobbying Act 2015

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