Open Letter from the UK Medical Freedom Alliance to:

- **Dr Gregor Smith – Chief Medical Officer / Scotland**
- **Professor Amanda Croft – Chief Nursing Officer / Scotland**
- **Professor Alison Strath – Interim Chief Pharmaceutical Officer / Scotland**

Dear Sir / Madams, 23 May 2021

Re: Scottish Covid-19 Vaccination Programme

Herewith, we notify you of our grave concerns regarding the policies and practices implemented in Scotland, relating to the Covid-19 Vaccination Programme and particularly regarding vaccination of pregnant women. We respond specifically to your latest update issued 7th May 2021, which was circulated to all Scottish Health Boards and Local Authorities.

With regards to vaccinating pregnant women, we have previously raised concerns with the Scottish Government and also with the Royal College of Obstetricians & Gynaecologists (RCOG) and Royal College of Midwives (RCM), specifically relating to the information that is supplied to facilitate decision-making[i]. We are fully aware of the recently amended advice by the Joint Committee on Vaccination and Immunisation (JCVI) and have raised our concerns with them directly as well, in an Open Letter dated 19th April 2021[ii].

Below, we lay out the reasons why the public and especially **pregnant women and their babies may be at risk of unnecessary harm** as a result of current practices, whilst factual and comprehensive information is withheld, compromising the validity of informed consent.

1. In the UK, it has been the unquestionable basis of all clinical practice to refer to **evidence-based medicine**. Medical professionals are scientifically educated to critically appraise any evidence and ensure recommendations and guidelines rest on robust foundations. The implementation of the Covid-19 vaccination programme, with its latest rollout to include pregnant women, completely disregards this concept. Recommendations are based only on interim analyses of clinical trials that have not been completed and did not include any pregnant women. It is not openly disclosed to the public that Covid-19 vaccines are still experimental, as Phase 3 trials are not complete until 2023.

2. The justification for the enhanced timelines for **emergency use authorization** of Covid-19 vaccines has been the urgency of the ongoing pandemic. However, there is no historical precedent where a pandemic was successfully ended by vaccinating the entire population. There has, however, been a precedent where a vaccine was developed and brought to market on an emergency basis, to halt the swine flu epidemic in 2009-2010. Tragically, this resulted in significant injuries - over 100 cases of narcolepsy in children and teenagers - and eventual withdrawal of the Pandemrix vaccine[iii] [iv]. We must exercise caution to prevent a re-occurrence of serious and unforeseen side effects of an untested product.

3. All Covid-19 vaccines used in the UK are based on **completely new gene technologies**[v], that have never before received full regulatory approval for mass roll-out in humans. It is difficult to comprehend why this strategy was pursued, when the aim was to produce a safe and effective product in the shortest time possible, rather than resorting to well-established vaccine technology. This fact must be shared with the public, before offering and urging them to accept an unlicensed product[vi], which remains experimental at this stage, specifically for those cohorts of the population who were not represented in the initial and ongoing trials, such as pregnant women.

4. You have stated categorically that vaccination is "always better than no vaccination", even for the group of young adults and women of childbearing age, who are at extremely low risk of serious disease from Covid-19, with an infection fatality rate of <0.05%[vii]. Your statement is unsupported by published data, as the availability of good quality and **scientifically validated evidence for Covid-19 vaccines remain extremely limited**. Neither mortality nor serious morbidity have been studied as outcomes in the trials, and the interim analyses of the currently ongoing trials merely indicated a reduction in mild symptoms[viii] [ix]. **Medium- and long-term effects of the vaccines are entirely unknown** at this stage and cannot be inferred as there is no prior experience with this novel technology.

5. The MHRA publishes weekly reports of adverse reactions to Covid-19 vaccines. There is however no transparency regarding the threshold at which further rollout, especially to population cohorts such as pregnant women and children, would be paused pending additional investigations. In the report published on 13th May 2021, there were 822,078 adverse reactions, some of them very serious including seizures, paralysis, blindness, strokes, blood clots and acute cardiac events. There were **1178 reports of fatalities**[x]. This risk of serious adverse reactions and death would appear to be more significant than the negligible risk of Covid-19 in young people.

6. We acknowledge that your recently updated information, regarding the risks of and cautions against the AstraZeneca vaccine in younger adults, followed the confirmation of an association with the occurrence of blood clots with concomitant thrombocytopenia. Your recommendations suggest that in people deemed at increased risk of this side effect, who have already received one dose, "an alternative vaccine should be considered for their second dose". This advice is entirely unsupported by science. Not only is it **possible that this reaction is a class effect prompted by the immune response to spike proteins** and therefore not specific to the AstraZeneca vaccine[xi], but there is also no data regarding the consequences of combining vaccines based on different, and completely new, technologies. Possible outcomes of mixing vaccines may only be subject to speculation at this point, and therefore it is difficult to comprehend how this recommendation may be made responsibly.

7. Regarding safety of Covid-19 vaccines in pregnancy, you have stated that there are "no safety concerns", based on a "study in the United States". This assertion completely fails to acknowledge that there is no trial data at all regarding vaccines in pregnancy, and **the absence of data does not support assurance about safety**. The "study" refers to the CDC's V-safe Covid-19 Vaccine Pregnancy Registry, which is a voluntary reporting system, collecting observational data of over 100,000 women who happened to be pregnant at the time of vaccination. It is notable that fewer than 5000 of these women have been formally enrolled[xii].

This is not comparable to robust, thorough, scientific evaluation and peer-reviewed evidence. It is also worth noting that most recently, the AstraZeneca vaccine was suspended in two Brazilian states following the death of a pregnant woman[xiii].
No data is available regarding potential effects on the foetus or other pregnancy outcomes, as the length of time Covid-19 vaccines have been tested and administered does not even equal the length of a single pregnancy at this point. Notably, as of the 13th May 2021, 126 miscarriages and 9 stillbirths / foetal deaths have been reported to the MHRA via the Yellow Card system[x].

8. In the UK, post-marketing surveillance is carried out by the MHRA via the Yellow Card System. It is claimed that if surveillance information was to highlight an area of safety concern, advice and recommendations would immediately be updated.
However, the Yellow Card Scheme is a passive reporting system, requiring all members of the public and all doctors to be fully aware of its existence and when to submit a report, to give an accurate reflection of the adverse event profile of these vaccines. In reality, there is poor awareness of this scheme among both doctors and the public, potentially leading to a significant underestimate of the true number of adverse events and deaths.

   We argue that **pregnant mothers and their babies deserve more than passive surveillance to guard and ensure their safety**. The effects of products based on novel technologies on pregnant women should only be studied and monitored under the stringent conditions of a clinical trial, with full and informed consent of the participants.

9. **Informed consent** is the foundation of good, ethical medical practice in the UK and is firmly enshrined in the code of conduct issued by the General Medical Council (GMC) and the Nursing and Midwifery Council (NMC). Currently available patient information leaflets for pregnant women from the RCOG & RCM and from Public Health Scotland (PHS) fail to highlight the experimental nature of the vaccines and the safety signals that have been observed so far, which is in violation of the requirements for fully informed consent. Factually accurate and comprehensive information, of risks and benefits, must be made available to the public, especially pregnant women, for them to make a fully informed decision about Covid-19 vaccination, in line with ethical and lawful practice of medicine.

All medical professionals are required to adhere to the GMC Code of Conduct as well as the Hippocratic Oath of “First Do No Harm”. We therefore appeal to you to examine all the available scientific evidence fully and the points raised in this letter, in acknowledgement of benefits and risks and the current limitations of reliable data.

In the interest of the health, wellbeing and safety of the Scottish people, we trust that such a close, impartial and thorough examination of the available data will lead to reconsideration and amendment of your current recommendations.

We thank you for reading this letter and sincerely hope you consider its contents in full.

UK Medical Freedom Alliance

https://ukmedfreedom.org

[i] https://uploads-ssl.webflow.com/5fa5866942937a4d73918723/6062f5749dcf789999655dd0_UKMFA_Open_Letter_RCOG_RCM.pdf

[ii] https://uploads-ssl.webflow.com/5fa5866942937a4d73918723/607ee895f5b16913aacaa45b_UKMFA_Open_Letter_JCVI.pdf

[iii] https://www.narcolepsy.org.uk/resources/pandemrix-narcolepsy

[iv] https://www.bmj.com/content/bmj/346/bmj.f794.full.pdf

[v] https://www.immunology.org/coronavirus/connect-coronavirus-public-engagement-resources/types-vaccines-for-covid-19

[vi] https://www.pfizer.com/science/coronavirus/vaccine/about-our-landmark-trial

[vii] https://www.rcog.org.uk/globalassets/documents/guidelines/2021-02-19-coronavirus-covid-19-infection-in-pregnancy-v13.pdf

[viii] https://www.fda.gov/media/144245/download

[ix] https://www.bmj.com/content/bmj/371/bmj.m4037.full.pdf

[x] https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting#analysis-of-data

[xi] https://ashpublications.org/blood/article/136/18/2080/463611/Direct-activation-of-the-alternative-complement

[xii] www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html

[xiii] https://www.rt.com/news/523498-brazil-suspend-covid-vaccine-pregnancy/