COOMBE WOMEN AND INFANTS UNIVERSITY HOSPITAL
COVID 19 VACCINATION PROGRAMME EXTERNAL REVIEW
REPORT OF BRIAN KENNEDY S.C., 22 MARCH 2021

INTRODUCTION AND PROCESS

1. A subcommittee ("*the Subcommittee*") of the Board of the Coombe Women and Infants University Hospital ("*the Hospital*") engaged me to carry out a review into the Covid-19 Vaccination Programme at the Hospital. This is the report of my review, which I have carried out pursuant to Terms of Reference, dated 26th January, 2021, which are attached as **Appendix 1** to this report. I was assisted in my review by A&L Goodbody Solicitors.

2. The Terms of Reference require me in this report to outline the review process followed, set out a summary of the factual information gathered and make findings of fact having regard to the scope of the review.

3. As regards the review process followed, I was provided with the Terms of Reference on 27th January, 2021 and received two folders of relevant documents from the Hospital on 29th January, 2021. Following an initial review of those documents, I arranged a series of interviews with relevant individuals, the first of which occurred on 5th February, 2021.

4. Between 5th February, 2021 and 16th February, 2021 I interviewed nineteen individuals and received further documents from a number of sources to review. I then arranged four further interviews with relevant individuals, which took place between 26th February, 2021 and 5th March, 2021. I prepared a draft report which was sent on 10th March, 2021, in whole or in part, with appropriate redactions, to twelve individuals, seeking their comments on or before 16th March, 2021. I considered the comments received and forwarded a revised draft report to the Subcommittee on 18th March, 2021, for its review pursuant to Clause 3.2 of the

Terms of Reference. Following receipt of two requests for clarification from the Subcommittee on 19th March, 2021, I forwarded a revised draft to the Subcommittee on 22nd March, 2021 and a final version on the same date, following confirmation that there were no further matters to be addressed.

5. I received full co-operation at all times from every individual with whom I dealt at every stage of the process.

6. I set out below my summary of the factual information gathered, together with findings of fact made having regard to the scope of the review, before summarising my conclusions, where appropriate, in relation to the key themes identified at paragraph 1.3 of the Terms of Reference.

BACKGROUND TO THE VACCINATION PROGRAMME

7. In the course of the month of December, 2020, the possibility of the vaccination of front-line medical staff in the State against the Covid 19 virus came increasingly into focus. Initially, it was anticipated that those hospitals receiving Covid 19 patients directly would have their staff vaccinated before the Hospital. Coombe Managerial / Administrative Staff B anticipated that Hospital staff might have to go to St. James's Hospital or somewhere similar to be vaccinated.

8. The first time that Consultant C had occasion to consider the issue in any detail was on the 24th December, 2020, when Consultant C had an informal conversation with HSE Employee A. Consultant C and HSE Employee A discussed the question of when staff in hospitals providing maternity services might be vaccinated and agreed to keep in touch.

9. It first became clear that Covid 19 vaccinations would take place at the Hospital itself on Saturday, 2nd January, 2021. Consultant C was contacted by DMHG Employee B, who asked whether the Hospital would be in a position to offer a vaccination programme. Consultant C readily agreed and turned their mind as to how such a programme would be managed.

10. It bears emphasis that within six days of this discussion, a complete vaccination programme was conceived, put in place and carried out which resulted in the successful administration of the first dose of vaccine within that period to almost 1,100 people, with the last eighteen vaccinated on the following Monday.

11. This required a range of measures to be planned and executed, including identifying and training relevant staff, identifying and setting up the physical locations for the programme, putting a process in place and making arrangements for the reception, storage, handling and dilution of the vaccine by the pharmacy staff. Furthermore, this was all done in a pandemic, with a significant number of staff absent either with Covid-19 symptoms or self-isolating and without a functioning IT system to assist with the process. At the same time, the normal functions of the Hospital had to continue.

Relevant Guidance

12. On the evening of 2nd January, 2021, DMHG Employee C who was one of the Vaccination Leads within the DMHG, forwarded an email with a number of attachments to Consultant C, which had been prepared by the HSE to assist with establishment of new vaccination sites.

13. Of relevance to this review is the first attachment, entitled "*Template for Vaccination Plan for Healthcare Workers for Covid 19 in Large Scale Healthcare*

Facilities" ("*Template for Vaccination Plan*"), which was apparently prepared by the HSE. Appendix 2 to the Template for Vaccination Plan, which I have attached as **Appendix 2** to this Report, contained a draft suggested prioritisation of healthcare workers for vaccination in the context of limited supply. It was silent as to what was to be done in the event that any vaccines were left over at the end of a vaccination.

14. Another attachment of relevance is the HSE's "*Clinical Guidance for Covid-19 Vaccination, Version 1.0*" ("*the Clinical Guidance*") dated 28th December, 2020. This is an evolving document and the most recent published version at time of writing appears to be Version 10.1, which was published on 12th March, 2021.

15. Version 1.0 of the Clinical Guidance identified a series of vaccine priority groups. Frontline healthcare workers in direct patient contact roles or who risk exposure to bodily fluids or aerosols were the second priority group identified, behind residents of long term care facilities over the age of sixty five. Other healthcare workers not in direct patient contact were the fourth priority group, behind those aged over seventy.

16. Version 1.0 of the Clinical Guidance went on to refer in Section 3 to the Comirnaty (Pfizer / BioNTech) vaccine, which is the vaccine which was administered in the Hospital leading to this review. It referred to the fact that the vaccine had been authorized for use in the European Union following a positive scientific recommendation by the European Medicines Agency on 21st December, 2020. The vaccine was to be diluted with a 0.9% sodium chloride solution and administered in doses of 0.3 ml. Each vial of the vaccine contained 0.45 ml, to which 1.8 ml of the sodium chloride solution was to be added.

17. Paragraph 3.1 of the Clinical Guidance stated, consistent with the then licensing position, that there would be five doses in each vial. It stated that there would be excess in the vial after five doses had been withdrawn but that the vial must be discarded.

18. Paragraph 3.3 of the Clinical Guidance referred to the limited shelf life of the vaccine of 120 hours following removal from an ultra-cold temperature freezer. It also stated that once diluted, the vaccine must be used within six hours and that when that time was reached, any unused or partially used diluted vials must be discarded.

19. Appendix 2 to the Clinical Guidance was entitled "*Management of Comirnaty (Pfizer / BioNTech) COVID-19 Vaccine, Guidance at Local Hubs*". It stated that after dilution the vaccine should be used as soon as practically possible and within six hours. It referred to the dilution of the vaccine and to the fact that there would be up to 0.75 ml of overage, which it stated must be discarded.

20. Similar statements were contained in a diagram in Appendix 2, entitled "*Process Flow 2: Overview of the Vaccine Pathways during Vaccination Sessions*". In particular, it stated that unused or partially used vials must not be returned to the fridge and that all remaining liquid in the vial must be discarded in the vial into a sharps bin.

21. Of those involved in the discussions on the evening of Friday 8th January to which I refer further below, Consultant C and Coombe Managerial / Administrative Staff B had received Appendix 2 to the Template for Vaccination Plan or of the Clinical Guidance. Of the others, while some were aware, in a general way, of the existence of guidance, none were aware of the terms of Appendix 2 to the Template for Vaccination Plan or of the Clinical Guidance.

22. The reference to five doses per vial was consistent with the relevant statutory instrument authorising the supply and administration of the Comirnaty vaccine then in force, S.I. No. 698/2020, Medicinal Products (Prescription and Control of

Supply) (Amendment) (No. 7) Regulations, 2020, which were signed by the Minister for Health on 24th December, 2020. The Regulations stated that one vial of the vaccine contained five doses of 0.3 ml after dilution.

23. Accordingly, while there had been discussion in other jurisdictions about the possibility of obtaining more than five doses per vial, the regulatory position which initially prevailed in Ireland was that only five doses were to be obtained per vial and that any remaining liquid was to be discarded.

24. From the evening of Saturday 2nd January onwards, Consultant C was keen to identify the number of staff who might be vaccinated as well as a team of vaccinators. The team was identified by Consultant C and others over the weekend and on Monday 4th January, based in part on those who had acted as peer vaccinators in relation to the Hospital's flu vaccination programme, supplemented with a number of additional consultants. The relevant individuals carried out further HSE online training specific to the administration of the Covid 19 vaccine. In total, there were eleven vaccinators, although only five or six were vaccinating at any one time.

MONDAY AND TUESDAY, 4-5 JANUARY

25. Over the course of the weekend, Consultant C also spoke with Coombe Managerial / Administrative Staff B about the proposed vaccination programme. Consultant C forwarded the email from DMHG Employee C and attachments to Coombe Managerial / Administrative Staff B on Monday morning.

26. On Monday morning, a call took place involving DMHG representatives and Consultant C in which it was confirmed that the Hospital was going to receive vaccines that week. It was still unclear how many vaccines would be received or when that would occur, although it was understood that vaccinations would take place from Wednesday to Friday.

27. Coombe Managerial / Administrative Staff B initially commenced preparing a database of potentially relevant staff but on realising that employees had to opt-in and request a vaccination, Coombe Managerial / Administrative Staff B arranged instead for an e-mail to be sent to all staff at 11:58 a.m. on Monday, indicating that vaccinations would take place from Wednesday to Friday.

28. The email indicated that this first phase of the vaccination programme was for "*frontline healthcare workers*", which was described as any staff member who had contact with patients for their daily work. Staff were invited to submit a request to be vaccinated, along with contact details and other relevant information. A dedicated email address (*email address removed*) was set up for these requests, which defaulted to the email address of Coombe Managerial / Administrative Staff A.

29. At the outset, Coombe Managerial / Administrative Staff B had estimated that there were approx. 1,100 staff in the Hospital who were eligible for vaccination. Ultimately, some 1,106 vaccines were administered at the Hospital, although as is detailed further below, not all of these were to Hospital staff.

30. Later on Monday, Coombe Managerial / Administrative Staff B queried with DMHG Employee B whether a lab person handling swabs would be considered a frontline worker. DMHG Employee B responded expressing a view that they did fall into the category and attaching an updated version of the Template for Vaccination Plan, which included a revised version of Appendix 2 to the Template.

31. This document, appended to this report as **Appendix 3**, set out a more refined prioritisation explanation, which appears to have been signed off on by HSE Employee B and HSE Employee C on 27th December, 2020. It contained no guidance as to what might be done if vaccines were left over at the end of a vaccination, although, as noted above, the earlier Clinical Guidance Version 1.0 had stated that left over vaccines were to be discarded.

32. On Monday it was decided that the Education Centre in the Hospital would be used as the vaccination hub. By Tuesday, the flow patterns for the vaccination process were considered and the centre was set up prior to start of vaccination on Wednesday afternoon.

33. Four rooms in the Education Centre were used for vaccination– one for the pharmacists, who were given the task of diluting the vaccines, and three others for the three phases of the vaccination process. A series of diagrams showing a mock-up of the three rooms is attached as **Appendix 4**.

34. The three stages of the vaccination process can be summarised as follows. First, individuals underwent a consent/registration process, which was carried out manually, with data subsequently being uploaded by the Hospital's administrative staff on to the HSE's Covax software system (described further below), a time consuming process which continued into the following week. Consent and registration forms were provided by the individuals and they were then asked a series of questions prior to vaccination to ensure suitability to receive the vaccine.

35. The second stage was the physical administration of the vaccine by the vaccinators. Six stations were set out in the Rita Kelly room of the Education Centre. The stations were set up in a manner which both ensured social distancing and provided a degree of privacy for those being vaccinated.

36. The third stage was an observation/recovery phase, during which an individual who had been vaccinated was in a recovery room and monitored for fifteen minutes or so by a junior anaesthetist.

37. Clinical Staff Member A, a clinical staff member who *duties removed*, was given the task of co-ordinating the vaccination process. This role included co-ordinating the peer vaccinators and assisting with setting up the rooms for vaccination and other logistical matters.

38. Separately, the Hospital's pharmacy staff had to make arrangements within the same very short time period for the reception, storage and handling of the vaccine, which was not straightforward, as well as for the carrying out of the dilution of the vaccine. The pharmacists also had to undertake online training.

39. Coombe Managerial / Administrative Staff B reviewed the lists of individuals who responded to the email and requested a vaccine and examined whether they were frontline workers. The frontline workers were placed on a list on a spreadsheet.

40. A difficulty which persisted over the course of the week was the absence of a functioning software system to manage the vaccination process. The Hospital does not have an existing human resources IT system which could assist and a specific software package for the administration of the vaccine, Covax, which the HSE had developed in conjunction with IBM and Salesforce, was not ready when the vaccinations took place. I understand that under the Covax system, a party wishing to obtain a vaccine sends an e-mail to an address and receives an e-mail back which allows him or her to register on a national system. When the individual attends to obtain a vaccination, his or her details are on the system, which facilitates the vaccination process.

41. As noted above, the absence of such a system meant that registration had to be carried out manually with hard copy documents taken from those being vaccinated and data subsequently uploaded. It also meant that staff had to be contacted on an individual basis by text message to inform them of their vaccination time, a cumbersome and time consuming process. Furthermore, as referred to further below, this meant that the Hospital did not have clear information at various times as to the precise number of front line staff still requiring vaccination.

42. In a subsequent letter to Consultant C and to the CEO's / General Managers of other hospitals of 2nd February, 2021, DMHG Employee D, stated that the beginning of the vaccination programme had been "*…an enormous logistical challenge particularly with developing ICT for the initial week or so*."

WEDNESDAY 6 JANUARY

43. 93 vials of the Comirnaty vaccine arrived at the Hospital on Wednesday morning. The Hospital had only been informed of the precise number late on Tuesday afternoon. The relevant equipment for vaccinating (consumables, such as needles, syringes etc.) arrived separately that morning.

44. The vaccination centre was set up in the Education Centre as detailed above and, after the vaccinators had themselves been vaccinated (which also enabled them to give the process a trial run), staff vaccinations commenced on Wednesday at 2:00 p.m.. Coombe Managerial / Administrative Staff A had prepared a list of those to be vaccinated in conjunction with Coombe Managerial / Administrative Staff B, who checked that those who were listed to ensure that they met the criteria for vaccination, and individuals were texted individually and asked to attend at thirty minute intervals.

45. As detailed above, prior to the vaccination process commencing, the Hospital was proceeding on the basis that, consistent with the regulatory position, five doses would be obtained from each vial. However, the regulatory position had changed in that on Monday 4th January, 2021, the Minister for Health had signed SI No. 2/2021, Medicinal Products (Prescription and Control of Supply) (Amendment)

Regulations, 2021. This statutory instrument amended SI 698/2000 by deleting the reference to five doses per vial of Comirnaty.

46. It appears that the pharmacy department of the Hospital was made aware of this on the previous evening but Consultant C indicated that they first became aware of the change on Wednesday afternoon at 2:25 p.m., when DMHG Employee B e-mailed Consultant C and Coombe Managerial / Administrative Staff B, attaching a letter from the HSE dated 6th December, 2021 (presumably intended to be a reference to 6th January, 2021) which referred to SI 2/2021 and to advice from the National Immunisation Advisory Committee, dated 4th January, 2021, recommending that when a vaccinator could withdraw a sixth dose from the vial, that could be used as a viable dose in the vaccination programme. The letter stated that the implementation of a sixth dose from each vial could take effect immediately.

47. This information was passed on to the vaccinators and they were able to take a sixth dose, and in some limited cases, a seventh dose, thereafter.

48. The vaccination process proceeded successfully on the Wednesday, continuing until the early evening. A total of 51 vials were used and approximately 300 people were vaccinated, 298 Hospital staff and *2 external persons who were present and assisting with the process*, an average of approximately 5.88 doses per vial.

49. The success in obtaining almost six doses per vial was due to a number of factors. Vaccinators had special syringes which minimised the "dead space" when drawing vaccines and ensured that only 0.3 ml, and not a greater amount, was drawn. A number of the vaccinators also pointed to the fact that they double checked with another vaccinator each time to ensure that the correct amount was being drawn as a factor which reduced wastage.

50. At certain stages on Wednesday, in particular where the vaccination centre was quieter, individuals who were due to be vaccinated later in the week attended and received vaccines. At least some of these individuals had initially been informed by email on Tuesday that they would be vaccinated on Wednesday. However, due

to the time at which the vaccines and the equipment arrived, the process only started on Wednesday afternoon, with the consequence that it was not possible for the Hospital to vaccinate as many on Wednesday as had been initially anticipated. Consequently, these individuals were ultimately not scheduled to be vaccinated on Wednesday and had not been sent text messages for that date. It appears that some of these individuals did not appreciate that they were no longer scheduled for Wednesday, attended and in some cases were vaccinated.

51. This, coupled with the lack of a real time picture of the precise number vaccinated, resulted in a position on Friday where more of the relevant staff had been vaccinated (perhaps 20 to 30) than was understood. An e-mail was sent by Coombe Managerial / Administrative Staff A to all staff at 4:48 p.m. on Wednesday, emphasising that vaccination was by appointment only and that staff should not arrive for a vaccination unless notified by text to arrive.

52. One of the issues which I was asked to consider was whether there was any "remnant" vaccine on Wednesday evening. I understand the term remnant vaccine to refer to doses which were left over after a vial was opened and once there were no more individuals waiting to receive a vaccine.

53. The evidence is that there were no remnant vaccines on Wednesday evening. By way of explanation, the vaccination programme was continuing into Thursday with the balance of the initial 93 vials being left over to be used on the following day. It was possible to draw a halt to the vaccination process so that all diluted vials were used in full. The dilution of vaccines was slowed down towards the end of the process so that at the time when it concluded there were no opened vials with remnant vaccine.

54. The possible vaccination of local GP's was a matter which Coombe Managerial / Administrative Staff B first discussed with the DMHG on Tuesday or Wednesday. From Wednesday, Coombe Managerial / Administrative Staff B was in contact with an External General Practice, a GP practice separate from the Hospital which rents space from the Hospital, through its Practice Manager, External General Practice Manager. It was proposed that GP's within that practice would be vaccinated if sufficient vaccines were obtained.

55. Coombe Managerial / Administrative Staff B also engaged with GP's who ran evening clinics in the Hospital, through the Lead General Practitioner, with a view to getting their details for vaccination. Aside from these GP's, the Hospital intended, if enough vaccinations were obtained, to vaccinate local GP's more generally.

THURSDAY 7 JANUARY

56. Vaccinations continued on Thursday. Following discussions with Coombe Managerial / Administrative Staff B, Coombe Managerial / Administrative Staff A sent texts on Wednesday evening to those who were to be vaccinated with relevant times. When they attended for vaccination on Thursday (and Friday), they were required to show the text message received.

57. Ongoing efforts were also made during Thursday to encourage those staff who had not yet taken up the opportunity to be vaccinated to do so.

58. While it was hoped that further vials would arrive on Thursday, it transpired in the course of Thursday morning that they would not arrive until Friday. Accordingly, once the remaining vials were used up, the vaccination concluded at approximately 2:30-3:00 p.m.

59. On Thursday 41 vials were used and approximately 234 people were vaccinated,

an average of approximately 5.71 doses per vial. One vial of the original 93 had to be discarded due to excess pressure in the vial when the sodium chloride solution was added which led to the needle popping out and the loss of an unknown volume of the solution.

60. Again, there was no issue in relation to remnant vaccines, in circumstances where all available vials were used on Thursday. At that stage, it was understood that further vials would arrive on Friday morning, but it was unclear precisely how many would be received.

61. That afternoon, Coombe Managerial / Administrative Staff B spoke by telephone with DMHG Employee A, *title within DMHG removed*, and indicated that the Hospital would offer 25 vaccines to GP's- 20 to the *name of clinic removed*, which I understand to be a reference to the External General Practice, and five to the GP's who supported the evening clinic in the Hospital. These GP's had already been asked by Coombe Managerial / Administrative Staff B to provide their details. At 5:02 p.m., DMHG Employee A e-mailed Coombe Managerial / Administrative Staff B, referring to the telephone conversation and stating that the DMHG would welcome it if there was an opportunity for the Hospital to support additional local GP's / community staff over the coming days with an allocation of 60-80 vaccines.

TCD Medical Students

62. Separately, on Thursday, External Clinical Academic, *title removed*, at University A, contacted Consultant C and Consultant D, *title removed*, by email in relation to the possibility of vaccinating University A medical students.

63. While it appears from External Clinical Academic's e-mail that HSE Employee D, had expressed the view at one point that medical students should be vaccinated alongside frontline healthcare workers, no such guidance had been given to the Hospital and the guidance which had been received did not reflect this. Furthermore, the medical students were viewed as relatively low priority for

vaccination from the Hospital's perspective, given their limited amount of direct contact with patients.

64. Consultant D has explained (and Consultant C and Coombe Managerial / Administrative Staff B agree) that while Consultant D acted as a peer vaccinator during the week, Consultant D was absent from work during much of the week, *personal information removed*, and consequently Consultant D did not review this e-mail until the following week.

65. In their e-mail, External Clinical Academic asked whether, if sufficient supplies were available, University A fourth year medical students who would be on placement at the Hospital at the relevant time would be vaccinated. Consultant C responded by e-mail the same day at 10:44 a.m.. Consultant C indicated that as the Hospital had been asked to vaccinate local GP's as well as its staff, their sense was that there would not enough vaccines but that the Hospital was happy to facilitate students if at all possible. A template was provided to External Clinical Academic for completion by the students and, following an IT issue, those details were provided to the Hospital on Friday at approx. 12:30 p.m..

66. It appears that the University A medical students were told by University A, including by Consultant E, who is *title removed*, that they should be on standby in case any excess vaccine was available to them. Consultant C, Coombe Managerial / Administrative Staff B and Consultant D, who were present on the Friday evening, were not aware on Friday evening of the fact that any University A medical students were standing by.

FRIDAY, 8TH JANUARY, 2021- DAY

67. While vaccines were scheduled to arrive on Friday morning, at the start of the day it was unclear precisely when they would arrive. While Hospital staff had been prepared to work on Saturday, the aim was to administer all doses on Friday if

possible. Thirty Hospital staff had been scheduled to attend every half hour up to 12:30 p.m., with additional appointments to be sent once there was confirmation of the receipt of the vaccine and the number of vials. Ongoing efforts were being made to ensure that all frontline staff in the Hospital were identified and offered a vaccine where possible and requests for vaccination continued to come in. As noted above, by this time, the Hospital had already committed to vaccinating 25 local GP's connected with the Hospital and the DMHG had requested it to make further vaccines available to local GP's / community healthcare staff.

68. The Hospital only had complete certainty as to the number of vials which would be available when 95 vials arrived at the Hospital before 10 a.m., implying that 570 doses would be available if six doses were obtained from each vial. Ultimately, 572 doses were obtained from the vials, 92 of which were used on Friday and the last three on the following Monday.

69. Following confirmation of the number of vials available, further text messages were then sent out to Hospital staff providing for appointments up to 4:30 p.m., while a separate list of GP's was prepared for 5:00 p.m. onwards.

70. At 9.49 a.m., DMHG Employee A e-mailed Community Healthcare Employee A and Community Healthcare Employee B, both of Community Healthcare, Dublin South, Kildare and West Wicklow ("*CHO7*"). DMHG Employee A indicated that the Hospital had 40 vaccine slots available that evening between 6 p.m. and 8 p.m. for additional GP's. CHO7 was requested to send appropriate data for the 40 GP's, intended to be from the local catchment area, who would avail of these slots. These slots were in addition to the 25 slots which had already been committed by the Hospital to local GP's.

71. Arrangements were made, in particular with Community Healthcare Employee B, *title within CHO7 removed*, to facilitate the vaccination of this group. Community Healthcare Employee B indicated that CHO7 would provide data for the 40 GP's. At least one of the additional local GP's vaccinated was not in fact on the list but was accommodated following a representation to Consultant C.

72. At 12:30 p.m., a Zoom video conference meeting took place of a Covid 19 Vaccination Steering Group made up of representatives of DMHG, CHO7, CHO8 and NAS (National Ambulance Service). Coombe Managerial / Administrative Staff B and DMHG Employee A were among those present on the call, and Consultant C joined for the later part of the call. I am informed that during this call, annoyance and frustration was articulated on behalf of frontline healthcare staff working in CHO7, CHO8 and NAS concerning the non-availability of vaccines and the absence of a clear plan for them. These groups were looking to the Hospital and other hospitals for assistance with their vaccination.

73. At the same time, the precise requirements of the Hospital in relation to vaccines were becoming clearer due to a better understanding of the precise number of people left to vaccinate and the likely number of doses to be obtained from each vial.

74. Arising out of this, Coombe Managerial / Administrative Staff B e-mailed DMHG Employee A at 2:39 p.m. stating that the Hospital seemed to be getting six vaccines per vial in the main which had increased the capacity to vaccinate, and believed it could do another 120 vaccinations between 7:00 p.m. and 8:30 p.m. that evening in addition to the 40 agreed earlier.

75. It bears emphasis that while the Hospital had been getting just under six doses per vial on the two previous days, and that in that sense, it was not a surprise that six doses per vial were being obtained, the fact that this ratio was being maintained on Friday, coupled with the increasing understanding as to the number of Hospital staff still to be vaccinated, gave Coombe Managerial / Administrative Staff B and Consultant C confidence that it should be possible to administer additional vaccines.

76. In an interview, Coombe Managerial / Administrative Staff B emphasised that this was a best estimate which they made in calculating the likely number which could be accommodated, as opposed to a number of vaccines which would be available

as a matter of certainty. It also appears that the position on the ground had changed in the sense that as more Hospital staff had been vaccinated on the Wednesday than had previously been appreciated, correspondingly fewer Hospital staff remained to be vaccinated on the Friday afternoon.

77. Various communications then followed, principally between DMHG Employee A, Community Healthcare Employee B and Community Healthcare Employee C, *title within CHO7 removed*, in which they set up arrangements for the arrival of 120 further individuals.

78. At 3:30 p.m., HSE Employee E, *title within HSE removed*, forwarded details of the 40 GP's who would be arriving between 6 p.m. and 8 p.m..

FRIDAY, 8TH JANUARY, 2021- EVENING

79. That evening, exclusively Hospital staff were vaccinated until sometime around 5 p.m. and thereafter GP's, and subsequently HSE/CHO7/CHO8 staff were vaccinated. There was not a precise division between the groups, which overlapped somewhat, and some Hospital staff continued to be vaccinated throughout the evening.

80. At the relevant times that evening, the principal individuals were present at the vaccination centre:

- Consultant C;
- Coombe Managerial / Administrative Staff B;

- Clinical Staff Member A, who was co-ordinating the vaccinators;
- Consultant A, who was vaccinating;
- Consultant B, who was vaccinating;
- Consultant D, who was vaccinating;
- Clinical Staff Member E, who was vaccinating;
- Clinical Staff Member D, who was vaccinating;
- Clinical Staff Member B, who was vaccinating;
- Clinical Staff Member G, who was making up vaccines from vials;
- Clinical Staff Member H, who was making up vaccines from vials;
- Clinical Staff Member C, who was at the stage 1 registration/consent station;
- Clinical Staff Member F, , who was involved in the stage 3 recovery / observation process.

81. Coombe Managerial / Administrative Staff B spent a considerable time period outside in the carpark, assisting in managing the flow of individuals who arrived. It was a very cold evening and a large queue developed outside at different stages. It was an extremely busy evening for those involved in the vaccination process.

82. The first group who attended were GP's and thereafter, other healthcare workers from HSE/CHO7/CHO8 arrived. Due to the limited time periods involved, the 120 individuals were not identified by CHO7 to the Hospital prior to their arrival. They apparently received text messages and phone calls and arrived on foot of those. It appears that some other frontline healthcare workers, who were not contacted directly by CHO7, may have arrived at the Hospital, having been informed by other frontline healthcare workers, and were vaccinated.

83. Coombe Managerial / Administrative Staff B indicated that formal identification was not sought from those who arrived but that Coombe Managerial / Administrative Staff B engaged in discussions with them to give a sense as to who they were. Coombe Managerial / Administrative Staff B's initial concern was more to martial people, so as to ensure that no one was injured and that appropriate queuing was maintained, as the queue was blocking the entrance/exit to the adjoining staff car parking area where cars were entering/exiting. On arrival at the registration station, stage 1 of the process, the individuals had to fill out registration and consent forms but there was no list against which to check the names of the other healthcare workers.

84. Over the course of the evening, further efforts were made to ensure that Hospital staff who were entitled to a vaccine were vaccinated. At approximately 7:00 p.m., Coombe Managerial / Administrative Staff B visited the main part of the Hospital and at approximately 8:20 p.m., Coombe Managerial / Administrative Staff B went to get a midwife who had earlier started to queue but had left in order to commence a shift at 8:00 p.m. in order to ensure that she was vaccinated, which she was.

85. Up to about 8:30 p.m. or so there was a consistent queue and Coombe Managerial / Administrative Staff B was concerned with the possibility of vaccines running out and individuals being left without vaccines. Vials were being prepared on an ongoing basis, with a view, inter alia, to ensuring that the vaccination process continued efficiently.

86. However, the queue thinned out very quickly shortly after 8:30 p.m., which was unanticipated. As those who were being vaccinated at this point in time were not Hospital staff, and their details had not been provided to the Hospital in advance, it had not been clear precisely how many would arrive. When Clinical Staff Member G saw the queue beginning to ease, Clinical Staff Member G held off on diluting vials but the drop off in attendance was such that there were remnant vaccines in a number of diluted vials.

87. When the queue thinned out, Coombe Managerial / Administrative Staff B

and Consultant C went back to the main part of the Hospital and between them went through the different floors, in order to ensure that as many eligible staff as possible were identified and obtained vaccines. In addition, telephone calls were made to wards to identify possible additional staff. While Coombe Managerial / Administrative Staff B did not come across any additional staff for vaccination, Consultant C identified two additional staff, a student midwife and a receptionist, who attended and obtained vaccinations.

88. I am informed by the Hospital that one medical student from University A was scheduled to be present in the Delivery Suite that evening from 8.30 p.m. onwards. No medical student from University B or University C was scheduled to be there. When Consultant C and Coombe Managerial / Administrative Staff B went through the main Hospital building that evening in order to identify potential candidates for vaccination, the Delivery Suite, which is on the second floor, was one of the areas which Consultant C went to. Consultant C did not come across the medical student but indicated that had they done so, the medical student would have been vaccinated. Coombe Managerial / Administrative Staff B did not understand there to be any medical students present at the time.

Conversation in the Vaccination Area

89. Around this time, a conversation began in the central area of the main hall where the vaccinations were being carried out. The six vaccinators who had been vaccinating at the time, Consultant A, Consultant B, Consultant D, Clinical Staff Member D, Clinical Staff Member E and Clinical Staff Member B (Clinical Staff Member B stated that they were only present for part of the conversation as they had finished vaccinating subsequent to the others) were all involved in the conversation, having come out from the stations at which they were vaccinating. Clinical Staff Member A was also involved, as were Clinical Staff Member G, Clinical Staff Member H (Clinical Staff Member H stated that they missed the first part of the conversation), Consultant C and Coombe Managerial / Administrative Staff B.

90. Coombe Managerial / Administrative Staff B stated in an interview that they did not participate in all of the conversation and that they considered the issue to be mainly a matter for the clinicians present. However, some of those present considered Coombe Managerial / Administrative Staff B, as a member of senior management, to be an important participant.

91. Neither Clinical Staff Member C, who was at the registration / consent area, nor Clinical Staff Member F, who was at the observation / recovery area, had any involvement in this conversation.

92. I have interviewed all of the participants in the conversation. All of them had incomplete recollections of the conversation and the precise versions of events given by them, while generally consistent, do not tally in every respect. This is unsurprising, having regard inter alia to the relatively informal and somewhat brief nature of the conversation. I have endeavoured to reconcile the various accounts of the conversation, although, as I indicate below, I have not been able to reach a definitive conclusion on every aspect of that conversation and subsequent events.

93. Initially, when the individuals began discussing the situation, there was a general expression of satisfaction at the fact that, after a very long week, the vaccination process had been completed successfully and that, despite the various obstacles faced, a large number of Hospital staff and other frontline healthcare workers had been vaccinated. A number of the individuals emphasised to me that, as a group, they were also extremely tired at this stage- most had worked long days all week, including the Friday, with few breaks. This fatigue appears to have impacted on the conversation and decisions made.

94. At some point in time, the topic of conversation switched to the fact that a number of doses remained. Efforts were made to ascertain precisely how many doses remained, by estimating the number of doses left in each vial. At some point, it was estimated that there were sixteen doses available, although ultimately it appears that nineteen doses were administered after 9:00 p.m., which was the approximate time of the conversation.

95. The view was articulated, possibly initially by Consultant C, that the remnant doses should be used rather than wasted, a view which was held generally and very strongly by the group. While, as detailed above, the guidance in place at the time (and, of the group present, only Consultant C and Coombe Managerial / Administrative Staff B were aware of the terms of the guidance) appeared to contemplate that remnant vaccine would be discarded, shortly afterwards that guidance changed (see further below) and the guidance which now prevails is that no dose should be wasted.

Options Available

96. As regards the options available, the vaccines had to be used by 2:30 a.m. at the latest. There was no standby list in place (and no guidance at the time which suggested having such a list). There was no software system in place which enabled potential recipients to be readily identified.

97. There was some discussion around potential options for use of the remnant vaccines. The general understanding was that the options had been exhausted.

98. In response to a query during the conversation as to whether there were other eligible staff in the Hospital who might avail of the vaccine, Consultant C stated that a number of efforts had been made to identify any eligible personnel in the Hospital and that there were no further individuals present. It was also observed that through the interaction with CHO7 earlier in the day which had resulted in GP's and other frontline HSE staff attending that evening, efforts had been made to identify GP's and other frontline HSE staff, and it appeared that no further staff were going to attend that evening.

99. There may have been a reference in that context to the possibility of making contact with the HSE (most of those who were present did not refer to this and I cannot express a concluded view on this point) but if this was raised, the possibility was discounted. Aside from anything else, the point was made to me in interviews

that it would have been unclear how or to whom contact would have been made at that time of the evening.

100. While Consultant C did not state it to the group at the time, Consultant C stated in an interview that they gave thought at the time to the possibility of seeking to get candidates from the nearest Garda Station or Fire Station. Consultant C indicated that they were concerned about consent procedures that would apply, as well as a lack of knowledge of medical history. They also had a concern as to whether medical legal cover would be available. That being so, Consultant C did not raise the possibility with the group.

101. One of the issues which I have been asked to consider is the options and information available in terms of identifying other potential recipients and the efforts made on the evening to explore those options. I do not understand that any options other than those referred to above were explored or discussed by the Group.

102. While it does not appear to have been expressly discussed, it appears that the understanding of many (but not all) of those present that evening was that it was not possible to transport the vaccine outside of the Hospital. This understanding was consistent with the information which had been given to vaccinators, considered further below. The understanding that it was not possible to transport the vaccine from the Hospital obviously limited potential options.

103. There was no consideration or discussion that evening of the possibility of vaccinating medical students. As detailed above, the Hospital (and, in particular, Consultant C and Coombe Managerial / Administrative Staff B) were not aware of the fact that University A medical students had been told to be on standby. Consultant C indicated in an interview that had there been a small number of medical students present on the evening, they would have been vaccinated. Both Coombe Managerial / Administrative Staff B and Consultant C stated in interviews that they did not consider medical students to be a high priority in the Hospital's vaccination process.

104. Similarly, no consideration was given to the possibility of trying to bring forward the vaccination of those due to be vaccinated on Monday. Consultant C made the point in an interview that there was no list of those individuals to hand and that it was not clear at that point to what extent incoming junior doctors would have already been vaccinated at their previous place of employment.

105. There was also no discussion about the possibility of attempting to identify frontline healthcare workers from other hospitals who had not been vaccinated and asking them to come to the Hospital to be vaccinated. When this possibility was put to Consultant C in an interview, Consultant C expressed the view that they doubted that there would be anyone easily identifiable and considered the option to be an unrealistic one. The point was also made that other hospitals had their own vaccination programmes.

106. As regards the possibility of consulting more broadly with the DMHG or with other colleagues, again, this is not a matter which was considered. Consultant C expressed the view in an interview that the group had a degree of expertise that was sufficient to discuss and decide the issue.

Vaccination of Family Members

107. At some stage in the conversation, the possibility of using the remnant vaccines to vaccinate family members was raised. It was not possible to establish who first raised this possibility from interviews with those present but it may be that the first reference was by one individual to the fact that another individual had an elderly family member or members living relatively nearby.

108. While it was not possible to get clarity as to precisely what transpired next, it appears that the subsequent consideration of the issue was relatively brief and that a consensus was reached that the remnant vaccines would be made available to family members of those present.

109. When I spoke with those involved, no one suggested that there had been any disagreement as to the course of action which ultimately was proceeded with or that there was any coercion or pressure. Some identified the fact, however, that Consultant C, was *role removed* and either understood what occurred as being a decision by Consultant C (or, in some cases, by senior management) or, alternatively, as being something which would not have occurred without their agreement.

110. Some participants stated that Consultant C expressly agreed with the proposed decision, and drew significance from this, while one participant has a recollection of Consultant C being asked whether family members would be the recipients and Consultant C both agreeing and making some form of assenting gesture. Another of those present described Consultant C as having "*the final say*".

111. Consultant C, in an interview, acknowledged the fact that as *role removed*, *responsibilities removed* they agreed with the decision and that had they not agreed with it, as *role removed*, there would have been a much more robust discussion and ultimately, as *role removed*, they would have "*made a call*". Consultant C characterised the decision as an "*agreed decision*". While Consultant C does not recall having made a statement or given a gesture which would have been viewed as amounting to a formal decision, Consultant C accepts that they may have said something which was perceived by others as being a decision on their part. Consultant C also accepted that if they had been against giving vaccines to family members, that would not have happened.

112. After the issue of the vaccination of family members came into the public domain through an article in The Irish Times on Monday, 18th January, 2021, Consultant C sent an e-mail to all staff at the Hospital on that day (a copy of which is attached as **Appendix 5**) in which they stated inter alia:

> *"I as* [role removed]*, having considered the options, made the decision to use the vaccines that had already been made up to ensure that not a single reconstituted vaccine dose was wasted. The sixteen were administered to family members of employees of the hospital…."*

113. In an interview, I suggested to Consultant C that the wording of the first sentence in that paragraph ("*I as* [role removed]*... made the decision*") was consistent with the decision being one made by them as *role removed*.

114. In response, Consultant C characterised this sentence as not being fully correct and not fully reflecting what happened on the Friday evening. Consultant C emphasised that the e-mail to staff had been prepared in conjunction with the Hospital's public relations advisors in response to the Irish Times article. Consultant C stated that the public relations advisors had expressed the view that for the staff of the Hospital it would be better to say that the decision was one which had come from the *role removed* rather than being a consensus decision, inter alia with a view to protecting the others who had been present on the evening.

115. In conclusion on this point, I think that it is correct to characterise the decision reached that evening as a consensus, in the sense that everyone present agreed with the decision and no one suggested that they had been pressurised into so doing. Having said that, it appears that Consultant C expressed some form of agreement and a material number of those present considered that to be a matter of significance and/or were of the understanding that a decision had to come (and did come) either from Consultant C or more generally from those in senior management or a position of authority. Furthermore, if Consultant C had not agreed with the decision, as Consultant C stated themselves, it would not have happened.

116. An issue on which there was not complete agreement as amongst the members of the group who I interviewed was as to whether the consensus was to proceed to vaccinate family members, which was the understanding of some, or whether the consensus was that elderly and/or vulnerable family members should be vaccinated, which was the understanding of others (more of those having that understanding referred to elderly family members, although some did refer to vulnerable or immuno-compromised family members). Some suggested that while the conversation initially focussed on elderly family members, the ultimate consensus applied generally to family members. Given the range of recollections of the participants on this particular issue, it is not possible for me to express a concluded view on the factual position.

117. Some of those in attendance later in the evening indicated to me that they were surprised when they saw that some of the family members who attended were not elderly. However, nobody indicated to me that they expressed such surprise at that time.

118. It does, however, bear emphasis that a formal decision does not appear to have been made and that different individuals appear to have taken bona fide different understandings as to the nature of the decision, perhaps unsurprising given the informal way in which it was reached.

119. One of the issues which I have been asked to consider is whether consideration was given to the implications of the requirement for the administration of a second vaccine to family members. It appears that this issue was not discussed.

120. While not entirely clear, it appears that the initial proposal was that each of those present would nominate one family member for vaccination but additional doses were either offered by those who were not availing of a vaccine for a family member or were ultimately left over and made available.

121. Eleven people were involved in the conversation (Consultant C, Coombe Managerial / Administrative Staff B, Clinical Staff Member A, Consultant A,

Consultant B, Consultant D, Clinical Staff Member D, Clinical Staff Member E, Clinical Staff Member B, Clinical Staff Member G and Clinical Staff Member H). In addition, a vaccine was offered to Clinical Staff Member C, who was located at the registration / consent station, but not to Clinical Staff Member F at the observation/recovery station. Consultant C expressed the view that the exclusion of Clinical Staff Member F was unintentional- they may have been excluded simply because they were not present and were continuing to observe patients at the time.

122. A number of the individuals present, Clinical Staff Member B, Coombe Managerial / Administrative Staff B, Clinical Staff Member D and Clinical Staff Member H, did not avail of the possibility of a vaccine for a family member(s) although nobody expressed an objection to the process of vaccinating family members. In total, sixteen vaccines were administered to one of more family members of eight members of staff:

- *Personal Information Removed*

123. While sixteen doses were ultimately administered to family members, there is a lack of clarity as to the point at which it became evident as to how many doses were available. As set out above, some of those present understood that it was clear in the course of the conversation which took place before 9 p.m. that sixteen doses remained, once Consultant C and Coombe Managerial / Administrative Staff B had gone through the main Hospital building looking for potential vaccinees. Some present, however, recalled non-family members being vaccinated after the conversation.

124. In order to clarify this, I sought, and obtained, from the Hospital the vaccination records of those who were vaccinated after 8:30 p.m., which was provided to me with the names and personal information redacted. From this list, it appears that three non-family members were vaccinated after 9:00 p.m.– at 9:08 p.m., 9:15 p.m. and 9:16 p.m. respectively. The two latter are stated to have presented at 9:10 p.m. and 9:15 p.m., although given the need to undergo a consent/ registration process and then present for vaccination, these timings may be slightly incorrect.

125. While I cannot be certain as to the times of vaccination of these individuals or, consequently, as to whether the group discussing vaccination of family members was aware of the fact that they would be vaccinated, it does appear that eligible individuals continued to be vaccinated beyond 9:00 p.m. and Consultant C has emphasised that had any other eligible vaccinees arrived after that stage, they would have been vaccinated in preference to family members. Consultant C, who went home to collect their family members, indicated to them that they would not necessarily be vaccinated and that that would depend on whether any vaccine remained when they returned.

126. Some of the Hospital staff members left the Hospital to collect their family member(s), while other family members arrived the Hospital by other means. The various family members arrived at the Hospital and were apparently vaccinated (according to the Hospital's vaccination records) between 9:40 p.m. and 10:10 p.m..

Conversation between Consultant B and Consultant C

127. When Consultant B had finished vaccinating *personal information removed* family members, Consultant B had a brief conversation with Consultant C at some time late in the process, after 10:00 p.m.. *Personal information removed*. Consultant C indicated to Consultant B that no one else was awaiting vaccination. Consultant B noted that there was still some vaccine in the diluted vial which Consultant B had been using- at the time Consultant B thought that there was probably one dose remaining but ultimately there were two doses available.

128. Following the conversation between Consultant B and Consultant C, Consultant B took the remaining vaccine home with them and administered it to two family members *personal information removed*.

129. For their part, Consultant B understood that Consultant C gave them permission to take the vaccine home. In an interview with me, Consultant B stated that they would not otherwise have taken the vaccine from the Hospital. For their part, Consultant

C stated in an interview with me that they agreed that Consultant B could take the vaccine home. When asked whether they gave permission to Consultant B, Consultant C characterised their understanding of the position as being more that if Consultant B, along with *personal information removed*, was comfortable to take the vaccine home, they were not standing in their way. Consultant C stated "*so if that's construed as permission, that's permission*" but further states that they do not recall actually stating that they permitted Consultant B to take the vaccine home.

130. I discussed with Consultant B the issue concerning the transportability of the vaccine. On the evening in question, Consultant B understood that it would still be effective even if transported. One of the on-line training videos watched by Consultant B as part of the course for vaccinators (Video 5) stated (in a slide- Slide 10- and in the oral presentation) that diluted vaccine should not be transported for administration in another location. When asked about this, Consultant B stated that while they had watched the relevant on-line video, they did not recall the reference to the transportability of the vaccine and did not give it any consideration on Friday evening.

131. Consultant B did not recall any discussion of the transportability of the vaccine on the evening. Consultant B lived relatively close to the Hospital and understood that the vaccine would still be effective if it were transported by car over a relatively short distance. Given Consultant B's training and knowledge of their *personal information removed* family members' medical history, they were confident that they could manage the administration of the vaccine to them at home.

132. Consultant B completed the relevant forms with the family members. The relevant forms did not make any inquiry as to the location at which any vaccine was administered and hence there was no indication on the forms as to where the family members were vaccinated. Consultant B, *personal information removed*, caused the forms to be brought in to the Hospital on Monday morning. It does not appear that any of the individuals present on the evening apart from Consultant C were aware that Consultant B took vaccines home and vaccinated family members at home.

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133. Three vials had been left over and on Monday, 11th January, eighteen doses were administered to staff who had been absent the previous week and/or had commenced work at the Hospital, having moved from other hospitals.

134. From the following week onwards, more detailed guidance became available in relation to the administration of Covid 19 vaccines.

135. On Tuesday, 12th January, the HSE provided DMHG with guidance from the HSE Chief Clinical Officer entitled "*Sequencing of Covid 19 Vaccination of FrontlineHealthcare Workers, Version 1.0, 12th January, 2021*" ("*the Sequencing Guidance*"). This document gave more detail as to the definition of a frontline healthcare worker, set out a more elaborate sequencing of frontline healthcare workers and included a number of what were described as "*guiding principles*", including that "*no dose should be wasted*".

136. The Sequencing Guidance stated that the vaccine should be administered to frontline healthcare workers earliest in the sequence order who were able to attend on a given day and that where such workers were not able to attend, those later in the sequence order should be vaccinated on the basis that no dose should be wasted.

137. The Sequencing Guidance further stated that centres should establish standby lists of frontline healthcare workers later in the sequence order that were available at short notice and were randomly selected from the lists for vaccination, in the event that frontline healthcare workers earlier in the sequence order did not attend or could not receive the vaccine. It stated that centres should consider establishing standby lists of other healthcare workers in the fourth priority grouping (i.e. healthcare workers who were not frontline) who were available at short notice and would be randomly selected from the lists for vaccination if, for any reason, frontline healthcare workers were not available and the alternative was that the vaccine dose expired.

138. The Sequencing Guidance evolved further and Version 1.1, dated 19th January, 2021, states that centres should consider establishing standby lists of other people in priority groups 3 (people aged 70 and older) and 4 (healthcare workers more generally) who were available at short notice and would be randomly selected from the lists for vaccination if, for any reason, frontline healthcare workers were not available and the alternative was that vaccine doses expired. Copies of the Sequencing Guidance are appended as **Appendix 6**.

139. This guidance and the suggestion of having standby lists available was not in place as of Friday, 8th January, 2021.

SUMMARY OF FACTUAL CONCLUSIONS ON "KEY THEMES" IN §1.3 OF TERMS OF REFERENCE

I set out below my factual conclusions on the "key themes" identified at paragraph 1.3 of the Terms of Reference.

- **The guidelines that were available to the vaccination team in the terms of the selection of vaccine participants and the extent to which those guidelines were followed.**

  The guidelines available were those set out in the Template for Vaccination Plan, two versions of which are set out at Appendix 2 and Appendix 3 to this report.

  These guidelines set out a priority list for vaccination, which I understand was followed at all times, save for the vaccination of family members on Friday evening. It was silent as to what might be done if vaccines were left over at the end of a vaccination and as to the preparation of standby lists.

  In addition, the version of the Clinical Guidance then available stated that leftover vaccines were to be discarded, although the subsequent Sequencing Guidance, which post-dated the first round of vaccinations at the Hospital, stated that no doses were to be wasted.

  Of those present on Friday evening, only Consultant C and Coombe Managerial / Administrative Staff B were aware of the terms of these guidelines.

- **Where no guidelines were available, what was the selection criteria adopted and by whom in terms of selection of vaccine recipients and what information was available to them to inform those decisions?**

  As noted above, guidelines were available, limited in the manner identified above.

- **If remnant vaccines were available after the completion of the vaccination role out on Wednesday, 6th January, to whom were these vaccines administered. Who were the decision makers in identifying those recipients and what information was available or sought to inform those decisions?**

  No remnant vaccines were available on Wednesday, 6th January.

- **On Friday, 8th January, when was it determined and by whom that there would be excess vaccines beyond the requirement of Coombe staff?**

  Prior to that date, it had been decided to vaccinate twenty five GP's who were associated with the Hospital, subject to availability. This decision was made by Coombe Managerial / Administrative Staff B in conjunction with the DMHG.

  On the morning of Friday 8th January, when the Hospital became aware that 95 vials had been delivered, a decision was made to vaccinate a further 40 local GP's with CHO7. Coombe Managerial / Administrative Staff B was the individual who was involved in this process on behalf of the Hospital and they liaised with CHO7.

  Early on Friday afternoon, Coombe Managerial / Administrative Staff B contacted DMHG Employee A indicating that the Hospital believed that it could vaccinate a further 120 frontline healthcare staff from the CHO7 group.

- **What was the process by which the recipients of these excess vaccines were identified and selected and how was their data shared with the Coombe? Who made the final decision?**

  It is necessary to divide the additional groups into the three categories identified above. First, the 25 GP's associated with the Hospital were identified through communications which Coombe Managerial / Administrative Staff B had with both an External General Practice and with GP's who ran evening clinics in the Hospital. On Thursday afternoon, Coombe Managerial / Administrative Staff B decided that

the Hospital was in a position to vaccinate these 25 GP's and so informed DMHG Employee A. Their details were provided by the GP's to the Hospital prior to their vaccination.

The further group of 40 GP's who were identified on Friday morning were identified by CHO7 and their details were provided by CHO7 to the Hospital.

The third group was again identified by CHO7. Due to pressure of time, their details were not provided in advance to the Hospital but were provided by them when they registered at the Hospital for the vaccination.

- **When was it determined and by whom that there would be remnant vaccines on Friday night?**

  The fact that there would be remnant vaccines was first identified at some stage shortly after 8:30 p.m. on Friday evening. There was not a "decision" as such that there would be remnant vaccines. The availability of remnant vaccines was a consequence of the fact that vials were being drawn up on an ongoing basis on Friday evening to cater for the large number of individuals who were arriving seeking vaccination. Shortly prior to this time, there was a sudden fall-off in those who attended. While the pharmacy staff stopped making up vaccines once there was a fall-off, the sudden nature of the fall-off meant that there were a number of remnant vaccines.

- **What options and information was available in terms of identifying potential recipients "other than family members" of the remnant vaccines on Friday night and what efforts were made to explore those other options?**

No specific guidance was available in terms of identifying other potential recipients. I have set out in the body of my report, a number of other potential options which might have been available, along with difficulties which would have applied in the case of each of those groups.

It was discussed that there were no alternative options available from within the Hospital and that through the interaction with CHO7 earlier in the day which had resulted in GP's and other frontline HSE staff attending that evening, efforts had already been made to identify GP's and other frontline healthcare workers and that it appeared that no further staff were going to attend that evening.

Otherwise, there does not appear to have been any material discussion around alternative options.

- **Who made the decision to select family members for vaccination on Friday night?**

The decision emerged from a relatively short and informal conversation between eleven individuals which took place shortly before or around 9 p.m. on the Friday evening. No one who was present indicated any disagreement, nor have any of those present suggested that they were coerced or pressurised into the decision. In that sense, the decision can be characterised as a consensus decision.

Having said that, it appears that Consultant C expressed some form of agreement and a material number of those present considered that to be a matter of significance and/or were of the understanding that a decision had to come (and did come) either from Consultant C or more generally from those in senior management or a position of authority. Furthermore, if Consultant C had not agreed with the decision, as Consultant C stated himself, it would not have happened.

- **Was consideration given to the implications of the requirement for the administration of the second vaccine to family members?**

  There was no discussion of the implications of the requirement for the administration of a second vaccine.