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

26th July 2021

Mr Stephen Donnelly TD
Minister for Health
Department of Health
Block 1, Miesian Plaza
50-58 Lower Baggot Street
Dublin 2

Via email to Private Secretary to the Minister for Health

Dear Minister

I am writing to apprise you of a number of recommendations (see enclosed) I received today from the National Immunisation Advisory Committee (NIAC) regarding the vaccination of children and young people (CYP) aged 12-15 years. In coming to their recommendations, NIAC considered several factors including the benefits and risks to this age group of receiving a COVID-19 vaccine, the short and longer-term impacts of SARS-CoV-2 infection on CYP in this age cohort, national and global equity considerations, as well as the voice of CYP themselves and their parents.

Since mid-June, COVID-19 infection rates have been increasing in younger people, and NIAC note that in the two-week period 7th -20th July 2021, 17.2% of confirmed COVID-19 cases were in CYP aged 13-18 years. As more adults are vaccinated, this will create selective pressure driving the disease into younger unvaccinated populations. SARS-CoV-2 infections in those aged 12-15 years are usually asymptomatic or mild. Hospitalisation rates, rates of ICU admission are very low; COVID-19 related death is rare. NIAC report that hospitalisation rates amongst those aged 0-19 years in Ireland is 1/100,000, while paediatric ICU admission is extremely rare for this age cohort, with less than five admissions recorded to date. There have been no deaths recorded from COVID-19 in this age group.

The low rates of hospitalisation and severe COVID-19 in children and adolescents reported in Ireland is consistent with international experience. Those CYP who are hospitalised because of COVID-19 are more likely to have an underlying chronic medical condition, and the existence of comorbidities has been associated with a significantly increased likelihood of more severe disease compared with their infected peers without a comorbidity. Moreover, NIAC observe that the predicted probability of hospitalisation for CYP aged 12-15 years with comorbidities is at least as high as that for people without an underlying condition in some adult age groups. There are several broad diagnostic categories identified as risk factors for more severe disease, but because of the small numbers of cases with a specific condition, it remains uncertain which conditions carry the greatest risk of adverse outcomes.

NIAC also describe other potential risk factors for CYP as a result of COVID-19 including Multisystem Inflammatory Syndrome in Children (MIS-C) and long-COVID. MIS-C is a rare but serious inflammatory disorder related to prior SARS-CoV-2 infection, with most cases occurring in children aged one to 14 years. NIAC point out that while there is no consensus regarding the frequency of long COVID in CYP, it does appear to be less than in adults, but for some CYP it can take many months to return to their pre-COVID health status. NIAC also note the significant psycho-social impact the pandemic has had on CYP, with increasing rates of anxiety and suicide ideation documented in this age group, as well as decreased educational and social opportunities.

To date, two mRNA vaccines have been approved by the European Medicines Agency (EMA) for use in CYP. In clinical trials of CYP aged 12-15 years in the case Comirnaty® and 12-17 years for Spikevax®, the point estimate for efficacy of both vaccines was reported as 100% in these age groups. Reactogenicity occurred at a slightly higher frequency in these age groups compared to adults, but side

effects from the vaccine were similar to those experienced by adults e.g. injection site pain, fatigue, headache. The clinical trials involved approximately 4,700 CYP and NIAC note that given the small numbers, these studies did not allow for the detection of rare or very rare side effects.

On 9th July 2021, the EMA recommended that myocarditis and pericarditis be added to the product information of Comirnaty® and Spikevax® as very rare adverse reactions. Data on the incidence of these events in younger people are currently limited and the longer-term health effects from myocarditis events are not well understood. The reported outcomes to date have indicated that the event is self-limited, associated with short in hospital stay and no deaths. NIAC notes that the EMA has concluded that the benefits of Comirnaty® and Spikevax® in CYP outweigh the risks, in particular in those with conditions that increase the risk of severe COVID-19. As noted by NIAC, there is a diversity of approaches being adopted by other countries, with some such as the UK, Belgium, Norway and Sweden opting to vaccinate those aged 12 and older at higher risk only, while Canada, the USA, The Netherlands, Austria, France and Denmark are offering COVID-19 vaccine to all CYP aged 12 and older.

The views of CYP and their parents toward COVID-19 vaccination were also explored in coming to the current NIAC recommendations. Amongst CYP, there was broad support for making vaccines available to their age group, the principal benefit perceived as being the protection that vaccination might afford to others around them. Parents were understandably eager to make the right choice for their children and felt they were best placed to do so. They wanted their decision regarding COVID-19 vaccination to be respected and that there should be no segregation/stigmatisation of children based on vaccination status.

Taking account of the increasing case numbers in this age group and the direct and indirect benefits of COVID-19 vaccination to CYP aged 12-15 years, both in terms of reducing the risk of severe disease and of maintaining access to educational opportunities and facilitating psycho-social development, **NIAC has recommended that <u>all</u> CYP aged 12-15 years should be offered an mRNA vaccine to protect themselves from frequent mild or very rare severe COVID-19 and its consequences (e.g. long-COVID, MIS-C). NIAC state that the decision to accept, refuse or defer vaccination should be respected. Further, NIAC is strongly encouraging those with underlying medical conditions, those living with a younger child with complex medical needs, or with an immunocompromised adult to accept vaccination at the earliest opportunity.**

I am endorsing the recommendations as set out above. Subject to logistical considerations, vaccination of this cohort should optimally be initiated prior to the new academic year commencing in September. Every effort should be made by the HSE to ensure that there is equitable access to authorised mRNA vaccines for this age group. There will be a requirement for the HSE to prepare age-appropriate information to assist CYP and their parents/guardians in coming to an informed decision as part of the consent process for receiving a COVID-19 vaccine. It will be important that parents/guardians and their children understand the ongoing need for non-pharmaceutical measures irrespective of vaccination in this age group. Reflecting the wishes of the parents whose views were sought in coming to these recommendations, there be no exclusion or stigmatisation of CYP based on vaccination status.

Separately, I have recently received advice from NIAC in relation to the potential requirements of COVID-19 booster vaccinations. The NIAC has provisionally identified the following priority groups to be considered for booster doses, following completion of the primary COVID-19 vaccination programme across all eligible age cohorts:

• Those aged 16 years and older with medical conditions associated with a suboptimal response to vaccines (as listed in Table 5a.2 of Chapter 5a)
• Residents of long-term care facilities aged 65 and older

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• Those aged 80 years and older
• Frontline healthcare workers.

It is the view of NIAC that ideally these groups should receive an mRNA vaccine which could be co-administered with the seasonal flu vaccine. Once completed, the next groups to be considered for booster doses would be those aged 60-79 years and those aged 16 years and older with a medical condition associated with very high risk or high risk of severe COVID-19 disease. It should be noted that these are preliminary proposals only from NIAC, which will be updated as more information becomes available over the coming weeks, including on disease epidemiology, clinical data on authorised COVID-19 vaccines, and information regarding homologous and heterologous booster vaccine schedules.

The Department of Health has previously written to the HSE to request its plan for autumn/winter immunisation programmes, to include COVID-19 boosters, influenza vaccines and both a catch-up programme and ongoing administration of the schools' immunisation programme. Further to this latest advice from NIAC on a booster programme, and subject to your approval, the Department will issue a letter to the HSE asking it to incorporate this advice into its ongoing preparations for the implementation of such a programme this Autumn.

Finally, as you are aware, I have previously received advice from NIAC with regard to heterologous vaccination and the Department has been liaising with the HPRA in this regard. The Department has today received correspondence from the HPRA in relation to this matter and further advice will be provided to you on this in the coming days.

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

Yours sincerely

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Dr Tony Holohan
Chief Medical Officer

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