Open letter to JCVI 19th August 2021

Dear Professor Lim and colleagues,

As you know, a group of 60 British doctors and scientists wrote to the MHRA in May with a copy to members of the JCVI, expressing our concerns about the potential rollout of COVID-19 vaccines to children, despite their extremely low vulnerability to this disease. The MHRA failed to reply within their agreed time-frame, only to reply 2 hours after their extension of Pfizer's emergency use authorisation down to 12-15 year-olds. We sent supplementary questions to them in June, again with a copy to you.

The JCVI's initial statement on 19th July, that 'any decision on deployment of vaccines must be made on the basis that the benefits of vaccination outweigh the risks to those people who are vaccinated' was welcomed, placing the safety of the young in a primary position and drawing attention to 'rare but serious adverse events': based on a balanced view of the available evidence, they stated clearly that 'the health benefits in this population are small, and the benefits to the wider population are highly uncertain. At this time, JCVI is of the view that the health benefits of universal vaccination in children and young people below the age of 18 years do not outweigh the potential risks'. The guidance that children at particularly high risk from COVID-19, such that the benefit was likely to outweigh any risks, would be offered vaccination, seemed a logical position, similar to that already covered under compassionate grounds in the previous JCVI guidance.

We were therefore extremely puzzled when two weeks later, new guidance was issued for the rollout to include healthy 16-17 year-olds but with no new data presented to explain this change in guidance. The adult Pfizer trial has recently published its 6 month follow-up which was reported as showing no new cases of myocarditis, but given that only 537 in the vaccinated arm of the trial came within the age bracket of 16-25 (the group identified as at highest risk), this negative trial report is of no relevance to the safety of the vaccine in young people. We note that the Israeli data show a myocarditis risk to young men aged 20-24 after the 2nd dose of Pfizer at 1 in 10,463, rising to 1 in 6,230 for 16-19s. It is therefore particularly concerning that while the 16-17s are only being offered one dose in the first instance (presumably out of concern for this risk), all 18-25s are continuing to be offered a second dose. A recent report of 63 cases of vaccination-associated myocarditis in under 21s from the US, showed significant abnormalities on Cardiac Magnetic Resonance imaging, noted to be more severe than that seen previously in children with MISC-C. There is no long-term follow-up available on these children. All the above concerns apply equally to the Moderna vaccine, now also given emergency use authorisation for 12-17 year-olds.

We have focussed here on the myocarditis risk, but there are also reports of microvascular clotting following mRNA vaccines, raising the possibility of pulmonary hypertension in future and no long-term safety data, regarding autoimmune disease, carcinogenesis and any possible effects on future fertility.

We are also concerned that the new guidance mentioned consideration of the mental health and educational impacts of COVID-19 and also of mathematical models of the impact of COVID-19 vaccination on the epidemiology of the pandemic. Vaccines are not required to prevent the educational disruption of school closures and/or isolation of healthy contacts, measures which have already been safely discontinued. Since the new guidance was published on 4th August, data has been published by both PHE and the CDC showing that viral loads / transmission rates are similar between vaccinated or unvaccinated individuals, making any consideration of societal benefits not only unethical but fruitless. The latest ONS data also suggests that 80% of 16-24 year-olds already have antibodies to Sars-CoV-2, obviating the need for any vaccination of these healthy young people.

We have grave concerns over the deviation from the long-accepted requirement for fully informed consent, the rollout to 16 and 17s commencing within days of the new statement, before the teenagers or their parents have had time to look at any information. We are not aware of any new leaflets on the NHS website pointing out the risks for this age-group. Much of the messaging focuses around protecting family and friends and helping get life back to normal and vaccination in schools will add to peer pressure. Celebrities are being used to promote vaccination, combined with the plans

for full vaccination requirements for night clubs by the end of next month and with offers of free Uber rides, holiday vouchers and more. Indeed it is hard to see how this is compliant with the legal requirement of fully informed consent, given without coercion or inducement.

Our final concern is around the issue of vaccination of 12-15 year-olds. Recruitment is already taking place for immunisation school nurses across the country and already immunisation dates are being posted in school calendars. But none of this alters the fact that these children are at extremely low risk from COVID-19, they are not drivers of infection and PHE and CDC have confirmed that vaccination does not prevent transmission so is irrelevant to protecting society as a whole or for preventing educational disruption.

The following questions require urgent replies:

- What additional information has led the JCVI to change their advice for 16-17s?
- What is the estimated risk posed by COVID-19 and the absolute risk reduction/benefit from vaccination, including calculations taking into account existing immunity in this cohort?
- What is the estimated risk of myocarditis and of other serious adverse events including microvascular coagulation?
- What studies have been considered, regarding potential effects on fertility?
- What advice is being given to families where vaccination is advised to protect an immunocompromised household member, to mitigate against the known increase in infection in the first two weeks post-vaccination?
- What efforts are being made to publicise full age-appropriate information of risks as well as benefits?
- What efforts are being made to counter inappropriate advertising and inducement which undermines the process and ethics of informed consent?
- How will you ensure that vaccination of children remains voluntary with no requirement to use vaccine certification to access any services or events?
- What plans will be put in place for full post-marketing surveillance for side-effects, such as providing a prepaid card to be returned at 30 days from every vaccine recipient, recording all symptoms and illnesses experienced post-vaccination?
- Why was the change in advice for 16 & 17s made so quickly, with no time for significant new data to acrue? Were broader political, social or psychological factors considered?
- Will there be a sample of 16–17 year-olds who will be invited to have blood tests before and after vaccination to include platelet count, D-dimers & troponin levels to monitor for incidence of microvascular clotting and myocarditis?
- When will a decision be taken about extending the vaccine rollout to 12-15 year-olds and what criteria will be used to make that decision?

Yours sincerely,

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