

Dr June Raine,
MHRA Chief Executive

6th June 2021

Dear Professor Raine,

Re safety of COVID-19 vaccines for children

Many thanks for your reply to our letter received yesterday after the approval had gone ahead. We are all extremely disappointed by this decision and indeed very puzzled by the statement it makes, regarding both safety and efficacy.

The Pfizer trial which you kindly linked, has 1134 children given the vaccine and 2 months follow-up. **How does this equate to 'rigorous' assessment of safety in this age group?** The introduction states that "adolescents may play an important role in SARS-CoV-2 transmission. Thus, their vaccination may prevent disease and contribute to herd immunity." Immediate systemic side effects such as fever and 'chills' appear to be more common in the younger cohorts and it is certainly possible that more serious side effects will have the same propensity to affect the young. There was three severe and one life-threatening event reported in the trial arm (three children had pulmonary emboli, extremely rare in general paediatric practice), obviously not sufficient to reach statistical significance in this very small study, but if rolled out to 5 million children, could result in 5000 children suffering significant harm.

Have these events been included in your review of safety, if not why not?

You also appear to have ignored the post-marketing reports from Israel and US of myocarditis now described by the Israeli health authority as 1 in 44,000 16-30 year-olds, but with higher incidence in the youngest groups.

What calculations of the risk of myocarditis have you included?

Similarly, in terms of rigorous post marketing surveillance, it took several months for the MHRA to withdraw AstraZeneca for <40s in spite of warnings, and only after significant numbers of healthy young adults had suffered from cerebral venous strokes, some fatal. Again, your own website states that the incidence of VITT is 1 in 77,000 but with higher rates in the younger age groups. **Why have you not published the data delineated by age band so that young adults can make properly informed choices?**

We know from the VAERS reporting system that some young adolescents in the US have already died shortly after vaccination. In the UK healthy children are not dying of COVID-19, so even a handful of deaths following the vaccine would be a travesty of 'First do no Harm'.

How have these been factored into your deliberations?

Have you seen pharmacokinetic animal studies for Pfizer showing concentration in liver, spleen and ovaries?

Have you seen any data which can predict the quantity of spike protein produced by individuals following a specified dose of mRNA?

What potential long term side effects have been considered?

In terms of efficacy, it is not surprising that children have good immune responses but, of course, they could safely obtain even broader immunity from naturally acquired infection. Positive PCR tests in children are only clinically meaningful if they result in hospitalisations or deaths, as opposed to asymptomatic infection or mild symptoms. From the data already known about the rarity of hospitalisations or deaths from SARS-CoV-2 in children, the numbers

needed to treat/vaccinate (NNT) to prevent one significant clinical outcome would be huge, putting all those vaccinated at risk from known and unknown short and long-term harm from the vaccine, with no direct benefit. We believe the numbers harmed would far exceed the numbers who would benefit. **What NNT have you used in your calculations?**

Further, you state in your letter that subjects in clinical trials will continue to be monitored for long-term protection and safety for two years after vaccination. If serious, long-term health impacts emerge, it will be too late for those who are vaccinated now, who will have to live with the consequences. This is not responsible medicine and is a reckless approach to children's health.

How will you ensure that the children's placebo group do not receive the vaccine as has occurred with the adult trials, thus nullifying the long term RCT follow-up?

Why are you not recommending waiting for this long-term safety data before granting the emergency authorisation?

We understand that a decision on the full rollout will lie with the JCVI and/or the Prime Minister but we have already seen 16 & 17 year-olds in greater Manchester being offered vaccination which was licenced but not recommended by either the JCVI or indeed the RCPCH, and talk of extending the rollout to infants and primary school children in the near future. If local health authorities roll this out to adolescents against JCVI or RCPCH advice, then the responsibility for any harm done to children receiving it will clearly rest with the MHRA alone.

How have you arranged indemnity for any children harmed by the vaccine?

How will they be compensated for injury or death and what figure is considered to be appropriate?

Given that children are not seriously impacted by COVID-19, and there has never been an emergency situation regarding children's health relating to SARS-Cov-2 infection, how have you defined 'Emergency' for the purposes of this authorisation?

We the undersigned doctors and biomedical scientists strongly urge you to revoke this decision, as you risk being responsible for a wholly avoidable, unnecessary, and unforgivable act of iatrogenic harm to the children of the UK..

In view of the critical urgency of this, we require answers to all of the above questions within 48 hours.

Yours sincerely,

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.....and 30 others