18 March 2021

Open Letter from the UK Medical Freedom Alliance to General Practitioners / Vaccinators

Re: OBTAINING INFORMED CONSENT FOR ADMINISTRATION OF COVID-19 VACCINES IN ORDER TO REDUCE PERSONAL LIABILITY

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

We are writing to you to set out our thoughts about the legal requirement upon all medical practitioners to obtain fully informed consent from a patient prior to administering the Covid-19 vaccine. By taking this course of action, it is hoped that you can protect yourself against any claims by patients that they did not fully understand the implications of receiving the vaccine.

The launch of the Covid-19 vaccines has been welcomed by public authorities and hailed as an unequivocally safe and effective intervention. The vaccines have been given temporary authorisation for emergency use. Once Covid-19 is no longer considered an "emergency", the authorisation ceases to be valid. Prompt and widespread implementation has been encouraged.

Despite all this publicity, it is important to remember that Covid-19 vaccination is a medical procedure, which requires fully informed consent. The UK Medical Freedom Alliance have previously published guidance regarding the specific requirements for consent in the UK with reference to the GMC and the Montgomery ruling.[i] Anyone administering a Covid-19 vaccine is legally and ethically obliged to first provide all the relevant information, specifically with regards to safety and efficacy, and to ensure that this information is understood and accepted before proceeding. We would also suggest that providing information about treatments as an alternative to the vaccine is a requirement.

We would like to highlight a few salient points which should be covered when obtaining informed consent:

1. Manufacturer's claims of up to 95% effectiveness of the vaccines are based on evidence of effectiveness in preventing mild symptoms[ii]. **Outcomes such as severe disease, long covid, hospitalisation and death have NOT been assessed in the trials**[iii] [iv].

2. Published claims of effectiveness were based on interim analyses of trial data, comprising an extremely small number of trial participants. Some population groups, such as the elderly, were not adequately represented, and statistical significance of outcomes may therefore not apply to them[v].

3. All Phase 3 clinical trials are ongoing and not due to be completed till late 2022/early 2023. The vaccines are therefore currently still in the **experimental** stage. There is therefore only **limited short-term safety data and no long-term safety data available**, to rule out rare short-term side-effects or late-onset effects such as cancers, autoimmune diseases, infertility, neurological disorders etc.

4. **Covid-19 has an infection fatality rate of <0.1% for most of the population** (aged <70 years). Even in the elderly, the recovery rate from Covid-19 is in the range of the claimed effectiveness of the currently approved vaccines[vi] [vii].

5. There is currently **no peer reviewed evidence that the Covid-19 vaccines prevent infection with or transmission** of the virus, so the recipient is still able to spread the virus to others[viii].

6. Covid-19 vaccines are based on a **completely new biotechnology**[ix]. mRNA and DNA viral-vector vaccines have never previously received full regulatory approval for mass public use and are more akin to genetic manipulation/modification than traditional vaccination. Multiple concerns have been raised by scientists regarding possible short- and long-term adverse effects, which at this stage remain unrefuted due to lack of data.

7. There is a risk that Covid-19 vaccines may worsen clinical disease due to **antibody-dependent enhancement** (ADE), which has been observed in animal trials during previous attempts at developing a vaccine against coronavirus[x] [xi] [xii]. Trials have so far not addressed this significant concern, and this information must be shared prior to vaccination [xiii] [xiv].

8. The Pfizer and Moderna vaccines contain polyethylene glycol (PEG). PEG is a known allergen which carries a **risk of serious, potentially fatal allergic reactions**[xv]. The US Centre for Disease Control (CDC) has issued advice that anyone allergic to PEG or its close relative, Polysorbate, should not receive either of the currently available mRNA vaccines[xvi].

9. In the brief time since the start of Covid-19 vaccine rollout to the population in December 2020, **thousands of vaccine-related illnesses and deaths have been reported** through databases in the US (VAERS[xvii,xviii]), Europe (Eudravigilance[xix]), the UK (MHRA[xx]) raising concerns about their short-term safety. On 18 March, seventeen countries had suspended use of the Astra Zeneca vaccine due to concerns about blood clots and bleeding disorders[xxi].

10. As of 16 March 2021, **249,762 adverse events and 1928 deaths** relating to Covid-19 vaccines have been reported to the WHO database[xxii]

11. Covid-19 **vaccine manufacturers demanded and have been granted exemption from any liability for adverse effects** caused by their products [xxiii] [xxiv]. There is therefore no recourse for compensation from the manufacturers and only limited compensation (£120,000 lump sum) will be available from the Government Vaccine Damage Payment scheme[xxv] in the event of serious disability or death resulting from a Covid-19 vaccine. It is worth noting that between the inception of the scheme in 1979 until December 2014 only 931 vaccine damages payment awards were made, out of a total of 6,026 claims submitted[xxvi]. You must bear in mind that your potential liability for any claims by a patient for adverse reactions is unaffected by this exemption if you cannot show that you followed the legal requirement to obtain fully informed consent.

Conclusion and Recommendations

As manufacturers and distributors have been granted exemption from liability, **potential claims for injury or death resulting from Covid-19 vaccines could be made against the individual administering the vaccine and are likely to rest on the question of whether all relevant information was provided to allow fully informed consent to be obtained.**

We recommend that the **all the information presented above should be disclosed to patients and documented as part of the process of obtaining fully informed consent**, with specific reference made to the fact that the **end of the clinical trials needs to be awaited before Covid-19 vaccines are declared safe.**

We do hope that you find this letter and the recommendations made to be of assistance.

UK Medical Freedom Alliance
www.ukmedfreedom.org

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[i] https://uploads-ssl.webflow.com/5fa5866942937a4d73918723/5ff46fd3fa0a18f0c8e0cbc2_UKMFA_CV19_vaccine_consent_form_v3.pdf
[ii] https://www.fda.gov/media/144245/download
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[xxi] https://www.cnbc.com/2021/03/15/covid-ireland-netherlands-suspend-astrazeneca-vaccine-amid-blood-clot-fears.html
[xxii] http://www.vigiaccess.org
[xxiii] https://www.nejm.org/doi/full/10.1056/NEJMp2030600
[xxiv] https://www.independent.co.uk/news/health/coronavirus-pfizer-vaccine-legal-indemnity-safety-ministers-b1765124.html
[xxv] https://www.gov.uk/government/news/government-to-add-covid-19-to-vaccine-damage-payments-scheme
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