Open letter to members of the JCVI
Copies: Members of Commission on Human Medicines
Members of the Pharmacovigilance Expert Advisory Group

23rd November 2021

Dear Professor Lim and colleagues,

Last week a group of 50 British doctors and scientists wrote to the MHRA copy to the JCVI, regarding ongoing concerns about the safety of the current children's covid-19 vaccination programme and the possibility it might be extended to 5-11s as in the US. We are now writing urgently to you because of the announcement of a second dose of Pfizer to 16 & 17-year-olds

The JCVI's initial statement on 19th July, that '*any decision on deployment of vaccines must be made on the basis that the benefits of vaccination outweigh the risks to those people who are vaccinated*' was welcomed, placing the safety of the young in a primary position and drawing attention to '*rare but serious adverse events*': based on a balanced view of the available evidence, you stated clearly that '*the health benefits in this population are small, and the benefits to the wider population are highly uncertain. At this time, JCVI is of the view that the health benefits of universal vaccination in children and young people below the age of 18 years do not outweigh the potential risks*'.

We were therefore extremely puzzled when on 4th August, new guidance was issued for the rollout to include healthy 16-17 year-olds but with no new data presented to explain the decision and wrote at the time to Professors Pollard and Finn and to the RCPCH expressing our concern. It is now clear from the minutes of your meeting of 29th July, published belatedly on October 29th, that the committee was fully aware of the increased risk of myocarditis in young males after the 2nd dose of Pfizer. The minutes note that '*active surveillance*' ongoing in Israel, may explain '*why higher risk was seen than the UK or USA*'. You also noted '*the increased number of first dose cases in the UK might be due to the proportion of children who were seropositive*'. Also minuted, the series of children with vaccination-associated myocarditis, showing significant abnormalities on Cardiac Magnetic Resonance imaging. '*Follow up of such cases (including MRI scans) was considered important for at least 3-6 months to check for cardiac fibrosis and to predict potential arrythmia risk'.* The JCVI's decision to only recommend one dose in the first instance (presumably out of concern for this risk) at least appeared to have some logic.

Despite all the concerns voiced by your committee, you have now recommended that 16-17 year-olds be offered a second dose of Pfizer vaccine, with all the attendant risks. The latest ONS data suggests that 96% of 16-24 year-olds already have antibodies to Sars-CoV-2, obviating the need for any vaccination of these healthy young people, let alone two doses. JCVI minutes confirm that, '*Immunisation from natural infection was likely to give broader protection than vaccination*.' There is also increasing concern that a normal broad immune response to infection is impaired by prior vaccination. You have now widened the time delay between infection and vaccination from 4 to 12 weeks, but surely the correct advice would be to say those with prior infection should avoid vaccination.

We have focussed here on the myocarditis risk, but there are also reports of microvascular clotting following mRNA vaccines, raising the possibility of pulmonary hypertension in future, plus the many adverse neurological effects reported on Yellow Cards and still no long-term safety data. A number of authors have also highlighted a worrying increase in all-cause mortality in young men in recent months. Sudden deaths have been reported in the press, leading to speculation of vaccine adverse events, but without the rigorous active surveillance required.

The following questions require replies as a matter of urgency:

- What additional information has led the JCVI to change their advice for 16-17s?
- Were more vaccine adverse events seen in those children with recent infection, leading to your decision to increase the advised time-lag?
- What is the estimated risk posed by COVID-19 and the absolute risk reduction/benefit from a second dose, including calculations taking into account existing immunity in this cohort?
- What led you to downgrade your safety concerns regarding the estimated risk of myocarditis?

- What plans were put in place for full post-marketing surveillance for side-effects, such as providing a prepaid card to be returned at 30 days from every vaccine recipient, recording all symptoms and illnesses experienced post-vaccination?
- Have you considered a sample of 16-17-year-olds who will be invited to have blood tests before and after their second dose to include platelet count, D-dimers & troponin levels to monitor for incidence of microvascular clotting and myocarditis?
- What guidelines on myocarditis are being sent to paediatricians, emergency medicine departments and cardiologists; specifically is cardiac MRI scanning recommended?
- What efforts are being made to counter inappropriate advertising and inducement which undermines the process and ethics of informed consent?
- How will you ensure that vaccination of children remains voluntary with no requirement to use vaccine certification to access any services or events?

Yours sincerely,

Dr Rosamond Jones, MD, FRCPCH, retired consultant paediatrician
Professor Anthony J Brookes, Department of Genetics & Genome Biology, University of Leicester
Professor Richard Ennos, MA, PhD. Honorary Professorial Fellow, University of Edinburgh
Professor John Fairclough FRCS FFSEM retired Honorary Consultant Surgeon
Prof Anthony Fryer, PhD, FRCPath, Professor of Clinical Biochemistry, Keele University
Professor Angus Dalgleish, MD, FRCP, FRACP, FRCPath, FMed Sci, Professor of Oncology, St Georges Hospital, London
Professor David Livermore, BSc, PhD, Professor of Medical Microbiology, University of East Anglia
Lord Moonie, MBChB, MRCPsych, MFCM, MSc, House of Lords, former parliamentary under-secretary of state 2001-2003, former consultant in Public Health Medicine
Dr Theresa Lawrie, MBBCh, PhD, Director, Evidence-Based Medicine Consultancy Ltd, Bath
Dr Alan Mordue, MBChB, FFPH. Retired Consultant in Public Health Medicine & Epidemiology
Dr John Flack, BPharm, PhD. Retired Director of Safety Evaluation,Beecham Pharmaceuticals 1980-1989 and Senior Vice-president for Drug Discovery 1990-92 SmithKline Beecham
Dr Gerry Quinn, PhD. Postdoctoral researcher in microbiology and immunology
Dr Christopher Exley, PhD, FRSB, Retired professor in Bioinorganic Chemistry
Mr Anthony Hinton, MBChB, FRCS, Consultant ENT surgeon, London
Dr Geoffrey Maidment, MD, FRCP, retired consultant physician
Mr Malcolm Loudon, MBChB, MD, FRCSEd, FRCS(Gen Surg), MIHM,VR, Consultant Surgeon
Dr Christina Peers, MBBS, DRCOG, DFSRH, FFSRH, Menopause specialist
Dr Noel Thomas, MA, MBChB, DCH, DObsRCOG, DTM&H, MFHom, retired doctor
Dr David Critchley, BSc, PhD, 32 years in pharmaceutical R&D as a clinical research scientist.
Dr Elizabeth Evans MA(Cantab), MBBS, DRCOG, Retired Doctor
Katherine MacGilchrist, BSc (Hons), MSc, CEO/Systematic Review Director, Epidemica Ltd.
Dr Greta Mushet, MBChB, MRCPsych, retired Consultant Psychiatrist in Psychotherapy
Mr James Royle, MBChB, FRCS, MMedEd, Colorectal surgeon
Mr Ian F Comaish, MA, BM BCh, FRCOphth, FRANZCO, Consultant ophthalmologist
Dr M, BSc(Hons) Medical Microbiology & Immunobiology, MBBCh BAO, MSc in Clinical Gerontology, MRCP(UK), FRCEM, FRCP(Edinburgh), NHS Emergency Medicine & geriatrics
Dr Helen Westwood MBChB MRCGP DCH DRCOG, General Practitioner
Dr David Morris, MBChB, MRCP(UK), General Practitioner
Dr Jonathan Engler, MBChB, LIB (hons), DipPharmMed
Dr Elizabeth Burton, MBChB, retired general practitioner
Dr Renée Hoenderkampf, General Practitioner
Dr Clare Craig, BMBCh, FRCPath, Pathologist
Dr Alan Black, MBBS, MSc, DipPharmMed, retired pharmaceutical physician
Dr Ruth Wilde, MB BCh, MRCEM, AFMCP, Integrative & Functional Medicine Doctor
Dr Mark Bell, MBChB, MRCP(UK), FRCEM, Consultant in Emergency Medicine
Dr Livia Tossici-Bolt, PhD, NHS Clinical Scientist
Dr Zac Cox, BDS, LCPH, Holistic Dentist, Homeopath
Dr Branko Latinkic, BSc, PhD, Molecular Biologist
Dr Kulvinder Singh Manik, MBBS, General Practitioner
Dr Rohaan Seth, Bsc (hons), MBChB (hons), MRCGP General Practitioner
Dr Jessica Robinson, BSc(Hons), MBBS, MRCPsych, MFHom, Psychiatrist & Integrative Medicine
Michael Cockayne, MSc, PGDip, SCPHNOH, BA, RN, Occupational health practitioner
Dr Jenny Goodman, MA, MB ChB, Ecological Medicine
Dr Michael D Bell, MBChB, MRCGP, retired General Practitioner
Dr Franziska Meuschel, MD, ND, PhD, LFHom, BSEM, Nutritional, Environmental and Integrated Medicine
Dr Charles Forsyth, MBBS, BSEM, Independent Medical Practitioner
Margaret Moss, MA (Cantab), CBiol, MRSB, Director, The Nutrition and Allergy Clinic, Cheshire
Julia Annakin, RN, Immunisation Nurse Specialist
Dr Stefanie Williams, Dermatologist
Dr Holly Young, BSc, MBChB, MRCP, Consultant Palliative Care Medicine
and others …