To: Sajid Javid MP, Secretary of State for Health and Social Care, HM Government

Eluned Morgan AS/MS, Minister for Health and Social Services, Welsh Government

Humza Yousaf MSP, Cabinet Secretary for Health and Social Care, Scottish Government

Robin Swann MLA, Minister of Health Northern Ireland Executive

13 September 2021

Dear Secretary of State, Cabinet Secretary and Ministers,

Universal vaccination of children and young people aged 12-15 years against COVID-19.

Background.

1) The Joint Committee on Vaccination and Immunisation (JCVI) in their advice to you on the 2nd September 2021 on this subject said:

"Overall, the committee is of the opinion that the benefits from vaccination are marginally greater than the potential known harms… but acknowledges that there is considerable uncertainty regarding the magnitude of the potential harms. The margin of benefit, based primarily on a health perspective, is considered too small to support advice on a universal programme of vaccination of otherwise healthy 12-15-year-old children at this time…. JCVI is constituted with expertise to allow consideration of the health benefits and risks of vaccination and it is not within its remit to incorporate in-depth considerations on wider societal impacts, including educational benefits. <u>The government may wish to seek further views on the wider societal and educational impacts from the Chief Medical Officers of the 4 nations, with representation from JCVI in these subsequent discussions</u>." (Our emphasis). Their full advice to you is appended in Annexe A.

2) You accepted this recommendation from JCVI, and wrote to us on 2nd September 2021 stating "We agree with the approach suggested by JCVI, and so we are writing to request that you take forward work (drawing on experts as you see fit) to consider the matter from a broader perspective, as suggested by the JCVI." The Terms of Reference (ToR) of this request, which the UK CMOs agreed, can be found at Annexe B.

3) In doing so we have been fortunate to have been informed by the independent expertise of leaders of the clinical and public health profession from across the UK. This has included Presidents and Chairs or their representative of the Royal College of Paediatrics and Child Health, the Royal

College of General Practice, the Royal College of Psychiatry, the Faculty of Public Health, the Academy of Medical Royal Colleges representing all the other Royal Colleges and Faculties, the Association of Directors of Public Health, Regional Directors of Public Health, national public health specialists and experts in data and modelling. We are very grateful to them for taking considerable time and effort to consult their own colleagues in all 4 nations at short notice to get a comprehensive view of the balance of informed medical opinion and experience across the UK.

4) In addition, we have examined data from the Office for National Statistics as well as published data on the impact of COVID-19 on education, and other relevant published sources. We attach key published inputs at Annexe C.

5) The UK's independent regulator of medicines and vaccines the Medicines and Healthcare products Regulatory Agency (MHRA) is in law the appropriate body to determine whether, based on risk-benefit grounds, a vaccine is safe and effective to use and so grant a licence. They have done so for children and young people aged over 12 years for two vaccines against COVID-19, those manufactured by Pfizer and Moderna. Their assessment is that benefits exceed risks on an individual basis. We take their independent opinion as read. The MHRA position on mRNA vaccines is similar to the relevant regulatory approvals granted in the same age groups in multiple other jurisdictions including but not limited to the USA, the European Union, and Canada.

6) The independent JCVI is the proper body to give advice on how to deploy a vaccine which has a prior favourable risk-benefit decision and authorisation from MHRA including whether it has a sufficiently large benefit to be worth deploying on a larger, population scale. Like MHRA they consider the benefits of vaccination in this age group exceed the risks (i.e. it is better to be vaccinated than not vaccinated in this age group). They balanced the risk of COVID-19 against the risks of vaccination, including myocarditis. When forming its advice, the JCVI considered vaccine use according to clinical risk groups, thus identifying different groups according to their potential to benefit from vaccination. For 12 – 15 year olds who do not have underlying health conditions that place them at higher risk from severe COVID-19, the JCVI considered that the size of *both* the risk and the benefit are at an individual level very small, and the overall advantage for vaccination, whilst present, is therefore not sufficiently large to recommend universal vaccination on their usual criteria. They deemed the extent to which vaccination might mitigate the impacts of COVID-19 on education was beyond the usual remit of the JCVI. They recognised however that given the substantial scale of the impact of COVID-19 on all children and young people, which goes beyond normal clinical benefit and risk, wider issues could, exceptionally, be relevant hence their suggestion to consult UK CMOs. The JCVI have already recommended that children and young people aged 12-17 with specific underlying health

conditions, and children and young people who are aged 12 years and over who are household contacts of persons who are immunocompromised are offered two doses of a vaccine, normally Pfizer BioNTech BNT162b2. They have recommended all young people 16-17 are offered an initial first dose of vaccine.

7) The UK has benefited from having data from the USA, Canada and Israel, which have already offered vaccines universally to children and young people aged 12-15.

8) The UK CMOs start from the position that the MHRA and JCVI set out on individual benefit-risk calculations for this age group, and have not revisited this. We accept that at an individual level benefit exceeds risk but this advantage is small, and we have taken the JCVI figures as the UK current position on this question.

9) The Chair of the JCVI Prof. Lim has been a member of our group to ensure that there is no duplication of effort or conflict between the views of UK CMOs and the JCVI. We have been fortunate to have been joined also by the lead Deputy Chief Medical Officers for vaccines Prof. Van Tam (England), Prof. Steedman (Scotland) and Dr. Chada (Northern Ireland) and the DHSC Chief Scientific Adviser, Prof. Chappell. The final advice is that of the Chief Medical Officers, but informed by independent senior clinical and public health input from across the UK.

10) UK CMOs have decided in their ToR that we will only consider benefits and disbenefits to those aged 12-15 from vaccinating this age group, including indirect benefits. Whilst there may be benefits to other age groups, these have not been considered in our advice below.

11) Issues of vaccine supply were not factors considered in decision making.

12) The UK CMOs are aware of the extensive range of non-clinical views but this UK CMOs advice is purely clinical and public health derived and has not taken issues outside their clinical and public health remit into account. There is a subsequent political process where wider societal issues may be considered by Ministers in deciding how they respond to this advice.

Advice.

13) All drugs, vaccines and surgical procedures have both risks and benefits. If the risks exceed benefits the drug, vaccine or procedure should not be advised, and a drug or vaccine will not be authorised by MHRA. If benefits exceed risks then medical practitioners may advise the drug or vaccine, but the strength of their advice will depend on the degree of benefit over risk.

14) At an individual level, the view of the MHRA, the JCVI and international regulators is that there is an advantage to someone aged 12-15 of being vaccinated over being unvaccinated. The COVID-19 Delta variant is highly infectious and very common, so the great majority of the unvaccinated will get COVID-19. In those aged 12-15, COVID-19 rarely, but occasionally, leads to serious illness, hospitalisation and even less commonly death. The risks of vaccination (mainly myocarditis) are also very rare. The absolute advantage to being vaccinated in this age group is therefore small ('marginal') in the view of the JCVI. On its own the view of the JCVI is that this advantage, whist present, is insufficient to justify a universal offer in this age group. Accepting this advice, UK CMOs looked at wider public health benefits and risks of universal vaccination in this age group to determine if this shifts the risk-benefit either way.

15) Of these, the most important in this age group was impact on education. UK CMOs also considered impact on mental health and operational issues such as any possible negative impact on other vaccine programmes, noting that influenza vaccination and other immunisations of children and young people are well-established, important, and that the annual flu vaccine deployment programme commences imminently.

16) The UK CMOs, in common with the clinical and wider public health community, consider education one of the most important drivers of improved public health and mental health, and have laid this out in their advice to parents and teachers in a previous joint statement (Annexe D). Evidence from clinical and public health colleagues, general practice, child health and mental health consistently makes clear the massive impact that absent, or disrupted, face-to-face education has had on the welfare and mental health of many children and young people. This is despite remarkable efforts by parents and teachers to maintain education in the face of disruption.

17) The negative impact has been especially great in areas of relative deprivation which have been particularly badly affected by COVID-19. The effects of missed or disrupted education are even more apparent and enduring in these areas. The effects of disrupted education, or uncertainty, on mental health are well recognised. There can be lifelong effects on health if extended disruption to education leads to reduced life chances.

18) Whilst full closures of schools due to lockdowns is much less likely to be necessary in the next stages of the COVID-19 epidemic, UK CMOs expect the epidemic to continue to be prolonged and unpredictable. Local surges of infection, including in schools, should be anticipated for some time. Where they occur, they are likely to be disruptive.

19) Every effort should be taken to minimise school disruption in policy decisions and local actions. Vaccination, if deployed, should only be seen as an adjunct

to other actions to maintain children and young people in secondary school and minimise further education disruption and therefore medium and longer term public health harm.

20) On balance however, UK CMOs judge that it is likely vaccination will help reduce transmission of COVID-19 in schools which are attended by children and young people aged 12-15 years. COVID-19 is a disease which can be very effectively transmitted by mass spreading events, especially with Delta variant. Having a significant proportion of pupils vaccinated is likely to reduce the probability of such events which are likely to cause local outbreaks in, or associated with, schools. They will also reduce the chance an individual child gets COVID-19. This means vaccination is likely to reduce (but not eliminate) education disruption.

21) Set against this there are operational risks that COVID-19 vaccination could interfere with other, important, vaccination programmes in schools including flu vaccines.

22) Overall however the view of the UK CMOs is that the additional likely benefits of reducing educational disruption, and the consequent reduction in public health harm from educational disruption, on balance provide sufficient extra advantage in addition to the marginal advantage at an individual level identified by the JCVI to recommend in favour of vaccinating this group. They therefore recommend on public health grounds that Ministers extend the offer of universal vaccination with a first dose of Pfizer-BioNTech COVID-19 vaccine to all children and young people aged 12-15 not already covered by existing JCVI advice.

23) If Ministers accept this advice, UK CMOs would want the JCVI to give a view on whether, and what, second doses to give to children and young people aged 12-15 once more data on second doses in this age group has accrued internationally. This will not be before the Spring term.

24) In recommending this to Ministers, UK CMOs recognise that the overwhelming benefits of vaccination for adults, where risk-benefit is very strongly in favour of vaccination for almost all groups, are not as clear-cut for children and young people aged 12-15. Children, young people and their parents will need to understand potential benefits, potential side effects and the balance between them.

25) If Ministers accept this advice, issues of consent need to take this much more balanced risk-benefit into account. UK CMOs recommend that the Royal Colleges and other professional groups are consulted in how best to present the risk-benefit decisions in a way that is accessible to children and young people as well as their parents. A childcentred approach to communication and deployment of the vaccine should be the primary objective.

26) If Ministers accept this advice, it is essential that children and young people aged 12-15 and their parents are supported in their decisions, whatever decisions they take, and are not stigmatised either for accepting, or not accepting, the vaccination offer. Individual choice should be respected.

Chief Medical Officer for England Prof. Christopher Whitty

Chief Medical Officer for Northern Ireland Sir Michael McBride

Chief Medical Officer for Scotland Dr. Gregor Smith

Chief Medical Officer for Wales Dr. Frank Atherton

Annexes:

Annexe A- JCVI statement on COVID-19 vaccination of children aged 12 to 15 years. Update 2 Sep 2021

Annexe B- Terms of Reference for UK CMO advice on universal vaccination of children and young people aged 12-15 years against COVID-19

Annexe C- Key published inputs to the UK CMOs advice on universal vaccination of children and young people aged 12-15 years against COVID-19

Annexe D- A statement from the UK Chief Medical Officers on schools and childcare reopening