Witness Name: Wei Shen Lim

Statement No.: 3

Exhibits: WSL3/1 - WSL3/ 28

Dated: 31/10/2024

**UK COVID-19 INQUIRY**

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**THIRD WITNESS STATEMENT OF WEI SHEN LIM**

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

1. I make this third statement in response to a request for a supplementary statement under Rule 9 of the Inquiry Rules 2006, received from the UK COVID-19 Public Inquiry ("the Inquiry") dated 12 September 2024. This statement addresses matters which I understand are in scope of Module 4 of the Inquiry, including public messaging and safety; AstraZeneca and Thrombosis with Thrombocytopenia Syndrome (TTS) and vaccine dosage intervals.

**Information provided to the public about COVID-19 vaccines**

2. I have been asked to provide the Joint Committee on Vaccination and Immunisation's (JCVI) view on whether the public messaging about the COVID-19 vaccines adequately reflected the risks of vaccination. As stated in paragraph 115 of my Second Witness Statement (Second Statement), the JCVI does not have a specified role in relation to public messaging over and above its transparency requirements.

3. The JCVI is not directly responsible for, nor is it resourced to develop and deliver public messaging about immunisation programmes. Such communication activities are carried out by UKHSA and deployment teams such as NHSE. It is also not the role of JCVI to review and measure the adequacy of public messaging by other agencies.

4. The role of JCVI is to advise UK health departments, with advice being provided to the Secretary of State. In order to fulfil the JCVI's transparency requirements, aid dissemination of information, and promote public trust, JCVI makes its advice public through the publication of meeting minutes and statements. During the pandemic, the JCVI focused efforts on the rapid publication of JCVI advice statements, complemented by public media engagements, such as by providing interviews on radio and television.

5. While JCVI does not review the breadth of public messaging formats used in support of immunisation programmes, public messaging regarding vaccination takes many forms and should be appropriate to the situation. For example, different people may require information in different formats and for any one individual it may be appropriate to provide different levels of information in different forms. Local deployment teams may therefore tailor public messaging to match the needs of local communities.

6. My personal belief is that, in general, adequate information was provided regarding COVID-19 vaccination over the course of the pandemic. While it is highly likely that more could have been done at any one time over any one issue or for different listeners, this is subject to the availability of appropriate resources, including time and expertise. A communications expert may be better placed to comment on specific examples.

7. As to the precise information about vaccines provided to the public, I have been asked whether this should include both relative and absolute risk statistics and an explanation of those concepts. Ideally, it would be good to do so. This is true not only for vaccines, but in general for almost all clinical interventions. All clinical interventions involve a consideration of potential benefits and risks, including an understanding of relative and absolute risks and benefits.

8. However, it should also be noted that in practice, it can sometimes be difficult to obtain robust data on absolute and relative risks that are specifically related to a population group of interest as data may only be available from different studies that are not directly comparable. Some interpretation may therefore be required when bringing together results from different studies.

**AstraZeneca and Thrombosis with Thrombocytopenia Syndrome (TTS)**

9. I am asked to explain why UK and regulatory advisory bodies including JCVI took action after some European states, regulators and health authorities in response to the TTS safety signal and the AstraZeneca vaccine. I am also asked to consider whether the UK should have suspended use of the AstraZeneca vaccine on a precautionary basis in early to mid-

March 2021. In my response, I first provide scientific and factual context which was relevant to the response to the TTS safety signal. I then explain JCVI's response with reference to the meetings where the relevant decisions were taken.

Responding to a vaccine safety signal in the context of COVID-19

10. In general terms, during the early part of the pandemic, the timing of advice regarding vaccination in any country was influenced by numerous factors, including: the scale and speed (epidemiology) of COVID-19 disease in the country at the time; vaccine supply; vaccine deployment strategy and the stage of vaccine roll-out.

11. When a potential vaccine safety signal is suspected, there are a number of factors to consider. This includes determining, firstly, whether there is a true safety concern and how common (or rare) the concern (the absolute risk) is and secondly, whether the safety concern is restricted to a single vaccine product and/or to a particular group of individuals, such as older or younger people. This is because indiscriminate labelling of 'all vaccines' as being equally implicated and 'all people' being at equal risk of potential harm could result in an unjustified loss in vaccine confidence.

12. JCVI first received in-depth information from the MHRA regarding the potential safety signal of Thrombosis and Thrombocytopenia Syndrome (TTS) on 18 March 2021. This was in the early part of the pandemic when population immunity against SARS-CoV-2 was low and Phase 1 of the vaccination programme continued to be rolled out (Phase 1 broadly covered adults aged 50 years and over, and younger adults with underlying health conditions that put them at specific risk from COVID-19). This meant that those receiving the vaccine in this period were people deemed at higher risk of severe COVID-19. The JCVI was also in the process of finalising its advice on Phase 2 of the vaccine programme.

13. The pace of vaccination across the population was therefore an important consideration at this time. A presentation given by UKHSA on 18 March 2021 highlighted the high uptake of dose 1 in adults over 60 years of age, a lower uptake of dose 1 in adults 50 to 60 years of age, and very few second doses in all adults **WSL3/1** – **INQ000512907 (dhsc006:04767766)**. A delay to vaccination would mean more people experiencing severe COVID-19 and therefore being hospitalised or dying because of more people being left unprotected for longer. Contemporaneous data show that on 18 March 2021, hospital admission rates were highest in adults over 40 years of age **WSL3/2** – **INQ000512906** **(dhsc006:04767767))**. Inappropriately pausing or delaying the vaccination programme therefore held potentially harmful public health consequences.

14. The UK vaccination programme relied on two main COVID-19 vaccines at this stage: the Pfizer-BioNTech mRNA vaccine and the AstraZeneca COVID-19 vaccine.

15. Below I discuss the 13-day period between 18 March 2021 and 1 April 2021, with a focus on those dates as well as on 25 March 2021. These dates are significant because they are when the relevant JCVI Committee or Sub-Committee meetings took place. They encapsulate key discussions concerning the TTS safety signal which JCVI was involved in and demonstrate the subsequent development of JCVI's advice on Phase 1 and Phase 2 of the vaccination programme. Throughout this period, many specialists and agencies worked closely together to provide a clearer understanding of the nature of the safety signal to inform the response.

16. It is in this context and setting that JCVI provided their advice.

JCVI response to the TTS safety signal

17. At the 25 February 2021 JCVI COVID-19 Sub-Committee meeting, MHRA highlighted a potential safety signal for immune thrombocytopenia (ITP) following the AstraZeneca vaccine, noting that the reports at this stage were close to the signal threshold and were being monitored closely. The MHRA stated that papers on the safety issue matter would be shared with JCVI after having been presented to the Commission on Human Medicines (CHM) **WSL3/3 – INQ000354487_0005).** The MHRA did not raise papers regarding this potential signal at the subsequent JCVI COVID-19 Sub-Committee meetings on 4 March 2021 and 11 March 2021, or at the JCVI COVID-19 Committee meeting on 16 March 2021 **(WSL3/4 - INQ000354489; WSL3/5 – INQ000354490; WSL3/6 – INQ000354491).**

18. The 16 March 2021 JCVI Committee meeting minutes record that I (as Chair) asked the MHRA *"…if there were any urgent safety updates about the recently reported thrombotic events following vaccination".* MHRA's response noted that *"there would be a CHM expert working group meeting later in the day. MHRA was continuing to work with European and international colleagues and to share any data. In the UK there had only been a very small number of reports of potential thrombotic events"* **WSL3/6 – INQ000354491_0002).**

19. The meeting minutes also record that "*Members highlighted the importance of being informed of any potential safety signals and would value receiving updates on data from other countries as well*" (**WSL3/6 – INQ000354491_0003).**

20. The TTS safety signal was next discussed by the JCVI on 18 March 2021, as discussed at paragraph 22 below. The minutes of each of the subsequent nine meetings capture the

Committee's discussion of the safety signal and identify the information available to the Committee at the time of each meeting. The minutes have been provided to the Inquiry and extracts from the minutes are discussed throughout my explanation **WSL3/7** - **INQ000354492**; **WSL3/8** - **INQ000354493**; **WSL3/9** - **INQ000354496**; **WSL3/10** - **INQ000354495**; **WSL3/11** - **INQ000354497**; **WSL3/12** - **INQ000354499**; **WSL3/13** - **INQ000354501**; **WSL3/14** **INQ000354502**; **WSL3/15** - **INQ000354504**).[1]

JCVI COVID-19 Committee meeting: 18 March 2021 (18 March meeting)

21. MHRA informed JCVI at the 18 March meeting that it was reviewing reports of adverse events following COVID-19 vaccines involving a low blood cell line (low platelet count, or thrombocytopenia) and increased blood clotting (thromboembolic events). This followed the suspension of the AstraZeneca vaccine in some European countries by their respective health authorities, based on some reported fatal thromboembolic events. The minutes of the meeting state:

    7) "*The MHRA and European Medicines Agency (EMA) respectively maintained the position that the benefits of the vaccine continued to outweigh the known risks although investigations were ongoing.*

    8) *The previous day an expert working group (EWG) of the Commission on Human Medicines (CHM) COVID-19 had been convened. This had included a haematologist to provide expert input into discussions.*

    9) *The investigations so far had concluded that there was no indication of an increased risk of thromboembolic events or of thrombocytopenia following the AZ vaccine. This was based on multiple epidemiological sources, including from EMA, from MHRA and from PHE.*

    10) *No increased risk was indicated with either of the COVID-19 vaccines in use at the time, however, MHRA and EMA were aware of a cluster of reports of unusual thromboembolic events in the cerebral veins combined with thrombocytopenia following first doses of the AZ vaccine, in the UK and Europe. MHRA were conducting further investigations into the reports.*

    [...]

[1] The dates of the relevant JCVI COVID-19 Committee/Sub-Committee meetings were as follows: 18 March 2021, 25 March 2021, 1 April 2021 (morning and afternoon), 6 April 2021, 13 April 2021, 22 April 2021, 29 April 2021, 6 May 2021.

15) *MHRA indicated that there was in the UK an age clustering in younger patients and that the time window after vaccination was typically around one week. The potential mechanism was being considered by haematologists.*

[…]

18) *MHRA indicated that communications would be developed that day, reflecting the EMA (European Medicines Agency) discussions. MHRA would consider, for inclusion in communications, what symptoms to look out for. The benefit/risk, particularly in younger people, would be kept under review"* **WSL3/7 - INQ000354492)**.

22. In particular, at the meeting JCVI also "*noted that there had been no advice from MHRA, so far, to pause the current Phase 1 [vaccination] programme"* **WSL3/7 - INQ000354492_0005)**.

23. The MHRA's position would be reflected by an MHRA statement issued on the same day, following the meeting (**WSL3/16 - INQ000408457**).

24. JCVI therefore agreed at the meeting that it was appropriate to continue with Phase 1 of the programme "*but to review on a very regular basis,"* and that *"the Committee would not change the approach until there was more evidence that would lead them to do so, and that it was important to be transparent about any potential risks"* **WSL3/7 - INQ000354492_0005)**. The following points were made with respect to particular groups identified below who were eligible for vaccination at Phase 1 of the programme:

27) *"Younger people with underlying health conditions - It was noted that in those eligible in Phase 1 below the age of 65 years with underlying health conditions, the benefit/risk was in favour of vaccination, because of their higher risk of COVID-19 hospitalisation and mortality.*

28) *Healthcare workers – it was noted that the personal risk to hospital-based healthcare workers was now lower than it had been early in the pandemic as the rate of infection in hospitals was lower"* **WSL3/7 - INQ000354492_0005).**

25. With respect to Phase 2 of the vaccination programme, it is important to note that JCVI had not yet issued its final advice for healthy persons aged 18 to 49 years at the time of the 18 March meeting. As stated in paragraph 93 of my Second Statement, advice on Phase 2 of the programme was only finalised on 13 April 2021.

26. The JCVI responded to the TTS signal at the 18 March meeting by agreeing to "*hold off making a final Phase 2 statement until the MHRA could clarify the safety signal*" **WSL3/7 - INQ000354492**). This in effect paused the roll-out of the vaccination programme to those aged less than 50 years old without clinical risk factors.

JCVI COVID-19 Sub-Committee meeting: 25 March 2021 (25 March meeting)

27. At the 25 March meeting, MHRA updated JCVI on the latest position from the CHM COVID-19 Vaccine Benefit Risk Expert Working Group (EWG) regarding reports of thrombosis with concurrent thrombocytopenia which were reported following COVID-19 vaccination. The minutes of the meeting record as follows:

> 21) *"EWG had agreed that there was insufficient evidence to establish a causal association with the AstraZeneca vaccine. While a number of cases had been seen, they were extremely rare […]*
>
> *22) EWG concluded that more communication was required regarding this condition, which was difficult to treat and that non-standard treatment protocols were required. A call for reporting through the Yellow Card scheme was to be undertaken. A proforma had been developed for follow up of Yellow Cards reporting suspected cases […]*
>
> […]
>
> *27) Members asked around timings for further MHRA communications activity. It was noted that this was being determined in discussion with CHM, but no dates had been set.*
>
> […]
>
> 30) *Members agreed that age specific incidence should be regularly reported to the Committee to inform the development of advice on use of COVID-19 vaccines.*
>
> […]
>
> 37) *Members considered that JCVI as an independent body should review the data regularly, although it was noted that MHRA were the experts in analysing the data and had access to more detailed information. It was considered that five questions needed to be answered by MHRA:*
>
> - *Will MHRA advice be put out on the syndrome and treatment options?*

- *Can an MHRA view on the risk-benefit of vaccination in those under 30 and under 50 years of age be provided?*
- *Can MHRA provide a view on the risk-benefit of vaccination in pregnant women?*
- *Can MHRA provide an assessment of the risk associated with the second dose?*
- *Can MHRA provide a view on whether this is an AstraZeneca or platform-specific issue?*

38) *Members also considered that it would be important to understand whether this was a unique clinical syndrome. It was considered very important for communications on the syndrome and current understanding of appropriate treatment.*

39) *It was considered important to consider the use of AstraZeneca vaccine in health and social care workers.*

40) *It was agreed that the questions would be taken forward by MHRA, CMH and EWG. MHRA representatives indicated that the questions could be considered by EWG at its next meeting. It was noted that robust epidemiological data would take time to accrue"* **WSL3/8 - INQ000354493_0004**).

28. As discussed at paragraph 13 above, a critical factor for the UK during this time period was the pace of roll-out of the vaccination programme. This issue was discussed at the 25 March meeting, the minutes of which state:

43) *"The timing of 'completion' of Phase 1 necessitating a need to move into Phase 2, which would involve vaccination of healthy younger adults, made it vital to get further evidence considered as soon as possible to support the development of advice. Phase 2 advice was still being developed, and it was considered important that this was not delayed. The need to consolidate delivery in Phase 1 populations before moving into Phase 2 was considered. Vaccine supply, and activity in maximising delivery of second doses in Phase 1 populations was noted. Any advice published should, as always, state that the advice would be kept under review as more data became available.*

44) *Members agreed it was important to publish advice on Phase 2 as soon as the advice was developed. Any advice would, as always, be conditional on continued evidence of favourable risk-benefit and vaccine supply.*

45) *Members agreed that the benefits of vaccination with the AstraZeneca vaccine clearly outweighed any risks in Phase 1 populations. It was also considered that the benefits of vaccination with the AstraZeneca vaccine outweighed the risks in healthy adults over the age of 40 years. Careful consideration would need to be given to the risk-benefit in healthy younger adults. Premature signalling of concerns could cause damage to the programme"* **WSL3/8 - INQ000354493).**

JCVI COVID-19 Sub-Committee meetings: 1 April 2021

29. Three meetings relevant to the JCVI's response to the TTS safety signal took place on 1 April 2021. JCVI held two COVID-19 Sub-Committee meetings: a morning meeting at 0800 hours (1 April morning meeting); and an afternoon meeting at 1600 hours (1 April afternoon meeting). The afternoon meeting followed a meeting of the MHRA EWG. Following these meetings, JCVI advised that Phase 2 of the vaccination programme should only be rolled-out to people aged 40 – 50 years until yet more information was available.

30. At the 1 April morning meeting, the MHRA provided an update to JCVI from the COVID-19 Vaccine Benefit-Risk EWG meeting that had taken place the previous day. JCVI was informed that:

15) *[…] "The EWG considered that causality could not be established at present due to the lack of a biological mechanism, however an association was still plausible. The EWG recommendation was being considered by the CHM"* (**WSL3/9 - INQ000354496_0004**).

31. Overall, JCVI considered that the data presented at the 1 April morning meeting "*strengthened the signal for AZ vaccine in younger people, compared to the Pfizer vaccine".* This differentiation of risk according to vaccine product and age was important (**WSL3/9 - INQ000354496_0005**).

32. I have provided other important points from the meeting, as recorded in the minutes below, with points I wish to draw to the Inquiry's attention in bold format:

42) *"The Chair stated that the CHM and MHRA would be releasing information about the AZ vaccine safety signal following their meeting. The Chair stressed that*

*information on risk/benefit should be given to the public immediately so they could make an informed decision.*

43) *The committee discussed potential ways to proceed with Phase 2 of the vaccination programme following their review of the safety data.*

44) *The committee was very clear that any communications needed to be transparent. The committee recognised the importance of maintaining the public's trust.*

45) *The committee considered the risk/benefit analysis and agreed that there was clear evidence the programme needed to continue in terms of overall risk/benefit.*

[…]

48) *The committee was confident that in the 40-50-year age group the risk/benefit was in favour of vaccination, including with the AZ vaccine. In those between the age of 20-30 years, there was the most concern; the benefits in that age group were heterogeneous. Those in the 30-40 years age group were the most difficult because of lack of information.*

49) ***The committee agreed to continue the AZ vaccination programme down to the 40-50 age group of Phase 2. The committee agreed that the best way to proceed was to continuously review new information, specifically before starting the offer of vaccine to each age group. This would be discussed with DHSC and NHSE. It was important that the benefits and risks be presented to the public so they could make an informed choice.***

50) *The committee considered the vaccination programme for those aged below 40 in phase 1. This consisted of four groups: those under age 40 years in priority groups 4 or 6; those under age 40 years that were health and social care workers, including unpaid carers, who were at increased risk due to exposure; those that had already had a first dose; those under age 40 years who were household contacts of immunocompromised individuals.*

51) *For people under age 40 years in priority groups 4 or 6, it had previously been estimated that their risk from COVID-19 was similar to someone aged 65 years. The committee agreed that the risk/benefit analysis was in favour of continuing to offer the AZ vaccine to this group because of their risk from COVID-19.*

52) *For health and social care workers under age 40 years in Phase 1 who had not yet had a vaccine the committee agreed that they should continue to be offered the AZ vaccine due to their higher occupational risk and because they have a duty of care issue. It was noted that the effect on transmission was an important consideration in this group.*

[…]

54) *Members queried how the* ***risk/benefit information would be given to the public as it was important for informed consent****. The Chair stated that PHE had prepared information that would be distributed after the MHRA released information about the AZ vaccine safety signal.*

55) *For people under the age of 40 years who were household contacts of immunocompromised individuals the committee agreed that they should continue to be offered the AZ vaccine. It was noted that these individuals were being vaccinated for the benefit of someone else* ***therefore the risk/benefit would need to be very clear for them, as they were not personally at risk.***

[…]

58) *The committee discussed what communications were required immediately and agreed this was dependent on the outcome of the MHRA meeting [which was to take place later the same day]. However, the committee felt that, notwithstanding the MHRA statement, it would be important to release a JCVI statement which stated the committee had considered the current risk/benefit ratio and there was a strong balance in favour of vaccination; the committee was aware of the situation abroad and would continue to review the available data on a regular basis.*

59) *The Chair stated that a letter would be sent to DHSC to describe* ***the current JCVI intent that Phase 2 should continue to those 40-50 years of age but that Phase 2 in those under the age of 40 years should proceed by age band, when the committee had received further data****"* (**WSL3/9** - **INQ000354496_0007**).

33. JCVI re-convened for the 1 April afternoon meeting at 1600 hours, following the MHRA EWG meeting already referred to. Key points from the minutes of the afternoon meeting are as follows, with points I wish to draw to the Inquiry's attention in bold format:

*"II. Update on external meetings about Astra Zeneca vaccine safety*

4) *CHM meeting - The Chair updated the committee on the CHM meeting he had observed. Similar to the JCVI discussion earlier in the day, CHM agreed that openness and transparency were critical, and that risk and benefit should be expressed in an age stratified manner. CHM also felt that information needed to be given to people being vaccinated. CHM had agreed to continue to review the data to determine if an age cut-off for vaccination with AstraZeneca (AZ) vaccine was necessary.*

5) *Meeting with the CMO and other health officials - The Chair updated the committee on a meeting he attended with the Chief Medical Officer, the Medicines and Healthcare products Regulatory Agency (MHRA), the Department of Health and Social Care (DHSC), Public Health England (PHE), and NHSE.*

6) *The Chair reassured the committee that he had made it clear that the JCVI would like information to be released to the public as soon as possible.*

7) *There had been discussion about making a statement at the start of a Bank Holiday weekend and the legal requirement for MHRA to inform the manufacturer prior to MHRA making any major statements.*

8) *It was therefore agreed in the meeting between the CMO and health officials that the best time to release a statement was after the Bank Holiday.*

9) *The MHRA had indicated that they planned to include information about the ongoing review of the situation as part of the regular weekly Coronavirus ADR reports going forward.*

*Discussion*

10) *Although the committee voiced concern about waiting until after the Bank Holiday weekend to make a formal public statement, it was recognised that patient information leaflets about risk/benefit could not be updated nor would PHE be able to release updates to leaflets to coincide with any statement. It was recognised that although the desire behind rapidly issuing an independent statement was to be transparent, it could do more damage than good if it was released in an uncoordinated way, without any supporting patient information material.*

11) *PHE indicated they would communicate with NHSE about updating their website to include information about blood clots.*

12) *After further reflection and discussion, the committee agreed that although openness and transparency were the aim of a JCVI statement and they would have preferred to release one as soon as possible, they understood the difficulties in doing so and having taken advice from PHE communications, agreed it was better to release information at the same time as MHRA with the proper support systems in place.*

13) ***The committee agreed that the Chair should write to DHSC to inform of the discussions they had and how important they felt it was that patient information be released in a timely way.***

14) *The committee agreed that a clear communications strategy was needed for over the weekend if members were approached by the media.*

15) *DHSC commented, as an observer, that it was crucial for JCVI to maintain their independence and if the committee chose to release a statement, it should do so without hindrance. DHSC recognised the time and effort that the committee had put into this discussion and supported the Chair writing to DHSC to indicate that the committee had arrived at a position"* (WSL3/10 - **INQ000354495_**0003).

Concluding remarks on the JCVI's response to the TTS safety signal

34. JCVI's response to the TTS safety signal was to adapt the timing and contents of advice on the roll-out of the vaccination programme based on the data available and as understanding of the risks presented by TTS associated with the AstraZeneca vaccine developed.

35. In particular, on 18 March 2021 JCVI held back finalising its advice on Phase 2 of the vaccination programme which in effect paused the roll-out of COVID-19 vaccines to those aged less than 50 years old without clinical risk factors: the broad group which would be assessed on 1 April 2021 to be at higher risk from TTS associated with the AstraZeneca vaccine. Then, on 1 April 2021, JCVI advised that Phase 2 of the vaccination programme should only be rolled-out to people aged 40 – 50 years old and not to those below that age until more information was available. This reflected the JCVI's assessment by that date that the risk/benefit balance of AstraZeneca vaccination in the former age group remained in favour of vaccination, whilst for those under 40 years of age there was more uncertainty in the size of the risk. This was to be coupled with updated information being made publicly available to allow those eligible for vaccination under the programme roll-out to give their informed consent before receiving a vaccine.

36. The JCVI's 18 March 2021 decision to not suspend roll-out of Phase 1 of the vaccination programme but to hold back finalising advice on Phase 2 sought to balance competing risks and had two key outcomes.

37. Firstly, by not prematurely suspending Phase 1 of the programme, those persons at higher risk of severe COVID-19 could continue to receive vaccination to protect themselves against severe illness, whilst also reducing the likelihood of an unjustified loss of vaccine confidence in the wider COVID-19 vaccine programme. Secondly, the decision to postpone the finalisation of advice for Phase 2 of the programme underlined the seriousness with which the Committee considered the early cluster of reports of TTS events in younger people notwithstanding the fact an increased risk associated with the AstraZeneca vaccine had not yet been determined. This prevented the AstraZeneca vaccine from being administered to those younger people for whom there was greater concern over the risk/benefit balance based on those early reports, *if* an increased risk was to be *later* found.

38. The close cooperation between specialists and agencies, including JCVI, MHRA and CHM from 18 March to 1 April 2021 enabled JCVI to issue more informed and effective advice on 1 April 2021, and therefore to balance the range of factors informing these decisions discussed in paragraphs 10-16 above.

39. The advice as provided was possible in the UK because of the level of control in the roll-out of the vaccination programme in the UK alongside strong surveillance systems. Without such controls and systems, cruder response strategies may have been required in mid-March 2021 such as pausing the entire vaccination programme. Such strategies could have resulted in other harms arising due to greater loss of vaccine confidence, lower vaccine uptake and greater delays to the roll-out of vaccines to those most likely to benefit from them.

**JCVI letter to Secretary of State: 1 April 2021**

40. I have been asked to explain the circumstances which led to JCVI writing the letter to the Secretary of State on 1 April 2021 (**WSL3/17** - **INQ000416156**). The circumstances which led to this have been discussed in some detail above. On the afternoon of 1 April, after much deliberation, the JCVI agreed that I would write as JCVI COVID-19 Chair to DHSC to inform the Government of the JCVI's discussions and how important the Committee felt it was that patient information was released in a timely way (**WSL3/10** - **INQ000354495_0003**). I provide additional comment as follows.

41. The view of JCVI was that the available information was sufficient to indicate a safety concern of TTS with respect to the AZ vaccine in younger people, as agreed with MHRA. In addition, the UK's vaccination programme was beginning to reach those people assessed to be most likely to be affected by this safety concern. Hence, JCVI's advice to the Government was that clear information should be communicated to the public *as soon as possible* to enable their informed consideration of the offer of COVID-19 vaccination.

42. DHSC did not seek to hinder JCVI issuing an independent statement of its own on 1 April 2021 (as stated at paragraph 15 of the April 1 afternoon meeting minutes set out at paragraph 33 above). JCVI recognised that for any public communication regarding TTS, clarity and consistency would be extremely important.

43. In particular, it was important for public communications to guard against any mistaken viewpoints taking hold, such as one that erroneously implicated *all* individuals as being at increased risk of potential harm from *all* COVID-19 vaccines. Dissemination of such an inaccurate viewpoint could have resulted in reduced uptake of the vaccine amongst those individuals at higher risk of severe COVID-19, resulting in increased public health harm. To mitigate against the risks arising from ineffective or potentially harmful public communications, JCVI agreed that its communication of advice regarding TTS would be best conducted in concert with MHRA, with the support of UKHSA and DHSC.

44. As I have explained and as stated in paragraph 10 of the 1 April afternoon meeting minutes set out at paragraph 33 above, JCVI is neither responsible nor resourced to develop and/or deliver large-scale public communications on its own. With a four-day Easter bank holiday taking place between 2 April 2021 to 5 April 2021, only the Government possessed the necessary resources and agencies to deliver an effective strategic communications exercise following JCVI's letter to the Secretary of State on 1 April 2021. The letter's purpose was, as stated in the meeting minutes and in the letter, to strongly urge action in "*a timely manner*" **WSL3/10** - **INQ000354495_0003**); (**WSL3/17** - **INQ000416156_0001**).

45. The Secretary of State's response on 2 April 2021 stated agreement with JCVI's view that individuals offered the vaccine should be informed of the benefits and risks in a timely manner. The letter also stated agreement, following advice from the Chief Medical Officers and others, that a rushed or incomplete public message before 6 April 2021 could cause confusion and undermine public confidence **WSL3/18** - **INQ000416158_0001**).

Communicating information to the public on risks associated with vaccines

46. I am asked to provide my view on the appropriateness of the length of time taken by the relevant UK bodies to convey information to the public about the risks associated with the AstraZeneca vaccine. I have described above the circumstances relating to the TTS signal which led to the JCVI's position in the 1 April 2021 letter that clear information should be communicated on the risks associated with the AstraZeneca vaccine as soon as possible. I have also described that it was essential that public communications relating to the TTS signal needed to be clear and consistent to safeguard against the risks of public health harm which could arise from ineffective communications.

47. My personal view is that the publication of information on 7 April 2021 by JCVI and MHRA in a coordinated manner, with a press conference also held, was preferable to a staggered approach to communications for the reasons I have stated. This is the case even if an uncoordinated approach may have allowed information to be published a small number of days earlier (**WSL3/19** - **INQ000354498**; **WSL3/20** - **INQ000408453**).

Lessons Learned

48. I am asked to comment on lessons learned and improvements which may be made for the future in a response to a safety signal. The JCVI's response to the TTS safety signal reiterated the necessity for clear, strong, honest communication, and demonstrated that such communication is paramount when responding to a public health emergency. In many situations when an unexpected and novel safety signal is first suspected, there will be a relative paucity of data. Consequently, the level of scientific uncertainty is often high in the initial stages. In highly dynamic situations, the pace of change in information and level of scientific uncertainty may also be high. These factors are important to consider with respect to the type and timing of any initial, and subsequent, responses.

49. In order to maintain public trust, the way in which we communicate different levels of uncertainty and the implications that arise from them is critical. Equally, pre-existing levels of trust influence how any communication about uncertainty is understood. As technological advances increase the available modes of public communication and their complexity, the skills and resources required to enable effective communication of safety signals will also increase.

50. For improvements to be realised in the future, building levels of public trust in the present is vital. This should be accompanied by adequate incremental improvements in skills and resources related to the communication of science, uncertainty, and policy.

**Vaccine dosage intervals**

51. I am asked to provide information in connection with the increased interval between doses of the Pfizer-BioNTech vaccine.

52. I am asked to clarify any agreement reached between Pfizer and JCVI in connection with the update to the Summary of Product Characteristics (SPC) on 30 December 2020 which reflected a change in information for healthcare providers on the interval between doses of the Pfizer-BioNTech vaccine as published by MHRA (**WSL3/25** – **INQ000512908 (dhsc006:04767765)**). JCVI did not have any direct communication with Pfizer in relation to this. In addition, there was no direct communication between JCVI and Pfizer on the extension of the dosage interval up to 12 weeks. The JCVI therefore holds no information relating to Pfizer's views on the interval extension at that time. The information provided in paragraph 85 of my Second Statement was provided to aid the Inquiry's contextual understanding of the events at the relevant time.

53. As I have stated in paragraph 81 of my Second Statement, JCVI has a long history of advising alternative schedules for vaccines used in routine programmes. The JCVI's publication of advice on 30 December 2020 on prioritisation of the first vaccine dose over the second, together with advice an extension of the dose interval to enable first dose prioritisation was an example of that practice. The advice from JCVI was formulated *before* the MHRA updated the SPC (**WSL3/22** - **INQ000256950)**. I was made aware of discussions which had taken place between MHRA and Pfizer in connection with the SPC update through informal conversations at a later date. JCVI does not discuss changes to the SPC with vaccine manufacturers.

54. I have also been asked to provide information on the advice or input the JCVI received from MHRA following their review of the SPC. JCVI's prioritisation advice was separate to and formulated *before* the MHRA's SPC update. It was not the result of advice or input from the MHRA. JCVI's decision to extend the dose interval was a result of careful analysis of the data JCVI had seen and the substantial public health benefit that JCVI considered could be achieved by prioritising the first dose.

55. In support of the above, I now provide an overview of the JCVI's decision making process which led to the JCVI's prioritisation advice.

JCVI Committee meeting: 30 November 2020 (30 November meeting)

56. JCVI first discussed the possibility of a single dose or delayed second dose schedule at the 30 November meeting. This arose in the context of potential vaccine supply delays. Clinical trial results had suggested high vaccine efficacy after the first dose of the Pfizer-BioNTech vaccine, and modelling suggested that an extended interval could double the number of people vaccinated with one dose in the short term. However, suggesting a single dose or delayed schedule would have required off-label advice which, as I have mentioned at paragraph 84 of my Second Statement, could not be pursued due to the status of the Pfizer-BioNTech vaccine's authorisation under Regulation 174. Due to this and the epidemiology at the time, it was agreed the advice should remain as a two-dose schedule but that the statement could include a comment on the efficacy of a single dose (**WSL3/23** - **INQ000354458_0005**).

JCVI Sub-Committee meeting: 22 December 2020 (22 December meeting)

57. JCVI further discussed the possibility of extending the interval between the first and second doses at the 22 December meeting. Data available from both AstraZeneca and Pfizer-BioNTech suggested a good level of protection was achieved following the first dose. In particular, the AstraZeneca clinical trials had included different dose intervals which had shown that there was a better immune response with an extended interval of 12 weeks than was seen with a shorter interval. This was not surprising as it followed first principles of vaccine immunology and our experience with many different vaccines; generally, a longer period between a primary dose and a booster dose will generate a better response to the booster **WSL3/24** - **INQ000354462_0007**).

58. At this time, the Alpha variant (also referred to as the Kent variant) had emerged and there were high rates of infection. The vaccine supply situation was such that vaccine deployment capacity was greater than vaccine supply. It was therefore agreed that the first dose should be prioritised to vaccinate a greater number of vulnerable people in a shorter space of time **WSL3/24** **INQ000354462_0008**).

59. In respect of both the AstraZeneca and Pfizer-BioNTech vaccines, JCVI agreed that the dose interval could be extended up to 12 weeks as there was no strong reason to believe that the reasoning supporting an extended dose interval would be substantially different between the vaccines **WSL3/24** - **INQ000354462_0007**).

JCVI Joint Committee meeting: 29 December 2020 (29 December meeting)

60. At the 29 December meeting, we were informed that the MHRA would be authorising the AstraZeneca vaccine under Regulation 174 to be announced to the market the following day. I had been provided with a draft of the SPC that was due to be released the next morning. We noted its wording which included that the interval between doses in the AstraZeneca vaccine trials ranged from 4 to 26 weeks. The Committee confirmed its advice for both the Pfizer-BioNTech and AstraZeneca vaccines that priority should be given to the first dose, with an interval of up to 12 weeks between the first and second doses. We agreed on the wording to be included in the JCVI's prioritisation advice (**WSL3/21** – **INQ000413715** **dhsc006:04767768**; **WSL3/26** - **INQ000354468_0007**).

61. On 30 December 2020, JCVI's prioritisation advice was published and based on the JCVI's expert advice, the four Chief Medical Officers issued a press release regarding prioritisation of the first vaccine dose and increasing the dose interval schedule to 12 weeks. On 31 December 2020 JCVI published a further short statement containing more information regarding first dose prioritisation and allowing for a dose interval of 12 weeks between the first and second doses for both Pfizer-BioNTech and AstraZeneca vaccines (**WSL3/22** - **INQ000256950**; **WSL3/27** - **INQ000399450** **WSL3/28** - **INQ000305157**.

**Statement of Truth**

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

**Signed**: **Personal Data** _____

**Dated**: 31/10/2024_____