Witness Name: Vaughan Gething
Statement No: M4-Gething-01
Exhibits: 164
Dated: 18/07/2024

UK COVID-19 INQUIRY

WITNESS STATEMENT OF VAUGHAN GETHING

I, VAUGHAN GETHING M.S., will say as follows: -

Introduction

1. The purpose of this statement is to assist the Inquiry in investigating how issues relating to vaccine delivery, access to vaccines and barriers to vaccine uptake were addressed in Wales during the course of the Covid-19 pandemic, and also covers questions of vaccine safety. This statement also addresses matters relating to novel and re-purposed therapeutics developed in response to the Covid-19 pandemic.

2. This statement covers the period from 30 January 2020 – the date upon which the first cases of Covid-19 were confirmed within the UK - until 13 May 2021 when I ceased to be Minister for Health and Social Services and became the Minister for the Economy.

Personal reflections

3. I cannot overstate how sorry I am that so many people lost their lives in the pandemic. I know that however genuine or heartfelt my sympathy is that it will not bring people back or take away the emotional or physical harm. I recognise that the harm done continues for many people. It is even clearer today how significant and long lasting that harm is.

4. I lived through the pandemic with my family, and I saw the impact it had around me. That does not mean that I know what that felt like for other families with a different experience. I remain incredibly grateful to all those people who made sacrifices in their work, their

friendships and family relationships, and the way they cared for each other right across Wales.

5. I remain especially affected by the experiences and commitment of staff across health and social care. I recognise that not everyone made it through the pandemic and for some people it has shortened the careers they were dedicated too.

6. I am also particularly grateful to the military personnel who provided their logistical and organisational expertise to assist with the roll-out of the vaccine programme. My role was to make decisions as Minister for Health. I did not and could not have worked at the frontline as so many did, be they military or civilian, and I remain deeply grateful to them all.

7. There were no easy choices to make. The Welsh Ministers have never had to take such extraordinary choices and I hope never to need to again in the future. I would not wish that on any future government of any make up. I would not wish that future on the people of Wales and the wider world. Crucially I hope that we learn what we might do differently and better in Wales and across the UK with the work of this inquiry. The development and deployment of vaccines was one of the real success stories in Wales and the UK that had a significant and tangible impact upon people's lives: it provided us with a vital additional tool to combat the virus. I hope that the structures developed inter-governmentally to that end are built upon, not dismantled. I will continue to be of help in any way I can.

Structure of the statement

8. The information provided in this statement is structured as follows:

15. Informal communications (271)
16. Lesson learning (para 274)

Personal Background

9. I have been the Member of the Senedd for Cardiff South and Penarth since 6 May 2011 before which I practised as a solicitor in Cardiff where I was a partner in the firm of Thompsons LLP.

10. I am a member of the GMB, UNISON and Unite Community unions, and I was the President of the Wales TUC Cymru in 2008. I have previously served as a county councillor, a school governor, and a community service volunteer.

11. I first entered the Welsh Government on 26 June 2013 when I was appointed the Deputy Minister for Tackling Poverty. On 11 September 2014, I was appointed Deputy Minister for Health, a position which I held until 19 May 2016 when I became the Cabinet Secretary for Health, Well-being and Sport. In 2018, the name of that portfolio was changed to the Minister for Health and Social Services, but for the purposes of this Inquiry, there was no relevant change in my responsibilities. For ease of reference, I shall use the latter term to describe the post in which I served between 2016 and 2021. I held that office until 13 May 2021 when I was appointed Minister for the Economy.

12. I held the role of Minister for Economy until I was appointed as First Minister of Wales on 20 March 2024.

The Devolution Settlement and Regulatory Framework

13. The Inquiry has already examined the devolution settlement, its structures and decision-making processes in other modules and I will not repeat the background in this statement. Both the Welsh Government's corporate statements and Andrew Goodall's statement in this module sets out in detail the structure of the NHS in Wales and a brief overview of the history of devolution in so far as is relevant to health. However, for the purpose of understanding the allocation of functions in relation to vaccines and therapeutics, it is important to note that notwithstanding the longstanding position of health as a devolved matter, the position is more nuanced and certain elements remain reserved to the UK Government.

14. The executive functions of the Welsh Ministers in general terms align with the devolved competence of the Senedd. Section 108A of the Government of Wales Act 2006 (as amended) provides that any provision of an Act of the Senedd is outside its competence

if (amongst other matters) it relates to reserved matters. Schedule 7A lists reserved matters. By Schedule 7A, Part 2, paragraph 12 of the Act, the following are reserved matters:

Head G – Professions

Section G1: Architects, auditors, health professionals and veterinary surgeons

140 Regulation of -

…

(c) health professions,

…

Exceptions

- *Regulation of the social care profession.*
- *Regulation of the social work profession.*

Interpretation

"Health professions" means—

(a) the professions regulated by the following—

- *the Medical Act 1983;*
- *the Dentists Act 1984;*
- *the Opticians Act 1989;*
- *the Osteopaths Act 1993;*
- *the Chiropractors Act 1994;*
- *the Nursing and Midwifery Order 2001 (S.I. 2002/253);*
- *the Health and Social Work Professions Order 2001 (S.I. 2002/254);*
- *the Pharmacy Order 2010 (S.I. 2010/231);*

(b) any other profession concerned with the physical or mental health of individuals.

Head J—Health, Safety and Medicines

Section J4: Medicines, medical supplies, biological substances etc

147 Medicinal products, including manufacture, authorisations for use and regulation of prices.

148 Regulation of prices of other medical supplies.

...

153 Vaccine damage payments.

Interpretation

- *""Medical supplies"" has the same meaning as in section 260 of the National Health Service Act 2006.*
- *""Medicinal products"" has the same meaning as in the Human Medicines Regulations 2012 (S.I. 2012/1916).*

15. Regulation 2 of The Human Medicines Regulations 2012 provides (in so far as is relevant):

> ***2.**— (1) In these Regulations "medicinal product" means—*
>
> *(a)any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or*
>
> *(b)any substance or combination of substances that may be used by or administered to human beings with a view to—*
>
> (i) *restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or*
>
> (ii) *making a medical diagnosis.*

16. Regulation 8 of the 2012 Regulations provides:

> ***8.**— (1) In these Regulations (unless the context otherwise requires)—*
>
> *"vaccine" means an antigenic substance which consists wholly or partly of—*
>
> *(a) any micro-organisms, viruses or other organisms in any state;*
>
> *(b) any toxins of microbial origin which have been detoxified (toxoids); or*
>
> *(c) any extracts or derivatives of any micro-organisms or of any viruses, being substances which, when administered to human beings, are used for the prevention of specific diseases.*

17. The regulation of healthcare professionals, medicines, vaccines and their authorisation, and vaccine damage payments are matters in respect of which legislative competence is reserved to the UK Government ("reserved matters"). The executive functions of Welsh Ministers can on occasion be wider than the devolved competence of the Senedd. Insofar as relevant to the matters covered in this statement, in October 2020, the Human Medicine Regulations 2012 were amended in a way which gave the Welsh Ministers a limited role in a reserved matter. Regulation 247A of those Regulations provided that one of the conditions for broadening the category of healthcare professionals who could administer Covid-19 vaccines was that the Welsh Ministers (amongst others) had approved a protocol setting out certain requirements.

Medical and Healthcare products Regulatory Agency

18. The Medical and Healthcare products Regulatory Agency (MHRA) is the regulator for medicines, medical devices and blood components for transfusion in the United Kingdom. This includes all relevant vaccines and therapeutics in respect of Covid-19.

19. By the Human Medicines Regulations 2012 (as amended) the Secretary of State for Health and the Minister for Health, Social Services and Public Safety are appointed as the licensing authority who are responsible for the grant, renewal, variation, suspension and revocation of licences, authorisations, certificates and registrations under those Regulations. The regulatory regime provided for by the Human Medicines Regulations 2012 (as amended) applies to the whole of the UK. An exception to the usual position in respect of marketing authorisation is set out at regulation 60 of those Regulations whereby medicinal products, whether therapeutics or vaccines, may be authorised by the licensing authority for serious and life-threatening diseases where no satisfactory treatments are available or where the product offers a major therapeutic advantage and where comprehensive clinical data is not yet complete, but it is judged that such data will become available soon. Regulation 174 also provides for the temporary authorisation of an unlicensed medicinal product where such an authorisation is needed in response to a public health threat, such as a pandemic. Regulation 174A provides for the imposition of conditions to be placed on supply and use of the product as safeguards without which authorisation would not be valid.

20. The Pfizer BioNTech and AstraZeneca vaccines were granted temporary authorisations by the MHRA on 2 December and 30 December 2020 respectively. Subsequently these vaccines were granted conditional marketing authorisations. On 8 January 2021, the Moderna vaccine was granted a temporary authorisation however no Moderna vaccine

was deployed under the temporary authorisation, with a conditional marketing authorisation being granted on 31 March 2021, ahead of its inclusion in the UK vaccination programme in April.

21. Use was made of the Early Access to Medicines Scheme in respect of an anti-viral medicine, remdesivir, which enabled Health Boards to use the same ahead of full market approval being confirmed.

22. Pharmacovigilance is a responsibility of medicines regulators and is undertaken by the MHRA on behalf of the whole UK working through established processes with other international regulators. Adverse drug reactions can be reported through the MHRA's yellow card scheme. Spontaneous reports (yellow cards) can be submitted by healthcare professionals and patients using hard copy cards, online or using the yellow card app. The MHRA developed a dedicated coronavirus yellow card reporting site for reporting adverse reactions to Covid-19 vaccines and therapeutics.

23. It is apparent from discussions with senior officials, and with the Chief Pharmaceutical Officer in particular, that there was a very good pre-existing working relationship with the MHRA.

Roles, Responsibilities and Key Individuals

24. The Welsh Government is headed by the First Minister, who selects and appoints ministers and deputy ministers. I have not set out my current responsibilities as First Minister as this does not relate to the relevant period under consideration.

25. As the Minister for Health and Social Services I held a broad range of responsibilities. Although this is not an exhaustive list, my responsibilities included:
    a. public health;
    b. NHS delivery and performance;
    c. escalation procedures;
    d. receipt of, response to, and direction of reports from Healthcare Inspectorate Wales;
    e. oversight of the Welsh Government's relationship with Audit Wales regarding activities relating to the NHS;
    f. subject to certain exceptions, medical workforce training and development; research and development in health and social care; mental health services;
    g. patient experience and involvement;

h. policy and oversight of the provision of all social service activities of Welsh local authorities;
i. oversight of Social Care Wales;
j. inspection of, and reporting on, the provision of social services by local authorities (by Care Inspectorate Wales), including joint reviews of social services and responding to reports.

26. A full list of the Minister for Health and Social Services' ministerial responsibilities is exhibited in **M4/VG/01 - INQ000321251**. Alongside the broader health and social care portfolio, I was the responsible minister for vaccination in Wales.

27. In order to undertake this role, I worked closely with the Director General of the Health and Social Services Group who was the most significant Senior Civil Servant with whom I had regular contact throughout the pandemic. Between June 2014 and my leaving the Health and Social Care portfolio in May 2021, the Director General was Dr Andrew Goodall. The Director General of the Health and Social Services Group supports and reports to the Minister for Health and Social Services on progress on achieving ministerial priorities.

28. The Director General of the Health and Social Services Group holds a combined role as Director General and a role referred to as the "Chief Executive NHS Wales". While the role of Chief Executive NHS Wales is not a statutory role it is a significant and distinctive post located in the Welsh Government, bringing together the responsibilities of a Director General in the Welsh Government with the leadership and oversight of NHS Wales. There is no separate NHS Wales entity, the NHS in Wales is made up of seven Local Health Boards, three NHS Trusts and two Special Health Authorities and the NHS in Wales is delivered via these NHS bodies.

29. I set out below other key health officials with whom I had regular direct contact in respect of the matters which are the subject of this Module during the relevant period:
    a. Sir Frank Atherton, Chief Medical Officer, who remains in post;
    b. Dr Rob Orford, Chief Scientific Adviser for Health, who remained in post during the relevant period but has now left the Welsh Government;
    c. Dr Gillian Richardson, Deputy Chief Medical Officer, who was on secondment from Public Health Wales and is no longer in the Welsh Government, who acted as Senior Responsible Owner for the Vaccination Programme until Claire Rowlands took on that role;

d. Claire Rowlands, Senior Responsible Owner, Vaccination Programme who has changed role but remains in the Welsh Government;
e. Andrew Evans, Chief Pharmaceutical Officer, who remains in post;

30. I was supported by the health Special Adviser, Claire Jenkins, who assisted me in responding to the Covid-19 pandemic by providing information from meetings held with internal and external stakeholders across the health and social care spheres. Special Advisers would meet with representatives from the public sector, scientific, professional advisers, policy leads and lawyers in order to highlight any cross-cutting issues or to provide updates on key areas. Special Advisers are appointed by the First Minister to help ministers on matters where the work of the Government and the work of the political party of Government overlap, and where it would be inappropriate for permanent civil servants to become involved. They are employed as civil servants but are subject to a separate code of conduct. They are not decision makers.

31. The corporate statements served in this module sets out the role and the purpose of the relevant groups which were involved with vaccine and therapeutics matters. I note we also had the benefit of advice from the following.

<u>The Technical Advisory Cell</u>

32. The Technical Advisory Cell (TAC) was set up on 27 February 2020. I attach its terms of refence in exhibit **M4/VG/02 - INQ000227962**. The Technical Advisory Cell provided scientific and technical information interpreted for Wales in adherence to advice provided by SAGE. Though most of the scientific and clinical advice was provided by the Vaccine Programme Board, or its members, the Technical Advisory Cell advice provided the contextual evidence as regards the virus generally and on occasion provided specific evidence dealing with vaccines. When that related to vaccines the relevant Technical Advisory Cell advice would be considered by and brought to my attention by the Chair of the Vaccines Programme Board.

<u>Knowledge and Analytical Services data monitor</u>

33. From late March 2020, the Welsh Government's Knowledge and Analytical Service (KAS) coordinated, with input from NHS Wales, a number of daily (seven days a week) data returns to both the Welsh and UK Governments, including data on cases, deaths and vaccinations, shielded and vulnerable people, and attitudes and behaviours. It is worth

noting that the availability and use of data in respect of the vaccine were key: both from the perspective of informing decision making and public messaging.

Public Health Wales

34. Public Health Wales led the collection, analysis, and dissemination of rapid surveillance data for Covid-19, which included vaccination uptake.

Other bodies and groups

35. Though I did not have direct involvement, I was kept up to date with the work of the Covid-19 Vaccine Stakeholder Forum. The views expressed at those meetings were important in informing my officials in respect of what was, and was not working, in terms of vaccine delivery and what issues were important to the public as regards vaccine hesitancy.

36. I was aware of many advisory bodies that provided clinical and scientific advice to clinicians. I did not engage directly with those bodies but, where relevant, would be provided with relevant advice by my officials.

37. As to the key bodies and/or collaborative strategies in relation to the development of therapeutics to treat Covid-19, these were established on a UK-wide basis. The Welsh Government was not represented on, and did not engage directly with, the UK Covid-19 Therapeutics Advisory Panel. The findings of clinical trials informed the development of UK wide clinical policies regarding the use of new and repurposed therapeutics for Covid-19 including those proposed for inclusion in trials by the UK Covid-19 Therapeutics Advisory Panel, which then applied and were implemented in Wales.

38. I did not engage directly with the National Institute for Health and Care Excellence (NICE) on matters relating to the use of therapeutics, however recommendations it made relating to Covid-19 treatments were made routinely available to Health Boards.

39. The Research to Access Pathway for Investigational Drugs for Covid-19 (RAPID C-19) was established early in the pandemic with the aim to get treatments for Covid-19 to patients quickly and safely as part of temporary, emergency pandemic arrangements. RAPID C-19 was a collaboration between NICE, NHS England, MHRA, the National Institute for Health and Care Research (NIHR), the Scottish Medicines Consortium (SMC), the All-Wales Therapeutics and Toxicology Centre, the Department of Health in Northern

Ireland and the Therapeutics Task Force (and subsequently the Antivirals Task Force and Antivirals and Therapeutics Task Force). I had no direct involvement.

UK Health Ministers

40. One evening per week the health ministers would speak by telephone to share information; these were not decision-making telephone calls. The telephone calls encouraged a level of honesty and openness in our discussions that I considered to be very useful. We did not always agree but we were able to speak freely about the challenges that we were facing and understand one another's decisions in response. I believe it is fair to say that the focus at the meetings was about getting the job done.

Governance

41. The Welsh Government seeks to be transparent about its conduct and decision-making, a commitment which continued throughout the pandemic. Key Welsh Government decisions were made within Cabinet or through Ministerial Advice. I have exhibited at **M4/VG/03 - INQ000410146** a table listing the Ministerial Advice relevant to the issue of vaccinations and therapeutics submitted to me either for a decision or to note during the relevant period, together with the decision taken.

42. Every week, on Tuesday mornings I delivered a Covid-19 update statement to the Senedd. Before doing so, I would meet with shadow health ministers to provide them with a briefing, the Chief Medical Officer and a Technical Advisory Group (TAG) co-chair usually joined me. Shadow ministers from the Welsh Conservatives and Plaid Cymru were also able to approach me individually and they did so on occasion. I wanted to ensure cross-party engagement to keep others up to date on the response to the pandemic. I considered this a courtesy, and I wanted them to understand the information that underpinned the decisions to be made.

43. As the responsible minister I gave advice to the public and to Members of the Senedd through oral or written statements when vaccines were available. Such statements were primarily led by the clinical advice that I received.

44. At paragraph 508 of my witness statement in M2B I said that we were always hopeful for a vaccine but it was such a complex process for development there was little we could do to factor in the prospect of a vaccine in the approach for non-pharmaceutical interventions. As the responsible minister I gave advice when vaccines were available and I continued

to update that advice with officials on delivery, prioritisation and efficacy. While we waited for a vaccine, I also updated on non-Covid-19 vaccinations.

45. That advice was informed by the Chief Medical Officer and the Chief Pharmaceutical Officer, together with the information that was being provided to me by the Vaccine Programme. Initially, with the candidate vaccines still some way away from being approved for use, I would provide informal updates so that other Ministers were aware of developments. Once candidate vaccines came nearer to being authorised, arrangements were put in place in respect of their purchase and as delivery plans were being developed, then I would provide updates to Cabinet.

46. From 6 April 2020 until 27 January 2022, daily ministerial calls were held on Monday to Friday by the then First Minister to discuss the most pressing issues at that time. When there were material updates relating to vaccines to be provided, I would do so in my role as Minister for Health and Social Services. The frequency of these meetings varied according to developments in the pandemic. Those updates would reflect the advice that I had been provided by my officials. Examples of meetings where vaccines were discussed can be seen exhibited at **M4/VG/04 - INQ000350196**, **M4/VG/05 - INQ000361705**, **M4/VG/06 - INQ000350277**, and **M4/VG/07- INQ000361735**. On occasion the leader of the Welsh Local Government Association was invited to attend the calls.

47. I was kept updated of details of the vaccination programme through a variety of ways such as official briefings or Ministerial Advice submissions. I also met with the then First Minister to discuss the vaccine roll out. These meetings were established in January 2021. These came in two forms, the first was a more general Covid-19 weekly update meeting and the second was a specific Covid-19 vaccination meeting. At these meetings, senior officials from the vaccination programme provided formal briefings on matters relating to the vaccination programme including the supplies and deliveries of vaccines, clinical matters including the latest information on variants, numbers of vaccines administered and matters relating to vaccine equity. These touchpoint meetings were not decision-making forums, but a mechanism for the First Minister and I to be kept updated on live issues faced by the vaccination programme. They took place weekly until 28 August 2021 and were thereafter fortnightly and would have been attended by Eluned Morgan MS when she took over the role of Minister for Health and Social Services. I exhibit an example of the type of briefing I received as **M4/VG/08 - INQ000410122.**

48. I frequently attended the Shadow Social Partnership Council, which was chaired by the First Minister, with other ministers attending where necessary. The Partnership Council was provided with the latest scientific advice and with an update from the Chief Medical Officer. I provided updates on the roll out of the vaccine and asked for support from attendees in terms of messaging and practicalities.

49. I also attended the Covid-19 Vaccination Programme Board meetings for Wales on certain occasions. I exhibit as an example, minutes of this meeting as **M4/VG/09 INQ000410067**.

Chronology

50. In this section, I set out chronologically the key events, advice and decisions relevant to the matters which are the subject of Module 4, insofar as relevant to my role and the period of my involvement. After this section, I will then address specific areas in more detail thematically. In relation to therapeutics, the relevant chronology has been set out in the corporate therapeutics statement and is not set out again here in full. I have only noted matters where particularly relevant to my involvement.

51. I chaired Cabinet on 4 March 2020. At that very early stage of the pandemic, the Chief Medical Officer's view was that it would be some time before a vaccine could be developed and there was no specific proven antiviral medication available.

52. On 22 May 2020 I received an informal briefing by e-mail from the Chief Pharmaceutical Officer in respect of remdesivir, which I exhibit as **M4/VG/10 – INQ000409973**. Earlier that week the MHRA had decided that remdesivir, an antiviral medicine, would be granted authorisation for use in the United Kingdom ahead of it receiving full market authorisation which would be provided under the Early Access to Medicines Scheme. In Wales, it was for the individual Health Boards to determine their approach to using medicines under this scheme. However, supply was limited, with the allocation to Wales meaning that only approximately nine patients per week could be treated.

53. At that time, I was informed by the Chief Pharmaceutical Officer that NHS England was developing criteria in order to limit use of remdesivir. The advice at that stage, which I accepted and exhibit as **M4/VG/11 - INQ000409974**, was that the Welsh Government should progress a common approach with the other parts of the UK to support the Early Access to Medicines Scheme where clinicians felt it appropriate in line with the common clinical criteria across the UK: that would be endorsed through an appropriate mechanism in Wales in due course, such as through approval by the Chief Medical Officer.

54. On 25 May 2020 the Chief Pharmaceutical Officer provided a further update that access to remdesivir under the Early Access to Medicines Scheme would be announced the following day. I was told that clinicians were comfortable with the proposed UK-wide criteria and that there was limited appetite to use remdesivir widely given the evidence available at that time.

55. During the summer 2020 and leading into autumn Welsh Government officials started to prepare for the possibility of a Covid-19 vaccine. Discussions between the four nations commenced on arrangements for purchase of Covid-19 vaccines and antivirals on a four nations basis. Officials also began work to ramp up the flu vaccination programme and explore options to expand this when a Covid-19 vaccine became available.

56. On 16 June 2020 I received advice from the Chief Pharmaceutical Officer that the RECOVERY trial, run by Oxford University, would announce that there had been positive results when using dexamethasone in the treatment of hospitalised Covid-19 patients requiring oxygen. The advice, which I exhibit as **M4/VG/12 – INQ000409975**, noted that a central alerting system would be issued to clinicians by the MHRA advising that they considered dexamethasone in the management of hospitalised patients with Covid-19 who required oxygen or ventilation. The Central Alerting System would be issued in Wales together with a covering letter from officials which would be signed by the Chief Medical Officer and the Chief Pharmaceutical Officer. It was noted that dexamethasone was in common use in the UK and business as usual supplies would meet the current and anticipated demands.

57. On 17 June 2020 I was asked to note that the Joint Committee on Vaccination and Immunisation (JCVI) was due to issue an interim statement regarding the planning of a national vaccination strategy. I exhibit the note as **M4/VG/13 – INQ000409976**. It was noted that there remained many unknown factors about potential vaccines and that there remained gaps in knowledge relating to Covid-19. The JVCI noted that its advice was, therefore, limited at that time. The Committee advised that priority vaccinations should be offered to:

    a. Frontline health and social care workers; and,
    b. Those at increased risk of serious disease and death from Covid-19 infection stratified according to age and risk factors. (The risk factors included those living with underlying comorbidities including chronic heart disease, chronic kidney disease, chronic pulmonary disease, malignancy, obesity and dementia).

58. It was noted that the Joint Committee on Vaccination and Immunisation would be keeping its advice under review as more information became available.

59. On 22 June 2020 I was asked by email to note that the MHRA had issued, on 26 May 2020, a positive Scientific Opinion for remdesivir, which I exhibit as **M4/VG/14 – INQ000409977**. That briefing echoed the earlier briefings in respect of remdesivir and confirmed that global demand was expected to outstrip supply. Since 1 June 2020 Wales had received a population-based share of the UK's allocation of remdesivir. It was noted that the manufacturer, Gilead, had indicated their intention to allocate stock to countries, with stock allocated on a UK wide basis. As allocation of stock was on a UK-wide basis it was desirable for there to be a joint UK approach to clinical policy for prescribing. NHS England had invited the Devolved Governments to develop an interim policy pending NICE appraisal and full market authorisation.

60. I was also informed in the email that the Remdesivir Access and Policy Group was being chaired by Professor Anthony Kessel and that medical and pharmacy colleagues form the All-Wales Therapeutics and Toxicology Centre would be participating in the UK wide policy discussion with Welsh Government officials receiving regular updates through the Chief Pharmaceutical Officer.

61. Kate Bingham, Chair of the UK Vaccine Taskforce, wrote to me and to the Chief Medical Officer on 24 June 2020 providing an update on the Vaccines Taskforce's steps in supporting large-scale vaccination trials, which I exhibit as **M4/VG/15 - INQ000409979**. She informed me of a database of individuals who were willing to be approached for the purpose of vaccine trials and that the system would be hosted on the NHS.UK site and managed by NHS Digital on behalf of the four nations. She noted that there would be work undertaken to ensure that translations were available as required.

62. She asked that we give our support to the project noting that there was a huge amount at stake in the need to attract as many vaccine studies to the UK as possible.

63. Following consideration of the contents of that letter by my officials I confirmed on 29 June 2020 that we should be a part of the UK Permission to Contact initiative, which I exhibit as **M4/VG/16 – INQ000409980**. I accepted the recommendation that my officials undertake the necessary work to ensure that delivery was in place by late August/early September and approved a response to Kate Bingham's letter. That response, a joint letter from myself

and the Chief Medical Officer, was sent on 6 July 2020, which I exhibit as **M4/VG/17 – INQ000409982**.

64. On 16 July 2020 I was provided with a further briefing (MA/VG/1938/20) ahead of the launch of the new NHS Covid-19 vaccine research registry, which I exhibit as **M4/VG/18 – INQ000409983**. Welsh Government officials had been working closely with the other Devolved Nations, the National Institute for Health Research and NHS Digital on the practical arrangements for the same. The launch, on 20 July, was to be a high-profile event with the Vaccines Taskforce focusing on how the UK was planning to accelerate the development of vaccines. That launch was expected to give rise to increased attention from the anti-vaccine community and Welsh Government officials were working with the UK Vaccine Taskforce to respond to those issues on an aligned four nations basis.

65. On 21 July 2020, officials advised me on the co-circulation of flu and Covid-19 over the winter and the options for reducing pressure of the health and social care system. The Influenza vaccination was noted as one of the most effective interventions and the advice from the Wales Immunisation Group was to increase the uptake of the flu vaccination in existing eligible groups, including health and social care staff, extending eligibility to members of shielded groups and (depending on vaccine availability) lower the eligibility age from 65 to 60 years and lower if possible, as well as expanding offers of injectables to eligible children who had refused the nasal spray. These recommendations were in line with plans being considered in the rest of the UK, apart from offering to prisoners. The additional vaccine required to offer to all prisoners was estimated to be relatively small and was considered to be beneficial to reduce transmission in these settings. I approved the recommendations and made a public announcement on the 24 July 2020, which I exhibit as **M4/VG/19 – INQ000410137**.

66. Cabinet met on 18 August 2020 where the First Minister gave an update as part of the 21-day review process. It was noted that work was continuing on developing a vaccine and one could be available sometime in the Autumn: however, supply would be limited.

67. On 18 August 2020 I also wrote to Matt Hancock MP, the then Secretary of State for Health and Social Care, regarding the UK-wide procurement of a stockpile of medicines to support the treatment of Covid-19 patients, which I exhibit as **M4/VG/20 – INQ000368300**. I agreed that the Department of Health and Social Care should include sufficient quantities of medicines to meet the requirements of NHS bodies in Wales and that the Welsh

Government would contribute its share of the costs towards the procurement and, if required, storage and distribution costs, based on the Barnett formula.

68. I noted at that time no decisions had been taken as regards authorisations or procedures for release of medicines from the stockpile. I said, my strong preference was that decisions regarding the use of stock held in Wales were made in Wales, and that should include flexibility for the stockpile to be used and replenished from the business as usual supply chain if possible. I welcomed Matt Hancock's continued engagement on the supply of medicines at that challenging time.

69. As I stated in my statement in Module 2B at paragraph 512, while a vaccine was being developed and approved, the four nations' health ministers agreed a transparent process as to how vaccine supply would be shared between UK nations and a Memorandum of Understanding was put in place with the Department of Business, Energy and Industrial Strategy (BEIS), who acted as lead purchaser for the four nations. The broad principles were agreed at Ministerial level, officials thereafter drafted the Memorandum of Understanding, and I ultimately approved the text upon specific advice.

70. The UK Government led the creation of the Vaccine Taskforce to progress the rapid development and production of a coronavirus vaccine. The Vaccine Taskforce built a portfolio that included established vaccine platforms with proven safety profiles and newer but clinically advanced platforms. The UK entered into agreements to access seven different vaccines across four different formats. Welsh Government officials worked closely with those in the UK Government to put in place arrangements for the procurement of vaccines for Wales. These arrangements were led largely via the Vaccine Taskforce and Covid-19 Vaccination Programme Board.

71. The Vaccine Taskforce pursued numerous commercial agreements in relation to vaccines that were in development. Officials were advised that the Vaccine Taskforce had been working on the basis that the Department of Business, Energy and Industrial Strategy would procure sufficient quantity of vaccine to inoculate on a UK wide basis, which was dependent on clinical advice around prioritisation for specific numbers.

72. On 21 July 2020, a meeting was held between Welsh Government officials, those from the Department of Business, Energy and Industrial Strategy and respective legal advisers, which I exhibit as **M4/VG/21 – INQ000409984**. I understand from my officials that it was agreed by the respective legal advisers that the most appropriate means of

accommodating the proposed arrangements for vaccine procurement to be led by the Department of Business, Energy and Industrial Strategy was via an agreement made under section 83 of the Government of Wales Act 2006. Section 83 enables arrangements to be made between the Welsh Ministers and any relevant authority for functions of one of them to be exercised by the other.

73. On 30 July 2020, the Department of Business, Energy and Industrial Strategy shared a draft copy of the agency agreement for the purchase of vaccines, which I exhibit as **M4/VG/22 - INQ000227246**. A further revised version was received on the 13 August 2020, which I exhibit as **M4/VG/23 - INQ000410139**.

74. Following consideration of the agreement by Welsh Government officials and legal advisers, advice was submitted on 20 August 2020, in MA-P-VG-2623-20, which I exhibit as **M4/VG/24 – INQ000116615**. On 20 August 2020, I agreed to recommendations set out in the advice to enter into the Agency Agreement with the Department of Business, Energy and Industrial Strategy, which I exhibit as **M4/VG/25 - INQ000368323**. The purpose of the Agency Agreement was to allow the department to enter into the commercial agreements necessary to secure UK access to the most promising vaccines and to do so at pace.

75. On 2 September 2020 I approved a Military Assistance to the Civil Authorities request. I exhibit the email as **M4/VG/26 - INQ000409994** and the request as **M4/VG/27 – INQ000409995**. The request related to two military medical planners to support the vaccination programme in circumstances where the Health Boards lacked the logistical planning knowledge.

76. On 9 September 2020 the Chief Medical Officer provided me with a briefing in respect of vaccine planning, which I exhibit as **M4/VG/28 - INQ000409998**. It noted at that stage there were 165 candidate vaccines worldwide with the Oxford/AstraZeneca being the furthest forward in development. It confirmed that the Department of Business, Energy and Industrial Strategy had announced the advanced purchase of six different vaccine technologies bringing the total number of doses to around 350 million. Planning in Wales assumed a vaccine delivery date of 19 October 2020 in the best-case scenario.

77. The Chief Medical Officer's briefing noted the challenges that lay ahead for vaccine delivery and that key milestones for the coming weeks would include the consultation on amendments to the Human Medicines Regulations 2012 to allow expansion of the vaccination workforce; a Memorandum of Understanding or Service Level Agreement to

be agreed with Public Health England on vaccine deployment; the Joint Committee on Vaccination and Immunisation's advice on further stratification of priority groups and further steps regarding vaccine delivery. It was confirmed that regular updates would be provided to me following each Programme Board.

78. On 25 September 2020 the Joint Committee on Vaccination and Immunisation published an update to its advice to facilitate planning for the deployment of any safe and effective vaccine(s) as soon as they are authorised for use in the UK. The advice is exhibited as **M4/VG/29 - INQ000354445[1].** The Committee strongly agreed that a simple age-based approach would result in faster delivery and better uptake in those at highest risk. A provisional ranking of prioritisation was:

    (a) Older adults' resident in a care home and care home workers;

    (b) All those 80 years of age and over, and health and social care workers;

    (c) All those 70 years of age and over;

    (d) All those 65 years of age and over;

    (e) High risk adults under 65 years of age;

    (f) Moderate risk adults under 65 years of age

    (g) All those 60 years of age and over;

    (h) All those 55 years of age and over;

    (i) All those 50 years of age and over;

    (j) The rest of the population.

79. On 15 October 2020 I was asked to note the UK Government's response to its consultation on the proposed amendments to the Human Medicine Regulations 2012 to enable specific provisions necessary for the rollout of the Covid-19 vaccine. This Ministerial Advice is exhibited as **M4/VG/30 - INQ000235845.**

80. The statutory instrument which made amendments to the Human Medicine Regulations 2012 was laid on 16 October 2020. I noted those changes to the Human Medicines Regulations 2012 on 22 October 2020 when officials provided me with an update by email,

[1] This exhibit has been provided by another material provider to the UK Covid-19 Inquiry and is a duplicate of a document held by the Welsh Government and disclosed to the UK Public Inquiry.

which I exhibit as **M4/VG/31 - INQ000410000.** It was noted that the amendments to the regulations would allow any person appropriately trained and assessed as competent to administer a vaccine; in Wales that would be governed by a national protocol. All vaccinations would be overseen by a qualified clinician and the decision to administer would be made by a suitably qualified clinician. Ensuring that there were sufficient individuals available to administer vaccines was key to ensuring the success of the vaccine delivery programme.

81. On 19 October 2020, I agreed to secure the services of a Senior Pharmacist to provide professional pharmacy logistics and expertise in good distribution practice, exhibited as **M4/VG/32 - INQ000409999** and the advice as **M4/VG/33 - INQ000136822**. This was in recognition that some of the vaccine candidates were likely to have complex distribution requirements and the need for a specialist lead on logistics and distribution for the vaccines. The role would also support other vaccination projects like the influenza vaccinations.

82. Welsh Government officials continued to work closely with UK Government officials and on the 4 November 2020, I was asked to agree to a draft protocol for vaccine allocation and delivery arrangements. The advice noted that the intention was for the Department for Business, Energy and Industrial Strategy to procure vaccine supply to be split, once a population share for Crown Dependencies and Overseas Territories had been allocated, in accordance with a Barnett formula calculation, with Wales receiving 4.78% of the vaccines. I also noted the "Agreed principles for Covid-19 vaccine deployment across the UK" which set out the broad issues agreed between the four nations. I wished to discuss the protocol at the four nations meeting to be held the following day, where these matters were to be agreed on a four nations basis. I exhibit the Ministerial Advice as **M4/VG/34 - INQ000235849**.

83. The exception was the Pfizer vaccine, where we had to accommodate the cold storage requirements for the vaccine. On the 27 November 2020 revised arrangements were recommended in MA/VG/3993/20, which I exhibit as **M4/VG/35 - INQ000361642** and which I approved on 30 November 2020. I was content with the contents of that Memorandum of Understanding save for certain provisions which required eight weeks' notice for delivery sites, and four weeks' notice for quantities. In my response to the Ministerial Advice, I noted that such notice periods would be impossible to achieve given the pace of the operation. My response is exhibited as **M4/VG/36 - INQ000410021**. Arrangements were subsequently put in place with the Department for Business, Energy

and Industrial Strategy in respect of the Pfizer vaccine. This agreement is exhibited as **M4/VG/37 - INQ000337321**.

84. There was a follow up on 7 December to the provisions which I had queried, as above, and it was noted the Welsh Government was in a position to provide the location of the delivery sites to the Department for Business, Energy and Industrial Strategy within those time frames, which I exhibit as **M4/VG/38 - INQ000410038**. Further, it was confirmed that assurances had been provided that the first weeks of deployment would be subject to special arrangements and that in fact delivery schedules were in place prior to drafting the Memorandum of Understanding. The Memorandum of Understanding between the Welsh Government and the Department for Business, Energy and Industrial Strategy in respect of the Pfizer vaccine was accordingly agreed.

85. Under the terms of that agreement, the Department for Business, Energy and Industrial Strategy negotiated and entered into the contracts with the manufacturers and suppliers of the Covid-19 vaccinations. Neither the Welsh Ministers nor the Welsh Government were a party to those contracts and as such we were not privy to the detail. These contracts were considered to be commercially sensitive, and I am unable to comment on the detail of the arrangements. Neither I nor my officials had sight of the contracts save for redacted versions of the Pfizer contract being provided to the Welsh Government's legal advisers to provide assurance that no duties, rights or liabilities were attached to the Welsh Ministers under the terms agreed by the Department for Business, Energy and Industrial Strategy. The arrangements for delivery of the other vaccines to Public Health England for storage were subsequently formalised in an amended Service Level Agreement agreed by my successor, Eluned Morgan MS on the 21 December 2021 as recommended by officials in MA/EM/3525/21, which I exhibit as **M4/VG/39 - INQ000176871**.

86. In respect of all vaccines procured by the Department for Business, Energy and Industrial Strategy's strategy, the decisions on their deployment in Wales were taken by the Welsh Government.

87. At the four nations health minister meeting on 5 November 2020, it was agreed that the key messages around Covid-19 vaccination should be common and consistent across the four nations. I exhibit minutes of the meeting as **M4/VG/40 - INQ000410012**. Following that agreement, I understand Welsh Government officials confirmed that a weekly four nations communications team call would be set up to facilitate regular sharing of information and to ensure that key messaging was consistent. It was also agreed that there

would be reciprocal sharing of insight between Public Health England and Public Health Wales. In these minutes, I am recorded as saying that I "was happy about Wales's involvement in the programme board and the way that was working but was concerned that Wales was no longer part of the task force". I was not the author of those minutes, but I believe they may have been referring to the Vaccine Task Force programme board which sat below the Vaccine Task Force. The Vaccine Task Force was established by BEIS. The Welsh Government did not sit on this taskforce. A Vaccine Task Force programme board was established under the Vaccine Task Force, again with no Welsh Government representative. I made a representation for greater involvement of Wales in the Vaccine Task Force, specifically the programme board, but this did not happen. It had been agreed that a specific Devolved Administrations Vaccine Task Force group was to be established to cover all aspects of the Vaccine Task Force work programmes except deployment, as this was covered by the UK Covid Vaccine Deployment Programme Board and other forums. As far as I am aware the Devolved Administrations group did not proceed and, in any event, this was not considered a substitute for the need to have a seat at the table on the Vaccine Task Force Programme Board. I received a briefing in advance of this meeting which is attached as **M4/VG/41 – INQ000492885.**

88. Around that time, I was also provided with information from the Technical Advisory Cell relating to the potential for dexamethasone to avoid deaths, which I exhibit as **M4/VG/42 - INQ000410003**. I was provided with a Technical Advisory Cell update on 4 November 2020 and the following day asked for more information on the position and use of dexamethasone in line with guidance in Wales. It was confirmed that dexamethasone was being used in Wales as part of the treatment pathway. It was also noted that because dexamethasone was kept on wards as a stock item, and was accordingly not prescribed to individual patients, there was no routine data available to determine the proportion of patients with Covid-19 who had been administered dexamethasone. I exhibit the note as **M4/VG/43 - INQ000410013**.

89. During the Ministerial Call on 10 November 2020, which I exhibit the note as **M4/VG/44 - INQ000361636** I provided an update on vaccines and noted the storage challenge presented by the Pfizer vaccine. I confirmed that Wales would get a share based on population from the UK Government and that work was ongoing with the Chief Medical Officer on prioritisation and distribution.

90. On 11 November 2020, the Chief Medical Officer confirmed the news that a Covid-19 vaccine could be ready that year. This was a huge relief and enabled active planning on

deployment to begin. On 17 November 2020, I made a Written Statement which provided a general update on vaccine deployment in Wales, as exhibited in **M4/VG/45 - INQ000320999.**

91. The Director General Health and Social Services Group/Chief Executive of the NHS, Andrew Goodall, provided me with an update, following a briefing that he attended on 12 November 2020. I was told that there were at least two vaccine options being expedited. I met with Andrew Goodall, Gill Richardson and military colleagues to discuss the vaccine programme on 16 November 2020.

92. I attended a four nations health ministers meeting on 19 November 2020, which I exhibit a note of the meeting as **M4/VG/46 - INQ000410015**. Matt Hancock MP provided an update in respect of the vaccine and noted that subject to the licence application being approved the vaccine would be released from the manufacturing plant and be distributed to the NHS in the four nations from a distribution centre. I noted during that call that all four nations needed to prioritise in the same way and to communicate simultaneously.

93. On 24 November 2020 I was provided with a proposal on the Pfizer Vaccine deployment in Wales by MA/VG/4049/20 which I exhibit as **M4/VG/47 - INQ000361639**. It had become apparent that as the vaccine required ultra-low temperature storage, at below minus 70 Celsius, there were concerns relating to the stability of the vaccine if thawing commenced during its transportation.

94. In light of those difficulties with transportation the recommendation, which I agreed with, was not to transport nor use the Pfizer vaccine in care homes for the first four weeks of delivery. That would enable officials and healthcare workers to learn more about the characteristics of the vaccine and provide an opportunity to train the workforce. There would be an opportunity to learn about practical handling of the vaccine in the field at static locations which would minimise harm to staff and vaccine wastage.

95. I approved Ministerial Advice on 25 November, which I exhibit as **M4/VG/48 - INQ000410016** and noted that I would welcome a note and discussion later in the week setting out the practicalities for the deployment, training and impact upon the workforce; and that thereafter I would like to share that note with Cabinet and provide a Written Statement to the Senedd the following week.

96. That note was provided to me on 28 November 2020, which I exhibit as **M4/VG/49 - INQ000410017**. Thereafter, I shared an update on readiness for deployment with my Cabinet colleagues, which I exhibit as **M4/VG/50 - INQ000410020**.

97. On 1 December 2020 I was asked, with the Minister for Finance, to approve funding for the Covid-19 Vaccine Programme. I did so on the same day, which I exhibit as **M4/VG/51 - INQ000410022** and exhibit the advice as **M4/VG/52 - INQ000136856**. However, when approving that funding from the Welsh Government's Covid-19 funding reserve I noted that it was not "really satisfactory not to have clarity from UKG on the consequential and how they have been worked out." That reflected ongoing uncertainty about whether, and if so the level, of Barnett consequential funding that the Welsh Government would receive in respect of Covid-19 vaccination. At that time the UK Government had only committed to funding the vaccination programme, in England, until the end of the year. As such there was no consequential funding for Wales in respect of the Vaccine Programme. As I noted in my response, however, "there was only one right answer to the MA: and that was to continue funding the vaccine programme". The term "MA" refers to a Ministerial Advice. A Ministerial Advice is a document submitted to a Minister for the purpose of providing them with information, advice and options, to enable them to make a Ministerial decision.

98. On 2 December 2020, the UK became the first country to give approval for use of the Pfizer–BioNTech vaccine, later branded as Comirnaty. This was in the form of a temporary authorisation given by the MHRA under regulation 174 of the Human Medicines Regulations 2012. The first batch arrived in the UK the next day and was initially stored at an undisclosed central hub before being distributed to hospital vaccination centres across the country.

99. I issued a Written Statement confirming that Wales would now begin to receive its share of the vaccine and we would start deployment. It was noted that the UK Government had submitted its Phase III data for the Oxford/AstraZeneca vaccine, and a decision from the MHRA was awaited. If approved as safe and effective for use, we were told to prepare for readiness for delivery later in December 2020.

100. Cabinet met later that afternoon and noted the contents of the Written Statement: it was hoped that deployment of the vaccine could begin the following week.

101. The Covid-19 Vaccination Programme Board met on 3 December 2020. I attended and provided some reflections on the programme to date. An update was provided by way of slides. I exhibit minutes of the meeting as **M4/VG/53 - INQ000410024**.

102. The vaccine roll-out started on 8 December 2020, and I issued a joint statement to the press with the First Minister setting out that we would be working hard to deliver the vaccine in Wales. I also made a Written Statement to the Senedd as exhibited in **M4/VG/54 - INQ000321010**.

103. On 9 December 2020 officials forwarded me an update provided to clinical and Health Board staff by Public Health Wales, which I exhibit as **M4/VG/55 - INQ000410039**. It noted that there had been two anaphylactic reactions to the Pfizer vaccine, out of 5,000 vaccines administered, in England, and that was a higher rate than for the other vaccines in common use. It was noted that officials were not aware of any such reactions in Wales where the previous day when an estimated 1,500 Pfizer vaccines had been administered. I was told that MHRA had been informed and was content that the vaccination programme proceeded with two conditions namely that those with a significant history of previous allergies should now be excluded and that resuscitation facilities should be available. It was noted correspondence from the Chief Medical Officer would follow a formal MHRA statement. Officials confirmed that anaphylaxis training and kits were standard for immunisation teams but as a precaution there should be enhanced provision made for anaphylaxis management at locations outside of hospital sites.

104. I met with Nadhim Zahawi MP, the Minister for Vaccine Programme on 16 December 2020. At that meeting I noted that vaccine deployment across all UK nations had worked well and was a positive example of collaborative working. As the four nations moved to publish more data on vaccine roll out, I suggested that officials work together to co-ordinate the type and timing of data which was released. It was inevitable that there would be comparisons, but I felt it important that the different models in each country should be explained when data was released. I exhibit a note of the meeting as **M4/VG/56 - INQ000410040**.

105. A four nations Health Ministers meeting was then held on 17 December 2020. The agenda included discussion around the progress of the vaccine rollout. I explained that the situation in Wales in terms of positive cases was extremely serious and that was why a change was made to the number of households meeting at Christmas. On data publication, Matt Hancock called for all four nations to agree via officials the consistency of high-quality data to be published. Briefings that I received in readiness for this meeting are exhibited as **M4/VG/57 – INQ000485989, M4/VG/58 - INQ000485991** and a note of what was discussed is exhibited as **M4/VG/59 - INQ000485992**.

106. Following amendments to the Human Medicines Regulations, on 18 December 2020 I agreed to issue a national protocol allowing registered health care professionals and certain people who were not registered health care professionals, to administer the Covid-19 vaccine, subject to appropriate training and clinical supervision, which I exhibit as **M4/VG/60 - INQ000410045.** This was the first of a number of similar protocols. Without the flexibility this gave to provide additional workforce it would not have been possible to vaccinate at the pace and to the scale that we did. I exhibit the Ministerial Advice as **M4/VG/61 - INQ000136833.**

107. I asked officials to provide me with updated information across all Health Boards as they trained and deployed people to deliver vaccines pursuant to the protocol.

108. Cabinet met on 19 December 2020 where the then First Minister provided an update on the new strain identified in South-East England following his meeting earlier that day with Michael Gove MP. This was the so-called Kent variant now identified as Alpha. It was noted that the disease pathways and outcomes of the new variation were understood to be in line with existing strains and that there was no evidence to suggest that the mutation would respond differently to vaccines. It was however more transmissible and more likely to cause harm.

109. There was a further four nations health minister meeting on 24 December 2020 where updates on the vaccine programme were provided. I exhibit the agenda and summary briefing of the meeting as **M4/VG/62 - INQ000410048**. Ahead of the meeting my officials and I had discussed the important issues that were likely to be raised in respect of Phase 2 of the programme and noted the importance of future Joint Committee on Vaccination and Immunisation recommendations as to prioritisation. Matt Hancock MP noted that the MHRA and Joint Committee on Vaccinations and Immunisations were assessing the possibility of declaring that a single dose provided protection with a second dose to follow some 12 weeks thereafter. It is my recollection that I had already had a similar conversation on dosage intervals and the health benefit of wider population coverage with the Chief Medical Officer and Chief Pharmaceutical Officer.

110. Welsh Government officials provided me with an update on 24 December 2020, which I exhibit as **M4/VG/63 - INQ000410049**. The update identified the emerging issues which included ensuring that the vaccine reached the over-80s; variation across Health Boards and looking at prioritising specific sectors within phase 2. I asked if, at the next update the following week, I could have further information on the pace of delivery, comparisons with

the other UK nations and whether we had anything to learn or adapt ahead of a possible authorisation of the Oxford AstraZeneca vaccine.

111. On 29 December 2020 Cabinet met and, during a discussion around the impact of Brexit, it was noted that there was good news as regards continuity of vaccine supply albeit that there could be some delays at ports. In particular, it was noted that there were plans to transport the Covid-19 vaccine by air.

112. I provided a further update on the Covid-19 pandemic generally. I noted that the Oxford AstraZeneca vaccine was expected to be approved by the MHRA later that week with roll-out across Wales expected the following week.

113. Also, on 29 December I was provided with an update from the Chief Medical Officer following the four nations Chief Medical Officer discussion and agreement which had been reached, which I exhibit as **M4/VG/64 - INQ000410050**. The joint position adopted by the four nations Chief Medical Officers was that they would support a 4-12 week interval between vaccination doses, as indicated by the Joint Committee on Vaccinations and Immunisation's guidance, for the AstraZeneca vaccine. In order to maximise the number of protected people priority would be given to first doses and so the interval would be towards the 12 weeks, rather than the 4. In respect of the Pfizer vaccine, it was agreed that the schedule could be extended as per the Joint Committee on Vaccination and Immunisation's guidance. The Chief Medical Officer told me he had raised concerns around the pipeline for the second dose but that he was given assurances of deliveries through to April. The advice I was given was to approve that approach but to seek my own assurances about supply. There was also agreement that there would be a ministerial call the following morning, at 06:30am, before AstraZeneca themselves would announce that their vaccine had been authorised. It would likely be followed by an announcement on dosage schedules at 07:30 am.

114. On 30 December I instructed my officials to make sure that Health Boards briefed their local authority leaders and Members of the Senedd in respect of the vaccine rollouts.

115. On 30 December 2020 the Joint Committee on Vaccination and Immunisation withdrew their interim advice of 25 September 2020 and replaced it with updated advice to facilitate the development of policy on Covid-19 vaccination in the UK, which I exhibit

as **M4/VG/65 - INQ000408135**[2]**.** The Committee advised that the first priority should be preventing mortality and protecting health and social care staff and systems. On this basis and, under phase 1, the slightly revised vaccine priority groups were:

a. Residents in care homes for older adults and their carers;
b. All those 80 years of age and over, and frontline health and social care workers;
c. All those 75 years of age and over;
d. All those 70 years of age and over and clinically extremely vulnerable individuals;
e. All those 65 years of age and over;
f. All individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease mortality;
g. All those 60 years of age and over;
h. All those 55 years of age and over;
i. All those 50 years of age and over;

116. On 30 December 2020 the Joint Committee on Vaccination and Immunisation provided further advice regarding the dosage intervals of the second dose. It advised that the second dose of each vaccine may be given up to 12 weeks following the first dose.

117. The Committee's advice about the dosage intervals of the two approved vaccines (the Pfizer BioNTech and AstraZeneca vaccines) was endorsed by all four UK Chief Medical Officers. They regarded the Committee's statement that 'delivery of the first dose to as many people as possible should be initially prioritised over delivery of a second dose of the vaccine' to declare that in order to protect the greatest number of people in the shortest time possible, thus reducing mortality and severe disease, meant that the second doses of both vaccines would be administered towards the end of the recommended dosing schedule of 12 weeks. The NHS in Wales was instructed to implement an approach of an 'up to' 12-week interval between first and second doses of both available vaccines with immediate effect, in particular to enable Health Boards to manage their postponement of second dose appointments, and to manage public messaging on this change. The Ministerial Advice including my response is exhibited as **M4/VG/66 INQ000386173**, I also noted in my response that I had discussed the advice with a range of officials that afternoon: I took the view that there were advantages and disadvantages but, on balance,

[2] This exhibit has been provided by another material provider to the UK Covid-19 Inquiry and is a duplicate of a document held by the Welsh Government and disclosed to the UK Public Inquiry.

that the need to re-arrange appointments over the coming week was outweighed by the benefits of providing initial protection to more people more quickly. I also accepted the recommendation that the NHS in Wales be advised of the same with immediate effect to enable operational action to take place that day.

118. That evening, the Chief Operating Officer of NHS Wales Delivery Unit confirmed that approach by e-mail to the Health Boards, which I exhibit as **M4/VG/67 - INQ000386179.**

119. I made an Oral Statement to the Senedd on 30 December 2020 and issued a Written Statement on 31 December 2020 providing an update on the latest Covid-19 position in Wales, the vaccine and the pressures in the health and care system. Copies of these are exhibited in **M4/VG/68 - INQ000321249** and **M4/VG/69 - INQ000321038.**

120. Also, on 31 December 2020 I approved a national protocol to allow registered health care providers who did not normally vaccinate to safely administer the Oxford AstraZeneca Covid-19 vaccine, which I exhibit as **M4/VG/70 - INQ000368675**.

121. On 3 January 2021 I was informed of concerns raised by NHS Blood and Transplant with the MHRA, which I exhibit as **M4/VG/71 - INQ000410051**. The concerns were in relation to the Oxford Astra Zeneca vaccine possibly causing certain antibodies (Human Leukocyte Antigen) to be generated that could be damaging to people who had had or who were awaiting a transplant. I was informed that urgent work had been carried out overnight by Histocompatibility and Immunogenetics laboratories in Cardiff and Birmingham and that those trials concluded that the vaccine did not cause sensitivity to the Human Leukocyte Antigen protein, which gave rise to the original concern. I was told that the MHRA had referred the matter of its expert panel to assess the position, and that any changes required at an operational level would be advised on by the MHRA in due course.

122. Later that evening I was provided with an update that NHS Blood and Transplant had endorsed the findings of the MHRA expert panel that there was no evidence of risk. Accordingly, there was no barrier to transplant candidates and organ recipients receiving the Covid-19 Astra Zeneca vaccine. I was also told that the experts were very clear that no proactive communications should be published on the matter. I exhibit the update as **M4/VG/72 - INQ000410054**.

123. On 4 January 2021 I issued a statement to update the Senedd on the vaccine deployment in Wales, which I exhibit as **M4/VG/73 - INQ000388300**. I confirmed that more than 35,000 people had received their first dose of the Pfizer BioNTech vaccine.

124. The statement explained that because the Astra-Zeneca vaccine did not have the storage issues associated with the Pfizer BioNTech vaccine it would allow more flexibility and mobile deployment models which meant every care home within Wales was now within reach and that this priority group, together with those of the age of 80, would be targeted by the NHS over the coming weeks.

125. When I cleared that statement, I noted that vaccine delivery could not be left to the Health Boards to determine the pace and suggested that greater detail on making greater use of primary care be included in the vaccine deployment plan. I said this was because this was not a normal vaccination delivery, it was at an unprecedented pace and scale. Primary care providers had the infrastructure and expertise to run large scale vaccination programmes and their offer to help was clear and they wanted to add to the process. I needed the Health Board and primary care providers to work together so that I could be satisfied that the vaccine delivery was achievable. I exhibit my note as **M4/VG/74 - INQ000410052**.

126. On 6 January 2021, all four nations agreed to commit to the Joint Committee on Vaccination and Immunisation's priority list, which I exhibit as **M4/VG/75 - INQ000256889**.

127. Cabinet met on 6 and 7 of January 2021 at which, amongst other matters, there was a discussion of the alignment of the Regulations then in force and school closures. As part of that discussion, it was noted that there would need to be further discussions between the Welsh Government and the relevant Trades Unions on the proposals generally, and the roll-out of vaccines in particular. It was noted that at a recent Chancellor of the Duchy of Lancaster meeting the Deputy Chief Medical Officer for England had robustly defended the vaccination programme and the priority groups identified by the Joint Committee on Vaccination and Immunisation. He had highlighted that the vaccination of 43 people in care homes would save one life; whereas there would be a need to immunise 62,000 teachers under the age of 30 to achieve the same results.

128. I was provided with a weekly vaccine update on 6 January 2021, which I exhibit as **M4/VG/76 - INQ000410055**, ahead of attending the Vaccine Programme Board meeting the following day. On 7 January 2021 I attended the Vaccine Programme Board's meeting.

129. Following that meeting I sent a letter to the Chairs of each of the Health Boards which I exhibit as **M4/VG/77 - INQ000410059**.

130. Following a draft UK Vaccine Delivery Plan having been shared by the Office of the Secretary of State for Health and Social Care on 8 January 2021, exhibited as **M4/VG/78 – INQ000386251**, concerns were raised about that draft by my officials. I recall a meeting at which it was decided that Dr Gill Richardson would respond to the Department for Health and Social Care the following day, together with my officials drafting a Welsh Vaccine Strategy for publication on 11 January 2021. Dr Gill Richardson responded to the Department of Health and Social Care the following day, which I exhibit **as M4/VG/79 - INQ000410062** stating that the Welsh Government would consider participating in a UK-wide strategy but that as a first step the UK Government ought to set out its approach to those matters that it was responsible for, importantly supply. Her response also noted that there were key areas in the UK-wide draft that did not represent the position in Wales and there were concerns that that would cause confusion with national stakeholders. At that time, therefore, the Welsh Government was unable to sign up to the UK-wide strategy but would welcome engagement in respect of developing the same. The Welsh Government's commitment to working together and to maintaining alignment was also noted.

131. The draft strategy and advice from my officials were provided to me on 10 January 2021. I approved the strategy for publication, which I exhibit as **M4/VG/80 - INQ000410079.** The National Vaccination Strategy was published on 11 January 2021 and reflected months of detailed delivery planning and set out the national strategy and priorities for the coming months. The strategy set out three key milestones:

- By mid-February all care home residents and staff, frontline health and social care staff, everyone over 70 and everyone who was clinically extremely vulnerable would have been offered vaccination.
- By the spring, vaccinations would have been offered to all the other phase one priority groups. This was everyone over 50 and everyone who was at-risk because they had an underlying health condition.
- By the autumn, vaccination would have been offered to all other eligible adults in Wales, in line with any guidance issued by the Joint Committee for Vaccination and Immunisation.

132. These milestones were predicated on sufficient supplies of vaccines being available. However, I made it clear that although assurances had been provided by the UK Government that supplies would be available, the availability of vaccines was a matter outside the Welsh Government's control. The three key milestones were achieved. On 12 February 2021 the then First Minister and I announced that the first milestone had been met, exhibit **M4/VG/81 - INQ000492062** refers. The second milestone was achieved on 4 April 2021, exhibit **M4/VG/82 - INQ000492870** refers and by 6 July 2021 the third milestone had been met, exhibit **M4/VG/83 - INQ000492867** refers.

133. Soon after publication of the first National Vaccination Strategy, the Welsh Government began publishing weekly updates on the programme, which I exhibit as **M4/VG/84 - INQ000388294**. These updates were intended to provide a regular flow of information on the Vaccination Programme, updating stakeholders and the public on progress and describing the anticipated next steps with the programme.

134. On 11 January 2021 Cabinet met to discuss the options available to it regarding the amendment of the restrictions then in place. Cabinet agreed that it was important to emphasise the need to remain at home whilst ensuring that guidance about the vaccine was made available. The main challenges were to get people vaccinated as quickly as possible and to ensure they understood the continued risk of transmitting the virus. It was suggested that those administering the vaccine should provide guidance notes highlighting the need for all people to adhere to restrictions at all times.

135. After receiving a clearer picture of vaccine delivery schedules, it was noted that additional operational capacity was required to ensure that the Pfizer BioNTech vaccine could be delivered. Accordingly, I supported the expansion of the existing delivery model to include the option for Health Boards to establish Community Vaccination Centres. I exhibit the Ministerial Advice as **M4/VG/85 - INQ000116617**.

136. On 15 January 2021 my officials provided me with an update following reports in the news about delays to deliveries of the Pfizer vaccines, which I exhibit as **M4/VG/86 - INQ000410080**. That advice noted that though Pfizer had informed the EU Commission that it would not be able to fulfil the promised delivery volume over the next three to four weeks it was not yet clear what the impact would be upon UK supplies. It was also noted that officials from the Department for Business, Energy and Industrial Strategy were due to meet with representatives from Pfizer to discuss the situation.

137. On 18 January 2021 I agreed to publish data in respect of the Vaccination Programme. In response to the overwhelming interest in the National Vaccination Strategy from the public and the media it was determined that further information should be made available on a weekly basis. It was agreed that a weekly summary report would be published in addition to the Knowledge and Analytical Services and Public Health Wales information that was already being published. On 25 January 2021 I agreed to publish the first of these weekly updates, which I exhibit as **M4/VG/87 - INQ000388303**.

138. I was aware at the time that there was criticism in the press that Wales was behind the other nations of the UK in delivering the first dose of the vaccine. The roll out in Wales was only marginally different to the other nations and was dictated by the volume of supply, along with challenges around the ultra-low storage temperature of the Pfizer vaccine. I engaged in correspondence with Dr David Bailey, chair of the British Medical Association Wales on the deployment of Pfizer. In my letter to him of 15 February 2021 I highlighted that we were following the latest scientific advice which included the advice of all four nations Chief Medical Officers who had agreed with the Joint Committee on Vaccination and Immunisation's advice that we should prioritise giving as many people in at-risk groups their first dose, rather than providing two doses in as short a time as possible. I attach Dr Bailey's letter of 8 January 2021 as exhibit **M4/VG/88 - INQ000118674** and my response dated 15 February 2021 as exhibit **M4/VG/ 89 - INQ000492064**. As noted above, the first milestone in our strategy was achieved by 12 February 2021.

139. The first publication of supply, stock and wastage data for Wales was due to be published at 9.30 am on 26 January 2021. Late on 25 January 2021 officials from the Department of Business, Energy and Industrial Strategy contacted Welsh Government officials to raise concerns around commercial sensitivity and security issues arising from certain information that was to be published. Internal advice provided to me suggested that all information could be published as it related to historical stock data and accordingly could not properly be said to be commercially sensitive. It was also noted that it was very likely that the Welsh Government would be criticised for failing to be transparent if we were not to publish materially relevant information. I exhibit the email chain as **M4/VG/90 - INQ000410083**.

140. In light of the concerns raised I messaged Matt Hancock MP directly as I did not have a direct contact number for Nadhim Zahawi MP. The response was that it was imperative the stocks delivered figures were not published given its sensitivity and the current tension with the EU on the issue of supply. I decided that we should publish the information on

wastage and should also issue a statement stating that the Welsh Government had been asked by the UK Government not to publish stock holding information due to commercial sensitivities.

141. On 26 January 2021, I made an Oral Statement, a copy of which is attached as **M4/VG/91 – INQ000492886** in which I confirmed that we had not reached the target that had been set to vaccinate 70% of people over 80 and in care homes by the preceding weekend. I explained that a key factor in this was centre closures and re-scheduling of appointments due to adverse weather. Centres were closed for safety reasons and vaccine appointments re-scheduled. Some GP practices also postponed weekend appointments to early the following week. I highlighted that whilst the NHS did everything it could to make sure the vaccination infrastructure was resilient, these issues served as a useful reminder that there were events outside of our control that impacted on delivery of our aims. The pace of the vaccination programme continued to increase, and strong progress was made; the effectiveness of the Welsh infrastructure and growth was clear to see going forward.

142. On 27 January 2021 I agreed to define, for the purpose of vaccination prioritisation, the meaning of "frontline social care workers". Frontline social care workers fell within cohort 2 of the Joint Committee on Vaccination and Immunisation's advice on prioritising categories and though there was guidance available in order to enact that advice, further clarification was required. I exhibit this advice **as M4/VG/92 - INQ000145056**. A commitment had already been made to include within cohort 2 all education staff who provided intimate personal care for children and young people with complex needs. It was further agreed that foster carers would be similarly categorised as frontline workers on the same basis with those caring for children and young persons with complex medical needs being prioritised within cohort 2; and others being placed alongside unpaid carers within cohort 6. I also decided that Care Inspectorate Wales inspectors and Cafcass social workers should not be included within the definition of frontline care workers and therefore not prioritised under cohort 2. Our definition of frontline worker was consistent with the UKHSA Green Book.

143. I also gave evidence to the Senedd's Health, Social Care and Sport Committee on 27 January 2021, together with Julie Morgan MS, the Deputy Minister for Health and Social Care and Dr Andrew Goodall. I discussed vaccination figures and the potential approach of how carers would be added to the vaccination priority group list.

144. Following the representation made from BEIS, to which I refer at paragraph 139 above, at the four nations Health Ministers meeting on 28 January 2021, I agreed not to comment on stock levels but emphasised the need to have a narrative to explain why we could not comment on these matters. There was agreement to try to come up with a suitable script across the four nations. Tess Walton representing BEIS advised that it was a matter of commercial confidentiality. I was eager to publish current vaccine levels for transparency. A note of the meeting is attached as exhibit **M4/VG/93 - INQ000492779.**

145. I was provided with advice on 29 January 2021 on ensuring that the NHS maximised its appointment potential. As the vaccine delivery programme moved through cohorts 1 to 4 the potential impact of individuals failing to attend for their appointment was greater. Accordingly, I accepted the recommendation which I exhibit as **M4/VG/94 - INQ000386348**, that the NHS could begin making appointments for the next cohort once 50% of the previous cohort had been vaccinated (what was referred to as the "50% gateway"). In practice, therefore, once 50% of cohorts 1 to 4 were vaccinated then the next cohort could be invited to receive their vaccine; and once 50% of that next cohort had been vaccinated then invitations for vaccinations could be sent to the next, and so on. That was not an uptake aspiration but rather a practical solution to potential operational challenges. I also agreed that first doses should continue to be the priority with second doses to be considered where there was no alternative to prevent vaccine waste. I did so on the basis that I did not want a pause in the vaccine process and delivery activity and that the NHS would continue to pursue people in priority cohorts. There also needed to be clear internal and external messaging on what was being done. That decision did not interfere nor depart from the Joint Committee on Vaccination and Immunisation's guidance on priority cohorts at all but did utilise the operational flexibility to ensure that there was as high a percentage of appointments being taken up as possible in order to reduce wastage.

146. During Cabinet's meeting on 1 February 2021 the First Minister provided an update on vaccine supplies. He had met Michael Gove and the First Ministers of Scotland and Northern Ireland on Saturday to discuss the supply of vaccines to the EU. It was noted that the Devolved Nations were, under the terms of an embargo, not to discuss the amount of vaccine being sent to the EU: however, UK Government Ministers had appeared to be disclosing that information freely.

147. The First Minister informed Cabinet that he would be writing to the Secretary of State for Wales requesting that the restrictions placed upon Devolved Governments were observed by his office.

148. I was provided with advice on the medium-term supply forecast for the Covid-19 vaccine together with the implications of this on 1 February 2021, which I exhibit as **M4/VG/95 - INQ000231293**. That Ministerial Advice noted that there was to be a planned fall in the number of doses of vaccine supplied between 15 February and the end of April because of the closure of Pfizer's Belgian manufacturing plant for renovations and, as such, a decision was required as to the approach to be taken to vaccine deployment. The advice provided to me, which I agreed and exhibit as **M4/VG/96 - INQ000410084**, was to scale back the administration of first doses of Pfizer BioNTech vaccine after 14 February and to start second doses a week earlier than had been previously planned, that is on 1 February. That approach reduced the risk of individuals vaccinated with a first dose waiting more than 12 weeks, mitigated against a hiatus in Pfizer BioNTech vaccinations and minimised the need to keep a reserve of doses, in June 2021 this was referred to by the First Minister as the strategy of "storing it [the vaccine] in people's arms, rather than in fridges". That did mean that the interval between first and second doses was reduced for some individuals to an interval of between seven and ten weeks but contributed to the longer-term success of the Programme. That recommendation was adopted and implemented; it was thereafter communicated to the Health Boards. The Joint Committee on Vaccination and Immunisation later recommended an interval of 8 weeks as providing a better immune response.

149. Following the advice I considered on 27 January 2021 which related to the definition of frontline social care workers for the purpose of vaccine prioritisation, on 2 February 2021 the Chief Medical Officer and Deputy Director of Health and Social Services wrote to the Chief Executives of the Health Boards / Trust and Directors of Social Services in the local authorities to clarify the definition of frontline social care workers for the purpose of the vaccination prioritisations, this was done because we had become aware that there are some differing interpretations of the Joint Committee on Vaccination and Immunisation's guidance on which social care workers fell within the scope of the definition for vaccine prioritisation purposes. This differing interpretation had led to divergence of practice in some areas. The overarching position as set out in the guidance at that time was that social care workers must be dealing directly with vulnerable people, delivering intimate personal care on a regular basis to those who were defined by the Committee as clinically vulnerable to Covid-19 to meet the priority criteria. Exhibit **M4/VG/97 - INQ000183715** refers.

150. Those 80 years of age and over and frontline health and social care workers were vaccinated in cohort 2 priority group as set out in the National Vaccination strategy and as recommended by the JCVI, as such, they were to be vaccinated in the same prioritisation group. To maximise the number of people vaccinated as quickly as possible and to minimise vaccine waste, there would have been some occasions where individuals from lower priority groups were called before all of those in higher priority groups had received their vaccine. For example, due to choreography of appointments at different vaccination centres or because of non-attendance at appointments e.g. due to illness. This position was adopted for operational efficiency and effectiveness, to minimise wastage.

151. At the four nations Health Ministers meeting on 4 February 2021, again I pressed for the publication of current vaccine stock levels and advised I would be doing so the following week. The Scottish Cabinet Secretary for Health was eager to make public the current vaccine stock levels also, but Matt Hancock MP said that publishing amount of vaccine due to be delivered was a problem. A note of the meeting is attached as exhibit **M4/VG/98 - INQ000492806**.

152. On 11 February 2021 I attended a Ministerial four nations meeting. The topics for discussion included vaccination figures, vaccine strategy, vaccine supply, data publication, prioritisation and cross border issues. I exhibit the agenda and summary briefing as **M4/VG/99 - INQ000410087**. During the meeting it was confirmed that a settled position on the publication of vaccine stock data had been achieved and the information would be published across the four nations shortly. I also noted the work being undertaken by Public Health Wales to look at defining the vaccination priority groups for those with caring responsibilities. It was hoped however, that Wales would have groups 1 to 9 vaccinated by early May 2021. I exhibit minutes of the meeting as **M4/VG/100 - INQ000410088.**The vaccine stock data was duly published on the 17 February 2021, exhibit **M4/VG/101 - INQ000492814** refers.

153. By 12 February 2021 the first milestone in the Vaccination Strategy for Wales had been achieved with the vaccine having been offered to all those in the priority groups 1-4. Wales was the first of the four UK nations to reach this key milestone.

154. During the 21-day review of restrictions discussed by Cabinet on 16 and 17 February 2021 it was noted that 780,000 people in Wales had received their first dose of the vaccine. The Chief Medical Officer noted that there needed to be some caution, however, as there

was a need to understand what impact the vaccination would have on transmission rates and how effective the vaccines would be at protecting the population as a whole.

155. As of 16 February 2021, 795,000 people had received their first dose of the vaccine in Wales and vaccinations were being administered in 514 locations across Wales, including 52 Vaccination Centres, 387 General Practice locations, 33 hospital locations, and 38 mobile teams which I exhibit as **M4/VG/102 - INQ000410143**.

156. The initial three markers outlined in the Vaccination Strategy for Wales had all been achieved:

a. Marker 1 was to have offered a first dose of the vaccine to all frontline Welsh Ambulance Trust staff by 18 January.
b. Marker 2 was to have offered the vaccine to all older person care home residents and staff by the end of January.
c. Marker 3 was to have 250 GP practices deploying the vaccine by the end of January. This was exceeded ahead of the target date for the marker.

157. The Welsh Government implemented a 'no one left behind' policy and actively followed up individuals that had not yet had their vaccine in priority groups 1-4, while starting to issue appointments for those in priority groups 5 and 6.

158. On 16 February 2021, I also agreed that unpaid carers be included within priority group 6 (the guidance was published on 24 February 2021). This followed the publication on 11 February 2021 of guidance defining front line social care workers for the purposes of Covid-19 vaccination, aiming to provide clarity to the NHS and to those eligible. I exhibit the guidance as **M4/VG/103 - INQ000081839**. Guidance was also issued allowing more than one person to be vaccinated due to their joint caring roles. This was agreed in MA/VG/0709/21 which is exhibited as **M4/VG/104 - INQ000410093** and the advice as **M4/VG/105 - INQ000116605**.

159. As set out in the MA/VG/0709/21 exhibited above, there were challenges in identifying eligible unpaid carers due to the lack of definitive data on the number of unpaid carers. - Furthermore, many do not self-identify. Some unpaid carers were known to local authorities due to involvement with the cared-for person and we engaged with local authorities in respect of the information they held. Another valuable source of information was from GPs who record patients with caring duties and held records of those unpaid carers who were also eligible for influenza vaccination in Wales. As a result, GPs had

tested approaches to accessing and vaccinating unpaid carers. We also worked with care organisations and Health Board vaccine teams to develop an online form for people who were not already registered as an unpaid carer (with GP or local authority) to be identified on the Welsh Immunisation System, exhibit **M4/VG/106 - INQ000492818** refers. Policy colleagues engaged extensively with the national carers' organisations in respect of the guidance and assisted with the national communications. The guidance was issued by the Welsh Government on 24 February 2021 and is attached as exhibit **M4/VG/107 – INQ000492866**.

160. I was also provided with the Wales Covid-19 vaccination enhanced surveillance report on 16 February 2021 which provided a summary of the analysis of coverage in Wales by sex, socio-economic deprivation and ethnic group. I exhibit the Covid-19 vaccination enhanced surveillance report as **M4/VG/108 - INQ000410092.**

161. In response to that report the First Minister sought, as a matter of urgency given the issues noted in the report, an update on identifying a mosque as a vaccination centre. Welsh Government officials responded to the First Minister and myself on 22 February 2021, which I exhibit as **M4/VG/109 - INQ000410097**, noting that the operations team had asked Health Boards to consider the use of mosques and other faith centres as potential vaccine centres and that an update was expected. It was noted that there were examples of Black, Asian and Minority Ethnic health staff becoming advocates of vaccinations and reaching out to specific cultural centres. The update also noted the Doctor who is a Muslim scheme, facilitated by Aneurin Bevan University Health Board, was also being used to provide insight into the opportunities and considerations for using mosques as part of the broader strategy to engage with Minority Ethnic communities.

162. I was informed by my special adviser that the scope of cohort 6 was discussed on a four nations policy call on 16 February 2021 and that it was likely to be an issue to discuss during the four nations ministerial call on 17 February 2021. My officials' advice to me, and my view which I exhibit as **M4/VG/110 - INQ000410094** was that a practical and generous view should be adopted, as opposed to a restrictive approach.

163. On 23 February 2021 I accepted advice on a proportionate and more inclusive approach to prioritisation for those with severe mental illness or learning disability, to avoid missing those vulnerable persons who should be vaccinated. I exhibit an email accepting the advice as **M4/VG/111 - INQ000410098** and the advice as **M4/VG/112 - INQ000145094**. The Vaccination Clinical Advisory and Prioritisation Group had considered the information on which this advice was based and were content. The

evidence from studies by both the Office for National Statistics and Public Health England showed that individuals with a learning disability were at a greater risk of Covid-19 mortality than with those with no learning disability. I decided to adopt an inclusive approach by adopting guidance which was closely based on the Joint Committee for Vaccination and Immunisation's advice and criteria but would result in the inclusion of some individuals outside the severe/profound learning disability definition and coded within the serious mental illness groups, which the Committee had adopted. That was due to the nature of current information systems on how these groups were identified, and the lack of shared definitions. The revised approach that I took meant that more vulnerable individuals eligible for vaccination than would have been the case had a strict interpretation of the Joint Committee on Vaccination and Immunisation's advice been adopted. The guidance was published the following day.

164. In the event, Matt Hancock sent me a text message saying that the Joint Committee on Vaccination and Immunisation had agreed that everyone with a learning disability would be included within cohort 6 on 24 February 2021.

165. On 25 February 2021 I agreed to adopt an age-based roll-out for the vaccine, which I exhibit as **M4/VG/113 - INQ000368869**. That approach was seen as the swiftest way of offering protection to those not falling within the priority groups. Age was the simplest way of explaining how the vaccine was being rolled out, was the quickest to operationalise and the fairest to most. As such I adopted the Joint Committee on Vaccination and Immunisation's advice. This advice has been exhibited as **M4/VG/114 - INQ000145090.**

166. Further advice was provided to me and the First Minister on that issue on 25 February 2021, where I agreed to the draft text of a joint ministerial statement. The issue to be further discussed during the four nations ministerial call late in the week. I exhibit the advice as **M4/VG/115 - INQ000386458**.

167. On 25 February 2021 I attended the Shadow Social Partnership Council meeting where Dr Heather Payne, a member of the Covid-19 Moral and Ethical Advisory Group for Wales, presented a paper entitled Ethical Issues: Workplace Vaccination – Developing an agreed approach. I exhibit the minutes of the meeting **as M4/VG/116 - INQ000310692.**

168. Officials understood that a high percentage of the homeless population would fall within priority groups 4 or 6 because of their likely underlying health conditions. However, many homeless people were not registered with a GP and/or their health records were not up to

date and so it was unlikely that they would be captured within those priority groups for vaccination. As such, I determined that rather than attempting to identify those that fell within a strict interpretation of the Joint Committee on Vaccination and Immunisation's advice, an inclusive and pragmatic approach which would see all homeless or recently homeless people offered the vaccination as part of cohort 6. The advice provided to me on the 5 March 2021, noted that that inclusive approach did risk setting a precedent. However, the scope of this interpretation was limited and for a relatively small cohort of vulnerable people. The advice has been exhibited as **M4/VG/117 - INQ000235860**. My view was that a position of inclusion over exclusion for this vulnerable group of the population was best to ensure that none were missed out. Operationally it was recognised that the approach would require harnessing the support of those who were trusted by people who were or had recently been homeless; and adopting a model centred around 'taking the vaccine to them' with guidance expecting vaccines to be given to people in the places where they lived, rather than expecting people with experience of homelessness to attend mass vaccination centres.

169. On 26 February 2021, we published our updated National Vaccine Strategy, which I attach as exhibit **M4/VG/118 – INQ000401712**. Whilst less than two months had passed since the publication of the first strategy, a huge amount had happened since then. At that point we were over halfway to protecting all those in priority groups 1 to 9 and had vaccinated over one-third of all those age 16 and over in Wales.

170. On 9 March 2021 there was a query raised by e-mail in respect of the possibility of using substance misuse professionals to administer the vaccine to those who were engaged with a substance misuse programme. I indicated that I accepted that approach and that I wanted us to take a "can do approach". I exhibit my e-mail as **M4/VG/119 - INQ000410102**. It was important that we utilised every tool at our disposal to ensure that those who were marginalised or otherwise at risk of not being vaccinated were included within the delivery programme. I was aware that different marginalised groups needed different strategies to ensure fair access to vaccines and high levels of take up of the vaccine. Consideration was given to the needs of different groups in society with a view to tailoring the vaccine rollout strategy so that obstacles were overcome.

171. On 11 March 2021 the media reported that the Danish authorities had suspended the use of the AstraZeneca vaccine due to concerns that there had been blood clots among several people who had been vaccinated. I was provided with advice by the Chief Pharmaceutical Officer, which I exhibit as **M4/VG/120 - INQ000410103**, who noted that

MHRA would shortly be issuing a statement confirming that the issue would be kept under review but that, in its view, there was no evidence that the vaccine caused blood clots. Accordingly, the MHRA advice was the people should still go and get their Covid-19 vaccinations.

172. I attended a four nations ministerial meeting on the 11 March 2021. A note of the meeting is exhibited at **M4/VG/121 - INQ000410104**.

173. On 15 March 2021 the then First Minister and I were provided with further advice in response to queries raised as to the safety of the AstraZeneca vaccine. There was also a briefing note provided by policy colleagues, which I exhibit as **M4/VG/122 - INQ000410142**. In preparing the briefing, policy colleagues had access to the Astra Zeneca safety report dated 12 March 2021 which had been shared with them by the Chief Medical Officers, exhibits **M4/VG/123 - INQ000492823** and **M4/VG/124 - INQ000492824** refer. The position remained that the evidence did not support any link between the vaccine and blood clots and the Welsh Government line mirrored the MHRA's approach of seeking to re-assure the public whilst making clear that the position was being monitored. The MHRA's "yellow card" scheme was also advertised so that any concerns that individuals had could be properly reported.

174. That position was re-iterated to me on 18 March 2021, which I exhibit as **M4/VG/125 - INQ000410105**.

175. On 20 March 2021, I agreed to extend the Primary Care Covid-19 Immunisation Scheme (PCCIS), which originally covered only primary care delivery of the Astra-Zeneca vaccine by MA/VG/1370/21, which I exhibit as **M4/VG/126 - INQ000410106** and the advice as M**4/VG/127 - INQ000136853**. I also agreed an extension of the Primary Care Covid-19 Immunisation Scheme to enable primary care providers to deliver the Moderna vaccine and legislative directions were made accordingly, which I exhibit as **M4/VG/128 - INQ000410107 and the advice as M4/VG/129 - INQ000136852.**

176. MA/VG/1397/21 was sent to me on the 22 March 2021 in relation to the publication of an updated vaccine strategy to reflect the progress made to date and to set out further information on the upcoming priorities. Alongside the updated strategy, I was asked to agree the publication of a vaccine equity strategy to ensure as many people as possible were offered, and took up the offer, of vaccination. The MA is attached as exhibit **M4/VG/ 130 - INQ000235851** and my agreement as **M4/VG/131- INQ000421877.**

177. The updated vaccination strategy was published on the 23 March 2021 in which we were able to reflect on the pace and progress of the vaccine programme, exhibit **M4/VG/132 - INQ000492873** refers. By this time more than 1.2 million people in Wales had received their first dose of the vaccine, and more than 350,000 people were fully vaccinated, having received both doses of the vaccine. We were quickly working our way through the nine priority groups. We had a 50% gateway in place for moving from one cohort to the next and expected to start inviting the under-50s to receive their first doses early in April.

178. The vaccination equity strategy for Wales was published alongside the updated vaccination strategy, the aim of the equity strategy was that all people in Wales should have fair access to the vaccination, with fair opportunity to receive their vaccination so that individuals, families, and their communities are protected from the harms of the virus. The equity strategy is attached as exhibit **M4/VG/133 - INQ000182538**.

179. On 24 March 2021 I received advice to adopt the Joint Committee on Vaccination and Immunisation's recommendation that household contacts of immunosuppressed adults should be vaccinated. I exhibit the advice as **M4/VG/134 - INQ000145120**.

180. Also, on 24 March 2021 I was asked to approve a draft ministerial statement issued, jointly, by the four nations health ministers. I exhibit the email as **M4/VG/135 - INQ000410108.** The Committee's final advice in respect of phase 2 had been delayed due to the above concerns about the AstraZeneca vaccine and so the draft statement built on the interim Committee advice that had been published in February. I exhibit the draft statement at **M4/VG/136 - INQ000410120**.

181. On 25 March 2021 I was provided with an update which noted that there might be an announcement in England that they had offered a vaccine to all those in the 9 priority groups. It also noted that the deployment of the vaccine in Wales was continuing at a good pace and that it was expected that confirmation of having reached milestone 2 could be provided at the end of the following week, which I exhibit as **M4/VG/137 - INQ000410110**.

182. I attended a four nations ministerial call on 26 March 2021. I exhibit a note of the meeting as **M4/VG/138 - INQ000410111**.

183. On 29 March 2021, the Joint Committee on Vaccination and Immunisation recommended that adults living with adults who were immunosuppressed should be

prioritised for the Covid-19 vaccine. I accepted this advice, which I exhibit as **M4/VG/139 - INQ000477044.**

184. On 31 March 2021, I agreed to funding of £89,709 to expand access to allergy advice for clinicians making decisions in respect of Covid-19 vaccines. At that time the assessment was that the level of expertise in respect of allergies was to be found within the Cardiff and Vale Health Board only, and whilst demand for the service was unclear the team was fully occupied at that time by enquiries from Cardiff alone. Accordingly, I agreed to that funding to expand the advisory service so that all Health Boards could access the advice which I exhibit as **M4/VG/140 - INQ000410115** and the advice as **M4/VG/141 - INQ000145122**.

185. Also, on 31 March 2021 I attended a four nations health minster meeting at which the vaccine was discussed. I exhibit a copy of the notes of that call as **M4/VG/142 - INQ000410112**.

186. Cabinet met on 29 and 31 March 2021. The 21-day review provided an update on the vaccination programme confirming that it was likely that Milestone 2, that is those within groups 5-9 being offered their first dose by the middle of April and achieving 75% take up across those groups, would be met by the end of that week.

187. I understand that in April 2021 the UK Government established the Antivirals Task Force the purpose of which was to identify safe and effective oral antiviral treatments that could be taken at home by patients, by winter 2021.

188. On 7 April 2021, the first person in the UK, outside clinical trials, received the Moderna vaccine. The vaccine was administered on a female unpaid carer from Ammanford, at Glangwili General Hospital, Carmarthen.

189. On the same date the MHRA issued new advice concluding there was a possible link between the Astra-Zeneca Covid-19 vaccine and an extremely rare form of blood clots. The risk was of a very specific and very rare type of clot with a low platelet count, known as thrombocytopenia. In light of these concerns, I confirmed that subject to vaccine supply, those under 30 would be offered an alternative vaccine. This was a precautionary measure, as the clinical advice was that there were no serious safety concerns and for the majority of the population, the AstraZeneca vaccine was still considered to be a safe and effective vaccine. I exhibit the advice as **M4/VG/143 - INQ000410116**.

190. On 9 April I was informed that the clinical advice from Public Health Wales was that it was preferable to offer an alternative vaccine to AstraZeneca to those under 30 with no underlying health problems or clinical risk who were still unvaccinated. I exhibit the advice as **M4/VG/144- INQ000410118.**

191. On 9 April 2021 I was provided with updated lines regarding the safety of the AstraZeneca vaccine. I had asked for a comparison to be drawn between the safety of the vaccine and flying, that being an assessment of risk that might contextualise the risks which the vaccine posed.

192. On 19 April 2021 the First Minister provided an update to Cabinet as part of the 21-day review. He noted that the vaccination programme had continued at pace with almost 50% take up of first vaccinations for the 40-49 age range. However, it remained unclear to what extent the vaccination had broken the link between community transmissions and the direct covid-19 harms.

193. Also, on 19 April 2021, I commissioned a note on the UK Government consultation on the compulsory vaccination of care home staff, exhibit **M4/VG/145 - INQ000492843** refers.

194. I received a briefing on the consultation of compulsory vaccination of care home workers (in England) and modelling of what that would look like in Wales by email on the 23 April and a supporting advice note, exhibits **M4/VG/146 – INQ000492844** and **M4/VG/147 – INQ000492845** refer. The materials confirmed that the vaccination uptake of care home workers in Wales was above SAGE recommendations to ensure minimum levels of protection against further outbreaks in care homes. Alternatives to compulsory vaccination recommendations included increased media coverage and working with faith leaders and community groups to better understand the cultural barriers to vaccine hesitancy. It was also recommended that identification of homes that fell under the SAGE minimum thresholds and speaking to those homes to ascertain how we could improve take-up rates. I understand that these recommendations were taken forward and are addressed further in Eluned Morgan MS' statement in this Module. I am also aware that Lee Waters MS conveyed a message from a care home in his constituency in Llanelli asking whether the compulsory vaccination of care homes staff would be adopted in Wales, and this was raised in the Ministerial WhatsApp group exhibit **M4/VG/148 - INQ000316403_0068** refers - and that he was encouraging vaccination uptake. The Ministerial WhatsApp group was not the appropriate place to respond to action points, but such points could be addressed in Cabinet and in any event, his

comment was made the day following the publication of the first Welsh vaccination strategy and in the context of increased communication on vaccine uptake.

195. On 29 April at the UK Health Ministers Forum, Ministers discussed the need for a four nations approach on vaccine certificates for international travel. I then wrote to the Secretary of State for Health and Social Care to reiterate support for a system of vaccine certification to assist outbound international travel to be delivered across England and Wales. A decision had been taken in the UK Government to proceed on an England only basis at this stage. I attach a record of the meeting as **M4/VG/149 – INQ000421880** and a copy of my letter to the Secretary of State as exhibit **M4/VG/150 - INQ000421882**.

196. A further update was provided to Cabinet on 10 and 12 May 2021 with the First Minister confirming that the vaccination programme was continuing at pace with a higher proportion of the population in Wales having received their first and second doses than the rest of the UK. Over 75% of the adult population had received their first dose with 25% having received their second. The Chief Medical Officer noted that there was some concern amongst the scientific community, given the rapid spread of the Kent variant, regarding vaccine escape.

197. On 7 May 2021 the MHRA confirmed its position remained that the benefits of the Covid-19 Astra-Zeneca vaccine continued to outweigh the risks for the vast majority of people. The balance of benefits and risks was deemed favourable for older people but finely balanced for younger people and the advice was that the evolving evidence be taken into account when considering the use of the vaccine. As such, the Joint Committee on Vaccination and Immunisation updated their expert advice and, as a precautionary measure, those under 40 years of age with no clinical risk factors who had not yet been vaccinated were advised to be offered an alternate to AstraZeneca. I immediately implemented this change to the Programme, adhering to the latest information as confirmed in the weekly update issued on the 11 May 2021. In line with the updated Committee advice, Health Boards would make the appropriate vaccine available at the right time for individuals, particularly those under 40 years of age who had not yet received a first dose.

198. On 7 May 2021, my officials advised me that the announcement did not pose any immediate risk to the vaccination programme in Wales, which I exhibit as **M4/VG/01-151 - INQ000410123**.

199. On 7 May, the UK Government confirmed its position on international outbound travel. I was copied into MA/FM/1636/21, exhibit **M4/VG/152 - INQ000361820** refers, in which the former First Minister was asked to remove legal restrictions on non-essential outbound international travel and to allow international travel from 17 May 2021. Vaccine certification as a condition of entry set by individual countries was included in the Ministerial Advice and in order to facilitate international travel, by 17 May, the UK Government said that it would utilise the existing NHS App for use by residents in England in which those wishing to travel could house a vaccination certificate to meet entry requirements set by other countries. The former First Minister agreed the Ministerial Advice on 13 May 2021, exhibit **M4/VG/153 - INQ000492847** refers.

200. On 11 May 2021 I became aware of the BBC reporting that the NHS app would become vaccine passport ready the following week. I immediately asked policy officials for an update on the position in Wales. My request and the response received is attached as **M4/VG/154 – INQ000492846.** This was followed shortly by MA/FM/1656/21, which I exhibit as **M4/VG/155 - INQ000176839**. The Ministerial Advice related to the Covid-19 vaccination status certification for outbound international travel and that the UK Government would be launching a system for Covid-19 status certification in England from 17 May 2021. I was asked to agree that the Welsh Government would operate an interim certification system until alignment of the digital system could be achieved.

201. The Health Protection (Coronavirus, International Travel, Operator Liability and Public Health Information to Travellers) (Wales) (Miscellaneous Amendments) Regulations 2021 were subsequently made on 14 May 2021 and came into force on the 17 May reflecting the changes to international travel. On the same day the then First Minister issued a statement confirming that vaccination status certificates would be available for people in Wales who had received two doses of their vaccination and needed to travel urgently to a country that required proof of Covid-19 vaccination from Monday 24 May, exhibit **M4/VG/156 – INQ000492892** refers. I took no further role in respect of the pass as this portfolio responsibility changed as noted below.

202. On 13 May 2021, following the Senedd elections, I was appointed as Minister for the Economy, Eluned Morgan MS was appointed Minister for Health and Social Services and therefore took over Ministerial responsibility for the delivery of the vaccination programme in Wales.

203. I attended my last four nations health minister meeting on that day. At that meeting, I noted that any advice from the Joint Committee on Vaccination and Immunisation would need to be shared as soon as possible so that the vaccine programmes could implement the same. I exhibit the minutes of the meeting as **M4/VG/157 - INQ000410130**.

Development, Procurement, Manufacture and Approval of Vaccines

204. In the earlier section of my statement covering the devolution settlement and regulatory framework, I set out the limitations on the Welsh Government's powers in respect of vaccines. There was no formal role for the Welsh Government or Welsh Ministers within the vaccine regulatory and approval process. As I stated in my statement in Module 2B at para 507, the Welsh Government did not have regulatory or advanced purchasing responsibility or financial capability to undertake research or development or procurement separately for Wales. I was broadly content with the approach that the UK Government took in respect of the development, procurement, manufacture and approval of the Covid-19 vaccines, but set out some more specific observations in the paragraphs below.

205. In the UK, the UK Government procures other nationally administered vaccines, such as the annual flu vaccine. The Welsh Government is not a part of that decision-making process and that process is built upon trust. In general terms I considered that the system worked and I was content to adopt it for the purpose of procuring the Covid-19 vaccines. Making the most of the UK's significant purchase power has obvious commercial benefits and in the case of the novel Covid-19 vaccines in particular, enabled a wider range of vaccines to be purchased in advance at a time when regulatory approval and efficacy was uncertain.

206. However, within the context of a dynamic and urgent pandemic response, especially against the backdrop of vaccine delivery being devolved, it does strike me that earlier and fuller engagement would be beneficial.

207. As regards information sharing, what this meant was that there was no direct line of engagement between ministers, and no formal relationship between officials from the Department for Business, Energy and Industrial Strategy, or the UK Vaccine Taskforce and relevant Welsh Government officials. Earlier and fuller engagement would in my view have been beneficial. I understand that there were good working relationships between individuals at official level (including the Chief Medical Officers, Chief Pharmaceutical Officers and the Senior Responsible Officers of the vaccine programmes). Officials were

kept up to date, generally with adequate advanced notice of regulatory decisions to enable them to plan ahead. That information in turn informed the advice that I was provided with. However, it is far from ideal that co-operation on such important matters were essentially based upon personal relationships.

208. When Nadhim Zahawi MP was appointed as the Minister for Vaccines, cooperation and working together did seem to improve, there was greater communication. As a result, I had a better idea of what was happening in terms of supply and therefore was able to plan ahead more effectively. I had greater assurance that I would not be informed of significant policy decisions in respect of vaccines only as they were being briefed to the press.

209. The consequence of more regular discussions at ministerial level is that almost inevitably there are more regular discussions between officials. Again, that was a real improvement which was noticeable following the appointment of a Minister for Vaccines.

210. The above was crucial to the successful roll out of the vaccine in Wales as we needed to know in good time when and where, and in what quantities, the vaccine was going to be delivered to us to enable the delivery process to be properly planned.

211. Where the Welsh Government did have a role to play, for example with the UK Permission to Contact initiative, we did what we could to support those initiatives.

212. As to procurement, this was a novel and urgent situation. The joint procurement approach is one area where I feel that the UK Government deserves praise. Having agreed that the UK Government would lead on the procurement process it was for it to determine what approach would be adopted. Through the UK Vaccine Taskforce, it appointed individuals who were well placed to make decisions on procurement and placed orders for large quantities of vaccine doses, spread across the various candidate vaccines at an early stage. It took an educated risk, and it paid off: it is an area to be positive about.

213. The economies of scale, and the nature of the procurement exercise meant that it would not have been as effective, in a practical or commercial sense, for the Welsh Government to procure its own vaccines.

214. As to Welsh involvement in vaccine development it is clear that Welsh businesses had a role to play in the manufacturing of vaccines and the Welsh Government did what it could to try and ensure that that was facilitated.

215. It is also worth noting that there were, at times, periods of difficulty between the UK Government and the EU due to manufacture and supply issues around the vaccine. Those issues were drawn to my attention by officials as well as some news coverage but in my view were largely political as opposed to having any real impact upon decision-making or the realities of vaccine procurement and delivery.

216. As vaccines were being developed, I would be provided with updates from my own officials who would have an understanding of the up-to-date position from a clinical perspective - through the various groups and taskforces, discussions with colleagues from the Department for Business, Energy and Industrial Strategy, or through the medical and scientific literature. I was satisfied that I was kept abreast of developments by my officials and that policy planning was properly informed. Given that no decisions around procurement lay with me there was no specific requirement for me to receive formal advice in respect of candidate vaccines and procurement issues. Such matters were, however, important within the context of the subsequent delivery of vaccines.

217. It is fair to say that the different requirements of the candidate vaccines meant that planning was contingent upon which vaccine would be approved. For example, it transpired that the Pfizer Vaccine required ultra-low temperature storage and so the deployment of that vaccine would necessarily differ from others.

218. I had some concerns when entering into the Memorandum of Understanding with the Department for Business, Energy and Industrial Strategy that the Welsh Government may not be able to provide sufficient notice of delivery locations. The nature of the exercise was that vaccines would be made available on days' notice, not weeks. However, that concern was answered by my officials on the basis that the roll out strategy was sufficiently developed for advanced notice of delivery sites to be given. That is a testament to the planning and preparatory work undertaken.

219. Given the importance of the issues and the scale of the project (both in practical and financial terms) transparency was key. The success of the decisions we took and the strategy we implemented rested in large part on the public's trust in government. Fundamentally my concern, and that of my officials, was when we would be getting a

vaccine, which vaccines would be available, how they would be distributed and administered and how effective they would be.

220. Agreement on delivery directly to Wales was an important factor: it meant that there could be direct involvement on the part of the Welsh Government and the NHS bodies in Wales from a very early stage which ensured that the Welsh vaccine roll out strategy could be fully implemented swiftly. Delivery was, of course, devolved.

221. As to how the vaccine supply would be shared between the UK nations there was a need for a quick decision and an understandable formula. The choice was between distribution on a population basis or adopting the Barnett formula. Given the timings there was no realistic prospect of a needs-based formula being calculated and adopted. It was clear that a population share would be bad for Wales. The obvious candidate was to adopt the Barnett formula.

222. The Barnett formula is the formula used by His Majesty's Treasury to calculate block grants for the Devolved Governments. The formula is based in part on population share and needs based factors, and in part on other factors so that, broadly, Wales would receive a percentage (105%) per capita of England's allocation. The Barnett share in Wales is higher than the per capita share for England because of the needs-based element of the calculation.

223. It is not based on need; and being an "off-the-shelf" formula would not reflect the particular needs in terms of vaccinations. Accordingly, the Barnett formula was always going to be something of a trade-off. However, in discussions with the four nation health ministers, agreement was struck.

224. I was content with that approach because it was easier and more understandable than trying to negotiate a needs-based alternative and was something that people understood. Adopting that approach did not compromise the vaccine roll out even though the numbers may have been less than Wales would have received had a purely needs based approach been adopted.

Development of vaccine alternatives (prophylactics)

225. One of the issues I understand the Inquiry will be considering within this Module is whether enough was done to develop and make available non-vaccine prophylactics for

Covid-19 (including Evusheld) to address the needs of immunosuppressed and immunocompromised people among whom vaccines are likely to be less effective. Being essentially a clinical question, I was advised at all times by the Chief Pharmaceutical Officer. This matter has been addressed within the therapeutics corporate statement provided in this module, which I understand was prepared with significant input from him. Where medicines were available it was then for the individual Health Boards to determine their approach and the decision to use prophylactics was, ultimately, a clinical one.

Eligibility and prioritisation decisions

226. I have set out the decisions in respect of eligibility and prioritisation, above.

227. It was agreed between the four nations Chief Medical Officers that the Joint Committee on Vaccination and Immunisation's advice would be adopted across all four nations. Though the status of the Committee's advice in Wales is advisory and not binding, given that it has specialist advisory boards made up of independent experts it is almost always adopted in Wales.

228. My approach was to consider the advice that was provided to me by my officials, in particular the clinical advice from my Chief Officers (Chief Medical Officer, Chief Pharmaceutical Officer, Chief Nursing Officer).

229. There were no occasions when I, nor my officials, took the view that we should depart from the Committee's advice. On occasion, I was advised that the Welsh Government, and the NHS in Wales, could use operational flexibility to ensure that the Vaccination Programme reached the largest possible numbers whilst reducing waste. However, that did not involve either a change in policy nor a departure from the four nations approach (and the Joint Committee on Vaccination and Immunisation's advice which underpinned the same).

230. The Welsh Government took a broad and practical approach to the priority cohorts. Messaging around that was consistent and when operational flexibility was used, we sought to make it absolutely clear that we were not diverging from the four nations approach. For example, when the 50% gateway (referred to in the chronology section above) was adopted, the messaging around the same was specifically targeted at clarifying that it was a practical decision to ensure that as high a proportion of appointments were filled and competed: it was not about changing priorities. Though there was some media (and political) interest around the issue of over 80s not yet having been vaccinated

whilst younger individuals had been, the reality is that the priority cohorts in Wales remained the same as in the other nations, the Committee's advice remained the basis for the vaccine roll out, and the use of operational flexibility led to a very high efficiency rate.

231. Decisions around eligibility and prioritisation, following approval, were matters for the Welsh Ministers and for me as the responsible Minister. In practice, there was adequate scope for operational flexibility to enable the Welsh Government to make very minor changes. These were seen with the definition of frontline workers and decisions around offering the vaccine to all those currently or recently experiencing homelessness.

232. There were specific issues which arose on a sector-by-sector basis, with difficult decisions to be taken. It was important in that context that the Joint Committee on Vaccination and Immunisation, as an independent organisation, provided advice which enabled those difficult decisions to be taken. There were difficult issues, with well-organised campaigns in respect of various sectors. However, the reality of the data made clear that those at greatest risk outside of healthcare settings, were bus and taxi drivers. It was important that our decisions were taken on the evidence available and the advice from the Joint Committee on Vaccination and Immunisation, and not swayed by what may have been politically popular.

Vaccine Roll-out

233. Deployment and roll-out of the vaccine fell within my remit. I was confident that I had sufficient powers to enable me to take the decisions that needed to be taken for that programme to be a success. I cannot identify any particular powers which were not available to me within the current regulatory framework. The pre-existing relationship between Welsh Government and the NHS in Wales meant that there were very few barriers to the roll-out of the vaccine. We were able to tailor that successfully, for example in rural areas, by using the primary care infrastructure.

234. I set out in the chronology, above, the circumstances which led to the Welsh Vaccine Strategy being developed. It was unfortunate that the UK Government provided a draft UK Strategy late in the day, with minimal co-operation in advance, seeking comments by lunchtime the following day (a Saturday).

235. My officials' view was that the contents of the strategy were clearly drafted from an Anglo-centric perspective. There were real concerns that in practice and on points of principle the strategy would not be appropriate or effective for Wales.

236. It accordingly became clear that there was a need for a Welsh Vaccine Strategy to be drafted quickly: there was a real risk that publishing a UK Vaccination Strategy, which had not been adopted by the Welsh Government, would lead to criticism in Wales that there was no plan in Wales, or a situation where the UK Vaccination Strategy became the de facto Welsh strategy. In my view, having a published document was important.

237. Though the Welsh Vaccination Strategy itself was drafted in a short space of time, it drew on well-developed work which my officials and the Vaccine Programme Board had been working on for some time.

238. I received advice by e-mail together with a draft of the strategy on 10 January 2021. I exhibit those documents as **M4/VG/158 - INQ000410063** and **M4/VG/159 - INQ000410065**. I recall reviewing the draft strategy ahead of its publication the following morning: it reflected a significant effort by my officials and provided real clarity on the approach to be adopted in Wales.

239. Following its publication, the roll-out strategy was closely monitored and updated by officials. In this regard, I refer to the two further updates published to the strategy above, the first of which was on 26 February 2021 and the second on 23 March 2021. I recall there being specific consideration of marginalised and vulnerable groups by the Vaccine Equity Committee, the details of which are set out in the corporate statements. As I noted in the chronology in respect of those suffering with substance misuse, my approach was to adopt a "can do attitude" to ensure that the vaccine was made as widely available as possible.

240. That approach of doing all that we could to vaccinate as many people as we could, and using operational flexibility where required to do so, was something that I recall Clare Rowlands and I discussed regularly. That steer which I provided meant that those working at the front line of practical decisions about deployment and roll-out adopted a similar approach. That general principle underpinned the work that my officials carried out and the roll-out of the vaccine generally in Wales. In the event, the real success story of the vaccine roll-out in Wales was testament to that work.

Covid-19 Moral and Ethical Advisory Group Wales

241. At paragraph 167 above, I refer to the work of the Covid-19 Moral and Ethical Advisory Group Wales (CMEAG).

242. Under cover of MA/VG/1177/20 dated 01 April 2020 I received advice that Covid-19 Moral and Ethical Advisory Group-Wales should be established, to be sponsored jointly by myself, the Deputy Minster and Chief Whip and Minister for Housing and Local Government, to offer ethical advice and support to public services in Wales relating to the Covid-19 emergency response. On the same day, I agreed to the establishment of the group and indicated that the setting up of the group made sense. Exhibits **M4/VG/160 - INQ000097679** and **M4/VG/161 - INQ000492674** refer.

243. The Covid-19 Moral and Ethical Advisory Group Wales was subsequently established with the first meeting taking place on the 6 April 2020. The terms of reference are attached as exhibit **M4/VG/162 – INQ000066079.**

244. Dr Heather Payne was the chair of the Covid-19 Moral and Ethical Advisory Group Wales and has provided a statement in Module 2B, the reference is INQ000319846. In that statement, Dr Payne confirms that she represented the Chief Medical Officer for Wales on the UK Moral and Ethical advisory Group, established via the Department of Health and Social Care. She also explains that the Covid-19 Moral and Ethical Advisory Group Wales was established as an inclusive group, and represented a broad cross section of the community, including Older People and Children's Commissioners, disability and learning disorder voices, faith and belief groups, Welsh Language Commissioner, clinicians, trade union, legal, human rights, NHS management and ethical experts.

245. As Dr Payne has set out in her statement, policy leads were encouraged to bring policy proposals to the group for analysis and advice and finalise their policies in light of the feedback they received from the group. The group focused on offering ethical advice and support to policy makers and practitioners on issues relating to the provision of health and social care during the pandemic, which extended to the vaccination roll-out in Wales.

246. As I have noted at paragraph 167 above, Dr Payne in her capacity as chair of Covid-19 Moral and Ethical Advisory Group Wales presented at the Social Partnership Council meeting on 25 February 2021 which I attended. The minutes of which are exhibited above. Dr Payne confirmed that the group would continue to model levels of risk, maximise the

effectiveness of existing data and ask the Joint Committee on Vaccination and Immunisation for greater clarity on their existing approach to vaccine prioritisation. I was therefore assured that the work of Covid-19 Moral and Ethical Advisory Group Wales was brought to the attention of the Committee.

247. Dr Payne also co-chaired the Black, Asian and Minority Ethnic Covid-19 Advisory Group which ensured that issue could be discussed across various platforms.

Public Messaging, Barriers to Uptake, Misinformation and Disinformation

248. The core purpose of public messaging, in my view, was to ensure that people had access to authoritative information about the vaccines which enabled them to understand its efficacy and safety. That work was led by the Health and Social Services Group's communication team together with specialist advisers as is set out in more detail in the Module 4 corporate vaccines statement.

249. At the heart of that communication strategy was trust. In general, the public had a high level of trust in the Welsh Government. It was also important that the vaccine roll-out was being carried out by the NHS and, in large parts of Wales, with significant involvement of general practitioners. That built on pre-existing relationships of trust to ensure that the public had as much confidence as possible in the vaccine. As the success of the vaccine roll-out strategy in Wales became apparent that built upon the confidence and trust that the public had in the decisions around the vaccine and meant that it went from strength to strength.

250. The communication strategy moved away from confronting and amplifying negative or false information. Instead, the purpose of the Welsh Government's and my personal public messaging was to provide factual content and educate the public.

251. I was also aware of the "*Keep Wales Safe*" campaign which was developed as an identifiably Welsh brand which applied across a range of Covid-19 related matters, including vaccination.

252. My role meant that I was the primary source of Ministerial Statements to the Senedd and to the media. It was clear that regular face to face communication was key to building trust. A conscious decision was taken that media appearances in respect of vaccines

would be done together with clinical experts and often I would host press conferences alongside the Chief Medical Officer or the Deputy Chief Medical Officer (Vaccines). I felt this was important as it ensured that the clinical information was accurately presented by those who were expert. Striking the balance between politicians and clinicians was key to ensuring that the public messaging was credible.

253. I saw my role within that communication strategy as providing assurance and ensuring that the factual position was clear to the public. That involved communicating information around the safety and efficacy of the vaccines and giving updates in respect of priority groups.

254. It was also important that the reality of the vaccine programme was properly understood and so providing information on the speed of roll out and future developments also played a significant part of my communication role. Transparency played an important role within that strategy. As such, I decided that it was beneficial for me to publicise my first vaccine through photographs and videos published on official Welsh Government channels. That was important both generally, to maintain public confidence in the vaccine, but also to counter specific concerns raised within some communities that the vaccine was detrimental to black people. There was a specific cohort for whom seeing me, as the Minister for Health and Social Services and a black man, receiving the vaccine was an important factor. There was an opportunity for that photograph of me being vaccinated to have a genuine impact and make the messaging opportunity a worthwhile one.

255. Misinformation and disinformation were significant challenges. There was an awareness of those risks from an early stage and steps were taken to counter the issue. It became apparent to me that not only was it highly problematic online but was also something that I came across on the doorstep in April 2021. Peoples' views ranged from a genuinely held concern around the risk of vaccines on the one hand, to views that the pandemic was a lie on the other.

256. There were specific issues within specific communities relating to the vaccines, too, for example suggestions that the vaccine was 'haram' (forbidden to certain communities) as it contained pig derivatives. Addressing those issues was a significant element of ensuring that the vaccine programme was a success.

257. One of the reasons why tackling misinformation itself was so difficult is that often it was shared privately, through messages between individuals or groups, as well as being discussed in public. That is one of the reasons why it was difficult to understand and address the motivation behind those who created mis-and disinformation.

258. I was, and am, acutely aware that some sections of society in Wales have an underlying distrust of the state.

259. The issue of communication and public messaging was discussed at four nation health minster meetings. In particular the importance of maintaining consistent communications was discussed. There was no detailed policy agreed at those meetings but the cross-party agreement as to the importance of clear, factual information delivery was clear. I also understood that the Chief Medical Officers of all four nations discussed communications and, where necessary, the Chief Medical Officer would provide me with updates as to their discussions to inform my decisions and my messaging.

260. The effectiveness of public messaging in Wales was in my view broadly positive. However, as time progressed there was a gathering pace of misinformation being published especially following concerns being raised internationally in respect of the AstraZeneca vaccine and growing levels of misinformation.

261. It was apparent that there was an important role for leaders to play at a community, faith and clinical level. Muslim Doctors Cymru is a very good example of specific action being taken at such a level. The Vaccine Equity Committee undertook a significant amount of work in this area with a targeted approach being adopted for a number of marginalised groups. Again, utilising existing leaders within those communities was an important factor in maintaining trust.

Coordination and communication between the four nations

262. The decisions made by the Welsh Government were to protect the people of Wales, we could not go beyond the powers and responsibilities devolved to the Welsh Government. As I set out above, the position as regards medicines and vaccines was that regulation and approval of those was a matter reserved to the UK Government.

263. I believe that I had an effective working relationship with my counterparts in the other governments. I would send notes to the other health ministers when we were due to make announcements to ensure they were sighted on our plans.

264. Those relationships were largely about trust. For example, when we agreed that the Department for Business, Energy and Industrial Strategy would act as lead purchaser it was done trusting that Wales would get its fair share: the formal agreements came later. It was necessary given the scale and urgency of the challenge to operate in that manner.

265. I was aware that officials were discussing the vaccine roll-out in the four nations with each other. I was clear that the focus in Wales should be on delivery and efficiency and believe officials proactively offered to share what we were doing with officials from the other nations (so that we might learn from one another's experiences about what we were doing well, and how obstacles could be overcome). I am aware that there were, for example, specific conversations about the delivery of the vaccine to rural communities held between my officials and those in Scotland and Northern Ireland.

Vaccine safety

266. I did not have a formal role in the post-approval monitoring of Covid-19 therapeutics.

267. The Welsh Government took steps to encourage yellow card reporting for Covid-19 therapeutics ensuring information on safety monitoring and reporting was included in all clinical policies relating to therapeutics and patient information leaflets. That said, however, from a public messaging perspective I felt it was important that the Welsh Government reacted to issues around safety. Accordingly, where there were concerns about vaccine safety, I would receive advice and updates usually via the Chief Pharmaceutical Officer.

268. I was clear that vaccination was fundamentally about balancing risk. There were some challenges by the spring of 2021 as the real risk posed by Covid-19 had started to be forgotten. I asked for messaging to put the risks into context, such as comparisons between the vaccine and air travel, for example. There was and is much greater prospect of harm from air travel compared to being vaccinated.

The Vaccine Damage Payment Scheme

269. The vaccine damage payments are a matter reserved to the UK Government. As such, it would be more appropriate for others to address questions about this aspect of Module 4 in detail.

Therapeutics

270. All decisions about eligibility for therapeutics were taken at the UK level and based both on evidence from clinical trials and the advice of the independent advisory group tasked with identifying which patient groups were at the highest risk of serious illness from Covid-19 and would benefit most from new treatments. The independent advisory group's recommendations were considered by the Covid-19 Therapeutics Clinical Review Panel made up of senior clinicians from all four UK nations including Dr James Coulson Clinical Director of the All-Wales Therapeutics and Toxicology Centre who was nominated by the Chief Medical Officer. The panel provided advice to the four UK Chief Medical Officers on the definition and revision of eligible cohorts for new Covid-19 therapeutics. All clinical policies were developed on a UK wide basis, agreed by officials from devolved governments and finally approved for publication by the four UK Chief Medical Officers.

Informal communications

271. I have addressed informal communications in my statements to the Covid-19 Public Inquiry in Module 2B. I have been asked specifically to address some WhatsApp exchanges in the context of Module 4.

272. In an exchange dated 21 February 2021 between the four nations Health Ministers, exhibit **M4/VG/163- INQ000095819** refers, I made a comment at 12:01pm which reads, "You know what my view is". The comment is made following the then Secretary of State for Health and Social Care, Matt Hancock's appearance on the Andrew Marr Show, during which he refers to early data figures. The exchange starts with the then Scottish Cabinet Secretary for Health, Jeane Freeman asking Matt Hancock why numbers from the Vaccine Taskforce were delayed being shared with the four nations and stating, "If we are moving on a 4N basis that leaves us behind in terms of confirmation given you've just given dated on Marr". This was a frustration shared by all devolved Health Ministers, where England would make early announcements on four nations issue. My comment reflected my frustration on this issue and in this instance, Matt Hancock had done a media round before the Vaccine Taskforce figures were provided to the devolved nations.

273. In an exchange dated 6 January 2021 between the Welsh Ministers, exhibit **M4/VG/148 - INQ000316403_0068** refers, I said "I should alert you to a UK Labour and TUC press release tomorrow launching in the Mirror a Vaccinate Britain campaign. It will of course not have quite the same impact given the staggering events in the USA. Vaccinate

Britain is very much designed for England. We have not been involved or endorsed it. It asks elected reps to promote getting vaccinated when it's their turn to do so and combatting anti-vaxxers. A key ask is also for millions of people to come forward and support the vaccination programme. That isn't the approach we are taking in Wales. We are accelerating primary care involvement and delivery. We have contacted Wales TUC and TULO unions and will pick up again tomorrow". I said this because we were taking a different approach in Wales, we did not need an army of volunteers as they were inviting in England because we were accelerating primary care involvement and ensuring delivery with a strategic approach as set out in our national vaccination strategy which was published on 11 January 2021 and to which I refer above. The USA reference was a reference to the storming of the United States Capitol Building in Washington on 6 January 2021.

Lesson Learning

274. With the benefit of hindsight, I remain of the view that supporting the UK Vaccine Taskforce and its procurement exercise is one area where the UK Government deserves credit.

275. The main challenge faced, which will inevitably be faced again with similar challenges in future, is dealing with disinformation. This was a novel virus and a novel vaccine and so it was inevitable that there would be initial hesitancy, but dealing with disinformation and misinformation was a real challenge.

276. It also became apparent that there were large numbers of healthcare staff, for example, who did not wish to be vaccinated.

277. Research has been undertaken on how to improve communication with certain communities and with young people. Mainstream news channels are trusted by a large proportion of the population, but those under the age of 30 are less likely to watch them. Making sure that accurate and informative communications can reach all sections of society is key. It became increasingly clear to me that the most significant matter underpinning any successful communication strategy was trust. I consider that in Wales, as a government, we managed to maintain a high level of trust for a significant period of time which, in turn, led to a successful messaging strategy for the vast majority of the public.

278. I believe one of the advantages we had which benefited the approach taken during the pandemic was the good relationships with trusted figures in local communities and groups. The very good relationships that the Welsh Government had with primary care, community venues and local government were real assets to the vaccine roll out programme.

279. The balance to be struck between diverting primary care away from its ordinary role to delivering the vaccine was a delicate one to strike. Ultimately, enabling society to return to some form of normality sooner than it otherwise would have by driving the vaccine programme was an effective use of resources.

280. I would also highlight the vaccine roll out as a particular example of where we found the right balance between the UK Government's role in providing oversight over, and procuring, vaccine supplies, with the Welsh Government's responsibility for organising the delivery of vaccines to our local population based on their needs.

281. The particular challenges of developing and deploying a vaccine for a novel virus drove innovation within the field. I remain firmly of the view that those innovations ought to be encouraged and further developed. It would be disappointing if the structures which enabled this level of innovation were now to be dismantled. In the event of a similar pandemic arising again in the future it would be far better to build on the structures and processes we developed in these most challenging circumstances, as opposed to having to re-invent them.

282. I consider we strived to adopt a pragmatic and efficient approach at every stage of the vaccine delivery process. That meant adopting an inclusive view of the Joint Committee on Vaccination and Immunisation's priority list and using the operational flexibility that we and the NHS had, in Wales, to reach as many people as we could, so that "no one is left behind". The efficiency of the approach at a planning level drove and facilitated operational efficiency at the point of delivery to the public, to minimise waste and optimise the use of the vaccines supplied. As explained in the corporate statements steps were taken, for example, to try to ensure each vial of Pfizer BioNTech vaccine yielded six doses of vaccine.

283. The vaccine programme was an overwhelming success story for the people of Wales, enabling the country to return to 'operational normality'. I am proud that the efforts and dedication of so many led to Wales being one of the first countries in the world to begin

protecting people against Covid-19, and that by 9 March 2021, one million people had received a vaccination, with a higher percentage of population vaccinated in Wales than in the other three nations. Shortly after this, it was reported that Wales had the third highest vaccination rate globally, behind the UAE and Israel. By 2 July 2021, all remaining adults had been offered a vaccination. As of 1 June 2022, according to a recent report in The Lancet dated 15 January 2024, exhibited at **M4/VG/164 INQ000410152**, the number of people under vaccinated in Wales (32.8%) was significantly lower than in the other three nations (49.8%, 45.8% and 34.2%).

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

Vaughan Gething M.S.

Dated: 18/07/2024