7 June 2021

URGENT Open Letter from the UK Medical Freedom Alliance to the Medicines and Healthcare products Regulatory Agency (MHRA)

- **Dr June Raine CBE – Chief Executive Officer**
- **Mr Stephen Lightfoot – Chair**
- **Professor David Webb – Deputy Chair**

Re: Covid-19 Vaccination in Children – Emergency Use Authorisation and Rollout in Schools

The UK Medical Freedom Alliance (UKMFA) is an alliance of UK medical professionals, scientists and lawyers campaigning for Medical Freedom, Informed Consent and Bodily Autonomy to be preserved and protected.

It is with the gravest of concern and utter incredulity that we assimilate the decision by the MHRA to grant regulatory approval for emergency use of the Pfizer-BioNTech Covid-19 vaccine in 12- to 15-year-old children[i]. **We wish to notify you of the multiple factors indicating that most likely your decision will have devastating consequences for a significant number of children in the UK and their families**.
We are adding our voice to doctors and experts around the world, including groups in the UK[ii] [iii], US[iv] [v] and Israel[vi], who have raised serious ethical and safety concerns, and demanded that Covid-19 vaccines are not rolled out to children.

We previously outlined our arguments against giving Covid-19 vaccines to children in an Open Letter to the MHRA, JVCI and Government Ministers, dated 25 February 2021[vii]. Considering new and mounting evidence of harm caused by Covid-19 vaccines, we wish to urgently re-enforce our appeal to reverse this latest decision immediately and halt all plans in relation to administration of Covid-19 vaccines to children.

Ethical and Safety Concerns

1. In the UK, **evidence-based medicine** has been the basis of all clinical practice. Medical professionals are educated to critically appraise scientific evidence and ensure recommendations and guidelines rest on robust foundations. The implementation of the Covid-19 vaccination program is in complete incongruence with this concept, and this has never been more obvious than in relation to young people and children.

   Rather than referring to peer-reviewed science, recommendations have been based only on interim analyses of clinical trials that have not been completed. Completion of the adult trials has already been compromised by offering the vaccine to participants in the placebo groups, thus removing the control arm[viii]. Trials to establish efficacy and safety of the Covid-19 vaccines are not conducted by independent research teams but by the pharmaceutical companies, who stand to gain financially from the sale of their products. Raw trial data are not yet accessible to be scrutinized. Instead, interim analyses and claims are communicated by press release, without peer review, and instantly assimilated into advice to the public. The Pfizer-BioNTech clinical trials involving children and teenagers only commenced in 2021 and are underpowered for obtaining meaningful safety data (there were only 1131 12–15-year-olds in treatment arm). Only 2 months'

worth of interim data was provided to the MHRA, giving extremely limited short-term and NO long-term safety profile. Safety cannot be established if due scientific process is not adhered to.

2. The justification for the enhanced timelines and the irregular process for **temporary emergency use authorization** of Covid-19 vaccines has been the urgency of the ongoing pandemic. There is no historical precedent where a pandemic was successfully ended or mitigated by vaccinating the entire population. Indeed, concerns have been raised that this approach may prolong the pandemic and risk promotion of more virulent variants[ix]. French virologist and Nobel Prize winner Luc Montagnier recently highlighted and warned about this potential issue[x] [xi]. As the concept of ending a pandemic by vaccinating the entire population has no basis in science, there is no imperative to vaccinate children.

3. The last time a vaccine was developed and brought to market on an emergency basis, was in an attempt to halt the swine flu epidemic in 2009-2010. Tragically, this resulted in significant, unexpected injuries, with over 1000 cases of life-changing narcolepsy in children and teenagers across Europe, and the eventual withdrawal of the Pandemrix vaccine[xii] [xiii]. We have an **obligation to exercise caution** to prevent a re-occurrence of serious and unforeseen side-effects of an inadequately tested product in children[xiv].

4. The benefits of Covid-19 vaccines for children are close to zero, yet they carry known and unknown risks. Experts are stating that vaccinating children is neither necessary nor justified:
    - The minutes of the Joint Committee on Vaccination and Immunisation (JCVI) dated 16 February 2021 *note "little impact of vaccinating children once all other adults were offered vaccine"* and "*that modelling results on the impact of vaccinating children were considered highly uncertain"* [xv].
    - Other experts have argued that "***Covid-19 vaccines for children should not get emergency use authorization***" [xvi] and that this would be "*hard to justify right now for most children in most countries*" [xvii].
    - Professor of Paediatrics and member of the JCVI, Adam Finn, said in an interview on the 20 May 2021 that it was "*an open question as to whether we need to immunise children at all*" and "*if we can control this virus without immunising children, we shouldn't immunise children as a matter of principle*" [xviii].

5. Below, we set out specific issues regarding Covid-19 vaccines in children – each sufficient to justify not proceeding any further with this proposal.

    a. **The risk of Covid-19 to children is miniscule**. The infection fatality rate in this age group is close to zero, and most remain asymptomatic or experience mild symptoms only[xix] [xx] [xxi] [xxii]. This has been reiterated by the Government[xxiii] and by Professor of Paediatrics, Adam Finn[xviii]. Even the low records of children hospitalized with Covid-19, may be an over-estimate, according to a recent study[xxiv]. The number of children and teens under the age of 20 without pre-existing conditions who have died in England with a positive Covid-19 test, as of 13 May 2021, is in single figures[xxv]. Mortality in children in the UK in 2020/21 has in fact been significantly lower than in previous years[xxvi] [xxvii]. **As the emergency does not, therefore, apply to children, there can be no justification to authorize any product for emergency use in the paediatric population**.

    b. **The absolute risk reduction by Covid-19 vaccines is around 1%** (0.84-1.3%)[xxviii]. This applies to the healthy adult trial participants and cannot be extrapolated to children,

who are already at extremely low risk from the disease. **The potential benefit to an individual child of receiving a Covid-19 vaccine is statistically zero**.

c. **Children play an insignificant role in transmission of Covid-19**[ix xviii xxix]. Living with children may even reduce the risks of the disease[xxx]. Transmission in schools has not been significant[xxxi xxxii xxxiii]. Trials have not demonstrated whether Covid-19 vaccines reduce asymptomatic infection or transmission[xxxiv]. **There is therefore no demonstrable benefit to the wider society in vaccinating children**.

d. In a population cohort at minimal risk of severe disease, such as young people and children, **acquiring natural immunity will serve a better purpose**, as this will be more comprehensive, longer lasting, and cover a broad range of virus variants. Vaccine-induced immunity does not cover the full spectrum of protection (mucosal immunity, IgA, and T-cell immunity to the whole virus) and may only be short-lived. Acquiring natural immunity will therefore also benefit the wider population, contributing to herd immunity[xxxv xxxvi xxxvii xxxviii xxxix].

e. All Covid-19 vaccines used in the UK are based on **completely new gene-based technologies** (mRNA / DNA vector technology)[xl], that have never received full regulatory approval for mass rollout in humans. They have not been licensed and remain **experimental** until Phase 3 trials have been completed[xli]. Thus, we cannot infer long-term safety without observing the impact on human health in those who have received the vaccines over the next few years.

f. There is currently no data to indicate whether **dose adjustment may be necessary in children**. This would appear relevant as side-effects in initial phase 1 dose-escalation trials were more significant with higher dosage[xlii].

g. **Covid-19 vaccines work completely differently to established childhood vaccines**. Traditional, live vaccines work using attenuated virus strains to prompt antibody development. Covid-19 vaccines introduce a synthetic gene which induces the recipient's own cells to produce spike proteins. **Spike proteins appear to contribute significantly to the pathogenicity of SARS-CoV-2**, and there are studies suggesting that they have the potential to cause pathology on their own[xliii xliv]. It is unknown how much spike protein will be produced by an individual, and it is plausible that younger, healthier people may produce higher quantities, potentially increasing the risk of side-effects. **The safety of this approach needs to be thoroughly investigated and firmly established** prior to full licensure in adults and prior to any use in children.

h. At this stage, **medium- and long-term effects** of Covid-19 vaccines are **completely unknown** and unpredictable, due to the short duration of the Phase 3 safety trials, which are ongoing and not due to complete until 2023. This is most relevant for young people and children. Before giving Covid-19 vaccines to children, **potential adverse, long-term, effects on fertility, carcinogenesis, and children's developing neurological and immune systems MUST be completely ruled out**, as is done with other drugs and vaccines. This may take years or decades to fully establish.

i. **Serious adverse events and vaccine-related deaths** have been reported in the UK[xlv], the US[xlvi] and Europe[xlvii]. In the report published by the MHRA on 13 May 2021, there were

822,078 adverse reactions in the UK, including seizures, paralysis, blindness, strokes, blood clots and acute cardiac events. There were **1178 reports of fatalities.**

j. **Some life-threatening effects, such as blood clots**[xlviii] **and myocarditis**[xlix]**, have been reported specifically in children and young adults**[l] [li]. Government advice has recently been amended to avoid the AstraZeneca vaccine in young people due to a concern regarding the risk of rare blood clots (now considered to be around 1:100,000). The new term **"vaccine-induced immune thrombotic thrombocytopenia"** acknowledges the causality of the vaccine in these events, often presenting as ischemic strokes[lii]. It is possible that this reaction could be a **class effect caused by spike proteins** and therefore not specific or limited to the AstraZeneca vaccine[liii]. Of the 4347 events of thrombosis and embolism reported to the MHRA as of 13 May 2021, 770 occurred following the Pizer-BioNTech vaccine[xlv]. According to the US VAERS reporting system, several children under the age of 18 have died following a Covid-19 vaccine[liv].

k. Vaccine manufacturers have requested and been granted **complete exemption from liability** for any injuries or deaths resulting from their products[lv] [lvi]. A spokesperson for AstraZeneca acknowledged the potential for unexpected long-term side-effects, stating that as a company, they "*simply cannot take the risk if in ... four years the vaccine is showing side-effects*" [lvii]. **If the risk is significant enough for manufacturers to anticipate economic loss, children must not be expected to take the same risk to their long-term health.**

6. **Informed consent** is the cornerstone of good, ethical medical practice and is firmly enshrined in the code of conduct issued by the General Medical Council (GMC) and the Nursing and Midwifery Council (NMC). Unless factually accurate information is made available, detailing risks as well as benefits, it is not possible for anyone, let alone children, to make a fully informed decision and give informed consent to Covid-19 vaccination. **Gillick Competence cannot be assumed under current circumstances, where the vaccines are based on novel technologies, and no long-term safety data is available**.
   We are alarmed at the targeting of the public, and more recently schoolchildren[lviii] [lix], with material conveying a one-sided and simplified message, without reflection or consideration for individual circumstances, or disclosure of the known and unknown risks we have outlined. Multiple resources are being made available that appear to be aimed at modifying behaviour to reduce "vaccine hesitancy". These appear to rely not on the strength of scientific arguments but on techniques of persuasion[lx] [lxi] [lxii]. Recent reports, suggesting that **the use of peer pressure to increase uptake of the vaccine in children has been condoned by some school leaders,** were very disturbing[lxiii]. This is not consistent with ethical and lawful practice of medicine and indeed constitutes a violation of Informed Consent, as required by the GMC, the NHS Constitution, and the Montgomery ruling[lxiv].

7. In the UK, post-marketing surveillance is carried out via the **Yellow Card System**, a passive reporting system that requires all members of the public and all doctors to be aware of its existence, and compliant with filling in reports of all potential side-effects observed, to be effective at recognizing unexpected adverse events and signals of safety concern. In fact, there is poor awareness of, and compliance with, this scheme among both doctors and the public, potentially leading to a **significant underestimate of the true number of adverse events and deaths connected with these vaccines**.

Conclusion and Request

We have presented evidence that **children are at no substantial risk from Covid-19, but face known and unknown risks from Covid-19 vaccines, including significant, life-changing injury and death**. Some of the serious reported injuries, such as blood clots and myocarditis, have specifically occurred in young people and children. In addition, children have a lifetime ahead of them and we have **no idea of the impact of these novel, gene-based vaccines on their health or fertility in 5-10 years' time.** Considering these facts, we cannot comprehend how the review by the MHRA can be described as rigorous, with a conclusion to grant regulatory approval.

We are already seeing **reports of deaths and injury in children in the US and Canada**, where vaccines are being trialed and rolled out to children. Even with rare risks (1:10,000 to 1:100,000), if these vaccines are rolled out to around 10 million UK children, it seems certain that we will see deaths and serious injuries in a significant number of children who would never have been harmed by Covid-19, devastating families and communities. **There may be healthy UK children who will not live to see another Christmas if Covid-19 vaccines are rolled out in schools over the summer/autumn.** This would be an unforgiveable act of completely avoidable harm, for which you would be responsible, individually and collectively.

We implore the MHRA to immediately reverse the decision to authorize the Pfizer-BioNTech Covid-19 vaccine for children and abide by the Hippocratic oath to "First do no Harm".

The UK public trusts and relies on you not to expose their children to unnecessary risk.

We thank you for taking the time to read this letter and consider its contents. We request that you kindly acknowledge this letter and all the references within, and either confirm that emergency authorization for use of Covid-19 vaccines in children will be withdrawn or otherwise lay out the reasoning for your considered actions.

UK Medical Freedom Alliance

www.ukmedfreedom.org

Cc: **Rt Hon Boris Johnson** - Prime Minister
Rt Hon Matt Hancock - Secretary of State for Health and Social Care
Professor Chris Whitty - Chief Medical Officer
Rt Hon Nicola Sturgeon - First Minister of Scotland
Rt Hon Mark Drakeford - First Minister of Wales
Rt Hon Arlene Foster - First Minister of Northern Ireland
Prof Andrew Pollard - Chair of the Joint Committee for Vaccination and Immunisation (JCVI)
Rt Hon Nadhim Zahawi - Minister for Covid-19 Vaccine Deployment

[i] https://www.bbc.co.uk/news/health-57358446
[ii] https://www.hartgroup.org/open-letter-child-vaccination/
[iii] https://www.bmj.com/content/373/bmj.n1197
[iv] https://blogs.bmj.com/bmj/2021/05/07/covid-vaccines-for-children-should-not-get-emergency-use-authorization/
[v] https://www.americasfrontlinedoctors.org/frontline-news/americas-frontline-doctors-files-motion-for-temporary-restraining-order-against-use-of-covid-vaccine-in-children
[vi] https://www.israelnationalnews.com/News/News.aspx/304124
[vii] https://uploads-ssl.webflow.com/5fa5866942937a4d73918723/60379523f61260115203f392_UKMFA%20_Covid-19_Vaccine_in_Children.pdf
[viii] https://www.nature.com/articles/s41591-021-01299-5
[ix] https://www.nature.com/articles/414751a
[x] https://www.lifesitenews.com/mobile/news/nobel-prize-winner-mass-covid-vaccination-an-unacceptable-mistake-that-is-creating-the-variants
[xi] https://www.bitchute.com/video/vET2E4xW6Gmp/
[xii] https://www.narcolepsy.org.uk/resources/pandemrix-narcolepsy
[xiii] https://www.bmj.com/content/bmj/346/bmj.f794.full.pdf
[xiv] https://www.bmj.com/content/362/bmj.k3948
[xv] https://app.box.com/s/iddfb4ppwkmtjusir2tc/file/801843118120
[xvi] https://blogs.bmj.com/bmj/2021/05/07/covid-vaccines-for-children-should-not-get-emergency-use-authorization/
[xvii] https://www.bmj.com/content/373/bmj.n1197
[xviii] https://www.bbc.co.uk/sounds/play/m000w5hb
[xix] https://pubmed.ncbi.nlm.nih.gov/33289900/
[xx] https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a
[xxi] https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(21)00066-3/fulltext
[xxii] https://pubmed.ncbi.nlm.nih.gov/33289900/
[xxiii] https://www.bbc.co.uk/news/uk-53877898
[xxiv] https://hosppeds.aappublications.org/content/hosppeds/early/2021/05/18/hpeds.2021-006084.full.pdf
[xxv] https://www.england.nhs.uk/statistics/statistical-work-areas/covid-19-daily-deaths/weekly-total-archive/
[xxvi] https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/weeklyprovisionalfiguresondeathsregisteredinenglandandwales
[xxvii] https://www.nrscotland.gov.uk/statistics-and-data/statistics/statistics-by-theme/vital-events/general-publications/births-deaths-and-other-vital-events-quarterly-figures/archive
[xxviii] https://www.thalancet.com/journals/lanmic/article/PIIS2666-5247(21)00069-0/fulltext
[xxix] https://onlinelibrary.wiley.com/doi/full/10.1111/jpc.14937
[xxx] https://adc.bmj.com/content/archdischild/early/2021/03/17/archdischild-2021-321604.full.pdf
[xxxi] https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(20)30251-0/fulltext
[xxxii] https://pediatrics.aappublications.org/content/pediatrics/early/2021/01/06/peds.2020-048090.full.pdf
[xxxiii] https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.26.1.2002011
[xxxiv] https://www.bmj.com/content/bmj/371/bmj.m4037.full.pdf
[xxxv] https://www.nature.com/articles/s41467-021-22036-z
[xxxvi] https://www.nature.com/articles/s41586-021-03207-w
[xxxvii] https://www.bmj.com/content/370/bmj.m3563
[xxxviii] https://pubmed.ncbi.nlm.nih.gov/32668444/
[xxxix] https://www.cell.com/cell/fulltext/S0092-8674(20)30610-3
[xl] https://www.immunology.org/coronavirus/connect-coronavirus-public-engagement-resources/types-vaccines-for-covid-19
[xli] https://www.pfizer.com/science/coronavirus/vaccine/about-our-landmark-trial
[xlii] https://www.nejm.org/doi/pdf/10.1056/NEJMoa2022483?articleTools=true
[xliii] https://pubmed.ncbi.nlm.nih.gov/33300001/
[xliv] https://pubmed.ncbi.nlm.nih.gov/33053430/
[xlv] https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions
[xlvi] https://www.openvaers.com/covid-data
[xlvii] http://www.adrreports.eu/en/index.html
[xlviii] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/984404/PHE_COVID-19_AZ_vaccine_and_blood_clots_factsheet_7May2021.pdf
[xlix] https://www.cdc.gov/vaccines/acip/work-groups-vast/technical-report-2021-05-17.html
[l] https://abc7.com/johnson-covid-teen-vaccine/10537228/
[li] https://www.fox13now.com/news/local-news/utah-teen-hospitalized-with-blood-clots-in-his-brain
[lii] https://jnnp.bmj.com/content/early/2021/05/20/jnnp-2021-326984
[liii] https://ashpublications.org/blood/article/136/18/2080/463611/Direct-activation-of-the-alternative-complement
[liv] https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&DIED=Yes
[lv] https://www.nejm.org/doi/full/10.1056/NEJMp2030600
[lvi] https://www.independent.co.uk/news/health/coronavirus-pfizer-vaccine-legal-indemnity-safety-ministers-b1765124.html
[lvii] https://www.reuters.com/article/us-astrazeneca-results-vaccine-liability-idUSKCN24V2EN
[lviii] https://stephenhawkingfoundation.org/vaccines/
[lix] https://www.youtube.com/watch?v=OC9vnISihKM
[lx] https://windowsontheworld.net/wp-content/uploads/2021/03/Vaccination_do_and_donts_by_audience_cohorts.pdf
[lxi] https://www.who.int/news/item/21-12-2020-behavioural-considerations-for-acceptance-and-uptake-of-covid-19-vaccines
[lxii] https://digitallibrary.un.org/record/3894424?ln=en
[lxiii] https://www.telegraph.co.uk/news/2021/05/02/schools-back-mass-vaccinations-children-headteachers-say-peer/
[lxiv] https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf