Open letter to the Rt Hon Matt Hancock MP
[By email and hard copy]

The Rt Hon Matt Hancock MP
Secretary of State for Health and Social Care
House of Commons
London
SW1A 0AA

29 April 2020

Dear Secretary of State

RE THE CRITICAL NEED FOR TRANSPARENCY AROUND COVID-19 VACCINES

As a non-profit organisation representing diverse interests in natural and sustainable health, and a medical association of doctors who practice ecological (including nutritional and environmental) medicine, we hereby request that the Department of Health, the Joint Committee on Vaccination and Immunisation (JVCI), the UK Vaccine Network, Public Health England and the Medicines and Healthcare products Regulatory Agency (MHRA) maintain a policy of full transparency around the development, testing and roll-out of vaccines targeting Covid-19.

The UK Government, other governments and health authorities, including the World Health Organization, have repeatedly made clear concerns over vaccine hesitancy and the potential impact on public health.

Two major drivers of vaccine hesitancy include:

a) **Low levels of trust in the medical science behind vaccination safety and effectiveness, pharmaceutical companies who produce these vaccines, and government health agencies who promote vaccination** (Xu et al, *Health Comm*. 2020; Apr 19: 1-14). Trust is readily eroded by misleading claims issued by health authorities which consistently refer to vaccines as 'safe' when it is clear that adverse events occur at varying, albeit low, frequencies. To-date, in the UK, around 1000 claims have been paid out to those who have been severely disabled (from over 6,000 claims) after establishing proof of causation through the Vaccine Damage Payment Act 1979. Furthermore, public trust in a pandemic vaccine will have been adversely affected by claims that vaccines targeting the influenza A/H1N1 'swine flu' pandemic of 2009 had been "thoroughly tested" when this was more recently found to be false (Doshi P. *BMJ* 2018; 362: k3948);

b) **Insufficient communication of relevant information, including trial designs and results by health authorities and vaccine manufacturers**. Such inadequacies have been revealed around HPV vaccine trials (Doshi et al. *BMJ*

Evid Based Med. 2020; pii: bmjebm-2019-111331) as part of the Restoring Invisible and Abandoned Trials initiative (RIAT) and in retrospective analysis of information and events surrounding the roll out of vaccines during the last pandemic (influenza A/H1N1, 'swine flu') in 2009 (Stephen W. *BMJ* 2018; 362: k3948).

Health authorities, as vaccine protagonists, must therefore take some responsibility for their role in creating an environment that fosters distrust and hesitancy over vaccination rather than always blaming citizens or scientists for being irrational when they express concerns about vaccine testing or safety. Coercive public policy on vaccination, coupled with the categorisation of comments by citizens, doctors and others that question vaccine safety as 'fake news', which then often leads to censorship, are therefore counter-productive.

Informed risk/utility decisions around mass vaccination require increasing public engagement (Williamson & Glaab. *BMC Med Ethics*. 2018; 19(1): 84) and benefit from clear disclosure of sponsorship bias and the capacity for re-analysis of raw data by independent researchers (Jefferson T. *J R Soc Med.* 2020; 113(4): 148-157). Full disclosure of results from clinical trials, including provision of raw data, is vital given data on fast-tracked vaccines will inevitably be uncertain and incomplete to some degree. It is important that the extent of such shortcomings are communicated to the public.

It is therefore in the public interest to ensure that all relevant data that could feed into properly informed decisions are placed in the academic and public domains. Public confidence in vaccination can only be re-established if there is much greater transparency and sharing of data than has been the case historically (Godlee F. *BMJ* 2018; 363: k4152). This is more relevant than ever with the prospect of Covid-19 vaccines, given their unprecedented rate of development.

Key areas for vaccine transparency

Having consulted with medical doctors, other health professionals, research scientists, lawyers and citizens in our various networks, we consider it imperative that the following information is released for public scrutiny prior to commercial release of any Covid-19 vaccines:

1. **Full disclosure of all raw data from safety studies of commercial Covid-19 vaccines**. Disclosure of raw data allows independent researchers to analyse data and draw conclusions independently of health authorities, regulators and vaccine manufacturers. Such transparency and data sharing are essential if the aim is to establish confidence in mass immunisation using a novel vaccine developed in a fraction of the time typical of previous vaccines;

2. **Transparency in relation to safety and efficacy studies**. Safety studies for any vaccine that is fast-tracked (6-18 months) prior to approval will be compromised as compared with those for which more time (several years) has been allowed for safety studies and regulatory approval. If the Government is planning to encourage vaccination, it is crucial that it is clear about the

limitations in safety and efficacy studies supporting public roll-out as compared with those required for normal licensing of vaccines. Without such knowledge, it is neither possible for citizens to balance risk versus utility, nor can they determine "*…if the safety of the product is not such as persons generally are entitled to expect*" (Consumer Protection Act 1987);

3. **Transparency over the type of platform used for commercial vaccines**. Currently there are several different platforms being investigated for candidate vaccines for Covid-19 and it appears that the most likely (and well funded) options involve platforms that have never been previously used on a global scale (Amanat & Krammer. *Immunity.* 2020; 52(4): 583-589). It is imperative that there is clear communication to the public over the nature of the platform(s) being used for Covid-19 vaccines prior to their commercial release, as well as the extent of their previous use, if relevant, for pre-existing commercial vaccines;

4. **Conduct and transparency of studies to elucidate any risks associated with adjuvants as distinct from antigens**. Given that commercial vaccines for Covid-19 are likely to be adjuvanted, it is essential that the safety of the adjuvanted vaccines are compared with non-adjuvanted vaccines and saline controls. Adjuvants may trigger specific side effects in susceptible individuals, which may include those with underlying conditions, including autoimmune diseases (e.g. Watad A, et al. *Front Endocrinol (Lausanne).* 2017; 7: 150);

5. **Transparency in relation to vaccine composition**. There is a significant public lack of confidence in the purity and composition of vaccines. It is essential that the detailed composition of Covid-19 vaccines are declared, this going beyond simply specifying added ingredients. It is also imperative that any impurities are also declared given some of these have the potential to trigger adverse reactions. Given there is a strong move towards transparency in labelling in the food sector, itself supported by the Food Standards Agency and Department of Health, it is even more important that such transparency occurs with vaccines given they are administered systemically;

6. **Full disclosure of cases and potential cases of vaccine injury**. Recent history of UK government communication around legal cases linked to vaccine injury caused by Pandemrix® and seasonal flu vaccines discovered during trials or post-marketing surveillance has been grossly inadequate. This inadequacy has only been revealed through multiple freedom of information requests under the Freedom of Information Act. Only a handful of cases have been made public, while many others have received Vaccine Damage Payments after establishing proof of vaccine causation but without any public communication of the cases or the nature of the injuries (see special report in Independent, 18 April; https://www.independent.co.uk/news/health/coronavirus-vaccine-risks-research-nhs-lockdown-pandemrix-adjuvant-a9470306.html). This non-disclosure does not afford the public a balanced view of the risks associated with a given vaccine, nor does it allow them to determine if their own health condition might make them more or less susceptible to adverse reactions;

7. **The Government must clarify eligibility and criteria for no-fault vaccine injury payments for Covid-19 vaccines**. We have noted that the Government no longer considers citizens eligible for vaccine injury payments in the event of proven damage caused by a "pandemic influenza virus" (https://www.gov.uk/vaccine-damage-payment/eligibility). This exclusion was made only after the Government recognised from post-marketing surveillance that narcolepsy was a significant, albeit uncommon, autoimmune side effect of Pandemrix®. The Government must ensure that vaccine injury payments will be made to individuals injured by any approved Covid-19 vaccines, while also clarifying the level of proof required to establish causation and the statutory time limit for making such claims in relation to Covid-19 vaccines, prior to their administration to the public;

8. **The Government must clarify indemnity offered to vaccine manufacturers**. In a reply made by the Department of Health to a freedom of information request (Your Ref: DE-1029593), it was stated that in relation to GlaxoSmithKline's Pandemrix®, Baxter International's Celvapan® and Sanofi Pasteur's Liquid Smallpox Vaccine, "*The Authority shall fully and completely indemnify the Contractor against all claims, proceedings, actions, legal suits, damages, legal costs and expenses and any other liabilities in respect of any death or personal injury arising from the Authority's use of the Goods*." The indemnity, if applicable to Covid-19 vaccines, must be made public prior to the commercial release of vaccines because, ultimately, the financial burden of such indemnity lies with the taxpayer;

9. **The public must be informed of the extent of naturally-acquired immunity prior to public release of Covid-19 vaccines**. In order to balance risk and utility, the public must be made aware of the extent of population herd immunity, which will necessitate carefully conducted, stratified, random sampling of the UK population and testing with a validated serological (antibody) test. We are aware that the Department of Health is evaluating such tests, and it is of paramount importance that comprehensive, periodic evaluation of population immunity is conducted to determine the persistence of such immunity. This would be greatly facilitated by quarterly testing of randomised, stratified samples of the national population and would not necessitate 'universal' testing of all individuals that has been correctly declared as not feasible. The public should also have ready access to validated antibody tests so that individuals can assess their own state of immunity prior to giving consent for vaccination;

10. **Parliament must be engaged to ensure due democratic process if the Government is planning to consider making Covid-19 vaccines mandatory**. While the Public Health (Control of Disease) Act 1984 technically allows for the mandatory treatment of persons who are, or may be, infected, the decision to apply these emergency measures to Covid-19, when it has not been applied to any previous infectious disease, is a matter of great public importance. It is therefore critical that due democratic process is followed so that the will of the people can be factored into any such decision.

As Secretary of State for Health and Social Care, we are extremely aware of how hard you and your team have been working in an effort to protect the public interest during the current pandemic. However, it is crucially important that in the drive to provide one or more vaccines to enhance the population's immunity to SARS-CoV-2, corners are not cut that expose the population to unnecessary risks, especially if these are undisclosed.

We look forward to receiving information about your Department's approach to transparency of information and data surrounding Covid-19 vaccine trials, including post-marketing surveillance once initiated. We especially request your response to specific points set out in the ten discrete areas we have highlighted above.

We greatly look forward to hearing from you, or a member of your Departmental team, at your earliest convenience. Our respective emails are given below.

Yours sincerely,

[original hard copy signed]

[original hard copy signed]

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