Witness Name: Wei Shen Lim

Statement No.: 2

Exhibits: WSL2/1 to WSL2/219

Dated: 27 March 2024

UK COVID-19 INQUIRY

SECOND WITNESS STATEMENT OF WEI SHEN LIM

I, Wei Shen Lim, of Nottingham University Hospitals NHS Trust, City Hospital Campus, Nottingham NG5 1PB, will say as follows:

1. I am employed by Nottingham University Hospitals NHS Trust as a Consultant Respiratory Physician. I have held this position since 2003. I am also an Honorary Professor of Respiratory Medicine for The University of Nottingham and have held this position since 2015.

2. I make this second statement in response to a Request for Evidence under Rule 9 of the Inquiry Rules 2006, received from the UK Covid-19 Public Inquiry ("the Inquiry") dated 1 September 2023. This statement addresses matters which I understand are in scope of Module 4 of the Inquiry, which is examining a range of issues relating to the development of COVID-19 vaccines and the implementation of the vaccine rollout programme.

3. Per the Module 4 Request, I will address the matters of interest to the Inquiry during the period 30 January 2020 to 28 June 2022 ("the relevant period"). Where a matter is of interest but falls outside of this date range, I will make this clear and explain why it is relevant to the issues in the scope of Module 4.

4. I became the Joint Committee on Vaccination and Immunisation (JCVI) COVID-19 Chair on 6 May 2020. In this statement I have sought both to provide an account of JCVI's

structure, role, people and processes, its key decision, actions, and documents, and its involvement in vaccine delivery and uptake. Where I have provided a view about the efficacy of structures or actions, and reflections on lessons learned, those views are given in my personal capacity, and do not reflect a corporate view of the JCVI.

5. Information regarding my professional background and participation in Government advisory committees was provided in my first witness statement, provided to assist Module 1 of the Inquiry [INQ000198954].

6. To the extent that the facts set out within this Witness Statement are within my own knowledge, I confirm that they are true. Where facts and matters are not within my own knowledge, I state their source and confirm that they are true to the best of my information, knowledge, and belief.

JCVI's Structure, Role, People and Processes

7. The JCVI (the Committee) is an independent Departmental Expert Committee and a statutory body. JCVI is a Standing Advisory Committee established by statute under the NHS (Standing Advisory Committees) Order 1981 (SI 1981/597); hence JCVI is a statutory advisory committee. This order specifies that the Committee is constituted for the purpose of advising the Secretary of State on:

"The provision of vaccination and immunisation services being facilities for the prevention of illness."

8. The JCVI's terms of reference as agreed by the UK health departments and described in the Code of Practice are:

"To advise UK health departments on immunisations for the prevention of infections and/or disease following due consideration of the evidence on the burden of disease, on vaccine safety and efficacy and on the impact and cost effectiveness of immunisation strategies. To consider and identify factors for the successful and effective implementation of immunisation strategies. To identify important knowledge gaps relating to immunisations or immunisation programmes where further research and/or surveillance should be considered." (**WSL2/1 - INQ000145984)**

9. The Committee was originally an advisory board for polio immunisation that became JCVI in 1963. It was put on a statutory footing when it became a Standing Advisory Committee, established in England and Wales under the NHS Act 1977. It sat under the Central Health Services Council until 1980. The NHS (Standing Advisory Committees) Order 1981 (SI

1981/597) established the JCVI in its current form as the Standing Advisory Committee on Vaccination and Immunisation.

10. Under the NHS (Standing Advisory Committee) Order 1981, which was prior to the devolution settlement, the Committee provided advice to the Secretary of State in relation to Wales as well as England. Under the National Assembly for Wales (Transfer of Functions) Order 1999 the functions of the Secretary of State set out in section 6 of the NHS Act 1977 (which gave the Secretary of State the power to establish standing advisory committees by order) exercisable in relation to Wales, transferred to the National Assembly for Wales. Section 6 was repealed and replaced by section 250 of the NHS Act 2006 as regards England and section 189 of the NHS (Wales) Act 2006 for Wales. Paragraph 1 of Schedule 2 to the NHS (Consequential Provisions) Act 2006 provides that any subordinate legislation made under provisions in the 1977 Act has effect as if made or done under or for the purposes of the corresponding provision in the 2006 Act. By operation of this paragraph, the 1981 Order is to be treated as an order made under section 189 as well as section 250.

11. Functions of the National Assembly subsequently transferred to Welsh Ministers under the Government of Wales Act 2006. Section 250 of the NHS Act 2006 (which provided the power for the Secretary of State to establish standing advisory committees by order) and Schedule 19 to that Act (which made further provision about the membership and procedures of such committees) were repealed by section 283 of the Health and Social Care Act 2012. However, section 283(3) provided that the repeal did not affect the continuing effect of the NHS (Standing Advisory Committees) Order 1981, meaning that the JCVI remains a standing advisory committee. However, with the repeal of Schedule 19 to the NHS Act 2006, its membership and procedures are no longer prescribed by statute. Following the Cabinet Office's review of public bodies that completed in 2012 (**WSL2/2 - INQ000354611**), JCVI was reconstituted as a Departmental Expert Committee and ceased to be an Advisory Non-Departmental Public Body, although its statutory status was retained as explained above.

12. JCVI has no statutory basis for providing advice to Ministers in Scotland or Northern Ireland. However, health departments from these countries may choose to accept the Committee's advice or recommendations. Specific advice given by JCVI in response to a request from any one UK health department or Minister is not binding on any of the other Ministers of the Devolved Administrations or UK Government. UK health departments are made aware of all JCVI advice through their designated observers who attend JCVI and Sub-committee meetings and receive committee papers.

13. The Secretary of State for Health and Social Care is accountable to Parliament for JCVI as a public body. The Minister for Health and Social Services of the Welsh Assembly Government has equivalent accountability to the National Assembly for Wales.

14. Since the JCVI has been reconstituted as a Departmental Expert Committee, appointments of the Chair and members are made by the Secretary of State for Health and Social Care, via the Department of Health and Social Care (DHSC) appointments team.

15. Membership is on a voluntary basis and is through fair and open competition. In practice, the Chair and members are usually appointed for a term of up to three years with expiry at a defined date. Reappointment of members is not automatic. Members cannot usually serve on the Committee for more than 10 consecutive years. Members are not paid for their work on JCVI; however, they are eligible to claim expenses in accordance with UKHSA rules for travel, subsistence, and overnight accommodation, as described in the JCVI Code of Practice.

16. To note, on 1 October 2021 Public Health England (PHE) officially became the UK Health Security Agency (UKHSA). For clarity, the agency has been referred to as UKHSA throughout this statement.

JCVI normal ways of working

17. The main committee of JCVI usually meets three times per year, on the first Wednesday of February, June, and October; with occasional extraordinary meetings held to discuss the response to an urgent issue such as a rapid rise in cases of a vaccine preventable disease. JCVI is the only body which provides advice on the use of vaccines to the Government.

18. JCVI may choose to set up a sub-committee to undertake a detailed assessment on a specific topic. Development of advice by JCVI is commonly supported by such sub-committees. Sub-committees meet as required/necessary to discuss a specific vaccine, a new programme, or a change to an existing programme; they may meet as many times as required and this is typically one to three times in any given year. Sub-committees are always chaired by a JCVI member and membership is formed of JCVI members and additional subject matter experts. Subject matter experts are chosen by the Chair, working with the secretariat, to ensure all relevant subject matter expertise is available. An example is the human papillomavirus (HPV) sub-committee which has provided advice to JCVI on the use of reduced dose schedules (3 doses to 2 doses, then 2 doses to 1 dose) and higher valency HPV vaccines (e.g., HPV9).

19. Sub-committees do not provide advice to the Government, which remains the responsibility of the main committee.

20. During the pandemic period there was a COVID-19 sub-committee and a COVID-19 main committee. While all members of the main committee were invited to the sub-committee meeting, the inclusion of additional experts delineates the sub-committee from the main committee. The main committee, made up of members appointed through fair and open competition by the DHSC public appointments team, is the only body able to advise the Government.

21. The standard process for developing JCVI advice is outlined below.

1) The need for advice is identified by JCVI through horizon scanning indicating the future authorisation of a new vaccine, evidence on the potential for alternative use of an existing vaccine, a change in vaccine availability, or a change in the epidemiology of a vaccine preventable disease (e.g., an unexpected and rapid increase in cases of a certain disease).

2) JCVI agrees to refer the matter to an existing sub-committee or to set up a new sub-committee.

3) The JCVI chair chooses the chair of the sub-committee.

4) The sub-committee chair agrees the sub-committee membership.

5) The sub-committee reviews evidence on the disease epidemiology, vaccine safety, vaccine efficacy, number and timing of doses, and requests mathematical modelling on the potential impact and cost-effectiveness of a vaccination programme (cost effectiveness is based on the National Institute for Health and Clinical Excellence (NICE) methods for appraisal and this is in part set out in the Code of Practice).

6) The secretariat identifies modelling resource and supports modellers in development of the model.

7) The model is presented to the sub-committee and the sub-committee provide feedback (this may be an iterative process).

8) Once the modelling is finalised and all other necessary evidence on the vaccine under consideration is available to the sub-committee, the sub-committee will

develop advice for the main committee on the potential impact and cost-effectiveness of a new programme.

9) The sub-committee findings and modelling will be presented to the main committee.

10) The main committee will develop advice for Government on a vaccination programme, where such a programme is likely to be cost-effective.

11) In cases where the Health Protection (Vaccination) Regulations 2009 are triggered, the advice of JCVI is referred to as a 'recommendation'.

22. To maintain the independence of JCVI, industry representatives are not invited to meetings and may not present to the main committee. Under protocols published on the JCVI webpage, it is agreed that where necessary industry representatives may present factual evidence to a JCVI sub-committee.

23. During the pandemic response period, much of this work was condensed and advice often had to be developed rapidly. Cost-effectiveness was not taken into consideration due to the pre-procurement of the vaccine, and the clear potential benefit of a vaccination programme on the wellbeing of the UK population.

24. As always with JCVI advice, advice in the pandemic was presented to the Secretary of State for Health and Social Care, and ministers in the devolved nations. This also fulfilled advice from '*The 2009 Influenza Pandemic: An independent review of the UK response to the 2009 influenza pandemic'* by Dame Deirdre Hine, which stated that *"The Joint Committee on Vaccination and Immunisation should report directly to the central emergency meetings in a future pandemic"* (**WSL2/3 - INQ000035085**).

Independence and Conflicts of Interest

25. JCVI members must declare all their interests at the time of their appointment and must promptly notify the Secretariat of any changes. Before or at the start of every meeting members will be asked to declare any changes to their interests and the minutes of each meeting will include interests that are declared and how they have been handled. In addition, it is the responsibility of each member to indicate if they have an interest in any item of business on the agenda of a meeting of JCVI or a JCVI Sub-committee at the appropriate time. These are handled in accordance with the JCVI Code of Practice (**WSL2/1 - INQ000145984**).

26. In accordance with the Code of Practice for Scientific Advisory Committees, the Secretariat reviews and maintains a register of members' relevant interests annually, publishing details as part of an annual report or similar routine progress update. The register of relevant declarations of interest are published as an annex to every minute.

27. JCVI members and sub-committee members must abide by the following rules when deciding whether to declare an interest:

1) Personal pecuniary (financial payment or other benefit) interest

i. If a member has in the last 12 months received, or plans to receive a financial payment or other benefit from a business or representative body relating to vaccines or any other product or service that could be under consideration by JCVI or a sub-committee including:

i. holding a directorship, or other paid position

ii. carrying out consultancy or fee paid work

iii. having shareholdings or other beneficial interests

iv. receiving expenses (e.g., travel to, or registration for, conferences) and hospitality

the member must declare this interest. If this interest is specific to an agenda item and the payment or other benefit is connected specifically with the product under consideration, the member will be required to absent him/herself from the discussion and any subsequent vote. If this interest is not specific to the agenda item (i.e., if the payment relates wholly to other products), the member will be able to participate in the discussion but not in any subsequent vote.

2) Personal family interest

i. In the last 12 months, if one of a member's family received, or plans to receive, a financial payment or other benefit from a business or representative body relating to vaccines or any other product or service that could be under consideration by JCVI or a sub-committee including

i. holding a directorship, or other paid position

ii. carrying out consultancy or fee paid work

iii. having shareholdings or other beneficial interests

iv. receiving expenses and hospitality over and above the equivalent level provided by UKHSA to JCVI members for travel and subsistence (see section on expenses) then the member must declare this interest.

If the payment is connected with a product or service under consideration, the member will be required to absent him/herself from the discussion and any subsequent vote. If this interest is not specific to the agenda item (i.e., if the payment relates wholly to other products), the member will be able to participate in the discussion but not in any subsequent vote.

3) Non-personal pecuniary interest

i. If a member has senior responsibility for a department or organisation that has received or plans to receive a financial payment, or other benefit in the last 12 months from a business or representative body relating to a product or service under consideration, including:

i. a grant or fellowship or other payment to sponsor a post, or contribute to the running costs of the department

ii. commissioning of research or other work

then the member must declare this interest. If the payment or benefit is connected with a product under consideration, the member will still be able to participate in the discussion, unless the Chair rules otherwise, but not any subsequent vote. If the payment or benefit relates wholly to other products, the member will be able to participate in the discussion and any subsequent vote.

4) Personal non-pecuniary interest

i. If a member has acted in a way such that the public might reasonably believe that he or she will not consider evidence in a fair and unbiased manner, such as active advocacy, in the last 12 months, on behalf of an organisation with a clear opinion on the matter under consideration then the

Member must declare this interest. The member will be able to participate in the discussion and decision according to the Chair's ruling.

UKHSA role

28. UKHSA provide the secretariat for the JCVI (**WSL2/4 - INQ000354610**). The secretariat assists in the preparation of agendas, meeting minutes, and public statements, working closely with myself as chair. Options for potential vaccination strategies are typically developed by the secretariat and experts within UKHSA. The secretariat facilitates decision making by the committee, but does not make decisions. In this regard, the secretariat undertakes the background work important to the deliberations of the Committee, such as identifying which vaccine products are approved and available for consideration by JCVI, and identifying programme options for consideration. The JCVI secretariat also acts as an intermediary between the Committee and government. Throughout the pandemic response period, the secretariat was in daily contact with policy officials in DHSC and regular contact with the Deputy Chief Medical Officer (DCMO). The continual dialogue between DHSC and the secretariat ensured that JCVI advice was clearly understood and met the needs of policy officials advising Ministers.

29. It is for JCVI to set its own agenda. Advice formulated by the JCVI are a product of deliberation and discussion of the Committee. All statements from JCVI are owned by JCVI. The secretariat assists in developing initial drafts of statements through to their final form in an iterative process involving the Committee.

30. Topics for consideration by JCVI are identified by UKHSA or the UK health departments following requests for advice, by Members themselves, health professionals, or the public. Health professionals and members of the public can contact the JCVI secretariat by email or letter. Topics can also be identified through the Committee's annual horizon scanning of vaccine developments. A request is sent annually to vaccine manufacturers by the secretariat to provide information on vaccine products in development. Returns are compiled in a report which is presented at the June meeting of the JCVI main committee.

31. The Director of Public Health Programmes provides expert medical advice to JCVI as an observer. No UKHSA official attending on behalf of UKHSA (as opposed to as a member of JCVI) has any part in the Committee's development of advice and they cannot vote. They are there to provide expert input when requested and to share experience gained through decades of work in immunisation. UKHSA employees may be members of the Committee,

and during meeting such members are there only as Committee members. UKHSA employment is registered in the declarations of interest.

32. UKHSA provides world leading evidence to JCVI on the epidemiology of vaccine preventable diseases and vaccine effectiveness in the UK. UKHSA also provides attitudinal research on immunisation programmes and bespoke mathematical modelling studies of the impact and cost effectiveness of immunisations strategies.

33. UKHSA has set up workshops to review pandemic influenza vaccines both currently available and in development. Such information has been shared with JCVI to support the development of advice on pre-pandemic influenza vaccine stockpiles and to inform the use of contracts for pandemic specific vaccines.

34. UKHSA may have a role in the development of potential influenza vaccines, but this is outside the role of JCVI.

Overview of JCVI during the COVID-19 pandemic

35. In or around early April 2020, during early planning for the delivery of a COVID-19 vaccination programme in the UK undertaken by DHSC and the Vaccine Taskforce (VTF), it was identified by DHSC and the VTF that prioritisation of vaccines by JCVI was a crucial pillar of the strategy. This is in accordance with JCVI's terms of reference (paragraph 8) as an independent *scientific* advisory body which is constituted to formulate advice according to scientific data, such as the epidemiology of disease and efficacy of vaccines. Prioritisation and eligibility are typically based on maximising health benefits and on clinical need, as determined by consideration of relevant evidence. As such, in late April 2020, JCVI was asked to provide advice to DHSC on potential prioritisation of the offer of COVID-19 vaccination when such vaccines might be approved for use in the UK.

36. At this time, it was noted by the members of the committee and the secretariat that the appointed Chair of JCVI, Professor Sir Andrew Pollard, was involved in the development of the AstraZeneca COVID-19 vaccine Vaxzevria®. The secretariat duly approached the Deputy Chief Medical officer (DCMO), Professor Sir Jonathan Van-Tam, to bring this potential conflict of interest to his attention (direct correspondence 5 and 6 May 2020). On 6 May 2020 it was agreed with the DCMO and Chief Medical Officer (CMO) that Professor Sir Andrew Pollard should recuse himself from JCVI discussions. In follow up conversations, it was agreed that a Chair should be chosen from the membership of the Committee, as per the Code of Practice. At the time, I believe the Deputy Chair, Professor Anthony Harnden was unfortunately unavailable due to personal reasons, and I was asked

if I would be willing to Chair the committee, given my work on the New and Emerging Respiratory Viral Threats Advisory Group (NERVTAG; which had been meeting regularly in response to COVID-19 since 13 January 2020 and hence contributing to my knowledge of COVID-19) and my specialism in respiratory infections. I agreed to take on the role of Chair for COVID-19 on 6 May 2020. The secretariat relayed this information to the committee at the start of the first meeting held to discuss COVID-19 vaccinations on 7 May 2020 (**WSL2/5 - INQ000354439**). Members noted and agreed with proceeding on this basis.

37. JCVI is an independent committee, and typically there is no direct contact between JCVI and Ministers and Special Advisors. Much of my contact with the DHSC was through the DCMO Professor Sir Jonathan Van-Tam and DHSC officials working with him. I have joined meetings of DHSC officials following JCVI meetings, where the outcomes of the meetings were discussed and clarified as necessary. For a short period during the early part of the pandemic (when Matt Hancock was SofS), I was invited to join occasional meetings chaired by the SofS to provide any relevant updates from JCVI. (I cannot recall exactly when these meetings occurred; there were perhaps about a dozen such meetings, all held on-line). At no time did I have direct discussions with SofS regarding the formulation of JCVI advice.

38. Interactions in my role included contact with:

1) COVID-19 Senior Civil Service 1 (SCS) - several people (DHSC)
2) Mary Ramsay, Head of Immunisation at UKHSA
3) Chief Medical Officer (CMO) and DCMO
4) Independent academics (long list), notable academic groups included OpenSAFELY, and QCOVID.
5) Non-Government bodies, including the Royal College of General Practitioners (RCGP), Royal College of Nursing (RCN), Royal College of Paediatrics and Child Health (RCPCH), Royal College of Physicians (RCP), Royal College of Psychiatrists, British Thoracic Society (BTS)
6) Scientific Advisory Group for Emergencies (SAGE)
7) New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) (member)
8) Vaccine Taskforce (VTF) (now COVID-19 Vaccines Unit (CVU)), Medicines and Healthcare products Regulatory Agency (MHRA) (observers at meetings)
9) NHS England (NHSE), devolved administrations (largely via JCVI meetings)
10) UKHSA Communications team

39. Three key JCVI committees were set up with respect to COVID-19:

1) The COVID-19 Committee, which has the same standing as JCVI and can provide advice to DHSC.
2) The COVID-19 sub-committee which undertook a deeper review of data and advised the main committee; it did not provide advice to DHSC.
3) The Vaccine Monitoring Working Group which reviewed the latest data on the use of COVID-19 vaccines in the UK and internationally and fed back to the COVID-19 Committee.

40. The JCVI COVID-19 Committee refers to JCVI when chaired by myself, and when COVID-19 was the single topic of discussion. All other meetings of main JCVI are chaired by Professor Sir Andrew Pollard and are referred to as JCVI meetings. The JCVI COVID-19 committee provided advice to four UK Health Departments and Ministers in the same way as 'regular' JCVI does. I also Chaired the COVID-19 sub-committee.

41. Membership of the JCVI COVID-19 committee during the relevant period:

i. Professor Lim Wei Shen (Chair)
ii. Professor Anthony Harnden, Deputy Chair (University of Oxford)
iii. Dr Kevin Brown (UKHSA)
iv. Dr Rebecca Cordery (UKHSA)
v. Professor Robert Read (Southampton General Hospital)
vi. Professor Anthony Scott (London School of Hygiene & Tropical Medicine)
vii. Professor Adam Finn (University of Bristol)
viii. Professor Maarten Postma (University of Groningen)
ix. Professor Simon Kroll (Imperial College London)
x. Dr Martin Williams (University Hospitals Bristol)
xi. Professor Jeremy Brown (University College London Hospitals)
xii. Prof Matt Keeling (Warwick University)
xiii. Dr Maggie Wearmouth (finished term 28 February 2022)
xiv. Dr Fiona Van der Klis (The Dutch National Institute for Public Health and the Environment) (stepped down 7 April 2022)
xv. Alison Lawrence (lay member)
xvi. Dr Jillian Johnston (Northern Ireland – Co-opted member)
xvii. Dr Julie Yates (England – Co-opted member)
xviii. Dr Lorna Willocks (Scotland – Co-opted member)
xix. Anne McGowan (Wales – Co-opted member)

42. Membership of the COVID-19 sub-committee was the same as the COVID-19 committee with the addition of three co-opted experts:

i. Prof Liz Miller (London School of Hygiene & Tropical Medicine) (Co-opted for COVID-19, non-voting) (expertise in vaccinology and immunology)
ii. Prof Bryan Charleston (Pirbright Institute) (Co-opted for COVID-19, non-voting) (expertise in immunology)
iii. Prof Robert Dingwall (Nottingham Trent University) (Co-opted for COVID-19, non-voting) (expertise in ethics, concurrent member of MEAG)

43. Additional expertise on human behaviour was provided by a regular representative from the Independent Scientific Pandemic Insights Group on Behaviours (SPI-B)

44. Membership of the Vaccine Monitoring Working Group was the same as the COVID-19 sub-committee but with Professor Anthony Scott as Chair. The Vaccine Monitoring Working Group was set up specifically to review data accumulating from the rollout of COVID-19 vaccines in the UK and internationally and focussed on vaccine safety and effectiveness. As this working group primarily reviewed unpublished data, formal minutes of these meetings were not taken. The first meeting took place on 9 March 2021.

45. The Key individuals undertaking preparatory work, including liaison with the Chair, evaluating programmatic options, commissioning data and analyses from UKHSA and identifying available evidence for JCVI were:

i. Dr Mary Ramsay
    i. Head of Immunisation (now Director of Public Health Programmes – UKHSA)
    ii. Grade SCS2
    iii. Medical Advisor to JCVI
    iv. Reports to Dr Susan Hopkins (UKHSA Chief Medical Officer)
    v. Head of Immunisation since 2009, Medical Advisor to JCVI from 2013 to present

ii. Mr Andrew Earnshaw
    i. Head of the JCVI Secretariat
    ii. Civil Service Grade 6
    iii. Reports to Dr Gayatri Amirthalingam and Dr Mary Ramsay
    iv. In the JCVI secretariat from December 2010 to present.

46. As stated, the JCVI first met to discuss COVID-19 vaccination on 7 May 2020 (**WSL2/5 – INQ000354439**). The aim of the meeting was to provide provisional advice on prioritisation of person groups for vaccination with a potential COVID-19 vaccine. The secretariat presented a paper on priority groups for immunisation at the meeting (**WSL2/6 -**

INQ000354438). The advice was to help the Department of Health and Social Care (DHSC) with their planning for a COVID-19 vaccination programme. The interim advice was published 18 June 2020 (**WSL2/7 - INQ000106485**).

47. It was noted at the meeting on 7 May 2020 that there could be a requirement for a COVID-19 sub-committee to be set up, which would allow for additional expertise to feed into JCVI and provide the opportunity for vaccine developers to present their data.

48. The first JCVI COVID-19 sub-committee was held on 24 September 2020. All JCVI members were invited to be a member of the COVID-19 sub-committee, and all members accepted the invitation. Three additional individuals were invited to join the sub-committee to expand the expertise on the committee regarding vaccinology, immunology, and ethics.

49. Between the start of May 2020 and the end of June 2022 the COVID-19 main committee met 59 times and the JCVI COVID-19 sub-committee met 39 times. A list of meeting dates is provided at Annex B.

Basis for formulation of advice to Secretary of State during the COVID-19 pandemic

50. In standard practice, JCVI uses the methodology and criteria of the NICE. Using the NICE approach, a vaccination programme can be considered to be cost effective if the health benefits (both the direct health benefits to those vaccinated and the indirect health benefits to the unvaccinated population) are greater than the opportunity costs measured in terms of the health benefits associated with programmes that may be displaced to fund the new vaccination programme. The Committee also takes account of the advice and recommendations of the Working Group on Uncertainty in Vaccine Evaluation and Procurement when assessing cost effectiveness (**WSL2/1 - INQ000145984**).

51. In response to the COVID-19 pandemic, JCVI was instructed by DHSC to formulate advice for the use of COVID-19 vaccines without taking formal account for the costs of vaccine procurement nor the costs of deployment of the vaccine. (During the pandemic, vaccine procurement decisions were taken independently by the VTF and without involvement of JCVI. Vaccines were procured on a 'no-regrets' basis, further clarification on this can be provided by DHSC and VTF.)

52. JCVI was also instructed not to take formal account of potential benefits from vaccination to wider social and economic spheres (to note: these wider societal benefits do not form part of JCVI's usual non-pandemic cost-effectiveness assessments either).

53. In developing its advice during the COVID-19 pandemic, JCVI took into consideration scientific rationale, vaccine programme deliverability, public acceptability, and equity (information on these considerations were provided or presented to JCVI at JCVI meetings by UKHSA, NHSE, MHRA, independent academics, and others as appropriate). From the outset, JCVI was keenly aware that the COVID-19 vaccine programme would be the largest mass vaccination programme ever delivered in the UK, conducted under circumstances where speed of deployment would be of major importance. In support of effective vaccine deployment, JCVI worked to provide advice that enabled a programme that was simple to communicate and simple to deliver.

54. The formulation of advice by JCVI was informed by the conduct and rapid reporting of high-quality research throughout the pandemic (the source of research was both global and UK-based; much of the research in the UK was funded by the NIHR – for more details on NHIR-funded UK research, please contact the NIHR). The UKHSA, UK academic institutions, and vaccine manufacturers provided important support in terms of acquisition and analysis of relevant data. Sharing of information by the MHRA on the regulation of vaccines and monitoring of vaccine safety was required for the development of timely advice on vaccine use and in response to potential safety concerns. Regular consideration of data from NHSE on vaccine deployment in England, and from the devolved nations on data arising in their respective countries, was important in monitoring the programme and advising adjustment where necessary. Regular updates from the VTF provided the Committee with important understanding of the vaccine pipeline and vaccine product options. The DHSC provided timely views and posed questions related to policy matters – these communications were with the secretariat through telephone, meetings, or email. On larger issues under consideration, instruction would be provided by letter (email).

55. There were many challenges in developing advice during a dynamic situation when scientific information was changing (and accumulating) at a high pace. There was a recognised need to provide advice which made clinical and scientific sense, whilst also giving attention to the importance of public understanding and acceptability of scientific advice in promoting vaccine confidence and ultimately vaccine uptake. All advice provided by JCVI was developed in Committee meetings, with advice agreed by consensus, or majority vote.

56. JCVI provided independent advice to SofS on 28 separate occasions during the period in question. SofS agreed with JCVI advice in all instances. Agreed advice was publicly issued through JCVI Statements; 25 statements were published. On other occasions, public announcement of JCVI advice was through DHSC. Operational aspects of JCVI advice

(directed towards vaccination deployment teams) was issued via updates to the Green Book: Immunisation against infectious disease (**WSL2/8 - INQ000354471**).

57. A summary of all advice provided to the Secretary of State for Health on COVID-19 vaccination from the start of the pandemic through to April 2022 is provided at Annex A.

58. Dissemination of JCVI advice was supported through official televised press briefings, background technical briefings with the media, or through engagement of JCVI members in media interviews (over 500 media interviews completed) and briefings for parliamentarians. These press briefings and media interviews were undertaken to improve public understanding of the rationale behind published advice.

59. With regards specifically to COVID-19 vaccines,

1) JCVI had no role in vaccine procurement; this was the responsibility of the VTF (and later the CVU)

2) JCVI had no role in delivery of COVID-19 vaccines; this was the responsibility of NHSE and equivalent bodies in the Devolved Administrations

3) JCVI had no role in performance management over NHSE

4) JCVI had no role in the Vaccine Damage Payment Scheme

5) JCVI had no role in vaccine donations

<u>Prioritisation, vaccine delivery and uptake</u>

60. Prior to any vaccines being authorised, JCVI considered how vaccines might best be deployed to counter the pandemic. Consideration was given to both eligibility for COVID-19 vaccines and prioritisation of cohorts.

61. Key points of consideration by the committee included:

1) The role of direct (individual) protection in the strategy

2) The role of reducing transmission in the strategy

3) The role of occupational vaccination

4) Prioritising prevention of severe disease

5) Protecting the NHS

62. In October 2020, the JCVI was asked by the Secretary of State and VTF to advise on the potential role of vaccination strategies in reducing reliance on non-pharmaceutical interventions. To consider this issue, a JCVI working group, involving representatives from the Government Chief Scientific Adviser('GCSA'), the New and Emerging Respiratory Virus Threats Advisory Group 'NERVTAG'), UKHSA, NHSE and VTF, reviewed the rationale for the use of different vaccination strategies in prioritisation. JCVI is a scientific advisory committee, as opposed to a policy advisory committee. JCVI was not specifically asked to take formal ethical advice when formulating its own advice. This is consistent with usual working practice where DHSC has responsibility for taking into account ethical issues, and seeking formal advice where required, when considering the advice from JCVI and developing Government policy. (Please also see paragraphs 75 and 76 where JCVI's ethical considerations in general are further explained.) UKHSA presented a paper on the potential role of different vaccination strategies on reducing the reliance on NPIs (**WSL2/9 - INQ000354448**). Specifically, two strategic options were considered:

1) targeting of groups at high-risk for COVID-19 related morbidity and mortality; and
2) targeting economically active people who are at lower risk of severe disease but play an important role in driving transmission.

These two options are consistent with the approach usually taken for immunisation programmes.

The main conclusions from the work were that:

i. "*The current JCVI prioritisation, which prioritises those at highest individual risk, will have the highest impact on mortality in a situation of constrained vaccine supply. Such a policy is likely to be the most acceptable option and would be able to achieve high vaccine coverage.*

ii. *As well as relaxation of shielding approaches in the high-risk population themselves, such a programme may allow the relaxation of NPIs in other sectors of the population by reducing visible morbidity and mortality and reducing pressure on ICU and hospital capacity. In response to this, the economically active younger population may see a lower risk of infection to others and this perception may allow them to resume consumption and therefore increase demand for services.*

iii. *A programme targeting the economically active population is a credible alternative strategy that could have a larger impact on preventing the total number of infections, as this age group are more likely to drive transmission. However, for such a programme to protect those at highest risk for mortality, modelling indicates that a high proportion of the population will need to be vaccinated.*

iv. *Given that vaccine supply will initially be constrained, using the strategy in paragraph 10* [note for clarity: that is, targeting the economically active population] *over the early months of a programme risks a large number of preventable deaths, unless very*

stringent NPIs and/or shielding of the vulnerable is in place. Such a programme may also be more challenging to implement, particularly if there are any safety concerns or uncertainties. There is already evidence that this age group is less willing to accept a vaccine, which suggests that their perception of their own individual risk from COVID-19 is lower, and so it is unclear how reducing that risk further will impact on reliance on NPIs, and on economic and social activity, particularly if they still perceive a high risk to others. A programme targeting economically active populations raises ethical concerns, including having a greater potential to increase inequalities." **(WSL2/9 - INQ000354448)**

63. Mathematical modelling from UKHSA, the London School of Hygiene and Tropical Medicine, and the University of Warwick assessed the impact of different vaccination strategies should vaccines be effective at reducing transmission of infection; these models suggested only limited differences in hospitalisations and deaths under different scenarios. It was further recognised that at the outset of any programme, it would not be known whether vaccines might reduce transmission. Therefore, there was a substantial risk that a vaccine programme which relied on vaccines capable of effectively preventing infection and onward transmission would not be optimal. The Committee's interim advice on prioritisation in 2020 was to prioritise those at higher risk of severe disease, rather than those more likely to transmit infection.

64. The paper containing these conclusions was provided to DCMO Professor Sir Jonathan Van-Tam from UKHSA in a submission dated 12 October 2020 (**WSL2/9 – INQ000354448**)[1]. My understanding is that this then informed a submission to SofS from DHSC officials and the DCMO. I understand that SofS and wider Government agreed with these findings allowing JCVI to proceed with agreeing a prioritisation approach to maximise prevention of morbidity and mortality.

65. Alongside the conclusion that the priority for vaccination should be the direct prevention of severe disease and mortality from COVID-19, alongside protection of the NHS and social care systems, the Committee agreed that it was important to have a simple vaccination programme that was deliverable at scale and pace, taking into account uncertainties with regard to vaccine availability and vaccine effectiveness in older adults. Prioritisation is necessary to maximise health benefits of a programme where there are constraints on vaccine supply and delivery capacity. A similar process was undertaken when advising on

[1] UKHSA prepared a paper on the role of different vaccination strategies on reducing the reliance on NPIs, which was presented at the meeting. UKHSA also provides the secretariat to the JCVI. The paper was submitted to DCMO by Dr Mary Ramsay, the medical advisor to JCVI and UKHSA expert lead for immunisation. It was then from within DHSC that the paper went up to SofS.

use of pandemic influenza vaccines in 2009 (**WSL2/10 - INQ000206619**; **WSL2/11 - INQ000206617**; **WSL2/12 - INQ000354431**).

66. UKHSA and UK academic departments routinely provided data to JCVI on the epidemiology of COVID-19 in the UK, and on individual person factors associated with an increased risk of hospitalisations and deaths from COVID-19. Two large primary care datasets provided important data: OpenSAFELY and QCOVID (**WSL2/13 - INQ000354442**; **WSL2/14 - INQ000315529**). Data from all sources indicated that the single factor most strongly associated with an increased risk of severe COVID-19 disease (hospitalisation and death) was advancing age; the risk increasing particularly from around age 50 years. Data also indicated certain underlying health conditions increased the risk of severe disease COVID-19, although in absolute terms the risk was still highest in those over the age of 70 years (**WSL2/15 - INQ000354449**; **WSL2/16 -INQ000354451**; **WSL2/17 - INQ000354453**).

67. In terms of vaccine deployment, JCVI took into consideration the logistics of delivery, including vaccine supply and storage requirements, and the potential speed of delivery to all adults in the UK. JCVI determined that a simple programme would maximise the ability to deliver vaccines at pace, allow the public to engage with the programme based on the evidence, and simplify communications activity around the benefits of vaccination and when someone was likely to become eligible for vaccination. As age was the single most important risk factor for severe disease, hospitalisation and mortality, JCVI concluded that an age-based programme should form the backbone of the COVID-19 vaccine programme. Experience from other immunisation programmes over many years has consistently found that simple age-based programmes are associated with higher vaccine coverage.

68. JCVI had no role in organising vaccine deployment. Vaccine deployment plans were presented by NHSE and deployment teams to JCVI for information, and while JCVI might offer comment or raise questions on these plans to deployment teams during Committee meetings, JCVI endorsement was not a requirement for the finalisation of deployment plans. Any comments or questions raised by JCVI would have been recorded in the relevant minutes.

69. The final JCVI advice on phase 1 priority groups for COVID-19 vaccination was published on 30 December 2020 (**WSL2/18 - INQ000256951**; **WSL2/19 - INQ000256950**). The nine priority groups were:

    1) residents in a care home for older adults and their carers
    2) all those 80 years of age and over and frontline health and social care workers
    3) all those 75 years of age and over

4) all those 70 years of age and over and clinically extremely vulnerable individuals
5) all those 65 years of age and over
6) all individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality
7) all those 60 years of age and over
8) all those 55 years of age and over
9) all those 50 years of age and over

Inequalities and barriers to uptake

70. Early data from PHE in the August 2020 published report *"Disparities in the risk and outcomes of COVID-19"* (**WSL2/20 - INQ000101218**) summarised the disproportionate impact of COVID-19 on certain ethnic groups, people experiencing social deprivation, working age males, those residing in urban conurbations, individuals residing in care homes for older adults, certain occupations groups, along with already described risk factors such as age and underlying health conditions. With such a wide variety of factors associated with poorer outcomes from COVID-19, it was reasonable to consider whether some specific groups should be prioritised for vaccination.

71. In the Annex to its advice on prioritisation, UKHSA summarised that *"…a programme that combines clinical risk stratification, an age-based approach and prioritisation of health and social care workers should optimise both outcomes and deliverability. Simple age-based programmes are usually easier to deliver and therefore achieve higher uptake including in the highest risk groups." "While prioritisation alone cannot address all inequalities in health that are rooted in social determinants, planning and implementation should, as a minimum, not worsen health inequalities, and present a unique opportunity to mitigate them"* (**WSL2/18 - INQ000256951**).

72. The Annex to the JCVI advice was well received, and credit should be given to the expert authors in UKHSA who developed the paper for JCVI (**WSL2/18 - INQ000256951**).

73. JCVI considered and identified barriers to vaccine uptake, including cultural and ideological barriers, at an early stage. This enabled delivery planners to take account of these barriers to uptake during planning of the programme. JCVI advised that due attention and effort should be given to promote vaccine uptake in marginalised communities whilst maintaining an overall high pace of vaccine delivery within the programme.

Ethical considerations

74. JCVI is a scientific advisory committee familiar with considering the ethical aspects of clinical decisions. At JCVI meetings, potential ethical issues which might arise in the translation of JCVI advice into Government policy were identified. The co-chair of the Moral and Ethical Advisory Group (MEAG), which provided advice to request from Government on moral and ethical aspects of the COVID-19 response, attended the first JCVI meeting on 7 May 2020 to introduce the work of the group. In addition, as a member of both MEAG and the JCVI COVID-19 sub-committee, Professor Robert Dingwall was able to provide regular vigilance on ethical issues at JCVI COVID-19 meetings.

75. The Government also had support from the Moral and Ethical Advisory Group (MEAG) and the JCVI Secretariat spoke and presented to MEAG on occasion to support them in their role.

76. JCVI advice has always been independent, and evidence based, and JCVI maintains political neutrality. JCVI took an independent view on vaccination of those who were homeless, in prison, or with uncertain immigration status. The guiding factor was that no group should have a higher priority for access to vaccination without a clear evidence-based rationale.

77. Specifically, JCVI reviewed evidence on risk factors associated with poor outcomes and the potential for outbreaks in relation to prison populations and people experiencing homelessness (**WSL2/21 - INQ000354478**).

78. On 1 March 2021, I sent a letter to the Secretary of State for Health regarding further considerations on phase 1 advice, particularly around homelessness and prison workers, prisoners, and detained estates (**WSL2/22 - INQ000354434**). For people experiencing homelessness and rough sleeping, JCVI advised that local teams exercise operational judgment and consider a universal offer to people experiencing homelessness and rough sleeping, alongside delivery of the programme to priority group 6, where appropriate. Given the high efficacy of the first vaccine dose, JCVI was of the view that these groups should be offered the first dose even where NHS registration was not possible. Regarding detention facilities, JCVI recognised that there may be an increased risk of transmission due to the high concentration of individuals, and potential difficulty in maintaining social distancing. However, we did not yet know the extent of the impact of COVID-19 vaccines on transmission, and vaccination solely for the prevention of transmission was not advised. Therefore, the Committee agreed that it would be difficult to advise additional prioritisation

of prison officers and detainees above the wider population based on the potential increased risk of exposure in a detained setting alone.

79. The potential for vaccination to impact health inequalities is well-recognised by JCVI. JCVI worked closely with UKHSA to formulate advice that would mitigate the effects of health inequalities, with careful sight of attendant ethical aspects. This work was informed by the PHE Health Equity Audit report, the PHE Equity Local Action Plan, and the PHE Equity Strategy these documents were unpublished at the time (October 2020) (**WSL2/23 - INQ000354479**; **WSL2/24 - INQ000354480**; **WSL2/25 - INQ000354481**).

80. A peer-reviewed paper published in the Lancet Regional Health – Europe "*Maximising benefit, reducing inequalities and ensuring deliverability: Prioritisation of COVID-19 vaccination in the UK*" co-authored by myself and UKHSA colleagues provides further information (**WSL2/26 - INQ000354467**).

    1) In this paper, a point is raised that "*It is recognised that prioritisation of some groups over others based on sociodemographic factors, such as ethnicity, can have unintended consequences*"…"*This view is supported by the findings of PHE's Beyond the Data report, which highlighted how some communities reported increased experiences of stigma and discrimination as they were viewed as being more likely to be infected with the disease. It is paramount that efforts at prioritisation do not inadvertently reinforce these negative stereotypes nor increase stigma and discrimination. In a context of low trust among some communities, being given early access to a new vaccine may feel like exploitation or experimentation rather than inclusivity.*" ……. "*As a result of its process, JCVI agreed that COVID-19 vaccination should be prioritised in a way that maximises benefit and reduces harm, reduces health inequalities, and can be implemented at pace whilst maintaining public trust*" (**WSL2/26 - INQ000354467; WSL2/27 - INQ000106482**). (Note: this refers to JCVI's advice that the backbone of Phase 1 of the COVID-19 vaccination programme should be prioritisation according to age, as age is the single most important factor associated with an absolute risk of severe COVID-19.)

<u>Prioritisation of the first dose / extended schedule – December 2020</u>

81. JCVI has a long history of advising alternative schedules for vaccines used in the routine vaccination programme, including on reduced dose schedules of Human Papilloma Virus (HPV) vaccines and pneumococcal conjugate vaccines. For vaccines with full marketing authorisations, using a vaccine 'off-label' means that although the vaccine is authorised for

use, it's being used in a way that is slightly different from the strict terms laid down in its license. Such 'off-label' use is common, with healthcare workers supported in administering vaccines off-label through guidance set out in the Green Book: Immunisation against infectious disease. In a fast-paced pandemic, the flexibility to provide 'off-label' advice is potentially even more apposite.

82. It should be noted that vaccine schedules for many vaccines are not the same around the world. National Immunization Technical Advisory Groups (NITAGs) formulate advice that is individualised to the needs of their country or jurisdiction, taking into account the regulatory position. As an example, the European Medicines Agency (EMA) is the regulatory body for Europe, but the vaccination policies of individual European countries are determined by different National Immunization Technical Advisory Groups ('NITAGs') and these policies may differ.

83. In December 2020, shortly after the start of the vaccine programme, JCVI was presented with an epidemiological picture of rapidly increasing COVID-19 cases associated with the Alpha variant, alongside forecasts for vaccine availability. At the time, it was noted that deployment teams were holding back some vaccine product to enable second doses to be delivered within 3 to 4 weeks of the first dose, in accordance with MHRA approvals. A decision was required on what additional actions could be taken to maximise the benefits from available vaccine doses at a time of high disease burden.

84. From trial data provided to the Committee by Pfizer-BioNTech and AstraZeneca (subsequently published), it was evident that substantial protection was afforded by the first dose of COVID-19 vaccine. JCVI considered whether prioritising delivery of the first dose could increase the public health benefit of available vaccine doses in the UK. At the time, the MHRA authorisation under regulation 174 of the Pfizer-BioNTech vaccine only allowed for vaccination with a two-dose schedule with an interval of three weeks between doses. Because of the legal status of a regulation 174 authorisation, off-label use of the vaccines could not be undertaken under a Patient Group Directive (PGD), thereby preventing off-label use in a mass vaccination setting.

85. Following review by the MHRA, and in agreement with Pfizer-BioNTech, the information for healthcare professionals was updated to indicate the interval between doses should be "at least" three weeks. The Summary of Product Characteristics (SPC) was updated on 30 December 2020. The next day, JCVI published advice on prioritisation of the first vaccine dose over the second dose with extension of the dose interval as appropriate to enable such prioritisation. (**WSL2/28 - INQ000354470; WSL2/29 - INQ000305156; WSL2/30 -**

INQ000305157; **WSL2/8 – INQ000354471**). This advice was based on immunological principles, published data relating to the Pfizer-BioNTech COVID-19 vaccine, and (at the time) unpublished data related to the AstraZeneca COVID-19 vaccine.

86. The JCVI advice dated 31 December 2020 stated as follows:

> *"Given the high level of protection afforded by the first dose, models suggest that initially vaccinating a greater number of people with a single dose will prevent more deaths and hospitalisations than vaccinating a smaller number of people with two doses."* **(WSL2/30 - INQ000305157)**

87. The output for the models referred to in the advice, was published in January 2021 and it concluded that *"...a strategy based on maximising the number of primary doses given (while ensuring everyone has their second booster dose within 12 weeks) will lead to a greater number of deaths averted than a strategy which prioritises giving a second dose at 3 weeks"* **(WSL2/30A - INQ000361216)**. The modelling was also discussed in the 8th main meeting of the JCVI on 22 December 2020 **(WSL2/32 - INQ000354462)**.

88. There have since been three publications that have provided some grounding to this modelling:

1) *"Comparison between one and two dose SARS-CoV-2 vaccine prioritization for a fixed number of vaccine doses"* published in September 2021 was essentially the peer-reviewed and more comprehensive version of the January 2021 publication **(WSL2/30B – INQ000421742).**

2) *"The impacts of SARS-CoV-2 vaccine dose separation and targeting on the COVID-19 epidemic in England"* published in February 2023 used much more complex models to address the counterfactual situation of using a 3-week dose interval; and concluded that *"The 12-week delay was also highly beneficial, estimated to have averted between 32-72 thousand hospital admissions and 4-9 thousand deaths over the first ten months of the campaign (December 2020–September 2021)"* **(WSL2/101 - INQ000354603)**.

3) *"Quantifying the effect of delaying the second COVID-19 vaccine dose in England: a mathematical modelling study"* also published in February 2023 (by the Imperial College group), provided an independent validation of the results: *"In the period from Dec 8, 2020, to Sept 13, 2021.... we estimated that delaying the interval between the first and second COVID-19 vaccine doses from 3 to 12 weeks averted*

a median of 58,000 COVID-19 hospital admissions and 10,100 deaths." **(WSL2/102 - INQ000354602)**.

89. JCVI comprises experts in, *inter alia*, vaccines, vaccinology, epidemiology, and immunology. This expertise has allowed the UK to have a highly innovative and comprehensive vaccination programme. Applying the expertise of the committee to the challenges faced in December 2020, alongside strong working relationships between the Secretariat and the MHRA, allowed for the implementation of a revised schedule which saved lives in the UK.

Pregnancy and breastfeeding women

90. When JCVI met on 1 December 2020, it was to finalise advice on Phase 1 of the COVID-19 vaccination programme, following the decision earlier that day by the MHRA to authorise use of the Pfizer-BioNTech COVID-19 vaccine under regulation 174. JCVI at this meeting noted wording in a draft Summary of Product Characteristic (SmPC) provided to the Chair by the MHRA.

91. The SPC noted the absence of data on the use of the vaccine in pregnant women and the SPC stated that the vaccine should not be offered to women who might be pregnant. The legal nature of the regulation 174 process meant that JCVI could not advise off-label use of the vaccine in a mass vaccination setting. Hence, at that time, JCVI's advice on vaccination in pregnancy reflected the prevailing regulatory position; the 2 December 2020 JCVI Statement of advice reads: "*There are no data as yet on the safety of COVID-19 vaccines in pregnancy, either from human or animal studies. Given the lack of evidence, JCVI favours a precautionary approach, and does not currently advise COVID-19 vaccination in pregnancy. Women should be advised not to come forward for vaccination if they may be pregnant or are planning a pregnancy within three months of the first dose. Data are anticipated which will inform discussions on vaccination in pregnancy. JCVI will review these as soon as they become available*." **(WSL2/50 - INQ000354461**) Operational challenges of the MHRA position were noted, particularly around delivery of the vaccine to health and social care workers.

92. Vaccination of pregnant women was discussed again on 03 December 2020 at the subcommittee meeting and at the JCVI COVID-19 meetings on 22 December 2020 and 29 December 2020 (**WSL2/31 - INQ000354463**; **WSL2/32 - INQ000354462**; **WSL2/33 - INQ000354468**). On 30 December 2020 JCVI updated its advice to women who are pregnant: "*There is no known risk associated with giving non-live vaccines during*

pregnancy. These vaccines cannot replicate, so they cannot cause infection in either the woman or the unborn child. Although the available data does not indicate any safety concern or harm to pregnancy, there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy. JCVI advises that, for women who are offered vaccination with the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines, vaccination in pregnancy should be considered where the risk of exposure to Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV2) infection is high and cannot be avoided, or where the woman has underlying conditions that put them at very high risk of serious complications of COVID-19. In these circumstances, clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnant women" (**WSL2/34 - INQ000354469**). The SPC for the Pfizer-BioNTech COVID-19 vaccine was updated by MHRA on 31 December 2020 to read "*Administration of the COVID-19 mRNA vaccine BNT162b2 in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus."*

93. On 13 April 2021, the Committee finalised its advice on Phase 2 of the programme for healthy persons aged 18 to 49 years, a group at much lower risk from COVID-19 (**WSL2/35 - INQ000257445**). On 16 April 2021 the Committee issued further advice for pregnant women that "*…it is preferable for pregnant women in the UK to be offered the Pfizer-BioNTech or Moderna vaccines, where available. There is no evidence to suggest that other vaccines are unsafe for pregnant women, but more research is needed."* (**WSL2/36 - INQ000354500**). This advice followed a review of data from the US on vaccination of over 90,000 pregnant women. These data were highly reassuring that there were no concerns with the use of mRNA vaccines in pregnant women. The Committee continued to advise that pregnant women should discuss the risks and benefits of vaccination with their clinician. There were also theoretical concerns around the signal for Thrombosis and Thrombocytopenia Syndrome (TTS) in younger adults following vaccination with the AstraZeneca COVID-19 vaccine, which further strengthened the preference for mRNA COVID-19 vaccine in pregnancy.

94. In a press release at the time, I stated:

"We encourage pregnant women to discuss the risks and benefits with their clinician – those at increased risk of severe outcomes from COVID-19 are encouraged to promptly take up the offer of vaccination when offered." (**WSL2/36 - INQ000354500)**

95. As the reassuring data coincided with Phase 2 of the programme, the Committee advised that pregnant women should be offered the COVID-19 vaccine at the same time as the rest

of the population, based on their age and clinical risk group. Given the pace of the programme, this was considered the most efficient means to deployment. At this time of the programme, both the UKHSA and RCOG agreed that offering vaccination to pregnant women in line with JCVI priority groups was the right approach (**WSL2/37 -INQ000354491**).

96. At a meeting on 02 December 2021 the Committee reviewed updated data from the UK on COVID-19 outcomes in pregnant women. These new data indicated a change in the risk profile for pregnant women potentially associated with circulation of the Delta variant of COVID-19 in the UK. In response JCVI advised on 16 December 2021 that all pregnant women should be offered COVID-19 vaccines in line with other groups considered to be at increased risk of COVID-19 due to underlying health conditions (**WSL2/38 - INQ000354556**; **WSL2/39 - INQ000354510**; **WSL2/40 - INQ000354541**; **WSL2/41 - INQ000354578**; **WSL2/42 - INQ000354551**; **WSL2/43 - INQ000112141**).

97. JCVI has received criticism for not prioritising pregnant women sooner. The Committee has always been led by the evidence on COVID-19 disease and evidence on the safety of the vaccine. Early evidence on the safety of vaccination in pregnancy was limited while evidence of the additional risk from COVID-19 in pregnancy was considered inconclusive. In April 2021, when good evidence became available on the safety of mRNA vaccines in pregnancy, all pregnant women were due to be offered vaccine imminently as part of Phase 2 of the programme; further prioritisation at that time would have had limited impact on the timing of the offer of vaccine. In December 2021, when more definitive data were available indicating an increased risk from COVID-19 to pregnant women, JCVI updated its advice by identifying pregnancy as a clinical risk factor for severe COVID-19. Throughout the pandemic, the Committee was committed to following scientific evidence and reviewed risk-benefit considerations regularly.

98. My personal reflection is that pregnancy is a key issue for consideration in any future pandemic. Data should be developed as early as possible on the safety of vaccination in pregnancy. Monitoring of the risk from a pandemic disease to women who are pregnant should continue throughout a pandemic as the risk profile may change over time, especially when there is rapid viral evolution, as was seen in the COVID-19 pandemic.

Rationale for advice for children

99. Formulation of JCVI advice related to children followed similar principles as the advice formulated for adults. The primary aim of the COVID-19 vaccination programme for children was to protect against severe COVID-19 illness, specifically hospitalisations and death.

100. JCVI agreed that an important principle to observe in relation to children (as it is for adults) was that vaccination should on balance benefit the person (child) receiving vaccination; that is, it would not be acceptable to advise that a child be vaccinated where the benefit was primarily to another individual (adult) who can be directly protected themselves (the adult receiving vaccination). This principle was important to bear in mind as children are at very low risk of severe COVID-19 themselves.

101. It was also recognised from experience with routine immunisation programmes that parents in the UK place more weight on potential harms from vaccination than on potential benefits (**WSL2/44 -INQ000354433**). This concept was discussed at the meeting on 4 May 2021 (**WSL2/45 - INQ000354503**).

102. These principles were stated in the JCVI Statement of advice on COVID-19 vaccination of children and young people aged 12 to 17 years published on 4 August 2021: "*When formulating advice in relation to childhood immunisations, JCVI has consistently held that the main focus of its decision should be the benefit to children and young people themselves, weighed against any potential harms from vaccination to children and young people. In providing its advice, JCVI also recognises that in relation to childhood immunisation programmes, the UK public places a higher relative value on safety compared to benefits.*" **(WSL2/45A - INQ000235154)**

103. In the phase 1 advice published 30 December 2020, it was advised that only those children at very high risk of exposure and serious outcomes including mortality, such as older children with severe neuro-disabilities that require residential care, should be offered vaccination with either the Pfizer-BioNTech or the AstraZeneca COVID-19 vaccine. It was stated that clinicians should discuss the risks and benefits of vaccination with a person with parental responsibility, who should be told about the paucity of safety data for the vaccine in children aged under 16 years (**WSL2/34 - INQ000354469)**. At this time, the Pfizer-BioNTech COVID-19 vaccine was approved by MHRA under regulation 174 for use in the UK for individuals aged 16 years and above, while the AstraZeneca COVID-19 vaccine was approved under regulation 174 for use in individuals aged 18 years and above. Therefore, the use of these vaccines outside the terms of the MHRA approval but within the scope of JCVI advice required individualised clinical assessment and prescription. The advice to offer COVID-19 vaccination to this very small number of children was made in recognition of their exceptionally high risk of severe COVID-19 when compared to healthy children and adults.

104. The Pfizer-BioNTech COVID-19 vaccine was authorised by the MHRA for use in children aged 12 to 15 years on 4 June 2021. The Moderna COVID-19 vaccine was authorised by the MHRA for use in children aged 12 to 17 years on 17 August 2021.

105. JCVI began considering COVID-19 vaccination in children without underlying health conditions in spring and summer 2021, just prior to authorisation of the Pfizer-BioNTech COVID-19 vaccine in children aged 12 to 15 years. By the time JCVI advice regarding COVID-19 vaccination in children without underlying health conditions was being formulated (June – July 2021), vaccine uptake in older aged adults was at very high levels, with high levels of protection against severe COVID-19 observed in these adults.

106. The JCVI Statement on COVID-19 vaccination of children and young people aged 12 – 17 years (15 July 2021), stated "*With regards to a COVID-19 immunisation programme for children and young people, JCVI's main consideration remains the potential benefits of vaccination in terms of reductions in hospitalisations and deaths in the population. As disruption of education is likely to have medium to long term impacts on public health, JCVI has also considered the potential for vaccination to prevent outbreaks in educational facilities. These potential benefits have been considered against the potential risks from vaccination."* That Statement also noted that "*Concerns have been raised regarding post-acute COVID-19 syndrome (long COVID) in children. Emerging large-scale epidemiological studies indicate that this risk is very low in children, especially in comparison with adults, and similar to the sequelae of other respiratory viral infections in children*" (**WSL2/46 - INQ000354523**).

107. *Education*. JCVI does not usually take into consideration the impact of vaccination on the educational attainment of children. JCVI membership is not constituted to advise on matters of education and there is no standardised agreed metric for integrating educational goals into vaccination cost-effectiveness assessment models.

108. JCVI met with representatives from the Department for Education (DfE) to share understanding with respect to vaccination and education, in particular on how COVID-19 vaccination for children might impact on their education. JCVI first met with DfE on 15 June 2021 when discussing vaccination of 12- to 17-year-olds (**WSL2/47 - INQ000354515)**.

109. During discussions at the meeting on 15 June 2021, it was recognised that a major part of the disruption to schooling was due to the rules around social distancing and isolation measures as applied to educational facilities. For the vast majority of pupils aged < 18 years, COVID-19 is a mild illness that is asymptomatic or mildly symptomatic. In addition,

in the pre-Omicron era, following recovery from infection, natural immunity to COVID-19 developed which greatly reduced the likelihood of acquiring a further symptomatic infection in the following 6 months (**WSL2/48 - INQ000354525_pg35**).

110. The impact on a pupil of a period of absence from school would be influenced by multiple individualised factors including the timing of absence in relation to the school year. Pupils from more socially deprived neighbourhoods were more likely to be negatively impacted by absences from school, and the impacts were likely to be greater.

111. When considering how COVID-19 vaccination for children might influence absences from school, JCVI noted that the effectiveness of vaccination in preventing asymptomatic or mild infection was expected to be modest for more transmissible variants such as the Delta variant (which was widespread in the UK by June 2021, having emerged in April 2021); that the rules around testing and isolation measures in schools were a major factor why pupils were absent from school; that it was difficult to place a value on a day of absence from school in educational or health terms and that there was no accepted means to integrating educational benefits or disbenefits from vaccination into the models usually used when assessing vaccination programmes.

112. JCVI meetings which discussed the vaccination of healthy 5- to 11-year-olds were held on 13 January, 20 January, 27 January, and 3 February 2022. The Omicron variant had emerged at this time. The proportion of 5 – 14-year-olds with prior natural infection by the end of January 2022 was estimated to be over 85%. On 16 February 2022, JCVI's published Statement stated: "*JCVI advises a non-urgent offer of two 10 mcg doses of the Pfizer-BioNTech COVID-19 vaccine (Comirnaty®) to children aged 5 to 11 years of age who are not in a clinical risk group. The 2 doses should be offered with an interval of at least 12 weeks between doses. The intention of this offer is to increase the immunity of vaccinated individuals against severe COVID-19 in advance of a potential future wave of COVID-19.*" Importantly, for deployment teams, JCVI advised that "*the offer of COVID-19 vaccination to 5 to 11 year olds who are not in a clinical risk group should not displace the delivery of other paediatric non-COVID-19 or COVID-19 immunisation programmes; and "delivery of paediatric non-COVID-19 immunisation programmes across all ages should receive due attention, particularly where vaccine coverage has fallen behind due to the COVID-19 pandemic and where there is evidence of health inequalities*" (**WSL2/49 - INQ000257288**).

Practicalities of roll-out

113. An independent report prepared by UKHSA was included as an Annex in the initial prioritisation advice (first published 2 December 2020). That report considered the ethics of prioritisation, including mitigation of health inequalities. It also focused on deliverability and implementation. The report concluded: "*While prioritisation is set nationally, the knowledge, experience, system leadership and collaborative approach with local partners of Screening and Immunisation Teams embedded within in Public Health Commissioning in NHS England (and their equivalent teams in Scotland, Wales and Northern Ireland) should be utilised to improve vaccine uptake and reduce inequalities in the implementation of the COVID-19 immunisation programme.*" (**WSL2/50 - INQ000354461)**

114. JCVI had no role in vaccine supply management. JCVI received updates on vaccine supply projections from the Vaccine Taskforce. These updates on vaccine availability were part of the considerations when JCVI formulated its advice.

Public messaging

115. According to the JCVI Code of Practice, JCVI does not have a specified role in relation to public messaging, over and above its requirement for transparency through the publication of minutes and statements.

116. The JCVI Code of Practice, para 68 states that: *"Members of JCVI or JCVI Sub-committees should not speak to the media as a member or voice of the JCVI or JCVI Sub-committee. All enquiries from the press should be directed via the PHE press office to the Chair of the JCVI. Members should inform the Chair and secretariat of all relevant contacts with the media. A JCVI member or Subcommittee member may discuss with the media, an issue that has also been discussed at JCVI, but should take care to explain that he/she is discussing it in an individual professional capacity and not as a member of JCVI or on behalf of JCVI or its Subcommittees."* **(WSL2/1 - INQ000145984)**

117. During the pandemic, requests from the media for information and interviews increased many-fold. As JCVI Chair of COVID-19 Immunisation, I was keenly aware of the importance of communication to the public, healthcare providers and stakeholders. There was more work than one person could manage. I therefore agreed with the Secretariat and the Deputy Chair of JCVI in late 2020 (this was around Nov 2020, although I cannot recall the exact date) that whilst I would undertake initial media engagements to explain new advice from JCVI to the public, the Deputy Chair would shoulder the majority burden of further engaging

with media platforms. Other JCVI members who were willing and able were also supported in engaging with the media. Hence, for instance, when major new advice from JCVI was developed, I would introduce the advice through televised technical media briefings to national media platforms, with other JCVI members subsequently providing interviews on radio and television to further disseminate this same advice.

118. JCVI members and I were also involved in disseminating and explaining JCVI advice to healthcare providers, charitable organisations representing patient bodies, and other stakeholders. From the 12 February 2021 through to 14 September 2021, the Deputy Chair attended parliamentary MP weekly meetings alongside Minister Zahawi. He also attended monthly Lords calls alongside Minister Bethell three times, in May, June, and July 2021. These were important for both engaging directly with parliament and for dissemination of information to MPs and onwards to their constituents.

119. Through having different voices (different JCVI members) on different media platforms explaining the same advice in different ways to different people, JCVI sought to reach as many different communities of people as possible. The intensity of scrutiny on JCVI members was substantial and the learning curve for members in relation to media engagement was very steep.

120. During the pandemic JCVI members gave hundreds of media interviews with the aim of helping the public to better understand the rationale behind its advice. The Deputy Chair of JCVI personally gave over 300 interviews over the pandemic period. Such interviews with the media were only ever given after advice was published, and in most cases, the Government's policy decision was published at the same time as the JCVI advice.

121. Media interviews provided the Committee with a voice to the public and put faces to a Committee which could otherwise have been viewed as anonymous. This work made the Committee's advice more accessible beyond the relatively technical statements and minutes. This was also important in allowing the Committee to demonstrate independence from Government. JCVI members were consistently clear that their role was to discuss and explain JCVI advice and not to discuss Government policy.

122. Vaccine uptake and coverage is monitored by UKHSA and NHSE. Regular reports were published by these organisations setting out the latest on coverage of vaccines in the UK. (**WSL2/51 - INQ000223938; WSL2/52 - INQ000354618; WSL2/53 - INQ000354620; WSL2/54 - INQ000354619; WSL2/55 - INQ000354621; WSL2/56 - INQ000354622; WSL2/57 - INQ000354623; WSL2/58 - INQ000354624; WSL2/59 - INQ000354625;**

WSL2/60 - INQ000354626; WSL2/61 - INQ000354627; WSL2/62 - INQ000354628; WSL2/63 - INQ000354629; WSL2/64 - INQ000354559; WSL2/65 - INQ000312423; WSL2/66 - INQ000354566; WSL2/67 - INQ000120675; WSL2/68 - INQ000354569; WSL2/69 - INQ000354571; WSL2/70 - INQ000354574; WSL2/71 - INQ000354577; WSL2/72 - INQ000354579; WSL2/73 - INQ000354580; WSL2/74 - INQ000354582; WSL2/75 - INQ000354584; WSL2/76 - INQ000354585; WSL2/77 - INQ000354586; WSL2/78 - INQ000354588; WSL2/79 - INQ000354590; WSL2/80 - INQ000354591; WSL2/81 - INQ000354592; WSL2/82 - INQ000354597).

123. JCVI monitors overall vaccine confidence through attitudinal research undertaken by UKHSA (**WSL2/83 - INQ000354601**). The circumstances of a pandemic with high media and public interest in vaccines was very different from usual non-pandemic periods. The rapid development of some COVID-19 vaccines, and the novel technologies involved, became a target for vaccine misinformation globally. Following on from the careful and detailed reviews undertaken by the MHRA, JCVI's role in terms of vaccine confidence was, as always, to be transparent and open regarding the evidence available and expert interpretation of the evidence.

124. JCVI contributes towards vaccine confidence by maintaining its independence and in being a trusted source of expert advice.

125. In the WHO Report on *'Ten threats to global health in 2019'*, vaccine hesitancy is defined as *"the reluctance or refusal to vaccinate despite the availability of vaccines"* (**WSL2/84 - INQ000354612**). Vaccine hesitancy is not a new phenomenon. JCVI has always been careful during the formulation and communication of its advice to mitigate against vaccine hesitancy.

126. The outbreak of the COVID-19 pandemic was closely accompanied by an 'infodemic'. A Report from WHO published in July 2023 on '*How to build an infodemic insights report in six steps*' explains: "*An infodemic is an overabundance of information, accurate or not, in the digital and physical space, accompanying an acute health event such as an outbreak or epidemic. Infodemics contain questions, concerns, information voids (where people seek credible, accurate information but cannot find it) and circulating mis- and disinformation. An infodemic is accelerated and amplified through digital media and offline, causing information overload and confusion. An infodemic can promote stigma, erode trust in health authorities, affect mental health and negatively influence health decisions and behaviours, thereby making it more difficult for health authorities to respond effectively and protect the population's health"* (**WSL2/85 - INQ000354606**).

127. It is recognised by many that social media platforms play a disproportionately large role in spreading misinformation. In addition, social media algorithms that feed similar messages to end-users intensify the dissemination of misinformation whilst at the same time, reducing exposure to other streams of information that may provide balancing viewpoints.

128. The damaging role of misinformation in reducing vaccine confidence is not limited to COVID-19 vaccines but has effects across all immunisation programmes. This is of particular concern with regards to infant/childhood immunisation programmes which are some of the most cost-effective health interventions in the course of an individual's lifetime. Often, high vaccine coverage within a community also has additional public health benefits through providing protection to unvaccinated individuals.

129. JCVI does not have a prescribed role in countering misinformation. Despite this, individual JCVI members have responded to media requests, in their individual capacity, to explain JCVI advice and, where questioned, counter misinformation.

Unequal uptake

130. Note: with regards to the above, it is useful to distinguish between the issue of health inequalities generally (see points under Ethics) versus the particular focus here on Inequalities in Vaccine Uptake, which is an issue of deployment.

131. JCVI received regular updates from UKHSA, NHSE and Devolved Administrations (DAs) on vaccine coverage throughout the pandemic; this information is publicly available in the Weekly National Influenza and COVID-19 reports. Particular attention was given to differences in coverage associated with underlying health inequalities. Lower vaccine uptake was noted amongst certain ethnic minority communities and individuals living in neighbourhoods of greater social deprivation. One of JCVI's roles throughout the pandemic was to provide a challenge function at JCVI meetings to deployment teams to undertake efforts at mitigating these inequalities in vaccine uptake.

132. JCVI noted the efforts of deployment teams and the importance of locally developed actions relevant to specific communities; different solutions were required to address the needs of different communities. JCVI was not involved in the details of these mitigation efforts, this being a responsibility of UKHSA and NHSE. One notable example of a change in vaccine confidence through local action was the rise in vaccine uptake in the Bangladeshi community; this was highlighted in the final report on progress to address COVID-19 health inequalities which is publicly available. (**WSL2/86 - INQ000354552**). However, disparities in vaccine uptake have persisted in other communities.

The relationship between JCVI and the MHRA

133. JCVI has always had a close working relationship with the MHRA, while also maintaining independence. There is an interchange of observers between JCVI and the Commission on Human Medicines (CHM) and its Expert Working Group on COVID-19 vaccine safety surveillance (EWG), with the JCVI secretariat and UKHSA representatives observing meetings of both the MHRA and JCVI. The sharing of information is important for timely advice from JCVI on new vaccine products and on any safety issues that might be identified. The MHRA are experts in vaccine safety and adverse event reporting, and JCVI relies on this expertise in assessing vaccine safety issues.

134. One area where close communication between the MHRA and JCVI was required to resolve potential difficulties was in the assessment of the comparative safety of different COVID-19 vaccines. Comparisons between vaccines is a regular part of JCVI's role, whether considering the additional benefit of one vaccine over another, or a differential in risk profile between one or more vaccine products. Such comparisons may inform advice that favours one vaccine product over another under certain circumstances. In contrast, the MHRA considers the merits of vaccine products in relation to their potential risks and benefits for the purposes of regulatory approval and does not usually compare one product against another.

135. Press and media reporting may at times imply a difference of opinion between JCVI and the MHRA where none exists. Perceptions of a misalignment of opinion between MHRA and JCVI could lead to public confusion and reduce public confidence in vaccines and/or the process for evaluating the safety of vaccines. This in turn could negatively influence vaccine uptake, damaging public health. The maintenance of independent views does not exclude open professional dialogue and a process for resolution of potentially differing viewpoints. In my view, it was good that JCVI could provide a challenge function to MHRA at JCVI meetings when appropriate, and vice versa.

136. My personal view is that the MHRA is an internationally highly respected regulatory body however I do not know the details of procedures and safeguards relevant to the impartiality and independence of MHRA. At the CHM and EWG subgroup meetings that I attended, my impressions were that discussions and decisions were grounded in science and were independent of politics or policy.

137. Maintaining the impartiality and independence of JCVI and MHRA is crucial in ensuring independent advice from both bodies. Ahead of the licensure of the first COVID-19 vaccine

products (Pfizer-BioNTech and AstraZeneca COVID-19 vaccines), there was very limited communication between JCVI and MHRA and the relevant officials. This was to ensure there was not pressure from any outside body on the process for authorisation of the vaccines under Regulation 174.

138. JCVI statements and minutes are written by the JCVI Secretariat and agreed by the Committee. Versions agreed by the Committee are shared with MHRA and comments may be received which are factual in nature. This allows for MHRA to provide a challenge function to JCVI without interference in the development of advice.

139. The Yellow Card scheme is run by the MHRA and helps monitor the safety of all healthcare products in the UK to ensure they are acceptably safe for patients and users. The scheme relies on voluntary reporting of problems to a healthcare product by the public through the Yellow Card website. My personal view is that the Yellow Card scheme is a well-established, easy means for anyone to report potential adverse events regarding any UK-approved medicinal product. As a clinician, I am very much aware of the Yellow Card scheme and have reported potential adverse events via this system myself.

140. The Yellow Card scheme provides a useful means for alerting the MHRA to possible safety signals which may be associated with vaccination, and which are too infrequent to be identified in a reasonably sized clinical trial. Assessing the background rate of certain conditions and comparing this with reports following the introduction of vaccination allows for timely and meaningful assessment of potential rare adverse events. Any potential safety signals require further evaluation to determine their relevance. Such further evaluation may require the use of different data sources such as national surveillance datasets or primary care datasets. Many events reported are chance occurrences rather than causally associated with the vaccine, and JCVI relies on MHRA's expertise in assessing and interpreting the data. On its own, the Yellow Card scheme is not a sufficient method for the detection and understanding of adverse events. The MHRA has processes for evaluation of potential adverse events beyond the Yellow Card scheme, including through the Commission on Human Medicines (CHM) and its Expert Working Group (EWG). I do not have the requisite understanding of all the safety systems employed by MHRA to suggest specific areas for improvement.

141. The Inquiry has asked whether the reporting of adverse events should be mandatory or voluntary. Mandatory reporting of adverse events by research investigators occurs in the context of clinical trials. There is currently no requirement for mandatory reporting of

adverse events by members of the public through the Yellow Card scheme, and personally, I do not think it would be feasible nor appropriate to mandate such reporting by the public.

142. A representative from MHRA attended JCVI COVID-19 meetings; for most of the period in question, JCVI COVID-19 meetings were held approximately 1 to 2 times per week. MHRA was invited to provide safety reports to JCVI at these meetings and/or at JCVI Vaccine Monitoring Working Group meetings, notwithstanding any particular safety concerns identified by MHRA. This allowed for near real time review of evidence on adverse events following vaccination, and for MHRA and CHM interpretation of the likelihood of a causal relationship. When a potentially concerning signal was identified MHRA would contact the Secretariat in the first instance and the issue would be timetabled into the next meeting. In addition, the deputy Chair of JCVI and I were both invited as observers at CHM COVID-19 meetings, and I attended many of these meetings.

143. Once JCVI reviewed the relevant data from MHRA, there were broadly three potential courses of action should safety concerns be raised:

1) To wait for further data to provide increased certainty in the safety signal;

2) To provide, or modify, advice on the relative benefits and risks of the different vaccines available;

3) To provide, or update, advice that there was no need for an amendment to the programme.

144. Throughout the pandemic, though especially during the early critical period of the vaccine programme, it was deemed important not only to publish statements on positive changes to the programme, but also where, after review, JCVI agreed no changes to the programme were required (for example, in the JCVI statement on the adult COVID-19 booster vaccination programme and the Omicron variant) (**WSL2/87 - INQ000354561**). This allowed JCVI to state publicly where the benefits of timely vaccination outweighed potential risks.

145. All safety signals were discussed at JCVI meetings and considered in relation to any impacts on existing and future advice provided by JCVI.

146. MHRA is responsible for monitoring for safety signals. JCVI is not involved in advising MHRA on its safety surveillance strategy.

147. Vaccine effectiveness is monitored by UKHSA (PHS in Scotland). Independent academic groups were also involved in assessing vaccine effectiveness. These groups would share their results with JCVI.

148. JCVI was briefed on the planned work of UKHSA and MHRA on post vaccination surveillance in the UK. JCVI was particularly interested in post marketing surveillance of the use of vaccines in pregnancy, both in the UK and internationally.

149. JCVI makes its views known (at JCVI meetings) to MHRA and UKHSA regarding the type of data that would be important for the formulation of advice.

150. In general, the UK public has a relatively high level of confidence in vaccines. This is reflected in high levels of vaccine coverage across routine immunisation programmes.

151. One gauge of public trust in the safety of COVID-19 vaccines is the level of vaccine uptake; noting that low uptake may be influenced by many factors other than safety alone whilst high uptake suggests concerns over safety are not causing a barrier to uptake. In UK sub-populations at high risk of severe COVID-19, uptake and coverage is very high; up to 30 June 2022, 90% of adults over 65 years of age and 89% of immunosuppressed individuals in England had been vaccinated with at least 3 doses (**WSL2/88 - INQ000354600**). In younger healthier sub-populations who are at lower risk of severe COVID-19, uptake is lower. The lower vaccine uptake in these sub-populations is likely to reflect, amongst other things, the balance between self-perceived risk from COVID-19 and perceived potential harms from vaccination.

152. Confidence in COVID-19 vaccines was not held at a static level during the pandemic. It was influenced by media reporting and fluctuated. Initially there was more uncertainty in the safety of COVID-19 vaccines, which reflected both a) the amount of scientific data available, b) experience of use.

153. From personal experience as a clinician speaking to different groups of people throughout the pandemic (including healthcare workers), individuals from some ethnic minority groups expressed greater concerns over vaccine safety than persons from White ethnic backgrounds.

154. Individuals that already hold lower levels of trust towards an authority are more likely to be mistrustful of further advice arising from the same authorities.

155. The opinion of trusted voices within local communities can have a strong influence on individuals.

156. Unfortunately, social media platforms are a common source of misinformation that can promote mistrust.

Vaccine safety issues

Vaccine-induced immune thrombotic thrombocytopenia (VITT) - also called Thrombosis and Thrombocytopenia Syndrome (TTS)

157. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a very rare adverse event following adenovirus vector-based COVID-19 vaccination. This adverse event was only identified and described following the introduction of COVID-19 vaccines.

158. In the UK, up to 4 August 2021, the MHRA received 412 reports of suspected cases of VITT out of a total of 24.8 million first doses and 23.9 million second doses of the AstraZeneca COVID-19 vaccine given by that date. Based on reports to 11 August 2021, the overall incidence following the AstraZeneca COVID-19 vaccine was around 14.9 per million first or unknown doses and 1.8 per million second doses administered (**WSL2/89 - INQ000354573**).

159. On 25 February 2021, JCVI first received reports from the MHRA of a potential post-vaccination risk of concurrent thrombosis (blood clots) and thrombocytopenia (low platelet count) following vaccination with the first dose of the AstraZeneca COVID-19 vaccine. At the time, a similar safety signal was not raised following receipt of other COVID-19 vaccines approved for use in the UK. Natural COVID-19 infection was also associated with thrombosis and urgent assessments were initiated to establish if a new vaccine-related adverse event had been identified. In the meantime, the MHRA's view was that no regulatory action was required.

160. Over the course of the next 4 to 5 weeks, data continued to accrue indicating that VITT was an idiosyncratic reaction on first exposure to the AstraZeneca COVID-19 vaccine with increasing risk associated with decreasing age amongst adults. This contrasted with the incidence of severe COVID-19 disease which increased steeply with increasing age.

161. On 7 April 2021, JCVI advised that it was preferable for adults aged less than 30 years without underlying health conditions that put them at higher risk of severe COVID-19 disease, to be offered an alternative COVID-19 vaccine, where available **(WSL2/120 - INQ000354498)**. This was during Phase 1 of the programme when individuals being offered vaccination were mostly over the age of 50 years or were in a clinical risk group for severe COVID-19.

162. On 7 May 2021, following accrual and review of additional scientific data on VITT from the MHRA and academic groups in the UK, JCVI advised that an alternative to the AstraZeneca COVID-19 vaccine should be offered to all adults aged 40 years and below. This was just before national roll-out of Phase 2 of the vaccine programme when 18 – 39-year-olds without underlying health conditions that put them at higher risk of severe COVID-19 would be offered vaccination **(WSL2/121 - INQ000354505)**.

163. This was a challenging period for the Committee. On the one hand, there were deep concerns for the safety of individuals receiving the AstraZeneca COVID-19 vaccine. On the other hand, there were concerns that inappropriate action against the COVID-19 vaccine programme could impact heavily on vaccine uptake for all COVID-19 vaccines which could in turn leave many individuals at high risk of falling severely ill with COVID-19.

164. JCVI worked closely with MHRA, UKHSA, and academic groups to understand the situation as it was unfolding.

165. For many months subsequently, JCVI continued to monitor the situation as regarded VITT with the help of MHRA and UKHSA.

166. To date, the exact mechanisms underlying VITT are incompletely understood (**WSL2/90 - INQ000354605**).

Myocarditis

167. One of the most challenging issues faced by the Committee during the pandemic was around vaccination of children and young people. JCVI held a series of meetings over summer 2021 to formulate relevant advice for 12 to 17-year-olds in step with emerging data. The Committee published its advice in stages:

30 June 2021 – Dateline for advice agreed with DHSC
02 July 2021 – JCVI agreed initial advice; advice submitted
19 July 2021 – Advice published: Offer vaccination to 12–17-year-olds in a clinical risk group
29 July 2021 – JCVI review of evidence; updated advice agreed
04 August 2021 – Updated advice published; Offer vaccination to all 16- to 17-year-olds
02 September 2021 – JCVI review of evidence; further advice agreed
03 September 2021 – Advice published; regarding all 12–15-year-olds.

168. The United States (US) and Canada were among the first countries in the world to grant regulatory approvals for the use of mRNA COVID-19 vaccines in persons aged 12 to 15

years (May 2021), closely followed by Israel (June 2021). Upon approval, these countries rapidly undertook programmes to offer vaccination to children and young people aged 12 to 15 years. In the UK, MHRA authorised use of the Pfizer-BioNTech COVID-19 vaccine (30 micrograms dose) for children and young people aged 12 to 15 years on 4 June 2021. Around the time that JCVI was considering whether to advise vaccination of children and young people in the UK, reports started to emerge from the US, Canada, and Israel of a potential new vaccine safety signal - post-vaccination myocarditis.

169. Early data on this adverse event were limited with large uncertainties regarding the medium and long-term outcomes. In particular, concerns were raised by members of the Committee regarding the longer-term sequelae, including the risk of future heart rhythm disturbances and even fatal outcomes. This concern over safety was set against the relatively small benefits from vaccination expected in children without underlying health conditions. Taking a precautionary stance and recognising the high value that the UK public places on vaccine safety in children, JCVI took a steady, cautious approach with advice formulated at a pace commensurate to the available and newly emerging evidence.

170. Contentions from outside of the Committee focussed on two key areas – a) that JCVI was being too cautious and should follow the lead of countries such as the US and Canada, and b) that vaccination could have a substantial positive impact on schooling.

171. Countries that had begun their programmes before the identification of post-vaccination myocarditis signal did not have to decide whether to initiate their programmes, but whether they should pause their programmes. The practical implications and consequences of these two different decisions (to start or to pause a programme) are different. JCVI took these matters into consideration and explained its position in the relevant JCVI statements.

172. In terms of schooling, the view of the Committee was that the vast majority of school absenteeism at the time was associated with the use of non-pharmaceutical interventions in the school setting (**WSL2/47 – INQ000354515**). In addition, due to the high transmissibility of the Delta variant dominant over summer 2021, the protection against infection (and transmission) provided by vaccination was not considered to be high. The Committee did not consider that it was constituted to provide an expert view on the impact additional days in school would have on the future prospects of the children affected and no common metric was available for assessing health and educational benefits together (for instance, how does averting 5 days of symptomatic illness and potentially 5 days of absence from school affect educational attainment or mental health, and how might that compare to the possibility of developing myocarditis following vaccination with consequent

medical advice to avoid strenuous exercise or sports for a period of months, alongside unclear medium to longer-term consequences?)

173. Over summer 2021, there was a continuous (month-by month) accumulation of data regarding the short and medium-term consequences of post-vaccination myocarditis. JCVI regularly reviewed the data emerging from countries that had already had programmes running and through which this new, rare adverse event had been identified. JCVI updated its advice accordingly.

174. On 2 July 2021, the Committee met and agreed to advise that "*children and young people aged 12 years and over with specific underlying health conditions that put them at risk of serious COVID-19, should be offered COVID-19 vaccination.*" This was in the statement published 19 July 2021 (**WSL2/91 - INQ000354522**).

175. On 29 July 2021, the Committee met and agreed to advise that "*all 16 to 17-year-olds should be offered a first dose of Pfizer-BNT162b2 vaccine. This is in addition to the existing offer of 2 doses of vaccine to 16 to 17-year-olds who are in 'at-risk' groups"* (and in addition to the offer to 12 – 15 year olds in a clinical risk group as advised on 2 July 2021) (**WSL2/92 - INQ000354527; WSL2/93 -** **INQ000235154**).

176. On 26 August, 1 September, and 2 September 2021 the Committee met to review data in relation to COVID-19 vaccination for children and young people. As summed up in the JCVI statement published on 3 September 2021, the Committee concluded that, "*The available evidence indicates that the individual health benefits from COVID-19 vaccination are small in those aged 12 to 15 years who do not have underlying health conditions which put them at risk of severe COVID-19. The potential risks from vaccination are also small, with reports of post-vaccination myocarditis being very rare, but potentially serious and still in the process of being described. Given the rarity of these events and the limited follow-up time of children and young people with post-vaccination myocarditis, substantial uncertainty remains regarding the health risks associated with these adverse events. 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 to 15-year-old children at this time"* (**WSL2/94 - INQ000257024**).

177. The Committee noted the strong views being presented on the impact vaccination could have on schooling. As such JCVI suggested to the Secretary of State for Health that in addition to the advice from JCVI:

> *"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. There is considerable uncertainty regarding the impact of vaccination in children and young people on peer-to-peer transmission and transmission in the wider (highly vaccinated) population. Estimates from modelling vary substantially, and the committee is of the view that any impact on transmission may be relatively small, given the lower effectiveness of the vaccine against infection with the Delta variant"* (**WSL2/94 - INQ000257024**).

178. There were two elements in suggesting that the Secretary of State for Health and Social Care may wish to obtain a further view from the CMOs before making a policy decision based on the combined viewpoints of JCVI and the CMOs. Firstly, the CMOs have a broader purview with regards to public health. Secondly, the CMOs had a direct understanding of and influence over the non-pharmaceutical interventions in place in schools.

179. Discussions and deliberations on the use of vaccines in children and young people were some of the most challenging undertaken by JCVI during the pandemic. COVID-19 is generally a mild illness in the vast majority of children and young people. For those at higher risk of severe COVID-19 due to underlying health conditions, the advice has consistently been in favour of vaccination. For otherwise healthy children, the potential harms and benefits of vaccination were finely balanced.

180. Different personal views were held by Committee members at the time, reflecting the wider academic, international, and public differences in opinion on this topic.

181. Regular review of the data on post-vaccination myocarditis was continued through the summer of 2021 and in 2022. As more follow-up time accrued, the data on the longer term effects of post-vaccination myocarditis were noted to be increasingly reassuring. By November 2021, countries that had started their childhood programmes before the UK were reporting on their experiences 5 to 6 months into their programmes. These reassuring follow-up data supported the subsequent advice from JCVI (in November 2021 **(WSL2/129 - INQ000354546)**, December 2021 **(WSL2/131 - INQ000257219)** and February 2022

(WSL2/133 - INQ000257287)) to move ahead with the offer of COVID-19 vaccination to children.

Ongoing evaluation of the COVID-19 vaccination programme

Extended dose schedule

182. The JCVI advice and subsequent DHSC policy decision to use an extended schedule for the COVID-19 vaccines was highly controversial at the time. On 30 Dec 2020, JCVI stated that:

"For both Pfizer-BioNTech and AstraZeneca vaccines, a 2-dose schedule is advised.

In the context of the epidemiology of COVID-19 in the UK in late 2020, the JCVI places a high priority on promoting rapid, high levels of vaccine uptake among vulnerable persons.

Therefore, given data indicating high efficacy from the first dose of both Pfizer-BioNTech and AstraZeneca vaccines, the committee advises that delivery of the first dose to as many eligible individuals as possible should be initially prioritised over delivery of a second vaccine dose. This should maximise the short-term impact of the programme. The second dose of the Pfizer-BioNTech vaccine may be given between 3 to 12 weeks following the first dose. The second dose of the AstraZeneca vaccine may be given between 4 to 12 weeks following the first dose." **(WSL2/34 - INQ000354469)**

183. The Committee's decision that the second vaccine dose could be given up to 12 weeks following the first dose was based on a combination of a) evidence from clinical trials indicating that the first dose of both vaccines was highly efficacious **(WSL2/116 - INQ000354613)**, b) evidence from the AstraZeneca clinical trials that two-dose vaccine efficacy was similar with varying dose interval schedules (of 6,8 or 12 weeks) – data unpublished at the time **(WSL2/94A - INQ000421743)** c) experience from other vaccines where longer intervals between vaccine doses are associated with *increased* immune responses compared with shorter dose intervals; such as with the inactivated polio vaccine, human papillomavirus vaccine, pneumococcal conjugate vaccine, d) expectation that the general principles of immunology as applied to other vaccines would likely apply to COVID-19 vaccines, e) the strong national surveillance system in the UK that would be closely monitoring vaccine effectiveness as the vaccine programme progressed, f) the competing risk of keeping a shorter dose interval at the cost of slower delivery of a first vaccine dose to the eligible population in the setting of an increasing wave of infection (from the Alpha variant) during a period of severe pressure on health services (Jan 2022).

184. A general principle of immunology is that after the immune system is stimulated (for example with a dose of vaccine) to generate an immune response against a particular target (an antigen), the immune response will continue to mature over time. This maturation process includes immune cells such as B cells which are involved in the production of antibodies. In general, the longer the maturation period before the next antigen stimulus (such as with a second vaccine dose), the stronger the subsequent immune response.

185. To note, the decision by JCVI to allow an extended dose interval was not dependent on there being a better immune response with a longer dose interval compared to a shorter dose interval, but the expectation that there would not be a lesser immune response with the longer versus shorter dose interval. The immediate public health benefit of permitting a longer dose interval was to enable prioritisation of the first vaccine dose to more people in the circumstances of a constrained vaccine supply occurring when pace of vaccine deployment was considered critical.

186. At the time of JCVI's advice, there were calls for JCVI to release unpublished data relevant to the decision. Data held by UKHSA and shared with JCVI were published on-line by UKHSA. Commercially sensitive data shared in confidence with JCVI are not owned by JCVI nor UKHSA. Nonetheless, JCVI encourages the prompt publication of scientific data shared at JCVI meetings.

187. Subsequent studies undertaken by UKHSA to review this decision stated: *"Our findings suggest higher effectiveness against infection using an extended vaccine schedule. Given the global vaccine constraints, these results are relevant to policymakers in low- and middle-income countries especially in the context of highly transmissible variants and rising incidence in many parts of the world. An additional yet undervalued benefit of extended schedules is higher boosting and better protection after two doses of either vaccine, which potentially confer better protection against variants and for a longer duration than short-interval schedules. Our data also confirm previous findings of high protection after a single vaccine dose in previously infected individuals, which is also important in the context of limited vaccine supplies."* (**WSL2/96 – INQ000354554**)

188. **Parliamentary Privilege**

189. Scientific studies have since found that an extended dose interval for the primary course (8 to 12 weeks interval between first and second vaccine doses) is associated with: **(WSL2/96 - INQ000354554; WSL2/97 - INQ000354544; WSL2/98 - INQ000354589; WSL2/99 - INQ000354609; WSL2/100 - INQ000354604)**:

1) Generation of greater immune responses (antibodies and cell-based immunity)

2) Greater breadth of immune responses

3) Greater vaccine effectiveness against SARS-CoV2 infection

4) Lower risks from vaccine-induced myocarditis

190. One subsequent modelling study estimated that the first dose prioritisation and extended dose interval strategy averted 32,000 to 72,000 hospital admissions and 4,000 to 9,000 deaths over the first 10 months of the campaign in England (Dec 2020 to Sep 2021) (**WSL2/101 - INQ000354603**). A separate modelling study found that, compared to a 3-week interval strategy, a 12- week interval strategy likely averted 59,000 hospitalisations and 10,000 deaths in England during the period 8 Dec 2020 to 13 Sep 2021. (**WSL2/102 - INQ000354602**).

Post-COVID syndrome

191. Scientific understanding regarding post-COVID syndrome (often termed 'long COVID') continues to be relatively poor. As an example, a recent (2023) academic review paper on considerations for vaccinating children against COVID-19 states "*Post-acute COVID-19 syndrome, or long COVID, is uncommon in children and difficult to distinguish from other effects of the pandemic as well as symptoms that occur frequently in children regardless of whether or not they have had COVID-19. Delayed recovery following an acute infection may occur but is less common than in adults and the majority of children make a full recovery*" (**WSL2/103 - INQ000354608**).

192. A further example from one large study conducted in Denmark, found symptoms consistent with 'long COVID' reported in both individuals who had experienced SARS-CoV2 infection (cases) and those who had not experienced SARS-CoV2 infection (controls). These

symptoms were reported by higher proportions in cases than in controls, but paradoxically, quality of life measures for emotional functioning and social functioning were better in cases than in controls (**WSL2/104 - INQ000354598**).

193. The Long COVID-19 (CLoCk) study is the largest national, matched longitudinal cohort study of children and young people in England. In CLoCk, children and young people (aged 11 to 14 years) self-reported their post-COVID-19 health after laboratory-confirmed SARS-CoV-2 infection. In the Discussion of results from their report of "*Symptom Profiles of Children and Young People 12 Months after SARS-CoV-2 Testing*" the authors state: *"Perhaps surprisingly, we found that self-rated health was broadly similar 12 months post-testing for all infection status groups. When we operationalised our research definition of Post-COVID condition (PCC), 20.4% of the NN (initial test-negatives with no subsequent positive test') group met this definition at 12-month follow-up (minus the need for a positive PCR test) compared to 26.6% of the PN ('initial test-positives with no report of subsequent re-infection') group. Are these prevalences of 26.6% and 20.4% similar because many of the problems reported are the consequence of a long pandemic rather than directly attributable to viral infection? Are the prevalences similar because 99% of teenagers have now been exposed to SARS-CoV-2 even if they never had a positive test? Or is the excess of 26.6% versus 20.4% a measure of the added burden attributable to PCC, over and above living through a long pandemic? These are challenging questions that have yet to be answered, and the findings should be placed in the context of other studies that face the same challenges of interpretation of findings"* (**WSL2/105 - INQ000354607**).

194. This poor scientific understanding of post-COVID syndrome itself compounds the uncertainty of whether COVID-19 vaccination influences the development, duration, severity, or recovery from post-COVID syndromes ('long COVID').

<u>Recommendations that JCVI would change in hindsight</u>

195. In commenting on advice that JCVI might change with the benefit of hindsight, some limitations should be considered. The health benefit of advice on vaccination policy is only realised when individuals take up the offer of vaccination and are vaccinated. Advice that is not perceived to be rational or acceptable would not promote confidence in vaccination and would likely not translate into high vaccine uptake. JCVI formulates its advice based on sound scientific principles and relevant scientific data. In a hypothetical situation where hindsight was only available to JCVI but not to any other scientific body or the public, any advice based on such 'unfounded' hindsight would be unlikely to be received favourably with consequent implications for public trust and vaccine uptake.

196. JCVI did change some of its advice over the course of the pandemic in response to the changing pandemic situation and emerging scientific information. All of JCVI's advice was kept under close, constant review.

197. There was always a tension in the timing of advice from JCVI within a highly dynamic situation; between giving advice early (often some months ahead) in order to enable reasonable time for operational and down-stream processes versus giving advice later when there is more situational and scientific certainty that the advice is appropriate but with less time for communication with the public, and delivery of the vaccine programme. Sometimes, relatively rapid changes in the pandemic situation required equally rapid changes in JCVI advice, such as occurred when the Alpha and Omicron variants first emerged.

198. In relation to the primary course dose interval, if, with hindsight, JCVI *and the public* had understood from the outset the many benefits of a longer dose interval compared to a shorter dose interval, and the MHRA had also shared the same insight in their regulatory position, then JCVI's advice on using a longer dose interval for the primary course could probably have been given from the start of the COVID-19 vaccine programme. This would have avoided the need for a later change in advice when the Alpha variant emerged and the challenges in making that change, relatively rapidly.

199. In relation to additional vaccine doses for immunosuppressed persons, if the benefit of an additional dose in generating improved immune responses for persons who are immunosuppressed had been understood from the outset, the relevant advice could have been issued earlier. This would have avoided the need for a later change in advice as happened when the relevant scientific data emerged.

200. In relation to pregnant women, if JCVI, MHRA *and the public* had known from the outset that there were going to be no major safety concerns with COVID-19 vaccination in this population, then it would have been possible to be more confident in the initial advice to pregnant women regarding safety.

201. In relation to VITT, if it was known from the outset that this extremely rare but major adverse event might occur, especially in younger persons, then JCVI would have provided advice to restrict use of the AstraZeneca COVID-19 vaccine to older adults from the outset. However, this was unknowable information at the time, and advice was altered as safety data emerged.

202. In relation to Myocarditis, if it was known from the outset that this extremely rare adverse event could occur in children and young people but recovery is good and it does not have long-lasting consequences (sudden death being the particular concern), then a firmer decision on the offer of COVID-19 vaccination might have been reached sooner and it would have been possible to communicate with less uncertainty over this issue from the outset, reducing public anxiety and controversy. However, this was unknowable information at the time, and advice moved in step with emerging evidence.

Lesson learning

203. It is critical that we learn lessons from the COVID-19 pandemic in order to be better prepared for the next pandemic. Preparations for a future pandemic should ideally be adaptable to a novel pathogen with novel disease characteristics that are not necessarily akin to influenza or COVID-19.

204. The work practices for JCVI during the pandemic differed in some important ways compared to JCVI's usual processes; a) vaccine procurement occurred ahead of JCVI advice on vaccine use, b) JCVI was instructed by Secretary of State for Health and Social Care to formulate advice without reference to cost-effectiveness assessments, and c) advice necessarily took into account the deliverability of a pandemic specific mass vaccination programme conducted at scale and at speed. Given this experience, in advance of the next pandemic, a clear and separate Code of Practice for the work of JCVI in a pandemic should be developed. Potential strategies for decision-making during a pandemic should be described, including whether and how to take into account factors such as cost-effectiveness, opportunity costs and non-health impacts. How the expertise of JCVI might benefit pandemic vaccine procurement should be considered.

205. The following key principles of working were important during the pandemic in preserving the integrity of the advice from JCVI; a) the independence of JCVI as a scientific advisory body; b) provision of vaccine advice from JCVI direct to the Secretary of State for Health and Social Care, England. Maintaining these principles of working in a JCVI Pandemic Code of Practice will support public trust in vaccine advice developed by JCVI during a future pandemic. This in turn will promote vaccine confidence and vaccine uptake. In my view, the importance of maintaining public trust in public health interventions during public health emergencies should not be underestimated.

206. In order to facilitate the timely shift in work practices according to a Pandemic Code of Practice when needed, a JCVI pandemic committee (notionally referred to as JCVI-P)

should be constituted at the earliest recognition of pandemic risk and no later than at the declaration of a Public Health Emergency of International Concern by the World Health Organisation (WHO). In a future pandemic, the global aspiration is for pandemic-specific vaccines to be available within 100 days (**WSL2/106 - INQ000101061**). To match vaccine availability with timely vaccine advice would require the prompt activation of JCVI-P with sufficient lead-time for the formulation of advice. JCVI-P should be provided with the support and resources necessary for the conduct of its work according to the Pandemic Code of Practice. This should include appropriate resources for the secretariat from an early stage which was not the case during the COVID 19 pandemic. (On various occasions during the response to the COVID-19 pandemic, key staff within the JCVI secretariat were working at full stretch to manage the workload of the committee. The limited resilience within the secretariat resource at those times was a risk to the functioning of the committee) Moving on to a pandemic footing early should enable earlier recruitment of high quality and appropriately trained staff to the secretariat before such resources are taken up into other aspects of the pandemic response, and to allow for specific training of new staff members in relation to JCVI processes and ways of working. While the secretariat is now larger than in pre-pandemic times, and should stay as such, significant expansion of the secretariat resource, and other capabilities such as modelling capacity, will still be required during a future pandemic. Large and rapid surges in demand for urgent advice from JCVI should be expected over the course of a pandemic. The large increase in workload consequent on a pandemic should be anticipated with appropriate measures taken to mitigate these pressures on JCVI members as well, many of whom may have other full-time occupations. Dedicated modelling capability for JCVI should be identified at an early stage, whether from UKHSA, DHSC or another independent academic group.

207. In the sphere of communications with the public, healthcare providers and stakeholders, the volume and pace of requests to JCVI was many times greater than in routine practice. Maintaining control of the message to avoid misinformation was important. For many JCVI members, there was a steep learning curve particularly with regards to engagement with the media. In advance of the next pandemic, a clear communications strategy appropriate to pandemic demands should be developed. It may not be practical, achievable, or desirable for all public communication to be handled by the Chair alone, as stated in the existing Code of Practice. As appropriate, JCVI-P members should be provided with training in communications with media, including social media platforms.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data

Dated: 27 March 2024

Annex A – Timeline of key events with brief description

7 May 2020. Initiation of JCVI work on COVID-19

JCVI held its first meeting on COVID-19 on 7 May 2020. Key data from the pandemic in the UK were considered, including data on COVID-19 epidemiology and identified clinical risk groups. At this stage no information was available regarding the properties of vaccines in development. Timelines for potential authorisation of vaccines ranged from Autumn 2020 to Summer 2021. The Committee agreed that overall, priority for vaccination should be those at increased risk of serious disease and death from COVID-19 and health and social care workers, with priority groups stratified according to age and clinical risk factors.

18 June 2020. Interim Phase 1 advice

JCVI first published interim advice on a COVID-19 vaccination strategy on 18 June 2020. This preliminary advice was developed following a request from the Department of Health and Social Care and UKHSA, to facilitate planning for the deployment of any safe and effective vaccine as soon as regulatory approvals were obtained for use in the UK. The advice set out JCVI's view that the underlying principle of any programme should be to save lives and protect the NHS during the pandemic. The interim advice was developed using UK epidemiological data on the impact of the COVID-19 pandemic. Information was not yet available on the efficacy and safety of COVID-19 vaccines in development (**WSL2/107 - INQ000354435; WSL2/108 - INQ000354436; WLS2/109 - INQ000151857 WSL2/110 - INQ000354440**).

24 September 2020. First JCVI COVID-19 sub-committee meeting

This was the first meeting of the COVID-19 sub-committee which reviewed detailed data in order to provide advice to the main committee.

25 September 2020. Updated interim Phase 1 advice

Updated interim advice was published on 25 September 2020 to facilitate planning for the deployment of any safe and effective vaccine authorised for use in the UK. This was the first published advice to set out an order of prioritisation of the population for an offer of COVID-19 vaccines, subject to authorisation of an appropriate vaccine.

JCVI utilised the pivotal work of UK academics to identify those at higher risk of severe disease and mortality. This advice took into account accumulating data on the disproportionate impact of COVID-19 on care homes for older adults in the UK (**WSL2/111 - INQ000354445**).

1 October 2020. Agreement with Ministers on a strategy – developed with UKHSA, GCSA, CMO.

On 1 October 2020, JCVI members met with UKHSA, GCSA, CMO and other advisors to discuss and agree on the potential strategic impact of a COVID-19 vaccination programme. In late October 2020, advice and options were provided to Ministers on the overall strategic aims of a COVID-19 vaccination programme (**WSL2/9 - INQ000354448**).

1 December 2020 (22:15 – 00:00). Review of Summary of Product Characteristics (SPC) from the MHRA.

Evening meeting held to finalise JCVI's advice after MHRA's deliberations regarding the SPC for the Pfizer-BioNTech COVID-19 vaccine, now known by the trade name Comirnaty®.

2 December 2020. Final Phase 1 advice

The Pfizer-BioNTech COVID-19 vaccine, now known by the trade name Comirnaty® was first authorised by the MHRA on 2 December 2020 under regulation 174). JCVI published advice on the use of the Pfizer-BioNTech COVID-19 vaccine on 2 December 2020 to coincide with MHRA's approval of the vaccine (**WSL2/50 - INQ000354461**; **WSL2/112 - INQ000354616**; **WSL2/113 - INQ000354615)**. A televised technical briefing was held to publicly announce this advice.

This advice was the first to take into account and prioritise those considered by the Government to be "Clinically Extremely Vulnerable" (CEV). JCVI was not associated with the development of definitions or terminology regarding the CEV group, and considerations on specific prioritisation of this group followed a request from the cross-Government committee COVID-O.

8 December 2020. Phase 1 commencement

The COVID-19 mass vaccination programme began in the UK on 8 December 2020 (**WSL2/114 - INQ000354614**).

December 2020. Alpha variant emergence

The Alpha variant was first detected in the UK by UKHSA in November 2020. The Alpha variant was originally identified in south east England and rapidly became the dominant variant in the UK during December 2020 and January 2021.

30 December 2020. AstraZeneca COVID-19 vaccine advice

The AstraZeneca COVID-19 vaccine, now known by the trade name Vaxzevria® was first authorised by the MHRA on 30 December 2020 under regulation 174.

JCVI published advice on the use of the AstraZeneca COVID-19 vaccine on 30 December 2020 to coincide with authorisation of the vaccine (**WSL2/34 - INQ000354469**). This followed a JCVI meeting held on 29 December 2020 between 19:00-21:00, to allow for consideration of information on the SPC from the MHRA.

30 December 2020 and 6 January 2021. Prioritisation of the first dose

Following a rapid increase in COVID-19 cases in the UK in December 2020 due to the emergent Alpha variant, JCVI advised prioritising delivery of the first vaccine dose to as many persons as possible. JCVI advised that the interval between the first and second vaccine doses could be extended to 12 weeks for both UK approved vaccines to facilitate prioritisation of the first vaccine dose as rapidly as possible (**WSL2/115 - INQ000234700; WSL2/116 - INQ000354613**).

21 January 2021. Consideration of Moderna COVID-19 vaccine

The COVID-19 sub-committee considered data on the Moderna COVID-19 vaccine for inclusion in the COVID-19 vaccination programme.

23 February 2021. Advice on prioritisation of individuals on the learning disability register

JCVI had previously advised that all individuals with Down's syndrome should be offered vaccination as part of Phase 1, priority group 4. JCVI had also advised that those with severe and profound learning disabilities, and those with learning disabilities residing in residential care, should be offered vaccination as part of priority group 6 alongside other individuals with a range of underlying neurological and respiratory conditions.

Due to concerns raised by NHSE about the coding of learning disability on GP systems, particularly with regard to the coding of severity of any disability, JCVI reviewed the operational and vaccination advice. JCVI wrote to the Secretary of State for Health and Social Care on 23 February 2021 to advise (in agreement with the operational plan) that all individuals on the GP Learning Disability Register plus those with codes for other related conditions, including cerebral palsy, be invited for vaccination as part of priority group 6 (unless already in priority group 4, such as those with Down's syndrome) (**WSL2/117 - INQ000354486**).

26 February 2021. Interim Phase 2 advice

JCVI published interim advice on Phase 2 of the COVID-19 vaccination programme on 26 February 2021. This interim advice indicated that prioritisation of vaccine should continue to be age-based, with priority given to the oldest adults. Priority groups were set out as those aged 40-49, 30-39 and 18-29 years (**WSL2/118 - INQ000354488**).

11 March 2021. Further considerations on Phase 1

On 11 March 2021 JCVI wrote to the Secretary of State setting out considerations on a number of key issues raised with the Committee, including prioritisation of those experiencing homelessness, prison workers and detainees, and on the extended schedule.

JCVI advised prioritisation of those experiencing homelessness alongside priority group 6. JCVI did not advise prioritisation of prison workers or detainees (**WSL2/22 - INQ000354434**).

JCVI continued to advise an extended schedule of up to 12 weeks between the first and second doses and advised a minimal interval of 8 weeks for the AstraZeneca COVID-19 vaccine.

24 March 2021. Household contacts of immunosuppressed individuals

On 24 March 2021 JCVI wrote to the Secretary of State for Health and Social Care setting out advice on prioritisation of household contacts of immunosuppressed individuals. This was prompted by emerging evidence that vaccination might offer some protection against infection. While there was not sufficient evidence on blocking of transmission to move forward on a mass vaccination scale to block outbreaks, it was thought reasonable to offer vaccination to household members of vulnerable individuals who could not themselves be vaccinated (**WSL2/119 - INQ000354494**).

7 April 2021. AstraZeneca COVID-19 vaccine update

In late February 2021, reports of an extremely rare adverse event of concurrent thrombosis (blood clots) and thrombocytopenia (low platelet count) following vaccination with the first dose of AstraZeneca COVID-19 vaccine were brought to the attention of JCVI by the MHRA. Following a series of review by the MHRA and JCVI, on 7 April JCVI advised that otherwise healthy adults aged 18 to 29 years should be offered an alternative to the AstraZeneca COVID-19 vaccine where available (**WSL2/120 - INQ000354498**).

13 April 2021. Phase 2 advice

On 13 April 2021, JCVI finalised advice for Phase 2 of the COVID-19 vaccination programme. This was timed to coincide with the point of near maximum uptake in Phase 1 of the programme. Phase 2 advice focussed on offering vaccination to the remainder of the adult population in three age cohorts, 40-49, 30-39 and 18-29 years (**WSL2/35 - INQ000257445**).

16 April 2021. Vaccination of pregnant women

JCVI provided further specific advice on vaccination of pregnant women on 16 April 2021. Earlier advice on the use of COVID-19 vaccines in pregnancy had been precautionary, due to a lack of data on vaccine safety in pregnant women. After a review of data from the United

States on safety reports following vaccine administration in pregnancy, JCVI advised that pregnant women should be offered vaccination at the same time as their age cohorts (**WSL2/36 - INQ000354500**). This advice coincided in timing with delivery of Phase 2 of the programme.

7 May 2021. Updated advice on the AstraZeneca COVID-19 vaccine

JCVI provided updated advice on the use of the AstraZeneca COVID-19 vaccine on 7 May 2021. This set out a preference for alternatives to the AstraZeneca COVID-19 vaccine in those aged less than 40 years. This advice took into account the availability of alternatives to the AstraZeneca COVID-19 vaccine in the UK (**WSL2/121 - INQ000354505**).

14 May 2021. Advice on the Delta variant

In response to the identification of the Delta variant in the UK, JCVI provided urgent advice on 14 May 2021. JCVI advised that the vaccination programme should press on with delivery of vaccines to all UK regions and not to re-distribute vaccination resources to areas with a higher incidence of Delta outbreaks at that time. The view of the Committee was that spread of the Delta variant would surpass the ability of deployment teams to focus vaccination on high Delta incidence areas, and that greater benefit would be achieved through increasing vaccine coverage of individuals at higher risk of severe COVID-19 in all parts of the UK including areas where the Delta variant was not already circulating. It was considered that attempting to delay spread of the Delta variant across the UK was not realistically achievable (**WSL2/122 - INQ000354509**).

30 June 2021. Interim statement on COVID-19 booster vaccination

JCVI set out interim advice on an Autumn/Winter 2021/22 booster vaccination programme on 30 June 2021. Persons initially deemed eligible for the booster programme included adults aged 50 years and over and those in a clinical risk group; these persons were considered to be at higher risk of serious disease (**WSL2/123 - INQ000354519**).

2 July 2021. Vaccination of 12- to 15-year-olds

The MHRA authorised the Pfizer-BioNTech vaccine in those aged 12 to 15 years on 4 June 2021. JCVI submitted its advice on vaccination of this group to the Department of Health and Social Care (DHSC) on 2 July 2021.

19 July 2021. Advice for 12- to 15-year-olds published

JCVI's advice regarding an offer of vaccination for 12- to 15-year-olds was published on 19 July 2021 after DHSC had completed its review of the advice and considered policy options. The advice from JCVI was for vaccination of those aged 12-15 years with certain underlying health conditions which put them at higher risk of severe COVID-19. This was in addition to

existing advice on vaccination of those aged 16 to 17 years with underlying health conditions which put them at a higher risk of severe COVID-19 (**WSL2/91 - INQ000354522**).

4 August 2021. Vaccination of 16- to 17-year-olds

JCVI published updated advice on vaccination of 16- to 17-year-olds on 4 August 2021. This advice was to offer a first dose to all those aged 16 to 17 years (**WSL2/93 - INQ000235154**).

1 September 2021. Third primary dose for severely immunosuppressed persons

JCVI issued advice on a third primary dose for severely immunosuppressed persons on 1 September 2021 (**WSL2/125 - INQ000257012**). This advice was contemporaneous with advice from National Immunisation Technical Advisory Groups (NITAGs) around the world.

3 September 2021. Updated advice on vaccination of 12- to 15-year-olds

JCVI issued updated advice on the vaccination of 12- to 15-year-olds on 3 September 2021. The followed a review of the latest evidence on the potential benefits and risks of vaccination in this age group (**WSL2/94 - INQ000257024**).

JCVI advised that the benefits from vaccination were marginally greater than the potential known harms, but the margin of benefit, based primarily on an individual health perspective, was considered too small to support advice on a universal programme of vaccination of otherwise healthy 12 to 15-year-old children. JCVI noted viewpoints regarding the potential educational benefits from extending vaccination to all children aged 12 to 15 years. JCVI therefore suggested that 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 the discussions.

The view of the four Chief Medical Officers of the UK, published on 13 September 2021, was that the additional likely benefits of reducing educational disruption, and the consequent reduction in public health harm from educational disruption, provided sufficient extra advantage in addition to the marginal advantage at an individual health level identified by the JCVI, to support in favour of vaccinating all persons aged 12 to 15 years (**WSL2/126 - INQ000257035**). They therefore recommended 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 to 15 years not already covered by existing JCVI advice.

6 September 2021. Consideration of Moderna COVID-19 vaccine as a booster

JCVI considered evidence on the Moderna COVID-19 vaccine and its role in the Autumn 2021 programme.

14 September 2021. Booster programme final advice

JCVI published final advice on the Autumn 2021 booster programme on 14 September 2021. This advice was to offer a booster dose of an mRNA COVID-19 vaccine to all those aged 50 years and over, and those aged less than 50 years in a clinical risk group. This programme aimed to increase protection against severe disease in those at higher risk, over the winter 2021/22 period (**WSL2/127 - INQ000257044**).

30 September 2021. Consideration of Janssen and Moderna COVID-19 vaccines

JCVI considered evidence on the Janssen COVID-19 vaccine and concluded that the benefits of introducing the vaccine into the existing national programme were small compared to the operational costs. There was sufficient vaccine from other manufacturers (limited added benefit to programme) and there were costs associated with training staff to use the vaccine, alongside the risk of adding complexity to the programme. JCVI advised the Janssen COVID-19 vaccine should not be introduced into the national COVID-19 vaccine programme.

Reviewing data on the potential risk of post-vaccination myocarditis, JCVI advised that the Moderna COVID-19 vaccine should not be offered to those aged less than 18 years.

7 and 19 October and 12 November 2021. Consideration of the risk of myocarditis following receipt of the Moderna COVID-19 vaccine

JCVI considered the use of the Moderna vaccine in the light of reports of myocarditis following vaccination in younger adult age groups. After discussions with the MHRA, it was agreed that no restrictions should be placed on the use of the Moderna vaccine in younger adults (individuals aged > 18 years).

15 November 2021. Booster vaccination for 40- to 49-year-olds

On 15 November 2021, JCVI issued updated advice extending the booster programme to 40–49-year-olds. This was part of a planned review and was timed to coincide with maximum uptake in older persons and those in clinical risk groups. JCVI advised that efforts should be undertaken to maximise uptake in those at a higher risk of severe COVID-19, prior to extension of the programme to those at a lower risk (**WSL2/128 - INQ000257106**).

15 November 2021. Vaccination of young people aged 16 to 17 years

On 15 November 2021, JCVI published advice on an offer of a second vaccine dose to otherwise healthy 16- to 17-year-olds (**WSL2/129 - INQ000354546**). This followed a review of the latest data on the potential risks and benefits of the Pfizer-BioNTech COVID-19 vaccine in this age group.

29 November 2021. Advice in response to emergence of the Omicron variant

The World Health Organisation recognised the Omicron variant on 26 November 2021. The variant was considered highly transmissible and the high number of mutations in the virus led to uncertainty and concern around the potential for immune escape. There was a realistic possibility that an Omicron wave over winter 2021/22 could result in a high number of hospitalisations and deaths in the UK.

In response to the emergence of the Omicron variant, JCVI rapidly developed advice which was published on 29 November 2021. JCVI advised an extension and acceleration of the Booster vaccination programme; to include all adults aged 18 years to 39 years; acceleration of the offer of third primary doses to severely immunosuppressed individuals; an equal preference for the Moderna (50 microgram) and Pfizer-BioNTech (30 microgram) COVID-19 vaccines; and the offer of a second primary dose of COVID-19 vaccine to all children and young people aged 12 to 15 years, with the minimum interval between primary doses reduced to 8 weeks (**WSL2/130 - INQ000257124**).

16 December 2021. Update on vaccination for pregnant women

On 16 December 2021 a press release was issued setting out JCVI's updated advice on vaccination in pregnancy. Following consideration of the latest UK data on the risk of COVID-19 disease in pregnancy, JCVI advised that all pregnant women should be prioritised for vaccination similarly to those in priority group 6 (**WSL2/38 – INQ000354556**).

22 December 2021. Children aged five to 11 years

MHRA approved paediatric dose COVID-19 vaccine for use in 5- to 11-year-olds in the UK on 22 December 2021. On the same day, JCVI published a statement, partly in response to emergence of the Omicron variant, advising a two-dose primary course of vaccine in those aged 5 to 11 years who were considered at higher risk of severe disease, a booster vaccine for those aged 16 to 17 years and a booster vaccine for those aged 12 to 15 years considered at higher risk of severe disease (**WSL2/131 - INQ000257219**).

7 January 2022. Omicron variant and booster vaccination

On 7 January 2022, JCVI published considerations on whether additional boosters should be offered to any adults, given the emergence of Omicron (**WSL2/132 - INQ000354561**). This followed a request for advice from DHSC. JCVI advised no change to existing advice and assured that the situation would be kept under review.

16 February 2022. Update on vaccination of children aged five to 11 years

On 16 February 2022, JCVI published advice on the vaccination of healthy 5- to 11-year-olds. JCVI advised a non-urgent offer of two 10 mcg doses of the Pfizer-BioNTech COVID-19 vaccine (Comirnaty®) to children aged 5 to 11 years of age who are not in a clinical risk

group. The 2 doses were advised to be offered with an interval of at least 12 weeks between doses (**WSL2/133 - INQ000257287**).

21 February 2022. Spring booster dose

On 21 February 2022, JCVI published advice on the offer of a spring vaccination dose to those aged 75 years and over, those resident in a care home for older adults, and those aged 12 years and over with immunosuppression (as defined in the Green Book). This was a precautionary programme aimed to protect those at the greatest risk from severe COVID-19 between the Autumn 2021 and Autumn 2022 programmes (**WSL2/134 - INQ000354575**).

20 May 2022. Interim statement on COVID-19 vaccination in autumn 2022

On 20 May 2022, JCVI published interim advice on a COVID-19 vaccination programme in autumn 2022. JCVI's view in this interim statement was that a COVID-19 vaccine should be offered to residents in a care home for older adults and staff working in care homes for older adults, frontline health and social care workers, all those aged 65 years and over, and all adults aged 16 to 64 years in a clinical risk group (as defined in the Green Book) (**WSL2/135 - INQ000354595**). This advice was subsequently replaced by the final advice for autumn 2022, published on 15 July 2022.

Annex B

JCVI Sub-committee meeting dates

24/09/2020 (**WSL2/136 - INQ000354444**)

01/10/2020 (**WSL2/137 - INQ000354446**)

08/10/2020 (**WSL2/138 - INQ000354447**)

15/10/2020 (**WSL2/15 - INQ000354449**)

22/10/2020 (**WSL2/16 - INQ000354451**)

29/10/2020 (**WSL2/139 - INQ000354452**)

05/11/2020 (**WSL2/17 - INQ000354453**)

12/11/2020 (**WSL2/140 - INQ000354455**)

19/11/2020 (**WSL2/141 - INQ000354456**)

30/11/2020 (**WSL2/142 - INQ000354457**)

03/12/2020 (**WSL2/31 - INQ000354463**)

08/12/2020 (**WSL2/143 - INQ000354464**)

15/12/2020 (**WSL2/144 - INQ000354465**)

22/12/2020 (**WSL2/145 - INQ000354466**)

07/01/2021 (**WSL2/146 - INQ000354475**)

14/01/2021 (**WSL2/147 - INQ000354476**)

21/01/2021 (**WSL2/148 - INQ000354477**)

28/01/2021 (**WSL2/21 - INQ000354478**)

04/02/2021 (**WSL2/149 - INQ000354482**)

11/02/2021 (**WSL2/150 - INQ000354483**)

18/02/2021 (**WSL2/151 - INQ000354485**)

25/02/2021 (**WSL2/152 - INQ000354487**)

04/03/2021 (**WSL2/153 - INQ000354489**)

11/03/2021 (**WSL2/154 - INQ000354490**)

25/03/2021 (**WSL2/155 - INQ000354493**)

01/04/2021 morning meeting (**WSL2/156 - INQ000354496**)

01/04/2021 afternoon meeting (**WSL2/157 - INQ000354495**)

13/04/2021 (**WSL2/158 - INQ000354499**)

22/04/2021 (**WSL2/159 - INQ000354501**)

29/04/2021 (**WSL2/160 - INQ000354502**)

06/05/2021 (**WSL2/161 - INQ000354504**)

11/05/2021 (**WSL2/162 - INQ000354506**)

13/05/2021 (**WSL2/163 - INQ000354507**)

20/05/2021 (**WSL2/164 - INQ000354511**)

27/05/2021 (**WSL2/165 - INQ000354512**)

10/06/2021 (**WSL2/166 - INQ000354514**)

17/06/2021 (**WSL2/167 - INQ000354516**)

22/07/2021 (**WSL2/168 - INQ000354524**)

27/07/2021 (**WSL2/169 - INQ000354526**)

JCVI Main Committee meeting dates

07/05/2020 (**WSL2/5 - INQ000354439**)

06/07/2020 (**WSL2/170 - INQ000354441**)

01/09/2020 (**WSL2/171 - INQ000354443**)

29/11/2020 (**WSL2/172 - INQ000354454**)

30/11/2020 (**WSL2/173 - INQ000354458**)

01/12/2020 #1 (**WSL2/174 - INQ000354460**)

01/12/2020 #2 (**WSL2/175 - INQ000354459**)

22/12/2020 (**WSL2/32 - INQ000354462**)

29/12/2020 (**WSL2/33 - INQ000354468**)

16/02/2021 (**WSL2/176 - INQ000354484**)

16/03/2021 (**WSL2/37 - INQ000354491**)

18/03/2021 (**WSL2/177 - INQ000354492**)

06/04/2021 (**WSL2/178 - INQ000354497**)

04/05/2021 (**WSL2/45 - INQ000354503**)

13/05/2021 (**WSL2/179 - INQ000354508**)

10/06/2021 (**WSL2/180 - INQ000354513**)

15/06/2021 (**WSL2/47 - INQ000354515**)

24/06/2021 (**WSL2/181 - INQ000354517**)

29/06/2021 (**WSL2/182 - INQ000354518**)

01/07/2021 (**WSL2/183 - INQ000354520**)

13/07/2021 (**WSL2/184 - INQ000354521**)

29/07/2021 (**WSL2/92 - INQ000354527**)

05/08/2021 (**WSL2/185 - INQ000354530**)

12/08/2021 (**WSL2/186 - INQ000354531**)

19/08/2021 (**WSL2/187 - INQ000354532**)

26/08/2021 (**WSL2/188 - INQ000354533**)

01/09/2021(**WSL2/189 - INQ000354534**)

02/09/2021 (**WSL2/190 - INQ000354535**)

06/09/2021 (**WSL2/191 - INQ000354536**)

09/09/2021 (**WSL2/192 - INQ000354537**)

30/09/2021 (**WSL2/193 - INQ000354538**)

07/10/2021 (**WSL2/194 - INQ000354539**)

19/10/2021 (**WSL2/195 - INQ000354540**)

02/11/2021 (**WSL2/196 - INQ000354542**)

04/11/2021 (**WSL2/197 - INQ000354543**)

12/11/2021 (**WSL2/198 - INQ000354545**)

18/11/2021 (**WSL2/199 - INQ000354547**)

25/11/2021 (**WSL2/200 - INQ000354548**)

27/11/2021 (**WSL2/201 - INQ000257121**)

30/11/2021 (**WSL2/202 - INQ000354550**)

02/12/2021 (**WSL2/42 - INQ000354551**)

09/12/2021 (**WSL2/203 - INQ000354553**)

21/12/2021 (**WSL2/204 - INQ000354557**)

30/12/2021 (**WSL2/205 - INQ000354558**)

06/01/2022 (**WSL2/206 - INQ000354560**)

13/01/2022 (**WSL2/207 - INQ000354564**)

20/01/2022 (**WSL2/208 - INQ000354565**)

27/01/2022 (**WSL2/209 - INQ000354568**)

03/02/2022 (**WSL2/210 - INQ000354570**)

10/02/2022 (**WSL2/211 - INQ000354572**)

24/02/2022 (**WSL2/212 - INQ000354576**)

10/03/2022 (**WSL2/213 - INQ000354581**)

24/03/2022 (**WSL2/214 - INQ000354583**)

07/04/2022 (**WSL2/215 - INQ000354587**)

12/05/2022 (**WSL2/216 - INQ000354593**)

19/05/2022 (**WSL2/217 - INQ000354594**)

26/05/2022 (**WSL2/218 - INQ000354596**)

28/06/2022 (**WSL2/219 - INQ000354599**)