Dr June Raine, CEO, MHRA 10 South Collonade, Canary Wharf, LONDON E14 4PU

23rd August 2021

Dear Dr Raine,

Re safety of COVID-19 vaccines in children

Thank you for your letter of 20th August in reply to our letter of 6th June. We had requested this information as a matter of urgency so are dismayed that even now, after a 10-week delay, you have provided no data to support the statements made. Our questions were very specific and I will reiterate them below.

Your statement that the benefit / risk balance for 12-15s is 'similar' to that for 16-24s, is particularly puzzling, given the death rate increases progressively with increasing age yet it appears that the correlation with age is in the reverse direction for adverse events, particularly myocarditis. From ONS data between 1st April 2020 and 31st July 2021 ie including 2 winter peaks of infections, there were precisely 4 deaths in the 0-9s, 9 deaths for 10-14s, 22 deaths in 15-19s and 55 deaths in 20-24s. Thus, the potential benefit for the younger age groups cannot be the same even when compared with young adults. Conversely data from the CDC and from Israel confirm that myocarditis risk is highest in the youngest age groups.

We must therefore ask again for the data you have used to be made public as a matter of urgency.

These questions from our 6th June letter have not been answered.

What calculations of the risk of myocarditis have you included?

Why have you not published the data delineated by age band so that young adults can make properly informed choices?

How have deaths in 12-17 year-olds from VAER been factored into your deliberations?

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?

What NNT have you used in your calculations?

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?

Yours sincerely,

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