Wednesday, 29 January 2025

(10.00 am)

LADY HALLETT: Ms Carey.

MS CAREY: My Lady, good morning. The first witness this morning is Ms Sarah Moore.

MS SARAH MOORE (affirmed)

Questions from COUNSEL TO THE INQUIRY

Q. Ms Moore, your full name, please.

A. My name is Sarah Esther Moore.

Q. Thank you very much for the statement you provided to the Inquiry which will be published later today, dated 21 October 2024, and you're going to help us, I hope, with some issues relating to the Vaccine Damage Payment Scheme, or VDPS for short.

Can I start with your background, though, please.

Ms Moore, I think, is this right, that you qualified as a solicitor in 2006?

A. That's right.

Q. You are now a partner at Leigh Day, and for much of your career you've been involved in group claims for people who have suffered injury or other forms of loss.

A. That's correct.

Q. And I think, in terms of relevance for this Inquiry, you act for approximately 50 individuals bringing a claim against AstraZeneca in respect of serious injuries or

result of doing what the government asked us all to do. They stepped forward and they were vaccinated and some of them have borne a very serious, in fact devastating, consequence of that through death or serious injury.

The Pearson Commission recognised this and proposed/recommended that a compensation scheme was put in place. However, there was a change of government between 1978 and 1979, so legislation was hastily put together by the Callaghan outgoing government, and then the Thatcher government came in and that legislation was never finalised or formalised. So what we have at the moment in our Vaccine Damage Payments Act, and the scheme that is devised under that Act, is, essentially, a stopgap piece of legislation.

Q. Right.

A. It's never been properly thought through, and to date, I think I can say this on the basis of the evidence that that's been given in last three weeks: there seems to have been a sort of governmental or institutional inertia around this particular piece of legislation. It has never been carried over the line in the way that the Pearson Commission intended it to be and I think that's something --

Q. Let me pause you there --

A. Sure, of course.

death, which they submit was caused by the AZ vaccine?

A. That's correct.

Q. And no doubt through that work with them and, indeed, other work that you've conducted, you have a knowledge and understanding of the Vaccine Damage Payment Scheme?

A. Yes.

Q. All right. Can I ask you about the scheme generally to start. We know that it was set up, I think, in 1979.

Ms Moore if it helps you, I'm at paragraph 16 onwards in your statement, where you say there were three key features of the scheme: firstly, to improve public confidence in vaccination; secondly, to recognise the special case that the vaccine injured constituted a group who had been injured and therefore as a result of being recommended for vaccinations, and I think you say this: at the outset the scheme was only intended to be an interim measure.

Can you just help with that last bit? In what way was it intended to be an interim measure?

A. Yes, absolutely. So the Pearson Commission was tasked with the job of looking at personal injury law in the UK and compensation. One of the recommendations that they came up with was to recognise the fact that vaccine injured and bereaved constitute a special group. They are a group of people who have been injured as a direct

Q. -- because we may come on to look at that, but in essence, is it that for the last 45 years there has been no reform of that scheme although there have been various changes that we may look at to the amount of payment and, indeed, obviously, the inclusion of Covid-19 vaccinations as falling within the ambit of the scheme?

A. Yes, that's absolutely right. So it's essentially the 1970s safety net that was hastily put together by the Pearson Commission and hasn't been changed since then.

Q. Just, briefly, it might be sensible to look at how the scheme works.

If we could have up on screen, please, paragraphs 22 onwards in Ms Moore's statement.

We can see there you've helpfully set out the aims of the Act and, indeed, the scheme as it exists is to provide a single tax-free payment for those who have been damaged, either through death or severe disablement; it has to be proved on the balance of probabilities to have been caused by vaccination, and presently it amounts to an £120,000 tax-free award.

A. Correct.

Q. You set out there that in December of 2020 the government announced that Covid-19 vaccines would be added to the Act, and then you go on to deal with some

of the detail of the scheme itself.

If we look down, there are various criteria that need to be met, not just geographical, obviously the vaccine has got to be within the Act, which Covid-19 is.

And if one goes over the page, importantly in relation to severity of injury:

"... a person is, or was, immediately before his death, 'severely disabled' because of vaccination against any of the diseases to which the Act applies."

Now, we'll look at the disablement provision in a moment. Is this the position, though: that a payment under the scheme does not preclude the bringing of a civil claim?

A. Yes, that's correct.

Q. And I think you have seen some evidence provided by others to the Inquiry, including that by Professor Duncan Fairgrieve, King's Counsel (Honorary), who says that redress by a civil claims is challenging --

A. Yes, absolutely.

Q. -- was his word. Would you agree with that assessment?

A. Absolutely. If I can just speak to that point very briefly. Yes, it's extremely challenging. Very many people will not have access to the kinds of litigation that are currently necessitated by the fact that the

Vaccine Damage Payment Scheme is not fit for purpose. These people have no other way to access redress apart from litigation, but litigation is not an option open to them. So for some people there is no option to litigate at all and for others it presents a formidable challenge, both in terms of the finances and the way in which the law is structured in this area.

So it is no mean feat to mount a case against a company like AstraZeneca, particularly in circumstances where we know they are indemnified by the British Government.

So these people who are vaccine injured and bereaved, these people who have paid the highest price for the vaccination programme, which we of course have all benefited from, are now being forced, because the Vaccine Damage Payment Scheme does not work, to take on the might of vaccine companies and the British Government.

Q. All right. I understand, therefore, that all the more reason to try to have a scheme that works for those that can't, for whatever reason, pursue a civil claim?

A. Yes.

Q. I think, is this the position though: that unlike a civil claim, there is no requirement to show negligence or any other wrongdoing under the VDPS?

A. That's right, it's a strict sort of liability, no-fault scheme.

Q. All right. Now, I think you set out in your statement that in your experience over the last few years, and certainly over 2021 and 2022, there was a significant backlog in processing applications for Covid-19-related damages, and there was essentially a campaign of reform. Can I ask you about this: in your statement you say there was a review announced in May 2024 --

A. Yes.

Q. -- of the scheme. Is there any update that you're able to give us, Ms Moore, since then?

A. To some extent yes. So we work with a group called VIB UK, and you've already heard Kate Scott giving evidence in the course of these proceedings.

Q. Yes.

A. VIB UK were invited to a meeting with Wes Streeting, the Secretary of State for Health, in September. Mr Streeting has subsequently written to the group and said that he was -- you know, he's impressed by what they -- the evidence that they provided. He understood the need to look at this very carefully, and that the government would do so.

Now, we understand from an update received just before Christmas that that review process is going on

behind the scenes, but to date, nothing has come out of it. And I think you can understand, in the context of the way in which this legislation was formed in the first place, sort of hastily, as a stopgap measure, also as a result of the fact that a review was announced in May 2024 and nothing came of it, that there are some concerns that, whilst Mr Streeting's intentions may be very good, actually, what we need to see is action.

And these people cannot wait indefinitely. Many of them have waited, you know, four years already.

Q. Can we turn to the scheme itself. I think, Ms Moore, you're aware that Ms Scott, in fact, the witness who gave evidence to her Ladyship earlier, described the scheme as "too little, too late, too few"?

A. Yes.

Q. Pithy but apposite, I suspect you would agree?

A. Yes, quite.

Q. Can we look at some of those headings, though. "Too late", may I start with that, please. Are you able to give us a summary -- and if it helps you, I'm at paragraph 73 or thereabouts in your statement -- of why the application process is taking so long to force through the applications and provide the redress to those applicants?

A. Well, first of all, I mean, the fact that it is taking

a very long time. If I can just speak to that in terms of the data, if that's helpful?
Q. Yes, please do.
A. So we know on the basis of a Freedom of Information Act response dated January 20205 that there have been 17,519 applications to the scheme for those specifically injured or bereaved as a result of --
Q. Can I pause you there, because I'm going to put up on the screen something which may help you and help everyone else follow the number and the state of applications in the scheme.
Could we have up on screen, please, paragraph 76, which is at INQ000474459_20.
And we're aware, Ms Moore, that there was a Freedom of Information Act request that gave us these figures, but I think if I understand you correctly they're updated figures?
A. Yes, that's correct.
Q. So as at 9 September they were just shy of 15,000 applications, and did you say it's now --
A. Just shy of 18,000, so 17,519.
Q. All right. As at 9 September only 47% had been notified of an outcome. Is there an improvement or not, in that regard?
A. Yes, so now there are 55% of decisions made. So 9,545,

we understand. So that's still 18,000 people without a decision.
And just to speak to the point of the delays, of those 8,000 who are still -- or 8,000 approximately who are still waiting for a decision, 1,027 people have been waiting for 12 months; 438 people have been waiting for more than 18 months, and 126 people have been waiting for more than two years.
Now, I know they are just figures on a page, but to animate those and to speak to the humanity of what those figures actually mean, we have people -- one gentleman within our group who has been waiting for two years. He suffered a very significant neurological injury as a result of one of the vaccines, and as a consequence of him having to wait so long to receive his £120,000 and his personal circumstances, he has been living in an elderly care home. He is in his mid-forties. And we now understand from the experts with whom we are working that that delay in accessing rehabilitation treatments has impacted his prognosis quite significantly.
So it has a real world impact, this does, both --
Q. Her Ladyship has heard some evidence, I think, indeed, from Ms Scott about the impact on her husband Jamie --
A. Yes.
Q. -- who can no longer work, to pick just two examples of

no doubt many.
A. Yes.
Q. The scheme was intended to provide prompt support. So clearly, those that have been waiting 12, 18, 24 months perhaps are not meeting that intended aim?
A. Definitely not.
Q. You set out in your statement that there were, pre-pandemic, four staff dealing with applications into the scheme. I think now there are something like 80 members of staff. But can I ask you this: do you think that the government ought to have realised sooner that there was likely to be, given the widespread rollout of the vaccination programme, more applications being made, and therefore have more staff and resourcing in place at the outset?
A. Yes, I think that's got to be the case, hasn't it? Logically, if you have an unprecedented vaccine rollout, then you are probably going to have an unprecedented number of adverse events. I don't think that's controversial to say.
Q. Are you help us, Ms Moore, with some of the reasons for, perhaps, the length of time it's taking to process the applications? Clearly there's got to be an application, medical records of a sort -- what in your experience has been the reasons for some of the longer application

processes that you've just told us about?
A. I think obtaining medical records has definitely been a problem that the medical assessment panels have been experiencing. And, you know, as a personal injury lawyer, I have some sympathy with that, it can be very difficult to get hold of medical records, of course. But we are talking about a government service here, so you would think that there would be more ready access to those records.
It is also important to remember that some of these people who are making these applications to the Vaccine Damage Payment Scheme are bereaved, so they are doing so where they have already been through an inquest, a coronial process, and they are making this application with the benefit of a confirmed death certificate which will say, on the face of the certificate, that the vaccine has caused the death. So, in those circumstances, it's very difficult to understand why somebody should be waiting 18 months for a medical assessment panel to make a decision about causation. And of course, very sadly, in a deceased case, you know, the extent of the disability caused is absolute. It's 100%.
Q. There may be a distinction, then, between the way that the -- where people who have died are treated and they

have a certificate that shows a link to the vaccine, and those that are injured and have a slightly different route through to receiving an award.

A. Possibly -- sorry, but can I just say that my experience has been very specifically around something called vaccine-induced immune thrombosis with thrombocytopenia, so VITT --

Q. VITT.

A. -- which is accepted as caused by the AstraZeneca vaccine specifically, and most of the applications that we've assisted with have been in that context where people have submitted expert reports. So expert haematologists and neurologists reporting on causation, and it is still taking 18 months for those results to come through or those verdicts from the panel to come through.

We know that the medical assessment panel have to be five years qualified but where you have coronial evidence or the best expert evidence in the country assisting them with causation, the delay does seem completely outwith what could be done here.

Q. So there's potentially, or certainly at the beginning, a lack of resourcing in terms of people to, help the applications being made and processed. There is potentially delays in gaining access to records.

A. Yes.

Q. Is there any other delay that you're able to point to to explain 18 months, 2 years of wait for some of these applicants?

A. I think some of the problems also come to the point about how the disability test is made or the eligibility criteria for that, so perhaps I can speak to that.

Q. Yes, I was going to come on to that, please. And it's really, I suppose, under the "too few" banner.

A. Yes.

Q. The criteria that need to be met, as I think was set out in your statement, is one of 60% disablement. Can you just help with what that looks like in the real world? What is really trying to be assessed there?

LADY HALLETT: Just before you do answer Ms Carey's question, could I ask you to avoid naming specific companies because of litigation pending and --

THE WITNESS: Yes, of course. My apologies.

MS CAREY: Thank you, my Lady, and I'll try to be alert to that too, it's my fault, Ms Moore.

Can we just come back to the too few --

A. Yes.

Q. -- and the disablement criteria and just help us with an overview of what really is being asked of the applicant in that part of the process?

A. Yes, so, I mean, I can try to explain the 60% but actually it's sort of beyond rational explanation, because this is a test that comes from, as I understand it, Social Security legislation -- I think it's schedule 2 of the 1982 regulations -- where there is a list of percentages attributed to specific types of injury. If you look at that schedule, they're all in the context of amputations or visual impairment, deafness, I think is also listed, and you will see that 60% equals below-knee amputation. There is also a percentage for the amputation of a hand or a finger or a thumb or various other parts of the body, and that is the 60% test that is used at the moment for the Vaccine Damage Payment Scheme.

Now, where we are talking about neurological injuries of the sort that Kate Scott outlined during her evidence, you can see that there is quite a big gap or quite a gymnastic calculation that needs to be done for the medical assessment panel to work out whether a brain injury the size of a credit card is equal or greater than a below-the-knee amputation.

Now, quite why the scheme is still working with that calibration in place is very difficult to understand, but I think it must be very difficult for the medical assessment panel to make those calculations as well.

Q. At what point does 59% become 60%, or -- I follow.

A. It's incredibly subjective and I think that also makes the scheme very opaque and it makes it very difficult for people to then trust the veracity of the results coming out and the people who are making the applications to the scheme are, of course, in extremis by definition. You don't make an application unless you feel you've suffered a significant injury.

Q. You say in your statement, certainly on the figures as they were in the autumn of 2024, that of the nearly 15,000 applications, 6,845 of those that had been notified of an outcome had claims that were rejected. And when a rejection is issued, does it tell the applicant "You've failed because you didn't meet the 60% threshold"?

A. Yes.

Q. Or does it tell you "You've failed because you didn't prove causation"?

A. Both.

Q. Both, right.

A. It will tell you whether or not you've met the causation test, and you may meet the causation test but you may not meet the disability threshold. So you may fall below the 60%.

Q. So may we take it that when you say in your statement of

the claims that had been notified of an outcome, 97% of those claims were rejected, is that because they didn't meet the 60% disablement threshold?

A. That's both.

Q. Both, right.

A. So we know there's around a 2% acceptance rate, which I should say is the lowest in the world, based on data that's now coming out of Oxford University. We have the slowest scheme in the world, based on that Oxford University study, and we have the scheme with the lowest acceptance rate as well.

But of the 9,000 -- now -- 351 rejected, around 416 of those people were rejected because they didn't meet the 60% test. So those people receive a report from the VDPS which says, "We accept that the vaccine caused this injury, but you are not disabled enough to be eligible for compensation of any sort or payment of any sort by the government."

And, again, to speak to the humanity of that, that's very difficult for somebody to understand why they are 45%, which in realistic terms may mean that their life is devastated, they cannot go back to work, they cannot care for their children, but that is not recognised as being disabled enough for the purposes of the current scheme.

Q. Yes. Too little, please.

A. Yes.

Q. We know that the award was raised to 120,000 in 2007, but there has been no -- even inflation adjustment since then. I think you've assessed that if it had been adjusted for inflation it would be, now, somewhere in the region of £196,000?

A. That's correct.

Q. This is not compensation, I make that clear, but an award to try to help the rehabilitation process, people deal with whatever immediate needs they may have, but clearly there are some people who may be so injured by the vaccine they're unable to work again.

A. Absolutely, absolutely. And I think what we've got at the moment is such a significant gap between what can be achieved under the VDPS and what could be achieved through civil litigation, albeit that path is very difficult for people to tread, and impossible for some, the fact of that gap is actually necessitating litigation, because people have no choice but to litigate.

I mean, if you're 59% injured and you cannot access statutory compensation or statutory financial support, then, you know, what are you supposed to do? And if you are in a situation where, to take Kate Scott's example

again, you know, your husband will never be able to go back to work, you are a full-time carer and you have two children, £120,000 is woefully inadequate. Nobody wants to litigate. I can speak to that. I'm not going to speak specifically about the litigation of course, but nobody really wants to be taking on a vaccine company and the British government. You know, they have other things to do with their lives: pick up the pieces of bereavement, care for those who have been -- you know, who suffered devastating injuries.

Q. Can I just pause you there, because clearly you've alluded to a number of potential problems with the scheme: it's too slow, it's very difficult to potentially satisfy the 60% disablement, and, on any view, the 120,000 for people who have many working years left and can no longer work is a drop in the ocean, if I may put it colloquially.

A. Yes.

Q. Is there any appeal process for those who have had their claims rejected?

A. Yes, there is, and actually the experience of people with whom we've been working is that quite often they are successful on appeal. But again, that's further delay. And I think that also raises some doubt about the validity of the initial assessments. There is a lot

of subjectivity in this process, but yes, there is an appeal, and --

Q. I think you've said if anyone wants to read more about it, they can read it in your witness statement.

Can I ask about another couple of discrete areas please. In relation to the scheme generally, do you have any views or observations to make about the awareness of the scheme and the profile that it received or didn't, perhaps?

And if it helps you, I'm at paragraphs 50 and 51 in your statement, Ms Moore.

Was there much publicity about the possibility of making an application if you did in fact receive a vaccine-related injury?

A. My understanding is that there wasn't. Certainly the people with whom we were speaking at the beginning of 2021 and throughout 2021 were not aware of the fact of the Vaccine Damage Payment Scheme. Quite rightly, the government put a lot of money and energy into promoting of the vaccines, encouraging people to come forward for the vaccines, but I don't think there was any or perhaps only a very small budget put into the Vaccine Damage Payment Scheme, alerting people to the fact of that.

Q. Were you aware or are you aware of any publicity or awareness raising that was aimed at ethnic minority

communities or those that may face additional barriers in accessing information? Do you know if any work was done in that area to try to publicise the scheme to people who may have been injured?

A. I'm not aware of any.

Q. And I think you say in your statement that initially, the application was not easy to fill in, just the practicalities of making --

A. Yeah, absolutely.

Q. -- an application. I think there was no way to apply online?

A. No way to apply online in the context of a pandemic where we were in lockdown and you couldn't leave your house. You had to print out the application form, if you had a printer, fill it out in ink, and then take it to the post box.

Q. Clearly, some people prefer paper form, some people prefer online --

A. But necessary to have the choice.

And also, there was no box for bereavement, so the form as it was initially constituted didn't now applicants to indicate that they were applying on behalf of a deceased loved one, so they had to literally draw in the box and tick it.

So that form was woefully inadequate. Little or no

thought, I think it's fair to say, was put into how that form would work for people in the context of a mass population vaccination rollout.

Q. I think the Inquiry has heard evidence, and certainly you have seen in the documents provided to you, that in Scotland the Scottish Social Security department provided a service to help people complete the actual forms. Do you know whether there was any additional -- sorry, any similar resources or services provided in England and Wales and Northern Ireland?

A. Not that I'm aware of. And anecdotally, based on my experience, I think that must be the case, because people were coming to us as a law firm and asking for help, and they were finding us through various routes, and there were support groups, sort of grassroots groups of people starting to get together and think: well, what can we do here? And they formed, just like VIB UK, their own support network, because there was nothing institutional in place.

What VIB UK did try to do quite early on -- and Hausfeld, the law firm I was with at the time, tried to support this -- was to set up a website where people could be signposted through the Vaccine Damage Payment Scheme system and thorough the benefits system and all of the mess, the necessary mess, that comes after

a serious injury or bereavement, and that was taken down by Facebook because it was, we presume, flagged as being, in some way, anti-vaccination, which of course it was not.

So, no, I think people were left with nowhere to go, and no clear pathway in terms of accessing financial support.

Q. No. Do you know if now, in 2025, there are any services provided to help an applicant fill in the form, Citizens Advice, or -- that's not a lawyer?

A. Not that I'm aware of. I'm sure the great work that Citizens Advice bureaus do -- perhaps there are people available, but no, I'm not aware of any scheme put in place.

I should say that the awareness of the scheme has probably increased, the number of applications going into the scheme has massively increased. So there is probably better general awareness, but that general awareness has been borne, I think, of headlines, advocacy by groups affected, rather than any concerted initiative by the government. As conceived of by the Pearson Commission originally, the point of a Vaccine Damage Payment Scheme, I think, was to shore up vaccine confidence.

Q. Yes.

A. It was seen very much as going hand in hand with, you know, encouraging people to step forward for vaccination. So it seems to me, if I can suggest, that the government has missed a trick here. There could have been concerted effort into saying: vaccines are, for the most part safe, but when the worst things happen, we will be there. There will be a meaningful safety net.

And we haven't heard that narrative at all, as far as I understand it, so far from the government.

Q. Can I turn, then, to a slightly wider issue. Clearly there's a statutory footing for the scheme, but can I ask you about, pending any statutory change which may take a long time and would be very difficult to get through government and Parliament, are there any short-term or more immediate recommendations that you would urge her Ladyship to consider to, perhaps, ameliorate some of the problems with the scheme that you've told us about this morning?

A. Yes, absolutely. I think we understand that any statutory reform would be forward facing, and we understand, based on discussions with Wes Streeting that it would require a lot of Parliamentary time and that, of course, would need to be done incredibly carefully and that work must be done. But as a more immediate

solution here, there could be the possibility of setting up a bespoke compensation scheme or support scheme specifically for those who have been injured or bereaved as a consequence of Covid-19 vaccinations. That would be, I think, a swifter measure to put in place.

We know that there are, you know, a large number of people who have been vaccine injured and bereaved. We know that for a proportion of them, causation has already been established. We know that some of them haven't got any compensation at all because they've not met that 60% threshold, but that is a defined group of people for whom a proper financial support system could be put in place now or quite rapidly, I would suggest.

We are very good in the UK at thinking up bespoke schemes, you know, from the Thalidomide Trust back in the 1980s, through to the vCJD, the mad cow, the BSE bespoke scheme, right through to the infected blood scheme. You know, we do have the wherewithal as a consequence of academic work, legal experts, to think through sensible schemes that balance the need to ensure that people are given fair amounts of money to support them but also are not too onerous on the public purse, and recognise the fact these people, through no fault of their own, have suffered these devastating consequences.

It could have been any of us. And I think as

a society to move to do that would be, potentially, if you'll excuse the pun, a shot in the arm for vaccine confidence because this would be the government, I think, recognising the necessity of holding up their end of the social contract, the pact that is formed between a government and a community when we are asked to step up for vaccination.

MS CAREY: Ms Moore, thank you very much. They are all the questions I have for you.

Are there any questions that your Ladyship would like to ask?

Questions from THE CHAIR

LADY HALLETT: Essentially, the whole point about having -- for those who are not lawyers, I've got a husband who is a personal injury lawyer, so I understand a bit about it, I did some work myself. But for those who don't understand, there's a difference between a grant or an award, which is basically the Vaccine Damage Payment Scheme as it is --

A. Yes.

LADY HALLETT: -- and compensation, is compensation assesses the damage that has been caused and what you're going to need to lead as effective a life as you can lead with your disability.

A. Yes, that's right.

LADY HALLETT: And what you're suggesting is that we move from the award system, the grant system, to a compensation system.

A. I think there is space in between. So at the moment we have got, sort of, two completely juxtaposed situations where we have a scheme that provides £120,000, or, as I'm sure you know or your husband will definitely know, for sort of significant neurological injuries you'd be looking at millions of pounds of damages.

Now, there is probably some space in between there and that gap could be closed, is my point. If we don't close that gap, then litigation is going to be necessitated, and I think that litigation is bad for everybody. It's bad for the vaccine companies, it's very pad for the people who are having to go through that process, the people that I represent. But I think it's also bad for public confidence and the wider, sort of, public health policy point.

The government have indemnified the vaccine companies, quite rightly, so they are paying out through -- for the litigation which is ongoing, they will pay out for compensation in the end if it's successful. They're paying out through the VDPS and all the administrative cots of that. That could all be streamlined by having a sensible scheme that's put in

place, that is somewhere between the civil compensation standards and the current statutory amount.

And I think that could actually solve a lot of the issues that we've seen over the last few years, and have the added bonus of potentially increasing vaccine confidence.

LADY HALLETT: You mentioned in your statement about how funds in other countries are -- how resources are provided -- (overspeaking) --

A. Mm.

LADY HALLETT: And you mentioned a levy on pharmaceutical companies -- is it Sweden or Switzerland -- it's Scandinavia --

A. Yes, Scandinavia, so Sweden, specifically, yes. So, that's right. So in accessing the market, essentially, the country with a vaccination programme, the vaccine companies are asked to pay a certain krona, or whatever it is in Sweden, into essentially a public pot, so that, in rare event that, you know, these rare consequences happen, there is a pot of money that will facilitate proper compensation. I think that has the benefit of also making sure that the risks are partially privatised as well as the benefits being socialised.

I think what we do there is we recognise that between the public sector and the private sector, there

are benefits and responsibilities, and the best way to make sure those funds are adequate is probably to do that. We've seen that with the Thalidomide Trust which is partially paid into by the company involved there as well. And those schemes then can be very well resourced, I think, with advantages for everybody.

To me, if I may say, Lady chair, it is shocking that we have a 1970s system that we have done nothing to reform, particularly in a context like we are today, post-pandemic. It was perhaps forgivable in the immediate, sort of, circumstances of the pandemic, but now, this many years on, I think the case for reform is overwhelming and I would argue that the case for a bespoke compensation scheme is significant and urgent.

LADY HALLETT: Another question. One of the advantages of the scheme when established was meant to be speed. I take your point about there not being the speed that was intended, but the more you go into how an individual is actually damaged, as you say, the longer it's going to take --

A. Yes.

LADY HALLETT: -- the more complex the medical reports are going to be, finding the specialist who can provide you with the reports is going to take time. To what extent do you lose the speed, if it were there? So let's

just --

A. Let's presume it's there for a moment. Yes.

LADY HALLETT: Let's push that to one side for a second. To what extent do you lose the speed when you go into the detail of individual cases?

A. I think there has to be a balance, you're absolutely right, but we do see speedy schemes that work on the basis of banding. Again, the Thalidomide Trust is one of those, the Infected Blood Scheme obviously is just in its nascence but will enable faster decisions to be made because bandings can be put in place.

So it's not that there's a bespoke sort of analysis as for each individual case but there could be criteria through which, you know, more rapid decisions could be made which still took full account of the injuries and the personal -- the individual's experiences.

At the moment it's a one-size-fits-all, and we know that that just doesn't work on the basis of the evidence that, you know, you've heard over the last few weeks, I think.

LADY HALLETT: Going back to your point -- sorry, I'm losing my voice for no reason -- about the criterion of 60% disability, supposing the government said: we're going to keep the Vaccine Damage Payment Scheme but we're prepared to look at the criterion.

The Equality Act has a definition for disability, as I'm sure you're aware. I think it's substantial -- what's it -- physical or mental impairment which has substantial and long-term effects on daily life.

I wondered about that as a possible criterion, except it talks about long-term effects. And of course the point is, as you say, you're trying to get money to people who needed it sooner.

So, just supposing the scheme stayed in place. What criterion would you suggest should be put in, instead of the 60%?

A. So I think we would need to have some assessment of the severity of the injury in the first instance and then you could have multiples.

So there's a scheme called COVAX, which is something which was set up during the course of the pandemic, and actually the British Government paid into that scheme, and that's for 92 lower and middle income countries across the world, and they have multiples based on severity from 0.25% up to 1.5%. So there is a calibration by severity. I don't think you can avoid that. And I think, you know, we would have to see, you know, the extent of the neurological or the personal injuries.

But then that could be -- we could also factor in

a future prognosis into that. There is enough learning, and wherewithal within the UK, based on, for example, the judicial college guidelines, precedence, and all the other data for us to be able to develop a sophisticated scheme, I think, that can take account of that. And we have really good examples, of these already. I don't think we necessarily need to reinvent the wheel. You know, we've got a pretty good map of what wheels should look like from other bespoke schemes; I think we could draw upon those.

LADY HALLETT: Bespokes and wheels. I think we had better -- (overspeaking) -- there, hadn't we?

THE WITNESS: Quite.

LADY HALLETT: Thank you very much indeed, Ms Moore. I have no other questions. I don't think there are any Core Participant questions.

MS CAREY: No, there are not.

LADY HALLETT: I'm really grateful to you for your help.

THE WITNESS: Thank you.

MS CAREY: Thank you, my Lady.

Thank you, Ms Moore.

(The witness withdrew)

MS CAREY: My Lady, the next witness this morning is Lord James Bethell, and it will just take a moment for him to come in ...

My Lady, may Lord Bethell please be sworn or affirmed.

LORD JAMES BETHELL (sworn)

Questions from COUNSEL TO THE INQUIRY

LADY HALLETT: Lord Bethell, I hope we haven't kept you waiting too long.

MS CAREY: Lord Bethell, some formalities. Your full name, please.

A. James Bethell.

Q. You've made a statement to the Inquiry dated, I think, 6 October of last year, and I'd like to ask you about number of different topics, please. Can I start with a little background about you. Is this right: that on 9 March you were confirmed formally as the minister for technology and life sciences, and you were, indeed, the House of Lords minister responsible for representing all health matters and legislation in the House of Lords?

A. (Witness nodded)

Q. We know from your statement that you had ministerial oversight of the Antivirals Taskforce, the Therapeutics Taskforce, the combined taskforce, and, as you've set out, you sat on a number of engagement boards and indeed other forum both for antivirals, therapeutics, and other groups?

A. That is correct. I think it's worth adding that I had

been a whip to the Health Department since the summer before, so I had been involved in the proceedings of the Department.

Q. Thank you.

May I ask about some initial observations that you make in your statement, and you say early on in your statement, at paragraph 7, that clearly there was a recommendation to explore existing common medicines to see if that might have an impact on Covid-19, and you say this:

"Our initial efforts faltered because of the weaknesses in our clinical trials system."

Can I ask you, please, at the outset, of an overview of what, from your perspective, were those weaknesses.

A. I think there were three main areas of weakness. One was about selecting the commonly used drugs that should be put to trial. That really needed clear leadership. We had very strong expert groups, because it is difficult to get an expert group to coalesce around a shortlist, and therefore we needed a better mechanism for doing that. Secondly, in terms of recruitment, it was extremely problematic to get people into the trials and that was partly data, partly trying to get clinicians to prioritise clinical trials, and partly just the clunky way in which the NHS was working around

trials in that date.

Those were resolved but at an early stage they were very weak.

Q. When you say early stages, are we talking March, April, May 2020 --

A. Yes, we are talking -- exactly. And then, thirdly, was actually liaising with the manufacturers themselves to get guidance from them about what they thought would work. We had great academic leadership but life sciences is best done when the academics, the clinicians, and the industry work together. And that wasn't happening very well at the beginning.

Q. Do I take it from what you said that it improved over time?

A. It did. The system kicked in in a big way and the RECOVERY trial which went on to deliver huge results was a good example of that.

Q. Right. May I ask, in respect of those three weaknesses you've identified, did you take in your role any steps to try to address or remedy those weaknesses, and if so, what did you do?

A. Yes, there was a -- I mean, listen, there was a big programme of trying to accelerate momentum in this. There were observers from outside -- some of the clinical advice I got from people like Sir John Bell was

that this needed to be accelerated much faster. So we looked at appointing external leads, people who could come in from industry to try to lead the programme, and some names were looked at for that. But really what made a big difference was having people like Professor Landray and Professor Horby, trusted clinicians, who knew how to drive clinical trials, put at the centre of the organisation.

Q. I think you say that for future pandemics we need a more robust emergency clinical trial system that can be stood up more quickly on a bigger scale as with the decision making around trial drugs.

Who do you think, Lord Bethell, or which department, do you think should be responsible for setting up an emergency clinical trial system?

A. Well, that's for sure, in terms of departments, the Department of Health and Social Care. But I think that the co-ordination between the NHS, the universities and the industry needs to be much, much clearer. Lord O'Shaughnessy has done an extremely good report on this. It has crystal clear recommendations. They need to be driven much harder than they are at the moment.

Q. Can I ask you this: do you consider now, looking back over your time, that vaccines were prioritised over therapeutics?

A. No, I think that's a false dichotomy. They are very different children. We weren't choosing one child over another. With vaccines, we have a specialism in the UK so that we know a lot about the science and the challenge was a lot about seeing through the clinical trials, and then ultimately the deployment.

So in that respect, although there are severe obstacles, it's relatively linear, it is relatively straightforward and the things you're going to be worried about is there are known unknowns.

With therapeutics it's a completely different kettle of fish. It's extremely complex. There are lots of different types of therapeutics and antivirals. The population itself changes as vaccination is rolled out. There are lots of different types of immuno -- of responses from individuals, it is highly personalised. The delivery of different medicines is completely different. Some might need an infusion into the arm that takes hours, some might be in a pill. Some need to be taken in advance, some afterwards. And also the clinical trials were bouncing around an enormous amount.

So that's a five-sided Rubik's cube which requires a completely different approach than vaccines.

Q. I understand that the dichotomy or false dichotomy, as you call it, is not one you have experienced yourself

but do you think there is a perception, nonetheless, that vaccines were prioritised over therapeutics?

A. Listen, the success of the vaccines programme is something that we can celebrate as a nation, and the therapeutic programme didn't have the same profile.

Q. Why not?

A. Well, because it wasn't on TV every night. Huge amounts of work by very dedicated teams who were very focused on outcomes was done in the background, and they delivered tremendous results which have saved many, many lives. So I think it's an unsung success for the UK in many ways.

Q. So it didn't get the attention it deserved?

A. No, attention is different to profile. The fact that it wasn't on the front pages of newspapers doesn't mean that it wasn't focused on by both the government and the NHS.

Q. Right. Didn't get the profile it deserved?

A. Profile in the newspapers but you don't measure saving lives in column inches.

Q. No. Understood. So from your perspective, there was focus on both vaccines and the therapeutics, and from your perspective, was there any ever, in your view, a hesitancy or a reluctance to pursue therapeutics with the force that the vaccine programme was rolled out?

A. Well, there were practicalities. In the very early days, it was assumed that the answer to this novel virus was going to be a therapeutic strategy. At the very beginning, we had no medicines at all to treat it. People were coming into hospital and being treated with paracetamol and if they deteriorated were being intubated. That is a terrible position to be in. So we worked hard on therapeutics and things like remdesivir came through that meant that we could treat people who were poorly. And that's a phenomenal thing that Britain really made a big contribution in doing.

Quite quickly, so we're talking April, May, June, the signals from the vaccine programme became much more encouraging than, I guess, at first we thought they would have been. And so quite reasonably, that became a focus, because we needed to stand up the delivery of the vaccine. But all along, we knew that we needed a fallback plan.

We were one phone call from disaster; we just needed to know about a clinical trial that had gone badly wrong, and then we would have to go to Plan B. So the therapeutics were very much seen as that Plan B. And certainly from my point of view, I had grave sense of urgency and importance in order to make sure that we delivered a fallback plan. And secondly, the vaccine

might not have worked for everyone, and definitely for some people, therapeutics and antivirals were going to be very important.

Q. I'm going to come on to look at some of those matters, Lord Bethell. Can I start, though, with one of the topics I'm going to ask you about is the ACCORD programme. Can you just help us with those who are not familiar, what was the aim of ACCORD and what was it trying to achieve?

A. Well, ACCORD -- the ACCORD programme was, as you said earlier, trying to look at some of the drugs that were already in use so we wouldn't need to have go through huge numbers of trials, which would take years to do. It's a very, very common approach and in terms of its mission did ultimately lead to some successes.

Q. I think it was announced towards the end of April of 2020, and was it really focused on trying to improve the treatments for the more serious symptoms that Covid had, and trying to stop people progressing to the severe complications that we saw?

You wrote, I think, in May, on 26 May, to the Secretary of State, Mr Hancock, concerned at the slow progress of ACCORD.

Can I just look, please, on screen at INQ000486320. If we see there in the middle of the page an email

from you asking to update the Secretary of State with the following note relating to ACCORD:

"As you will remember, this was going to be done by the private sector, but UKRI grab it at the last minute. Based on the recent oversight committee it is going very slowly. Initially problems getting the trial medicines. Now problems recruiting the trial patients. For example, drugs have been in recruitment for weeks but only have one recruit. Many have none. Alok [Sharma] is battling hard to make progress. This is a hugely important project to mobilise established drugs for Covid treatment ..."

Why were you so keen to let Mr Hancock know that there were problems with the ACCORD programme?

A. The ACCORD programme was extremely well intentioned but it fell into the worst of the bureaucratic and low-energy approach to clinical trials that may work well for academic study, but were not suitable for either an emergency or the very large-scale challenge that we had. I sat in meetings on a weekly basis in order to go through progress, and had quite a detailed understanding of where we were going, and you only had to look at the arithmetic progress to realise that the epidemic was going to be over before we came up with a solution.

In particular, recruitment was simply way off the scale we needed. And therefore, I was recommending a re-boot, which did in fact happen, and led to RECOVERY which moved much more quickly.

Q. RECOVERY was, I think, a little later or something running alongside this, but here we are a month into ACCORD, and it's already making slow progress. Was there any noticeable uptake, you having emailed the Secretary of State and as you say, encouraging Alok Sharma to battle hard and make progress?

A. No, I think this was an approach problem rather than a lack of scrutiny problem. Alok was doing everything he could do. But listen, the way in which an intellectual, academic-led organisation like UKRI does clinical trials is simply completely off the pace when it comes to an epidemic and we moved on to a different approach.

Q. All right, I was going to ask you about that, please, because certainly you wrote to Alok Sharma on 23 June.

Could we have on screen, please, INQ000478977, where you're writing to him to suggest how we might move forward with a renewed national programme for clinical trials.

And you set out that it's important to test repurposed drugs through large-scale trials. And you note your disappointment with recruitment in relation to

ACCORD.

And towards the bottom of the page, Lord Bethell, you say:

"I want to also share my thoughts on how to build on all the work in this space to date, particularly learning what works and what does not ..."

You say there:

"It is essential that research is driven by clinical need, with a rigorous focus on finding treatments ..."

You suggest that the CMO or DCMO should lead on identifying the critical questions.

"This should be delivered primarily through a new single lead National Trials Programme for Covid-19 therapeutics."

And then there was other suggestions on the second page of that.

But it's really that final line there, Lord Bethell, the new single lead National Trials Programme for Covid-19 therapeutics.

Why were you so keen to advocate for such a programme?

A. The problems with ACCORD, and actually some other trials that were going on, were very typical of the problems we have in our clinical trials system in the UK overall, and we were trying to apply ordinary, day-to-day

practices to an emergency situation, and the system creaked badly. Actually, what we needed to have had before the epidemic hit us, was a programme for warp speed style acceleration, and central decision making.

The reference here to the CMO leading on identifying critical questions refers to what I said earlier about identifying the compounds that should go into the system.

Q. Yes.

A. And having a national trials programme referred, in part, to that liaison with industry and with the NHS, so that prioritisation could be given to these trials, and that should be a recommendation that I'd like to put to the Inquiry: that this should be in place for when the next epidemic comes along.

Q. And who would you envisage leading the programme or being responsible for it? DHSC again?

A. Well, I'm agnostic about institutionally where there that should be. DHSC isn't really a clinical organisation and often during the epidemic stepped in when there was a gap. So it could be UKHSA, it could be an updated JCVI. There are a number of possible homes. Certainly someone like Professor Van-Tam did provide personally the kind of leadership that we needed and I'd like to see that institutionalised rather than relying

on individuals stepping up to solving problems.
Q. I think just finally on this topic, I think you chaired a roundtable in relation to clinical trials reform, and you made a call for a renewed national programme?
A. Yes.
Q. What happened in response to your call, Lord Bethell?
A. Well, we got a lot of very good papers. I happen to remember Baroness Blackwood, my predecessor, and Lord O'Shaughnessy both putting in papers that were very thoughtful, and it did provide some energy and some focus, Be Part of Research, the very good scheme, were involved in some of the response, and there were individual programs to try to accelerate clinical trials of the kind that I would like to see more of.
I fear that since then, a lot of that energy has fallen back and, in fact, clinical trials in the UK have fallen back in quite a worrying way since that moment of energy.
Q. A slightly different topic in relation to --
LADY HALLETT: Just before you move on, if I may.
MS CAREY: Certainly.
LADY HALLETT: You say you think you fear that the clinical trials have fallen back. Apart from the national -- do you believe that if there were a national trials programme, that would solve the problems you've been

identifying or are there other things that would need to be in place to solve the problems?
A. I'm afraid that the problem to our Covid trials is a list of about 20 things. So having one programme is a good way of providing leadership and structure, but there is a lot more things that need to be done and I could drop a note, if that would be helpful.
LADY HALLETT: That would. Thank you very much.
MS CAREY: It's not the silver bullet but it is part of the way to --
A. Correct.
Q. -- solving the problem. I understand.
Just on a wider angle in relation to clinical trials, did you take any measures, as minister, to address the lack of diversity in clinical trials, and help ensure that there was adequate representation of ethnic minorities, particularly given that we know the disproportionate impact that Covid-19 had on those communities?
A. Yes, well, getting equality in clinical trials is a massive priority of any clinical trial system. I don't think I necessarily had to drive that hard. It is a priority for anyone organising the testing of drugs, and in particular, both gender, ethnic, and any other kind of diversity. So I think that was uppermost in

everyone's minds.
Certainly issues like pregnant women, which I think has come up before in the Inquiry, were things that came up in our conversations and I drove as hard as I could.
Q. Were you aware of any specific efforts to try to drive up diversity within ethnic minorities?
A. Not off the top of my head. I'd have to refer to my papers for that.
Q. Thank you.
Can I turn to some questions about antivirals, please. And if it helps you, Lord Bethell, I'm at paragraphs 59 and 60 onwards in your statement.
We are moving forwards in time, I think, to 2021. And you set out there that in February 2021 you received plans for the proposed antivirals programme to look at three effective antivirals. And there was a proposal put to you, I think, that Charlotte Taylor shared with you and the Secretary of State, setting out the plan. Clearly, you say there, it was important, because the vaccine was not 100% effective and not everyone can have it, and so there was a need for the antivirals.
And you say this in your statement: that you were excited about the antivirals programme, noting, to quote you, it was a "really impressive piece of work".
Just help us, what was it about the programme that

enthused you?
A. Well, I think that we were grabbing it and something was being done. I think that there is a -- as you said yourself, that it didn't get the profile of the vaccination programme, but actually, there were some very ambitious and high energy work that was being done.
I could see, like everyone, that there were gaps in the vaccine delivery mechanism, there were going to be people who didn't respond to the vaccine. There was also the chance that the variant would escape the vaccine, that suddenly we would be dealing with a new virus that was not easily controlled by our plan A. That was very much on my mind.
It seems an odd thing to be worried about in retrospect, but right then, in February 2021, I didn't want to be walking into another epidemic because the virus had somehow jumped the shark and become immune to the vaccine.
So having that in place was a really big priority and I was impressed by the team's work.
Q. Do you know -- I know you left, I think, in September 2021 --
A. Yes.
Q. -- but had there been a discernible improvement or outcome as a result of the programme that was being

suggested to you back in February of that year?
A. Sorry, could you repeat the question.
Q. Yes. By the time you left office, effectively, had you seen the benefit of the fruits of the antivirals programme?
A. Well, yes. They had -- you know, Eddie had done a good job-off identifying key antivirals that could potentially be put to use, but in some ways history had moved on. The vaccination programme had delivered, for most of the population, a really good protection, certainly from severe disease and death.

It didn't stop transmission, it didn't stop Long Covid, it didn't work for absolutely everyone, but, broadly speaking, it was a route to escaping the epidemic. So in some ways, this work was less important than it had been in February.
Q. You say in your statement that, regarding antivirals, you believe that:

"... we might have been more creative about the possible ways we could mobilise antivirals using modern diagnostic, digital and delivery technologies [there]."

What were you trying to say in that statement, Lord Bethell?
A. Sure. So the big problem with antivirals is you need to give them to people before they show symptoms, really.

Once your nose is running and you're coughing it's probably too late, the medicine can't get in early enough. I take antivirals for a condition I have, so I know this personally to be true.

In order to get antivirals into someone before they show symptoms, you kind of need to know -- you need to get them to them very, very quickly, for instance on a motorbike, the moment that they test positive. So you'd need to test and treat. And also, you maybe give them to other people in their household or in their care home because they are most likely to catch the disease from the infected person.

I felt that within the NHS we could have been more creative about test, trace and treat, and within care home communities within prophylactically giving people antivirals and having them available for moments of outbreak.
Q. So, from your perspective, they had a dual benefit, potentially, for those who needed them once they had early symptoms, but indeed for those pre-symptoms to --
A. Correct. It was prophylactic and -- treatment -- (overspeaking) --
Q. I understand. All right. Now you say in that paragraph that "we could mobilise". Who is the "we" that you're referring to there?

A. Yes, I think in terms of delivery mechanisms, I'm really thinking about the NHS. Antivirals are a very commonly used medicine, they are regularly very difficult to get to people at the right moment, so this is a longstanding complexity within our treatment system.

Our treatment system relies on people falling ill, having a symptomatic, and then going to the GP. That is a very reactive way of doing medicine, and I'm making the observation that there are ways of trying to use data and home diagnostics to spot people much earlier on, and therefore get the kinds of medicines that catch disease at a very early stage to knock it out before the symptoms emerge.

That is the way that medicine is going across the board, and in order for our health system to be up to date and ready for the next epidemic, it is worth us thinking today about how we put in place those kinds of mechanisms.
Q. Now, you say candidly in your paragraph 68 that you think we could have been more creative.

"We were, perhaps, put off by the initial costs of the drugs and the prospects of huge unaffordable bills ..."

Can you help us, please, perhaps with that tension about the costs, the creativity, the need to protect

those for whom the vaccine may not work; was this people just saying it's just too expensive?
A. So there are two separate things. So antivirals are typically very cheap. They're short molecules, pretty easy to make once you've got them. Biologics can be incredibly expensive. It's sort of like claret wine, I think Professor Van-Tam explained the manufacture of it is incredibly complicated. Also you also have to infuse people. So, often they have to go to hospital and sit in a chair for an hour or two, and then be observed afterwards. So there are practical challenges with delivering some of these medicines. Some of them have high costs, some of them have low costs.

There is then the actual delivery mechanism, the use of motorcycles and also issuing large amounts of drugs to households on a pre-emptive basis.

So we did do that with diagnostics, we essentially gave every household an LFD, a lateral flow device, so they could use it the moment that someone within the household was spotted with the disease.

It is possible that if you had the right antiviral you could do roughly the same thing and issue them very widely. Of course that's -- we're talking, there, massive costs. So yes, money is a consideration.
Q. Coming on to the test, trace, treat option. You say in

your statement that you had early discussions about trialling a test, trace and treat option whereby a household or care homes would receive a delivery of the antivirals by bike for the non-symptomatic. But you say:

"... it was unfortunate that this approach was not pursued more emphatically early on, as it was offered strong potential for containing the spread of the disease ..."

Why wasn't it pursued and who did not pursue it?

A. I think it's unfortunate because we might need it in the next epidemic. Actually, in this epidemic the sequence of it was that we didn't identify effective antivirals until later by which time, frankly, the vaccine had got it mostly covered. By the time of the next epidemic, we should be in a place where we are studying the right antivirals against the right diseases in advance, and have the delivery mechanism stood up beforehand so that we have this alternative platform to respond to a disease. Otherwise we'll be scrambling again, as we were. And we shouldn't put all of our eggs in the vaccine basket because next time round, maybe the vaccine won't be the one that comes through; we'll be relying on therapeutics and antivirals for our primary response.

I shall return at 11.25.

(11.10 am)

(A short break)

(11.25 am)

LADY HALLETT: Ms Carey.

MS CAREY: Thank you, my Lady.

Lord Bethell, may we turn, please, to some of the work you did in relation to the immunocompromised members of society, and in particular if it helps you, paragraph 69 onwards in your statement.

Now, I think the Inquiry has already heard that in 2021, the CMO and DCMO decided not to buy Evusheld -- subsequently known as Astronaut, and there's various other ways in which it's referred to -- for use as a prophylactic. Do I take it from that that it was not your decision to not go ahead with that purchase? Were you consulted on the CMO and DCMO's decision not to purchase?

A. What was the date of their ...?

Q. February 2021.

A. So -- well, I wasn't consulted in terms of their decision -- in their submission. Their submission did come to me and I think I commented on it. I had, though, been a champion for measures to try to meet the concerns of the immunocompromised and had a huge amount

Q. I think you explain there perhaps why it wasn't pursued, but who or which department was the impediment to the pursuit of this potential option?

A. Look, I wasn't aware of an obstacle, a lot of people were very busy and it didn't get prioritised -- I think partly because, frankly, NHS and primary care in particular were flat out in their response, and weren't -- didn't have the spare capacity to look at this interesting but secondary mechanism.

Q. Final question on this topic, please: do you know, was any thought given to trialling this option on a small geographical area or in some way just seeing if it did in fact work and what the logistical problems may or may not be and the success or otherwise of this option? Was that ever thought about?

A. It's funny you should say that because I think it was, but when I went through my papers to try to find details of it, I couldn't find it. So I apologise for that. And I am afraid I can't give a conclusive answer.

MS CAREY: Not at all.

My Lady, I'm moving on to a totally different topic. Would that be a convenient moment?

LADY HALLETT: Certainly. I hope you were warned that we take a break, Lord Bethell, but I promise we will finish your evidence shortly after we return, I'm sure.

of sympathy for the situation that they were in.

Q. Right. May I add, it wasn't their decision, but it was their recommendation not to purchase Evusheld and I ought to correct myself before there are any misunderstandings.

A. Yes, of course.

Q. Did you agree with the recommendation not to buy Evusheld?

A. Yes, of course. If the CMO puts in a thoughtful, substantial evidence submission, a recommendation like that, then absolutely, one would go along with that.

Q. Now, I ask you that because certainly by 19 February 2021, you were -- emailed Matt Hancock to ask about the strategy for the immunocompromised.

Can we have on screen, please, INQ000497981.

At the top of the page, can we see there an email effectively between the private secretaries but from you to him:

"Lord Bethell fed back on this ... he is inclined to agree, but before, he would like to ask:

"'what is our strategy for the immunocompromised who cannot take the vaccine or who might not be protected by the vaccine, and how are we going to protect them."

And what was the answer to the questions that you were posing of the Secretary of State there?

A. Well, in some ways the answer was a large number -- a large investment in therapeutics and antivirals, and also a research programme led by NIHR around it, that it included the OCTAVE clinical trials and research. So there was activity in order to try to answer this question.

I think the reason why I flagged this to the Secretary of State is that I did want that activity to be thoughtfully coordinated, and that this is one group -- and there were many groups -- the autistic, the homeless, the -- who were particularly hard hit by this horrible virus, and given the state of where we were in terms of the national response, it seemed to me important that they had -- there was some kind of leadership that targeted the situation they were in.

Q. And was there, certainly whilst you were involved, someone put in place to provide that thoughtful coordination., of not just the immunocompromised but all of the other hardest hit communities?

A. Well, I think collectively, the response came from our collective actions. You couldn't necessarily appoint a tsar for every single group. It did occur to me, though, that because the situation that the immunocompromised were in was particularly complicated, and where the data was particularly patchy, it was

worthy of focus.

Q. I think in response to that email there was a strategy that was devised in March of 2021, and I won't go through all of it, but did the strategy, to your mind, alleviate the concerns that you were raising on behalf of the immunocompromised?

A. Well, yes, and no. Yes, that it was a strategy and it was the best response we could come up with, but no because I felt heartbroken that there wasn't more that we could do.

If you have a virus that attacks the immune system, and a vaccine that supports the immune system, those with compromised immune systems are particularly hard hit. So some of those questions don't have great answers, frankly.

Q. You say not more we could do. Do I take it from the answer you gave that it was inherent with the problems that Covid causes --

A. Yeah.

Q. -- that we couldn't do more, or was there anything that actually could be done, more, at ministerial level, departmental level?

A. Well, not wishing to avoid the question, concretely, what more could have been done was to have a plan for the immunocompromised before we began. And I'm happy to

talk about that if that would --

Q. We'll follow the thread through and perhaps we'll come back to that, Lord Bethell.

So there was a strategy devised in March of 2021, and as you set out in your statement, you met -- in July of 2021, there was a meeting with the immunocompromised, where there was the Department of Health and Social Care and, indeed, blood cancer charities in attendance.

And can we have a look, please, briefly at INQ00497986. Thank you.

12 July, there's a readout of the meeting that looked like it happened on 7 July. Various attendees, including Baroness Brinton, and if we look towards the bottom of the page, Lord Bethell, the baroness noted she would like to know who is the clinical lead for the work on prophylactic antibodies:

"Who is leading the policy on how to protect the immunocompromised? Is there a responsible minister?"

Do you know the answers to those questions that the baroness posed?

A. Yes. If I may just add, can I just point out that I was up in the House of Lords, two, three, four, five times a day, and peers raised the immunocompromised with me almost every day, and Baroness Brinton in particular, partly because her own personal expertise in the

situation, was an advocate. So this wasn't an issue that wasn't flagged to me --

Q. No.

A. -- on an almost daily basis and therefore I was very live to it. Was there a lead on it? There wasn't a named individual, but it was very much part of the system's priorities, including JVT, who had met them and done an enormous amount of work on it. And was there a responsible minister? Yes, that was me.

Q. Do you think a clinical lead would have lead to a different outcome in terms of how to best protect or try to protect the immunocompromised?

A. Well, if I may answer that in the round a little bit, if you'll give me a second. I think one of the things I learnt from this is that there are, with a big epidemic like this, national responses that address the whole population, and it's reasonable to prioritise those. But there are also a large number of special groups who are going to not be necessarily catered for by the national response. And therefore, you need to have a system that deals with edge cases and special cases. We didn't have that programme, we didn't have a 'What do we do with the immunocompromised' plan at the very beginning, and so we were putting these things together after the fact.

Now, partly that's because you don't necessarily know who is going to be, as it were, let down by the national response. So it's difficult. But there are going to be some groups you definitely know might be a problem, and it did strike me that the immunocompromised were one of those groups.

Q. And can I stand back from that for a moment, because I think you are aware that in August 2021, in an email thread -- and can we have it up on screen, please, INQ000066712_2. We are -- the date has been excised but it's 20 August 2021, Lord Bethell.

Can you see there in an email from Charlotte Taylor, she has had a brief conversation with the Government Chief Scientific Adviser including the Astronaut data, or Evusheld data, on prophylactics:

"I said there is limited enthusiasm for prophylactic use across the system. His reply:

"'I think that is misguided. There is a clear place for them and it just needs to be defined."

Two questions, please. Did you, as your time as minister, sense a limited enthusiasm for prophylactic use?

A. I think the response was based on evidence. I don't think that there was a -- sort of a prejudice. I think, as I've said before, and as the Chief Scientific Adviser

pointed out, it's good to challenge assumptions, and maybe there could have been scope for more creativity, which was the point I think I made earlier, so in that respect, I was probably aligned with his thinking, but no, I don't think that there was in any way a sort of built-in prejudice against any particular vector of treatment.

Q. Do I take it from your answer that if there had been that limited enthusiasm, you would agree that it was misguided?

A. Well, I pushed against it quite hard, as you saw in my note to the Secretary of State. So I was in there challenging and pushing, but decisions were made on the basis of evidence and non-clinical ministers can only go so far in terms of questioning the evidence.

Q. Right. That's August of 2021, and by September 2021 you left the government. What was the state of play as at the time you left the government in terms of prophylactics and, indeed, protection of the immunocompromised? So we are coming into about to be the autumn/winter of 2021. What was the state of play at that time?

A. Well, we were swinging out of lockdowns and intense national programmes, and one of the things that we were focusing on was: how do you deal with the people who

remain vulnerable to the disease? And that included, but not only, the immunocompromised.

And that's when the renewed focus was put on all of the other therapies, including the antivirals, to offer those who were shielding, who had led very worried lives for nearly two years -- how were we going to protect them? And that's really the state of things when I was leaving.

Q. Okay, just a few questions, please, about Evusheld itself, and please say if you're not able or in a position to answer some of them, because they may relate to after your tenure.

But from your perspective, did you get a sense of how much, if at all, cost was an issue in the decision not to purchase Evusheld?

A. Well, across the board, cost did not arise as issues, generally speaking. We were, largely speaking, given everything that we needed in order to fight the virus, and recommendations from the CMO and others were based on clinical evidence, not on economic evidence.

That said, cost isn't just a pound, shilling and pence; there's an opportunity cost in terms of how do you prioritise healthcare resources, which were extremely limited. So I wouldn't say that resources in the broad sense weren't a consideration.

Q. Do you think by not procuring Evusheld, there was a missed opportunity to provide protection and, indeed, short-term freedoms, perhaps, for the immunocompromised?

A. I don't think I'm qualified to answer that. I saw the submissions on the pre-purchase agreements earlier in the year, and there they were based on the clinical evidence, the -- the compounds hadn't been through clinical trials yet. The later decisions came after I'd left.

Q. Let me see if you can help with this, and please say if you can't. In light of the decision not to procure Evusheld, how do you consider the needs of the immunosuppressed were probably taken into account after that decision had been made?

A. I don't know if I can answer after. I would be happy to make comment on the period before.

Q. Finally this, please: the Inquiry has heard evidence that the vaccines were purchased on an at-risk basis.

A. Yes.

Q. Are you able to help with why the position was not the same for Evusheld?

A. Yes, well, I don't know if I can say -- well, yes, and not just Evusheld, you know, across the board. The Therapeutics Taskforce did not have a blank chequebook. It was the big distinction between the Vaccine Taskforce

and the therapeutics.

One of the reasons for that is the therapeutics and antivirals worked in different ways in different circumstances. The five-sided Rubik's cube that I mentioned earlier. Putting taxpayers' money at risk for that complexity of procurement really wouldn't have made sense. It would also have been a big distraction for the healthcare system which, by implication, would have had to twist to meet the delivery demands of each treatment vector, which frankly was beyond the scope of the resources we had.

Q. Different topic, please, Lord Bethell, and just a few questions, please, about the Moral and Ethical Advisory Group, or MEAG, as it is sometimes known.

A. Mm.

Q. Clearly you set out, and we know, that they provide independent advice to the government. The advice is not binding. But you, in your statement, certainly say that it's important to have external ethical advice. You consider it to be important, particularly during the pandemic.

Are you aware, certainly, of any advice that specifically addressed the health inequalities faced by ethnic minority groups and how that was integrated into policy decisions or the decisions that you had to make?

A. Well, our day-to-day conversations about the impact of the vaccine always included the vulnerable and health inequalities generally. They were a massive priority in everything that we did. I don't think we needed an ethical group to remind us of the importance of that.

Q. In relation to MEAG itself, I think you were, in May of 2020, asked to decide whether to publish MEAG's advice on the government website and you agreed to that.

A. Mm.

Q. You were also asked to create what was called a shortlist of principles on moral and ethical issues for policymakers to consider when developing a new policy. Let's call it a framework for short.

A. Yes.

Q. Why did you decide against the creation of such a framework?

A. Well, I thought that the MEAG was an excellent organisation that worked extremely hard and thoughtfully, in particular when there were requests from ministers on particular issues that had technical, ethical considerations. So something like vaccine as a condition of deployment. That has a political implication, an economic implication, a clinical implication, but also a highly technical ethical implication that would go beyond day-to-day political

analysis. So their analysis on something like that was highly valued.

But I didn't agree with the Nuffield blog that said politicians needed to have handholding by ethicists in order to understand the implications of their own decisions. That's what we have in Parliament. I was up every day being challenged on our decisions. So having a broad framework against which our homework would be scored, as it were, seemed to me to be a bit of overreach and I would draw the line at that kind of generalised ethical advice.

Q. Do you think, and I am asked to ask you this, whether the publication of a framework could have benefitted and, indeed, protected the vulnerable groups?

A. No, we were doing that every day.

Q. Finally, this, please Lord Bethell. I think we may have touched on it throughout your evidence. But you make in your statement a number of recommendations and, indeed, you've already spoken powerfully about the need for preparedness, something which will resonate with her Ladyship's evidence in Module 1, no doubt, but is there a key lesson that you would wish to put before her Ladyship?

A. Yes, I think there are probably two, and they are consistent with a lot of what has been said already here

before: there should have been a plan for containing the disease, and then treating those both who caught the disease and who -- for whom the vaccine didn't work in advance. Instead, we put one together, and I admire the hard work, diligence and effectiveness of those who were part of that response. But it was notable that we were working from a really, not from a blank sheet in as much as there was previous work obviously in this field, but without a clear framework.

And secondly, the shape of the healthcare system was not suited for a fast response and delivery. So if you look at the clinical trials or the delivery of antivirals, or of biologics, or of the manufacture and supply chain elements, no thought or consideration had been put into the resilience of the system for when we were going to be hit. And that's really what held us back in this area the most, is the lack of warm resources, resources that were in play on a day-to-day basis but could be scaled on a national basis when needed.

Q. Can I ask you this, then: in your statement you refer to gaps in the system, perhaps the weaknesses that we alluded to at the beginning of your evidence, certainly falling behind in terms of commercial clinical trials. Do you think now that, perhaps, rather than learning

lessons and being more resilient, we are less resilient than we were when we went into the pandemic?
A. Frustratingly, I do. I think we are in worse shape today than we were five years ago. The NHS is clearly under a huge amount of pressure in terms of capacity, the workforce are under pressure and there's been a drop-off on recruitment. International surveillance of viruses is not where it could or should be. In terms of the institutions of resilience, UKHSA, for instance, should be a national agency with heft and resources, and I'm disappointed that it has been denuded in the way it has been.

Local Resilience Forums remain a shadow organisation rather than something with strong local reach.

Your Ladyship, I could go on, but there are a dozen of these areas where we should have learnt the lessons on where we simply haven't moved forwards.
Q. Finally this please: would you support the development of a more diverse portfolio of vaccines and, indeed, antivirals as part of future pandemic preparedness plans?
A. Yes. As an illustrative point, there is an organisation called REDDI, that is trying to put together today genomic data on future viruses in order to have the resources in place to design antivirals for the future.

That is an illustration of the kind of preparedness that I think we should be committed in to, and, you know, would be a strong recommendation that should come from this Inquiry.
MS CAREY: No doubt one of many.

Lord Bethell, thank you very much.
LADY HALLETT: I think there is one more question I've allowed from Mr Wagner. If you can't answer it, please say, Lord Bethell, but I've given Mr Wagner permission to ask one question.

Questions from MR WAGNER

MR WAGNER: Thank you, and I'm grateful for the permission.

Good morning, Lord Bethell, I ask questions on behalf of Clinically Vulnerable Families. I just wanted to ask you a question about something you said earlier which was: you felt that within the NHS, we could have been more creative about Test and Trace and Treat, and within care home communities within prophylactically -- I don't know whether the draft transcript is quite right -- prophylactically giving people antivirals, having them available for moments of outbreak.

Is the implication of what you're saying that the urgent distribution of antivirals during the pandemic to those who needed them was not as effective as it perhaps could have been with more creative thinking?

A. Well, "should have" is carrying a lot of weight in that sentence. I think that the use of antivirals is fundamentally challenging, because of the problem I mentioned, which is you need to get them to people either before they've got the disease or at the very earliest stages, probably before they've got a symptom.

And that, not unreasonably, means that they are not put into work very often, because of the basic challenge of getting them to work.

I think we've reached a moment in history where the technologies around identifying risk and of distributing medicine, and of also manufacturing, extremely cheaply, antivirals means that we should be rethinking that whole mindset. It was difficult to do right in the middle of an epidemic, because it requires mechanistically putting together new processes, new arrangements, new ethical agreements and a whole different pathway for clinicians. These are not insubstantial things to do. But I would highly recommend we look at that agenda so that we are in better shape for next time.
Q. But the systems that were in place, that you'll have overseen, such as the five-day window you needed to apply for antivirals, in certain circumstances, do you think those systems were effective or are you suggesting that they weren't -- they weren't particularly

effective?
A. Well, I'm not a clinician, but my impression is that a five-day window is not a great way of running the antivirals programme, yes.
MR WAGNER: Thank you.
LADY HALLETT: Thank you, Mr Wagner.

Thank you very much indeed, Lord Bethell, those are all the questions we have for you. I'm very grateful to you for your insight and your candour and also for the fact that you highlighted the important work on therapeutics and antivirals, and thank you for the pressure you tried to maintain while you were in office. Thank you very much indeed.
THE WITNESS: Thank you.

(The witness withdrew).
MR KEITH: My Lady, the next witness is Eddie Gray.

MR EDDIE GRAY (affirmed)

Questions from LEAD COUNSEL TO THE INQUIRY FOR MODULE 4

LADY HALLETT: I hope you were warned you weren't the first witness on, Mr Gray.
THE WITNESS: Thank you.
MR KEITH: Good morning, Mr Gray.

Can you commence your evidence this morning, please, by giving us your full name.
A. Yes. My full name is Edward James Gray.

Q. Thank you very much and thank you for attending today and also for the provision of your witness statement dated 2 October 2024.

Mr Gray, you have, I think, some 40 years in the pharmaceutical and biotechnology sectors.

A. Correct.

Q. You were president of European Pharmaceutical Business at GlaxoSmithKline, GSK, and I think you were CEO of a company called Dynavax Technologies and, for some time, a board member of the Association of the British Pharmaceutical Industry.

For our purposes, the most relevant part of your career is that you were chair of the Antivirals Taskforce from 1 June 2021 to 1 April 2022; is that right?

A. That is correct.

Q. And we'll look at the detail, of course, of what you did as the chair of the Antivirals Taskforce in a moment, but, very broadly, was it the Antivirals Taskforce that led on the negotiations for, and secured the provision of, around 5 million courses of two oral antivirals? And they were: Paxlovid, nirmatrelvir/ritonavir, a Pfizer product known to you as Project Tyne; and also molnupiravir, known as Project Arrow, a Merck product called, I think, Lagevrio?

A. Yes, it was.

Q. This is a complex field, Mr Gray, and I'd like you to start, please, just by highlighting some of the differences between antivirals and more broadly, therapeutics and vaccines, because we've heard a great deal of evidence about various types of therapeutics and, of course, vaccines. And we need to put it into its proper context.

Therapeutics, in the form of drugs, are not necessarily vaccines. That's right, isn't it? And drugs or medicines, or therapeutics, may fall into number of different categories.

A. **(Witness nodded)**

Q. You might have small molecule drugs, which are known also as --

A. **(Witness nodded)**

Q. -- or generally are antivirals, and you may also have something called neutralising monoclonal antibodies, and we've heard of one in particular: Evusheld.

But you were concerned in the Antivirals Taskforce with molnupiravir and nirmatrelvir, which are not neutralising monoclonal antibodies, are they?

A. They are not.

Q. And unlike vaccines, drugs may be given prophylactically as well as by way of treatment for a disease?

And in the case of antivirals, and you were concerned with oral antivirals, is that something that can be given prophylactically as well as by way of treatment, or is it something that, in general terms, needs to be given as you're under attack from the virus, and therefore needing the beneficial impact of the antivirals?

A. Right.

Q. It does what it says on the tin?

A. Yes. So I think you referenced differences between the Antivirals Taskforce task and that of the vaccines. And I think clarity around the utility of the different medicines was one of the key differences. Because I think, for vaccines, a very early position was adopted that if you could find effective vaccines, as a population intervention they were likely to be the most effective response to the pandemic.

But there was no real question about their utility. If Kate and her team could identify and find these vaccines, then we were all going to get lined up and jabbed with them. So that was fairly straightforward.

But with antivirals, there are different ways in which they can be employed.

Q. So do you mean by way of oral ingestion or injection, that sort of means?

A. No, they were oral medicines, and we were seeking oral medicines because that was the easiest way to deliver them when we had them.

But you can utilise them in a broad population basis, possibly prophylactically, where the goal that you're trying to achieve there is really to interrupt transmission, to reduce the level of impact upon individual patients of having contracted the virus, and to clear them of the virus and to stop them passing it on to other people.

Alternatively, you can not give to it a widespread population but you can hold it back and recognise that there are certain people in the population who are more badly affected by the virus, and in this instance the focus was really on people who might go on to be hospitalised or indeed to -- death as a consequence, and in that instance, you're really looking for a very high-value response in reducing hospitalisation and death, but you're restricting its use and it's really then only about treatment. There is no prophylaxis involved in that particular case.

Q. So at some stage in the process a clear strategic decision needs to be taken as to whether or not you're aiming to try to protect the country at a population level --

A. Yes.
Q. -- or whether you're trying to focus on, and if you have only the means to try to focus on sectorial groups, those special cases who are particularly vulnerable?
A. Yes, I think it's reflected by when I arrived as the chair of the taskforce, I basically arrived with three questions: why are we buying these medicines? What are we trying to achieve with them? And do we know how to get the best out of them? And driving through responses to those questions really gets you then to the choices that you make.
Q. You became the chair on 1 June 2021. There had already been in existence for almost a year the Therapeutics Taskforce, which was constituted, I think, in April 2020.
A. Yes.
Q. Why was an Antivirals Taskforce needed in your view? Why could not the issue of oral antivirals be addressed by the Therapeutics Taskforce, oral antivirals being, of course, a therapeutic?
A. Well, as I understand the decision-making process, and it was only communicated to me, I think there was a view felt that with the winter approaching, and that was going to be the most fertile period of use of effective antivirals, that much like the decision around the

Vaccine Taskforce, there was benefit to separating it out and having focus upon it, and therefore it was removed from the therapeutics and set up as a separate taskforce.
Q. And were you aware of a clear political imperative or drive or direction that you tried to identify, and then procure and make available two antivirals in particular? Not two particular types, but you were tasked to try to identify two oral antivirals?
A. Yes. And actually, that made a great deal of sense. And actually, to the point you just made there, actually, you do want them to be two slightly different modes of action because if you have two different modes of actions in antivirals within a certain patient population -- that's a long story as to why, but it's beneficial in heading off the potential for resistance if you have different modes of action operating in the population at the same time.

So we did want two and we were hopeful that we would get two different modes of action.
Q. And you were hopeful that you would get them there by the winter of that year?
A. That was the key issue, yes.
Q. And was that because of the prospect of a further wave of Covid or because it was winter?

A. Well, the waves of Covid were coming to their own pattern, I think is the best way of doing it, but generally speaking, yes, in a winter environment, respiratory infections are generally more prevalent and more likely to cause widespread problems. So we did expect winter to be more of an issue, yeah.
Q. And antivirals themselves need to be speedily given, that is to say they need to be given at a relatively early stage in the disease path, bluntly, in --
A. -- (overspeaking) -- sorry.
Q. -- they need to be given as quickly as you can get them into people who are beginning to show signs of suffering from -- (overspeaking) --
A. Generally in respiratory infections there's a benefit to getting them in early, yes.
Q. You were approached, I think, first, in March 2021 to become the Chair of the Antivirals Taskforce, but you weren't appointed until 1 June.
A. Yes.
Q. In the context of trying to identify and make available two oral antivirals by that same winter, that seems to be quite a significant elapse of time?
A. Well, I think from my written statement I went through the process of calculating it was 25% of the available time which, I have to say, I felt a strange use of the

time. It wasn't clear to me why that was the case. I think I speculate in my witness statement around why the possible reasons for that, although you kindly sent me some other witness statements as part of preparation for this, and I did note in there, I think it was Patrick Vallance's statement that the Permanent Secretary at the time was advocating not to have an external chair so I presume that was part of the background to the delay.
Q. We needn't, perhaps, look at the reasons why the process did become so protracted, but it must have been obvious to you that by comparison, perhaps, to Dame Kate Bingham, whose appointment as the external chair of the Vaccine Taskforce went through within a matter of weeks, and also, perhaps, by comparison to Charlotte Taylor of the DHSC who chaired the Therapeutics Taskforce, the process of getting you in place seemed to have been much more protracted?
A. Yes, it was. And I think -- we're talking a year on, and I think obviously, when you look at Kate's evidence and Kate's experience, the concern about the pandemic at that point in time led to a lot of very different decisions and the set-up of the Vaccine Taskforce in BEIS with the direct reporting line to the Prime Minister. I think by the time antivirals were set

up a year later, the world had moved on and I think we were rather more -- what's the right way to phrase it? There was a greater sense of a return to normal business and this had a taskforce plonked on top of it, and that's the situation we found ourselves in.

Q. Were you able to form an understanding as to the degree of autonomy that you would be permitted -- the Antivirals Taskforce was within the DHSC, was it not?

A. Yes.

Q. So not BEIS like the Vaccine Taskforce and not an entirely external body. Do you happen to know whether or not the DHSC, for example, welcomed the existence of the Antivirals Taskforce within the DHSC, and whether or not perhaps it opposed having a more external and independent body?

A. Well, as I say, I've learnt from the other submissions that you've provided to me that the Permanent Secretary at the time was apparently arguing against Patrick's support of an external chair. The fact that I was appointed presumably means that others thought it was important to have the external chair. And I think perhaps on this subject, I've taken a point of having a look through various submissions' lessons, and watching some of the other people giving evidence to you in this particular molecule. It has struck me that

there has been much acknowledgement of the need for different decision making, for embedding of certain skills, et cetera. Nowhere in the lessons learned is there a comment around the contribution or value of an external chair in these things that I could find. There may be one there but if there is, I couldn't find it.

Q. Actually, my Lady asked a question directly of an earlier witness as to the undoubted benefits --

A. Ah, I missed that, apologies.

Q. -- of external experience, and of course we're well aware of the differences between the private and the public sectors in terms of running such bodies.

Let's have a look, please, at your letter of appointment. Was it from Mr Hancock?

Were you appointed by Mr Hancock?

A. I was.

Q. At INQ000410503.

If we look at that page -- and the letter is dated 27 May 2021, so four or five days before your formal appointment -- we can see that at the bottom of the page, he refers to the great success of the vaccination programme. But he is alert to -- and of course this was a very obvious concern -- that there would be certain groups in relation to whom presentation for vaccine was lower, and also significant groups who could not take

the vaccine or for whom the vaccines would have comparatively a lesser degree of benefit.

So the government was hopping to achieve the same success as the Vaccine Taskforce.

Over the page, we can see the objectives which were identified for your taskforce: to have two effective antiviral treatments deployable by the winter, identify the most promising treatments, work with developers, licence holders, help manufacturers to scale up, drive commercial discussions, and create a pipeline -- and this is obviously a nod to the future -- of additional promising novel antivirals.

Were those core objectives the right ones, as you saw it, Mr Gray?

A. Yes.

Q. And in terms of reporting, was there a proper system in place for your reporting structures?

A. Well, as you can see here, I was reporting to Lord Bethell, but there was an expectation that I would work independently and show leadership of the taskforce personnel.

I'd gone through quite a protracted process in ensuring that I had clearance to what was called "direct people" on the team and officials, and that was something I insisted on, having consulted people like

Kate and others who had worked in these environments before, because I did feel that was important, you couldn't be sidelined just as an adviser whose input could be followed or not followed, depending on which way the wind was blowing.

And so I think it was very clear at this point that we were not going to get an organisation, a structure and a reporting line similar to the vaccine question, but I did feel this was a very important job that needed doing, and therefore felt I should say yes to doing it, but secured that as a mechanism for ensuring that I could have an impact.

And of course, there was nothing, as we will no doubt come on to discuss later, stopping me writing to whoever I chose to write to where I --

Q. And you wrote I think prolifically, didn't you --

A. Yes, I did.

Q. -- to the Prime Minister repeatedly --

A. Yes.

Q. -- and to the Secretary of State on an almost weekly basis.

A. Exactly.

Q. It is notable that when Dame Kate Bingham agreed to become the Chair of the Vaccine Taskforce, she demanded and got the condition, or at least the agreement of

government that she would have a clear mandate with a direct reporting line to the Prime Minister. Also that the Vaccine Taskforce would be located within BEIS, not, by implication, the DHSC. And also that she would have the ability to establish a dedicated budget across government.

You were not given -- perhaps you didn't seek them, but you were not given that degree of largesse, were you?

A. No, but as I say, I think the world had moved on. It was clear that there had been conversations behind the scenes both about the BEIS decisions, and I think you've been investigating them here, and -- you know, one person's fruitful discussion between colleagues is another person's turf war. I have no idea where on that spectrum all of this sat, but, again, I did feel that the issue of getting these two across the line for winter was the most critical issue. And at some point you just have to get started.

Q. And to that end, you had a number of structures within the taskforce. You had a steering committee, you had a programme board, and within your organisation, you had a number of subgroups, did you not, that dealt with specific topics such as trial implementation, deployment, planning, procurement, supply, manufacture,

policy, and so on?

A. That is correct.

Q. In general terms what did you understand to be the position in terms of budget when you took on the task of becoming the chair?

A. So about two or three weeks in, we indicated that a budget had been set for the purchase of antivirals. It became clear that that was calculated by going back to a prior pandemic in the, sort of, 2008, and there had been antivirals employed there which were already available, were there for flu, and the price was set, and -- et cetera. And so a calculation had been simply, say, multiply that up by however many we think we might need this time, and that was the budget.

But of course, in this instance, the medicines were developed in a very different way. The companies involved, to their credit, took on the most difficult challenge by setting their phase III trial endpoints to be the reduction in hospitalisation and death. And as a consequence of that, they could see, and expected to be, recompensed for a much higher value product. The consequence of that then meant that, actually, the original calculations were sort of comparing apples to oranges, and I think it was always likely from that point on that the budget that had been set was going to

be challenging to meet.

Q. Ie, you would need a lot more money than provisionally had been set aside?

A. Correct.

Q. The Vaccine Taskforce proceeded on the basis that it would be able to enter negotiations with manufacturers and ultimately procure vaccines at risk, that is to say they would be able to enter into commercial arrangements, even quite a long way down that path, so not just by way of entering into heads of agreement, but agreeing contracts, at risk. That is to say without knowing whether or not the particular vaccine would work, let alone be authorised.

Was that the same approach that was applied to the purchase of the potential two oral antivirals?

A. Yes. And of course we also took every opportunity to mitigate that risk. So every contract that we signed was subject to completion of the clinical trials and approval of the medicines by the MHRA.

Q. So you were given that same strategic opportunity as the Vaccine Taskforce had been given?

A. We were.

Q. Was there, in relation to the budgeting and approval of the financing for individual oral antivirals, any form of ministerial panel, of which we've heard much in the

context of the Vaccine Taskforce, a body bringing together ministers from the Treasury as well as DHSC and perhaps other governmental spending departments, to authorise payments above a certain amount?

A. There was, I believe, a sort of mechanism for approval of financial decisions which was primarily set up within the Therapeutics Taskforce, and I think the idea was that, as antivirals, we would use that same mechanism. But I think the speed at which we were moving and the questions we were answering, and the fact that we were buttressing up against what I think was a poorly calculated initial budget meant that we moved to different mechanisms of trying to get decisions made.

Q. And very soon after you became the chair, did you have to address the issue of whether or not, in reality, that funding would be available?

A. Yes. So if you recall what I said about the different ways that you can use these, if you look at the initial brief to the taskforce, basically every single possible way of using them was in the brief. And the consequence, of course, when you then calculate against that brief, you come up with an immense number, literally billions, of how much that would cost.

And I don't remember who it was, but somebody at the time said: well, look, we have to acknowledge that the

taskforce have very comprehensively answered the exam question that was set, we just don't like the answer. And I had sympathy with that, it was that the original brief hadn't been thought through properly.

But the fact that that number came up and got everybody's attention I think was very useful because it stimulated, then, a much more sensible conversation around how should we use these? What is the appropriate way to use them? We had more information now on vaccines, and their rollout, and what we were starting to see, and whilst you could never take away the idea that a true vaccine escape would put greater pressure back on antiviral use, you could then start to have a sensible conversation which resulted in a recommendation that we should purchase antivirals to cover those people who were immune compromised and would struggle with getting a good vaccine response, and that's what we then started to focus all our activity on.

Q. Of course by June 2021, the United Kingdom had gone through the entirety of the phase I of the JCVI's priority list?

A. Yes.

Q. 99% of those most vulnerable to morbidity or mortality had been offered vaccination, and it was becoming clear

that the vaccination programme, to a very large extent, was going to succeed?

A. Correct.

Q. Do you think that against that political backdrop, there was less willingness on the part of the government to give you the funding that you felt you needed, or to give you the degree of largesse, my word, that the Vaccine Taskforce was itself permitted?

A. I think I should probably say that I've never taken a business decision, I can recall, where some element of affordability -- or, in small companies, even whether you've got the cash available -- is not part of the equation. So the idea that somebody somewhere was trying to sort of balance out the public health position that we were advocating with the country's ability to afford it, in principle I had no objection to.

The issue for me was really: was the process in place and the appropriate people in place to make that trade-off? And I didn't believe that was what was happening. And that's what led me to try to step out of the system to sort of do that.

But yes, I think in 2021 the world had undoubtedly moved on. There was a great deal more commentary in the public environment about how the pandemic was being managed, what was deemed to be going well, or not going

well, and there was a very open debate at this point in time about the economic impacts of the pandemic, which I think it's fair to say back in 2020 you didn't see in the public commentary at all.

So we were caught up in that, undoubtedly, yes.

Q. I should have asked you -- I neglected to do so -- in terms of the devolved administrations, Scotland, Wales and Northern Ireland, did the remit of the Antivirals Taskforce extend across the United Kingdom, so whatever oral antivirals you were able to identify, procure and make available, were you doing so for the whole of the United Kingdom?

A. We were, and there were meetings with the devolved administrations where the plans were presented to them, and they all agreed that they would prefer to be with the taskforce's work rather than reproduce it for themselves.

Q. They were happy for you to lead the charge --

A. Correct.

Q. -- and to take whatever benefit you were able to --

A. Correct.

Q. Let's look, then, at the chronology of how you reached the position whereby you were able to procure 5 million of those courses.

In your statement you've very helpfully set out

a chronology of the events, and we're just going to look at a few of the paragraphs.

INQ000474342, page 9.

Paragraph 27.4, you refer to the fact that on 18 June you were informed that the Treasury had approved a funding envelope with the Antivirals Taskforce of £621.5 million for the financial year 2021-22.

Obviously you were in June of 2021, so you were looking for approval for expenditure throughout the rest of that financial year.

Going forward from April 2022 would be another matter.

A. Correct.

Q. You weren't in fact the chair after April 2022, were you?

A. No, but obviously we were looking, as we may get on to talk to, we came to the conclusion that attempting to purchase to cover the first two winters was the appropriate strategic picture to take, given a whole host of factors, not the least of which was likely availability of supply, and so that would have incurred additional costs later in the system after I had in fact left, yes.

Q. All right.

Now, I don't want you to give me the exact amount,

because some might be able to work out, from the overall amount that you sought, the unit cost of the individual courses --

A. Yes.

Q. -- for the two drugs. But in general terms, although the Treasury had approved a funding envelope for 621.5 million, had a figure in the billions been initially suggested and perhaps put round government departments to the effect that that was the sort of funding which might be required if you were going to try to provide therapeutic remedy to a much larger part of the population?

A. So I think that I did hear somebody earlier in their evidence talk about two phases. I'd actually describe it as three phases. So the first phase was -- the first phase was answering the original exam question, which was many, many billions, and was clearly not appropriate in the circumstances.

The second phase was when we started to advocate what we felt was necessary to cover the immunocompromised. And we were doing so now having found out that this was the budget set.

The number we recommended was not of the original magnitude, but was greater than the 621, had we procured the full amount that we recommended. But as I think you

see in the documentation, we secured less than was originally --

Q. We'll come to that.

A. -- but was consistent with this number.

Q. Just on that first point, though, of the first phase: the importance of this point is, though, that there are some who say the government should have made billions of pounds available, but you, as the professional, and the external head of The Antivirals Taskforce, appreciated and proceeded on the basis that you had to be much more realistic in terms of what level of funding would be available from the Treasury?

A. Yes. And I think that was based on this continuing accumulation of evidence about the progress of the pandemic and, in particular, the success that the vaccine --

Q. Programme was having.

A. Was having.

There was always one big unknown that you simply couldn't control for, and that was an escape variant. And that was a completely different environment, obviously, and the scale of what response you would have to generate on antivirals was out there.

But I think the emerging view of the CMO and others was that that was a manageable risk.

Q. By escape variant you mean the possibility of a variant of coronavirus SARS-2 coming into play meaning that the existing vaccines would no longer be as efficient --

A. Correct, correct.

Q. Or would be no longer as effective. All right.

Then in August, the middle of August, on the 18th -- INQ000064095 -- you wrote to the Prime Minister to say that you had identified three antiviral candidates. Two of them were molnupiravir and nirmatrelvir/ritonavir, the Paxlovid Pfizer oral antiviral, and those two were the two you went on to procure. There was a third one that didn't go anywhere.

On page 2, having identified the two novel antiviral treatments, you deal with the process of supporting priority antiviral candidates to progress rapidly in clinical trials.

Presumably whatever oral antiviral you had identified would have to go through clinical trials, in order to be able to secure authorisation from the MHRA?

A. Correct.

Q. And was there a system already in place for the carrying out of those clinical trials?

A. So the clinical trials for antiviral candidates were the responsibility of the companies that were developing them. And by the time I became the chair, those trials

were well advanced. Clearly, this is very much a normal operational practice for these organisations. They -- I think I'm right in saying at the time I started that two of the three candidates were already in phase III, and the third one was in phase II.

And so they were progressing, and we did talk to both organisations about the ability of having trial sites in the UK, and I think one of the companies, if my recollection is correct, did recruit some UK patients. But we were not in any way getting formally involved in the trial. That was their responsibility, and I think one company had UK patients and the other didn't, if memory serves me correctly.

Q. So you didn't have to deal with the difficulties that other, particularly phase II clinical trials --

A. We did not.

Q. -- for therapeutics had to encounter, which was difficulties of recruitment and whether the trials were sufficiently diverse or underpowered, or managed.

A. We did not.

Q. You had a clear line of sight?

A. We did. And the issues of things like diversity, of course, these large pharmaceutical companies are doing these trials in different areas all the time. Those goals of diversity, et cetera, are part of their normal

standard operating procedures. So I was confident that we were going to get properly managed, high-quality studies, and that the MHRA would be able to make their decision.

Q. All right. Then at the end of August you wrote to the Secretary of State, INQ000489913, I think on 30 August, to give advice as to what he should do, and by this stage, August 2021, the Secretary of State would have been Sir Sajid Javid --

A. Yes.

Q. -- Mr Hancock having resigned, and you submitted options for purchase of antivirals over the next two years. And how many courses did you, in terms of millions, recommend be purchased?

A. So -- 25 million.

Q. And was that over that year to the winter 2021 --

A. No, that was --

Q. -- or was it over the two years?

A. No, that was over the two years.

Q. All right. And in the middle of the page we can see, I believe, reference to the amount of the funding which had been available, and if it's not on this page it'll be on the next.

Yes, it's the top of the page, thank you. The top line:

"... highlight that the ATF budget of £623 million is insufficient to allow procurement of any reasonable volume, given market dynamics ... and the international context of constraint global supply until at least 2024."

So, in essence, were you saying, "The budget is not going to be enough to get the number of courses that we would recommend that we pursue, you're going to have to increase it"?

A. That is what I was saying, yes.

Q. Further down the page, at paragraph 8, if we scroll out, we'll see that you say this:

"... I do feel it is important that decisions are not 'reverse engineered' from a financial target ..."

What did you mean by that?

A. What I felt it was important was that we were -- that we -- in negotiating the balance between the public health goal and the affordability, that we started from the process of public health, and ensuring that we reached absolutely what we felt was, at the very least, the minimum that would achieve our goal, rather than starting from 623, and working out what you could get for that.

Q. All right. And was that why, if we look at page 3, paragraph 14, you provided -- thank you very much -- you

provided a number of options, but you identified that as an absolute minimum, you had to get 1.8 million courses from Arrow, Arrow being Merck, that's the molnupiravir --

A. Yes.

Q. -- oral antiviral, isn't it? And the full 250,000 from Tyne, so that's the Paxlovid and the Pfizer:

"... from this autumn and winter, giving us a total of 2.05 million doses."

And then you wanted another 700,000 courses of molnupiravir.

A. That was our advice, yes.

Q. Around this time the Inquiry has seen evidence in the form of emails from you to Sir John Bell and the then Government's Chief Scientific Adviser Sir Patrick Vallance, saying, in essence, about the Secretary of State, Sir Sajid Javid, "He's supported our recommendations, which is good, but getting decisions across him, the Prime Minister and the Chancellor has been ridiculously hard."

Why were you saying that in email correspondence whilst at the same time you had given the government or the Treasury options as to how they should proceed in terms of funding?

A. Well, the memo that you've just shown was consistent,

I think, with the frustration I was starting to feel at this point in time about the decision-making process. And the only way in which I had -- I was concerned that the process on constant reiteration meant that this potential trade-off between public health goals and affordability goals ended up being -- the decision being made by junior civil servants. Because in the system that operates, there appears to be a premium for the Civil Service to agree an answer to a question, feed that answer up on both sides of the house, and then, so the same recommendation goes to ministers in two separate pots. And I didn't, in this instance, feel that that was appropriate.

I thought that if we were making a trade-off of this nature, I fully understand that it may have to be made, but the senior responsible people should be making that decision, and consequently, rather than allow that to sort of continue, I simply wrote to the Secretary of State saying, "Here's my advice."

Now, separately, we were starting to stimulate the process around thinking about the next phase, and future medicines, and John Bell was involved in helping us set that up and introduce us to people who could contribute, but as you said, John was involved in many other things in the -- Sir John was involved in many other things,

and he'd picked up from somewhere that, you know, the conversation over this particular decision was sort of getting a bit mired and going a bit slow and not necessarily going very well.

So I think I'm right in saying, if you follow that email trail back, it started with John's letter, not mine. John's email, not mine --

Q. It did.

A. -- and I was responding to that and sharing my frustration that he'd already identified.

Q. So in essence, Mr Gray, what you're saying is that you would have preferred your departmental officials, the people within the DHSC, the people who were assisting you within government and assisting the Antivirals Taskforce, to be more proactive in terms of putting their fiscal case to the Treasury --

A. Yes.

Q. -- and then seeing where the cards fell?

A. Yes.

Q. As opposed to, within the bureaucracy of government, trying to find the lowest common denominator?

A. Yes.

Q. That is to say, a fiscal package that would itself be acceptable to the Treasury; is that what you're saying?

A. I am.

Q. Right.

A. I think part of the concern I had with the process I was observing was a clear power imbalance. And I could see officials in the Department of Health and Social Care essentially starting to undermine their own argument for the recommendation we were making before we'd ever had the proper discussion at the right level. And as I have said, my conclusion was the only way to sort of spike that was to step out of the system --

Q. -- (overspeaking) -- all right.

A. -- and go directly to those people I felt should be making the decision.

Q. So, in fact, you emailed the Secretary of State on 8 September and then, not content with that, or perhaps the reaction in the meantime, you emailed the Prime Minister directly on 15 September.

If we just look, please, at the email to the Prime Minister of 15 September, INQ000410527.

In essence, you, if I can summarise your email in this way: you set out what the aims of your Antivirals Taskforce were, and in particular, the procurement of the two oral antivirals for that winter, and of course, by now we're talking September, and you say at the bottom of the page: you recognise that you were in competition with other countries for a limited supply of

medicines -- so, in essence, you need to get on and buy them.

And on page 2 -- page 3, I'm sorry, you set out again the options:

"... order immediately from Arrow 2.5 million courses ... intermediate ... order some lower than 2.5 million courses from Arrow ..."

Arrow being Merck.

"Not affordable option: order no further courses or only those courses affordable under the current budget or only sufficient courses to support the [National Institute of Health Research] trial."

In the event, on 26 September, so about ten days later, you were informed, were you not, that what had been agreed at that, presumably very high, level that you may proceed to buy or negotiate over the purchase of 480,000 molnupiravir courses, that is to say Project Arrow? That was way short of what you were looking for, was it not?

A. Yeah.

Q. And did there come a time where you had to go back in to bat, you had to try to get the numbers up, and you pursued the DHSC and HMT to agree a larger number of courses?

LADY HALLETT: Just before you go on, Mr Keith, I remember

once when I was having to negotiate with ministers that I was told that only certain people necessarily have their letters or emails forwarded directly to the minister or Secretary of State.

A. Right.

LADY HALLETT: Were you confident that your emails and letters were going to either Mr Hancock or the Prime Minister?

A. Yes, because, generally speaking, I asked for a reply. And so I knew if I didn't get one of those, yes. Yes.

MR KEITH: And I think it's fair to say, Mr Gray, that when you emailed the Secretary of State and the Prime Minister, you made sure that you'd emailed all the private secretaries, permanent secretaries, undersecretaries.

A. Yes.

Q. There wasn't any way that it wasn't going to get to their attention in the end?

A. No. And I think it goes back a little to the point you were making right at the very beginning about the different set-up. I think, you know, my view was that I always that the option, if that's the right phrase, of throwing my toys out of the pram if necessary, and this felt like an appropriate time to do.

Q. So the amount -- the number of courses agreed by the

Prime Minister, you presume it was the Prime Minister, but somebody at a high level, was less than you thought, but you had got, then, agreement in principle to that purchase.

However, in the middle of October, on the 21st, the evidence before the Inquiry suggests that HMT, the Treasury, requested of you, your taskforce, what was called a deployment plan. That is to say, evidence of why you needed the courses of molnupiravir, how they were going to be deployed if you got them and what benefit, I suppose, would be derived thereby.

A. Mm.

Q. Agreement having been made to that purchase, although it was a purchase you wouldn't have agreed to yourself -- it was less than you wanted -- why was the Treasury asking for further information in support of your request for authority to purchase?

A. So I think I read it slightly differently.

So, first of all, I think the fact that we had an operational plan to get the best from what we'd been able to secure, I had, in principle, no issue with. Absolutely, particularly if you have been restricted in how much you want, I think one of the big benefits of the PANORAMIC trial that we eventually went on to utilise was that it absolutely guaranteed that the

courses that we'd bought would in fact go to the people who really needed them, rather than to, sort of, just dissipate throughout the system.

I think the Treasury saw it as their responsibility to ensure that, having spent the money, that we were getting cost effective use out of it, and it was a natural fallout of a plan we were putting together anyway, so it didn't strike me as a particular hindrance or a burden.

Q. All right. In the event, negotiations with government or at least communications with government as to the procurement of a larger number of courses of stocks proceeded, and Sir Sajid Javid, I think, authorised more stocks to be bought, more courses to be bought, by the end of November.

There was an email that we asked Sir Sajid to comment on, it's not on the screen and won't be in the system, but it was an email dated 1 December 2021 in which you referred to a "dreadful sense of deja vu and being mired in the treacle of interdepartmental process and argument".

Lovely prose, but by 1 December, Mr Gray, Sir Sajid had authorised the purchase of, or the pursuit of the procurement of the greater number of stocks that you'd looked for.

A. Yes, I think there were two sources of frustration for me in this whole process. One was bypassing the normal practice to get right people to make the decision. But even when you did that, the timeliness of that decision was then a separate problem.

And so Sajid -- or the Secretary of State had requested us to go out and secure more supply. We had negotiated with the companies concerned. Clearly we were not the only country coming back to them at this point in time, because this whole initiative was now on the back of the emergence of Omicron and of course all other countries had the emergence of Omicron at the same time.

So, having responded swiftly and effectively to the request, we were then in the same situation of how do we get the final approval for the spend. And that turned out to be as slow as previous occasions, which was equally frustrating as previous occasions.

Q. All right.

In November and December, authorisation was granted for the two oral antivirals by the MHRA, we know from other evidence, and you had reached agreement with the manufacturers for those further courses to be bought.

And then, were the two oral antivirals put through what was called the PANORAMIC trial, a clinical trial

process, in order to ensure that, of course, in terms of effectiveness and safety, they were appropriate for use?

A. Yes. I think there were two reasons why I supported PANORAMIC. One of them I've already mentioned, which was to simply put the stock we had out into the national health system ran the risk of people who were not in the most vulnerable groups getting courses, and then we get to a point in the process where people on the vulnerable list needed the courses and we'd run out.

So this was a means of managing the process by which the people who we'd bought them for were the people who got them.

I think the second value of PANORAMIC was a reflection now that we were in a world where everybody had been vaccinated and, whilst the outcome of PANORAMIC wasn't necessarily going to determine any of our actions in that first winter, a much better understanding of the impact of these antivirals in a vaccinated setting was going to be useful going forward in the future. So I thought they were the two primary reasons that led me to support PANORAMIC as a good idea.

Q. Once the oral antivirals had been authorised and they'd been trialled -- they're two separate processes, of course --

A. Yeah.

Q. -- and therefore proved to be effective and safe, they were allowed to be made available --
A. Correct.
Q. -- to those groups for whom vaccines, for a variety of reasons, may not work?
A. Correct.
Q. We know from the evidence before the Inquiry that the route by which, in general terms, the antivirals were made available was through a body called the Covid Medicines Delivery Unit. Was that something of which you had oversight? Was that a process with which you were involved at all, or was that down the road -- further down the course of making antivirals available and for other parts of government?
A. So that was within the National Health Service. And my recollection, which -- I'm happy to be contradicted if my recollection is not right, but the setting up of PANORAMIC primarily involved people's presentations of general practice, identification and confirmation of infection, and then they were given the antiviral medicine.

Two things came up. The CMO, if my recollection is correct, identified that within that highly -- within that population, there was an even more vulnerable group, the most vulnerable group of all, a smaller

group, for whom putting them in a trial setting was not appropriate. So they had to have the antiviral.
Q. They had to be offered it outwith the --
A. Any other -- outwith of the treatment thing.

And there was also, I seem to remember, some question mark as well about very rural areas being able to get the antivirals to them. So CDMUs, in my recollection, were set up to sort of help address those two questions. But, as I say, I would accept if my recollection of that is not wholly accurate.

So, no, I wasn't responsible for it, but I was involved in meetings and discussions about the need for them.
Q. Yes. Within your functions, Mr Gray, lay an obligation to consider future pandemic preparedness, and in for the autumn of 2021 did you task a team within your taskforce to look at future pandemic preparedness, and were a number of papers -- (overspeaking) --
A. We did, although the paper did not -- wasn't finalised until after I'd left, but I did kick it off, yes.
Q. We've seen a paper, it's undated, but it talks about a meeting called the "Eddie/FPP", future pandemic preparedness group, regarding future pandemic preparedness, and it talks about the need, of course, for onshore manufacturing, the need for speed, for

adhering to what we've heard was the 100 Days Mission, which was the United Kingdom/G7 promoted policy.

You wrote a number of letters to the Secretary of State on 10 January 2022 and then later in January 2022, about manufacturing in future pandemic preparedness. Why did you feel there was a need to write directly to the Secretary of State on these issues?
A. My recollection at the time was that that was in response to a request to do so.
Q. In your emails, we needn't put them up, you deal with the issues of onshore manufacturing, you call or you observe that there's a great need to develop appropriate infrastructure. You need different options for manufacturing, alternatives to manufacturing, and of course having as wide a range of therapeutics, or particularly oral antivirals, as possible.

That process culminated in a letter you sent to the Secretary of State on 28 March 2022, which must have been a week or so before you stood down. And you talk in that letter of questions needing to be addressed, and challenges needed to be overcome. And you talk in terms of the interface, to use a neutral word, between Civil Service and external professional experience, and how your job, in terms of getting these two oral antivirals out of the door, was made a great deal harder by that

working relationship --
A. Yeah.
Q. -- or the lack of working relationship.

Why, again, did you think it necessary to write to the Secretary of State about this aspect of the administrative structures inside government?
A. Well, this was essentially my goodbye letter, and I think I knew that the decision post my leaving wasn't to have antivirals remain as a separate taskforce; it was going to be folded back into the Therapeutics Taskforce. And I also knew, with my own departure, that all the other external people were leaving as well. I just felt it would be important for the Secretary of State to have, as a resource, essentially my summation of where we were and what -- and the things that I thought he would need to have at the front of his mind as the pandemic continued to play out.

So it was simply meant as a sort of helpful, you know, "Here's my leaving, here's a mind dump of the things I think I've learned. Hopefully it's of use to you."
Q. In 2020 there was no vaccine. Did you therefore ask, in your letter, the Secretary of State to consider what might have happened, what might have been possible if, in the course of 2020, there had been available oral

antivirals or, perhaps, neutralising monoclonal antibodies, in the absence of the vaccine? What would have been the likely impact, in terms of hospitalisation and death in the United Kingdom?

A. Yes. I felt, thinking about 2020 was just a useful analytical construct for thinking about a future pandemic, because even with 100 day missions and other good plans in place, I think one of the things we have to recognise in this pandemic was we were very fortunate that we got a vaccine quickly that worked, and as I believe you've had in evidence from other people, we cannot guarantee that that will happen next time.

So the idea of looking at this current pandemic and saying, "How do we avoid 2020 next time," just seemed to me a useful way to think about it, and to sort of then, in thinking about preparation for another one, don't have the concentration of that thinking upon getting to a vaccine as the only thing you're thinking about, because there may well be things that you can do in the run-up to that, which mitigates some of the impacts that we experienced in 2020 this time round.

So that was my thought process.

Q. And that's an appeal which you presumably reiterate to this Tribunal?

A. Absolutely, yes.

Q. Your statement doesn't pull its punches, Mr Gray, in terms of your reflections on working in government. And I'm just going to summarise them, if I may.

You, like, in fact, Dame Kate Bingham before you, note the lack of what you describe are necessary skills and experience to make informed decisions in this technical/business/scientific arena. And you say that the Civil Service suffered from a lack of relevant experience. There were too many generalists, not enough, I think you would say STEM graduates, too many committees, too much paperwork, writing endless submissions and emails, and therefore a process which was burdened by its administrative weight --

A. Yes.

Q. -- and leading to decisions which seemed to you being made that were safer, and therefore wrong --

A. Yes.

Q. -- than a decision that was perhaps just riskier and braver, and more likely to get us to where we needed to be? Is that a fair summary?

A. Sadly, yes, it is.

Q. You mentioned earlier how you'd started in November of 2021 formulating some policy proposals for the future, in particular in relation to future pandemic preparedness, and were three of them in fact

recommendations which my Lady has heard much about: firstly, to develop a research and development infrastructure that supports the exploration of a broad spectrum of oral antivirals or therapeutics; secondly, build a library of prototype antivirals that can then be put properly but safely, but rapidly through phase II/III clinical trials; and also increase investment in diagnostic development work?

A. Yes.

Q. Are those the three, in your assessment, the three most important recommendations that you've put in your statement, and which in fact appear in the report that was finalised after you left?

A. Yes, I would still be in support of all of those three.

MR KEITH: Thank you very much.

LADY HALLETT: Thank you very much, Mr Keith.

Mr Gray, thank you so much for the help you've given the Inquiry. I think your evidence has highlighted the need to have external chairs, if I say so -- not that I needed any persuading. It must have been very frustrating for you at times.

And may I say on behalf of the population of the United Kingdom, we are extremely fortunate that people like you and Kate Bingham were prepared to bring your skills and expertise to chair the taskforces, and I'd

like to offer you our thanks.

THE WITNESS: Well, firstly, thank you. I did put in my final letter to the Secretary of State that I think it was -- I know everybody outside of government to have contributed felt very positive about the opportunity to do so. And I should actually say, despite my criticisms of the Civil Service, that the team that we formed, combining external and Civil Service people in the taskforce, I think did an outstanding job, including a very smart and impressive cohort of young civil servants, and I remain very proud of what they achieved, and I should thank them.

MR KEITH: My Lady, would you allow me simply also to observe, through Mr Gray, that the head of your programme board was, I think, Charlotte Taylor.

A. She was.

MR KEITH: And she was also the official who was in charge of the Therapeutics Taskforce?

A. Correct.

MR KEITH: And she obviously did an amazing job.

My Lady, for a variety of reasons, it hasn't been possible to call her to give evidence before you, but she is possibly the last person in the trilogy of chairs to whom great tribute must be paid.

LADY HALLETT: And thank you for what you said too about the

officials with whom you worked closely, obviously, Mr Gray. I'm not suggesting the entire Civil Service is full of people who impose bureaucracy, but I think one of the messages that I'm getting from you and from Dame Kate is that processes may be important in peacetime, but when it comes to an emergency, you need to be able to push aside some of the --

THE WITNESS: I would 100% agree with that, yes.

(The witness withdrew)

LADY HALLETT: Thank you very much. I shall return at 1.55 pm.

(12.53 pm)

(The Short Adjournment)

(1.55 pm)

LADY HALLETT: Mr Keith.

MR KEITH: My Lady, the next witness is Sir Munir Pirmohamed, if he could be sworn, please.

SIR MUNIR PIRMOHAMED (affirmed)

Questions from LEAD COUNSEL TO THE INQUIRY FOR MODULE 4

LADY HALLETT: I hope you were told you wouldn't be on until this afternoon.

THE WITNESS: Yes.

MR KEITH: Sir Munir, could you commence your evidence, please, by giving us your full name.

A. Munir Pirmohamed.

Q. Thank you for attending today and also for your provision of your witness statement, which is dated 5 September 2024, including a large number of exhibits, all of which, of course, has been very carefully looked at by the Inquiry and will continue to be so.

By way of background, please, and your qualifications and experience, Sir Munir, you qualified in medicine, did you not, from the University of Liverpool in July 1985, you've undertaken clinical work in the NHS for many years, you're a consultant physician, but you first joined the Commission on Human Medicines in 1996; is that right?

A. I joined the -- one of the expert working groups, which was the Pharmacovigilance Expert Advisory Group, in 1996.

Q. When you give your answers, could you try to go as slow as you can, it simply makes the task a bit easier for our hardworking stenographer. Thank you.

You have carried out a vast amount of research in the field of the safety of medicines, I think you've published over 660 academic papers in that area.

You are a clinical academic researcher and you hold the David Weatherall Chair of Medicine at the University of Liverpool and a number of other chairs; is that right? In particular in the field of pharmacogenetics.

A. That's right.

Q. Having joined, as you say, the Pharmacovigilance Expert Working Group in 1996, did you become a member of the Commission on Human Medicines in January 2020?

A. That is correct.

Q. And were you appointed the chair of that body on 12 February 2021 for a four-year term?

A. That's correct.

Q. So you're still in harness.

A. **(Witness nodded)**

Q. We've heard a considerable amount of evidence about the expert working groups which form part of the Commission on Human Medicines. During Covid, were you member of three of those expert working groups, the vaccine safety surveillance methodologies expert working group, the vaccine benefit risk expert working group, and the therapeutics expert working group?

A. That is correct, I chaired the vaccine benefit risk expert working group.

Q. The Commission on Human Medicines is obviously a statutory body because it was established by the Human Medicines Regulations 2012. But how long had its predecessor statutory body been around for, and before then, how long had the *ad hoc* committee dealing with giving advice on the safety of medicines been around

for?

A. So the first committee was set up after the thalidomide disaster, which was in 1964. It was the Committee on Safety of Drugs, which was called the Dunlop Committee. This was then succeeded by the Committee on Safety of Medicines, and then in 2005, this was then changed to the Commission on Human Medicines.

Q. Was the Yellow Card Scheme first introduced at the time of the Dunlop Committee?

A. It was.

Q. So it's been around for a very long time?

A. A long time, yeah. 70 years last year.

Q. In very general terms, do the functions of the Commission on Human Medicines extend to looking at safety with a high degree of exactitude in the context of the clinical trial process, the authorisation process the process by which the MHRA authorises therapeutics and vaccines, medicines, but also post-authorisation. So from the very beginning of the process by which any medicine is developed, right to the end of the process years after it may have been authorised?

A. That is correct.

Q. Is it operationally independent of the MHRA, the JCVI, the DHSC, and all the other myriad bodies about which we have heard?

A. Yes, it is an independent body and it is important it remains an independent body.
Q. I think your secretariat is provided by the MHRA, but is the CHM, I am going to use the acronym from now on, operationally and functionally completely independent from the MHRA? You don't adopt its advice, you won't necessarily take the same position as it will and it has no influence on any of your thinking?
A. Yes, it is independent. We get the secretariat from the MHRA but it is independent and provides advice as an independent body to the MHRA and the Secretary of State.
Q. Formerly, you give advice, do you not, to the MHRA and where there is a Licensing Minister in place as the licensing authority, which is what the MHRA is ordinarily, to the Licensing Minister as well.
A. That's correct.
Q. During the course of the pandemic did the MHRA and/or the Licensing Minister -- and there were a number of licensing ministers during the course of the pandemic -- following the advice given by the CHM?
A. Yes, they followed all the advice that was given by CHM. I do not know of any incident where CHM advice was not followed.
Q. You're subject, I think, to a very strict Code of Practice; is that right?

A. That's correct.
Q. And do we see, and we'll see perhaps in a moment, that in the course of every CHM meeting, there are long pages devoted every single individual member of the committee declaring relevant connections and links and also at the end of the meeting minutes, again, a long list of declarations of links, personal, non-personal, specific, non-specific, and so on?
A. That is correct.
Q. In terms of the devolved administrations, is the CHM UK-wide?
A. It is UK-wide.
Q. So it gives advice to the MHRA which is itself a statutory body --
A. Yeah.
Q. -- which has UK remit, and did you happen to have a close working relationship with representatives of the devolved administrations?
A. So we advise the MHRA. We did have representatives from the devolved nations attending some of our meetings as observers.
Q. So not as members but as observers?
A. As observers.
Q. And were those observers from in England the NHSE, and PHE, UKHSA, Scotland, Public Health Scotland, Public

Health Wales and the Health and Social Care Committee in Northern Ireland?
A. That's correct, as well as JCVI.
Q. And JCVI. All right. Give us, please, some scale of the degree of work and attention paid to the issue of vaccine safety. Roughly, how many times did the vaccine benefit risk expert working group meet between 2020 and 2023?
A. There were 93 formal meetings but there were other meetings in between as well, so I would expect that we probably met more than 100 times.
Q. We needn't, I think, spend any time looking at the role of the CHM in the course of the clinical trial process. We've looked at the clinical trial procedures from a number of different angles already, so we can focus on the introduction of the CHM's input from the moment of authorisation onwards.

But presumably, prior to authorisation being granted in the case of each of the three Covid-19 UK vaccines, the CHM was very well aware of the nature of the vaccines in each case: the clinical position, safety-related issues, really everything to do with their development, and production, because you were involved from the very start?
A. That's right. So obviously the rolling review that

happened was very important, you know, in order for us to be able to look at the data that was coming in with regard to efficacy, but we spent a lot of time on the quality particularly at the beginning, because if you don't have a product which is of good enough quality then it won't go through the authorisation process. But then, when the safety issues also started coming through, we were able to look at that as part of the rolling review.
Q. Coming forward to 8 December, the Pfizer vaccine had been authorised on the 2nd, and the first vaccination was given to Mrs Keenan --
A. Yes.
Q. -- on the 8th. When the Pfizer vaccine was rolled out on that first day, was there, at the moment the programme started, a 15-minute observation period?
A. There wasn't when the first vaccine was given.
Q. What happened on that night, the first day of the programme?
A. So there were two reports of anaphylaxis on the first day, and I got a phone call at quarter to midnight saying that we need to meet now to be able to discuss what happened and what are we going to do to be able to make sure that the vaccination programme can continue but ensure that we monitor the safety of the vaccines

and ensure there is mitigation in case of further cases occur.
Q. Were you able, that night to, to establish whether there was any link, other than temporal, between the occurrence, the incidence of anaphylaxis and the receipt of the Pfizer vaccine?
A. Obviously anaphylaxis, by definition, is an adverse event which occurs very soon after the administration of a medicine such as a vaccine. So from that we were able to assess that temporal relationship and it was clear that these individuals who had developed the reaction had a complex history but nevertheless we felt that the vaccine was probably responsible and therefore we then instituted changes to the drug label, to the product information, patient information leaflet, as well as introduce the 15-minute waiting time after vaccination.
Q. Overnight?
A. Overnight.
Q. So that when vaccination continued in the morning, the up-to-date position was being given to the public as well as the clinicians or the vaccinators?
A. Yeah. I should also say that on the next day, we got together with experts in immunology, allergy, and brought them together to get further advice in terms of making sure that we were looking after the risks

associated with the vaccine in terms of anaphylaxis.
Q. It was no small matter to introduce a 15-minute observation time?
A. No.
Q. Because presumably there was a huge impact in terms of the arrangements that were being made in every single vaccination site?
A. Absolutely. Because all the processes which had been developed in the weeks before the first vaccine was authorised was all based on getting large numbers through. But then when you have a 15-minute waiting time you need more space in the waiting room, and your throughput actually goes down.
Q. So you were concerned about slowing down the rollout by doing this?
A. Right.
Q. Were there also concerns about whether or not by requiring everyone to wait for 15 minutes, you would inadvertently add to the risk of transmission in vaccination sites?
A. Absolutely, and we discussed all the risks associated with that 15-minute period, particularly with people in close contact with each other in a small waiting room, and the increased risk of transmission, but also the reduction in throughput.

Q. But regardless of those concerns, you thought, and you advised accordingly, that the right thing to do was to introduce this observation period nevertheless?
A. Absolutely. We felt it was important for the safety of the people who were being vaccinated. As we got more data, and you may want to go through that later, we were able to relax that 15 minutes.
Q. So during the booster campaign, 2022, the 15-minute observation period was removed, was it not?
A. Yes, we said we would remove it first of all for anybody who had had two doses of the mRNA vaccine and therefore for them to get anaphylaxis on the third dose would be extremely unlikely, so we removed the 15-minute period for them first, and then we got further data later on and we removed it for other people getting vaccines for the first time, but at the same time, we asked the UKHSA, as well as NHS England, to provide us with data to make sure there were no adverse incidents occurring and that patient safety was paramount at all times.
Q. Having said we wouldn't look at the clinical trials, there is one area that I wanted to ask you about. I apologise. It's a matter of particular concern to many people, but in particular, some of the Core Participant groups in this process, as to whether there was sufficient diversity in the clinical trial process

for the Covid-19 UK vaccines. The Commission on Human Medicines is not directly responsible for the setting up of trials. It appears to be a process which has many parents, in terms of the manufacturers, the funders, government bodies, and the MHRA.

So to what extent did the Commission on Human Medicines express views on the diversity of the clinical trials as they were ongoing?
A. So when we looked at the data through the rolling review we were able to look at the diversity aspects of the trials which had been undertaken, and by diversity, not only ethnicity but also sex, but also age as well, and importantly, to make sure that elderly who were the most vulnerable, were included in the trials.
Q. Why, in general terms, is it important for the CHM to express views on the diversity of particular sectoral groups, whether it be defined by age or sex or ethnicity?
A. It's important because we want to make sure that the vaccine is going to be effective, equally, in the whole of the population that is present in the United Kingdom. If there was a particular group that was not included, then it is possible that we may, at the time of licensing advise the MHRA that that particular group should be excluded from receiving the vaccines. So, for

example, for the Valneva vaccine which came later on, there wasn't enough evidence for over 65s, so we actually just licensed it for under 65s.

Q. So issues of width of diversity are directly linked to, firstly, whether or not authorisation will be given, for a particular sector or age, and secondly, any conditions that might be imposed on the grant of authorisation subsequently.

A. That's right. We will always give advice on a particular medicine, a vaccine, based on the clinical trial population that was included in the pivotal trial.

Q. And did you have access to data on diversity for those trials that were physically taking place in the United Kingdom -- and AstraZeneca had at least two trials, CoV-1 and 2 in the United Kingdom --

A. Yes.

Q. -- or trials globally?

A. Yes, we were -- we had data on age, sex, and the ethnic characteristics, as well, of the participants.

Q. From everywhere in the world where the trials were being conducted, or just the United Kingdom?

A. So, because most of the trials which were undertaken were international, we did ask for all the data from all the different trials.

Q. And did you get it?

A. Yes. And I should say, sorry, it was published as well when -- the papers were published in the New England Journal of Medicine or The Lancet, very respectable journals, which data on the groups which were included in the trials was published in those papers.

Q. Yes, we've seen The Lancet article, including the AstraZeneca data, published, I think, in December 2020.

Presumably the data which you sought and you were provided with included not just data on diversity, but the data in relation to those cohorts of people who were excluded necessarily from trials on account of the risk or because it was obvious that they wouldn't benefit from trials and therefore wouldn't benefit from vaccines.

A. Absolutely. And this is where the risk management plan comes in, where there's data not available in a particular group, for example, the immunosuppressed or immunocompromised individuals, for example people with HIV, and so on. So it was important for us to be able to identify where there was missing information, and that becomes part of the risk management plan to ensure there's post-authorisation commitments to get that data for the future.

Q. Turning now to the procedures and the processes which were in place for the CHM to be able to advise on

safety.

Could we look, please, at INQ000274036.

This is a report dated 5 February 2021 or at least published on 5 February 2021. It's a document that comes from the -- one of the expert working groups, the vaccine safety surveillance working group, of the Commission on Human Medicines, and therefore is concerned with safety surveillance. If we look at it -- and perhaps we'll just go to page 2 or 3, thank you very much -- the document refers to the background, obviously the emergence of the vaccines and their authorisation, and then, at the bottom of that page, the need for post-authorisation vigilance.

It sets out, in very large part, the MHRA's own working practices relating to pharmacovigilance, in particular, what we now know to be the four pillars of the MHRA's pharmacovigilance system.

Why was it necessary for the CHM expert group to be opining upon the nature of the MHRA's pharmacovigilance system? I mean, you could not be unaware of it, you must know this issue like the back of your hand. Why was the working group concerning itself with reporting on this?

A. So very early on in the pandemic, if a vaccine was going to become available, we knew that we would have to

vaccinate millions of people, so it was important to have a very robust plan in place to ensure that we could monitor the safety of the vaccine.

So the MHRA -- this expert working group was set up, really, with experts in all sorts of fields to advise the MHRA on what those four pillars should be and the necessary requirements for those four pillars.

Q. Ah, so the MHRA changed its working practices in the course of the pandemic, or at least at the beginning of the pandemic, on advice, in part, from the Commission on Human Medicines, in order to tighten up and improve, insofar as it could be improved, the pharmacovigilance system?

A. Yes. So, for the other vaccines which had been authorised before the pandemic, some of these processes were already in place, but in this particular area, the four processes were brought together so that we could have the most robust proactive pharmacovigilance system.

Q. Part of one of the four pillars is the Yellow Card Scheme, is it not?

A. Yes.

Q. You told us that had long been established, it had been first commenced in 1964. Is it a scheme that's run by the MHRA or CHM or both?

A. It's both. It's part of -- when it was set up, it was

under the aegis of the regulatory agency at that time, which wasn't called the MHRA, and the CSM.
Q. We've heard evidence that in May 2020 a dedicated portal was set up to report Covid-related adverse events.
A. Yes.
Q. Was that in part because of the report from the CHM's working group or was that something that was already envisaged and brought into play?
A. So the portal was set up, as far as I can remember, largely to help people to be able to report. It was very important to make sure that people were aware of it and report through a particular portal to recognise when they had their Covid vaccines or Covid therapeutics.
There was the other portal, which is for the other medicines, which were continued at the same time.
In the end, they all went to the same database and, using statistical techniques, you can identify which are the Covid-related reports compared to the non-Covid-related reports.
Q. Can you please tell us what the broad benefits are or the broad purposes are of the Yellow Card Scheme?
Firstly, it's obvious that when a reporter submits a report through the Yellow Card Scheme, online or on paper, that person brings to the attention of the MHRA and the CHM the actuality of a possible adverse event.

They're telling you about something that's happened.
How important is it, though, also, for the CHM and the MHRA to understand the perspective from the patient as to what they believe has occurred to them.
A. So, if you look at the Yellow Card Scheme from the time it was set up in 1964, it has evolved quite a lot. Initially it was set up for doctors, dentists and coroners, and then work was undertaken, by one of my predecessors as chair of the commission of medicines, looking at pharmacists reporting and that -- then introduced pharmacists to be able to report the Yellow Card Scheme.
I then undertook a study in nurses and then produced the evidence that enabled the nurses to start reporting. And then there was another report, and work done on patients.
And all those different groups can provide valuable data to the overall scheme, but they come from different perspectives. And that's part of the richness of the data that we receive in the Yellow Card Scheme, which allows us to be able to assess potential signals of adverse reactions.
Q. And if a reporter makes a report and tells you about a possible or suspected adverse event, is the scheme designed so that you can, or somebody in the MHRA can,

request additional information, either from the reporter or from the GP (primary care) or the hospital (secondary care)?
A. Yes, absolutely. So that is very important because the amount of information received in different Yellow Cards from different people varies, and the quality varies. So it is important to ensure that we can get as much information as possible, particularly when you are reporting serious adverse reactions.
Q. And presumably the database and the software to which you've already referred crunches all the events, the reports, all the associated information -- and I'll come back to what additional information you can get -- crunches it, and tells you whether or not there is a significant identifiable trend in terms of a particular adverse event?
A. That's right. So there are various statistical techniques, and they've been covered by other expert reports, in terms of how you can actually identify signals that are occurring for the large numbers of reports that are received.
Q. Do you, on the back of the Yellow Card report, go directly to the manufacturer and say, "What's this about? What's happened?"
A. So the Yellow Card Scheme is a signal-generating system.

There's a potential signal arising. Further work then has to be undertaken to determine whether the signal is a true signal or a false signal, in which case the advice from the CHM to the MHRA might be that you do need to go to the manufacturer for them to be able to undertake further evaluation. And a manufacturer may have reports from all over the world, which the MHRA may not have, so to be able to provide us with the overall totality of data of in the global population, for example.
Q. And what proportion during Covid of the Yellow Card reports related to reactogenic injury, that is to say injection site reactions?
A. The majority of the reports that we received were reactogenic events.
Q. Was there a proportion of the Yellow Card reports that were, to use the expression in your statement, placebo related?
A. So obviously the Yellow Card Scheme is designed to report suspected -- so there's no determination of causality from individual reports, but studies have been undertaken since then, and systematic reviews and meta-analysis, which have highlighted that, of all the reactogenicity events which have been reported, at least two-thirds are probably nocebo effects while one-third

are truly related to the vaccine.
Q. What does that mean, placebo effects?
A. So, a nocebo effect is a negative expectation --
Q. Oh, sorry, nocebo, not placebo --
A. Nocebo effect. A placebo is a positive expectation of something's going work, a nocebo effect is a negative expectation that something is going to cause harm to you.
Q. How easy is it for the CHM and the MHRA to follow up an individual Yellow Card report in terms of getting access to primary care data, GPs notes, GP observations, treatment, and, perhaps more relevantly, hospital notes, so that's notes from treating clinicians, and also X-rays or radiographical information?
A. Sure, on an individual basis, if we get an individual Yellow Card report, to get more information one has to contact the reporter. So it becomes hugely resource-intensive, reporters may be moved, the doctors may have moved, nurses may have moved. They often don't respond to the MHRA, which means that the process of actually getting more information on individual Yellow Cards is quite difficult and takes a long time. And the team at the MHRA worked very hard to be able to get as much information as possible from the individual Yellow Card reports, which was hugely important, because some

of the data which was being received was -- did not have enough information. So it was really important that we got as much information as possible, so that we could make the right decisions.
Q. And if a reporter did respond, and gave you access to their medical records, how difficult was it to get into GP databases and hospital databases to get the clinical information?
A. So when the reporter does respond, they respond in terms of questions which are asked. They don't give us access to the medical notes. So we don't get access to individual medical case -- (overspeaking) --
Q. Ever?
A. No.
Q. All right. Sadly, there were a number of Yellow Card reports involving death, fatality, where somebody, a member of a family had reported the death of a loved one through the Yellow Card system. Were all Yellow Card fatality reports followed up by the MHRA or the CHM by way of going back to the reporter and following it up?
A. That's correct. Every phase -- every report which -- or, as I say, fatality is followed up by the MHRA.
Q. Concerns have been expressed in some of the Core Participant material as to the liaison between the MHRA

and CHM and the coronial system.
Are coroners able to report the outcome of inquests directly to the MHRA or CHM, or do they have to go through the Yellow Card Scheme themselves?
A. So when the Yellow Card system was set up, it was set up for doctors, dentists and coroners so they could report via the Yellow Card system. However, they can also write directly to the MHRA if there are particular concerns. And sometimes, sorry, the coroner's report comes to some of the expert advisory groups, such as the Pharmacovigilance Expert Advisory Group on particular issues.
Q. All right. In terms of -- and you have many, many years of experience nationally, internationally, of dealing with systems for the reporting of safety signals and adverse events, how does the Yellow Card Scheme in the United Kingdom compare to its international analogues?
A. Maybe I'm biased but I would say it is one of the better ones across the world. You know, there are many systems out there and many countries have copied the Yellow Card system once it was set up, but it is perhaps one of the most robust ones. That doesn't mean there is no room for improvement. Any system can be improved.
Q. There appears to be considerable material before the Inquiry suggesting that, perhaps surprisingly, a lot of

people are simply not aware of the Yellow Card Scheme, or if they are aware of it, don't know how to use it to their best benefit. Putting aside the mechanics, I'm not going to ask you about the mechanics of the scheme, is there anything that could be done, do you think, to raise awareness of the scheme in the public sphere, or to encourage reporting of adverse events or possible adverse events by clinicians?
A. Sure. So there are many things which have been done in the past to be able to improve reporting. For example, when I was a junior doctor, because this was my area of interest, which is drug safety, I developed a poster which I posted all around the Royal Liverpool Hospital which says, "Don't delay, report today", and simple things like that can help in terms of improving of reporting from hospitals, for example. But the important thing to do, always, is to continue with continual reminders to people. You can do an advertising --
Q. You mean in the public sphere?
A. Yes, that's right. You can do an advertising campaign which leads to a spike of reports, but then within a few weeks it's gone down back to baseline. So it's the continual reminders which become really important.
Q. I don't think His Majesty's Treasury will thank me for

asking you this question, but have there in the past been processes, I think in France, where people were paid if they made a Yellow Card report?

A. -- (overspeaking) --

Q. That had the effect of increasing the use of the system, albeit when the process of paying people ended, the figures went back down.

A. So it was in fact done in Ireland by Professor John Feeley. He did a very nice study which he paid people to report, and that led to a spike in the reports but as soon as the payments were withdrawn, the numbers of the report went down again.

Q. All right. I think, Professor, the Inquiry's own expert, Professor Stephen Evans, suggested that there be prizes awarded to clinicians who first reported on a novel adverse event.

A. Yes.

LADY HALLETT: How do you ensure they're reliable reports, if you've given someone a financial incentive?

A. So, obviously, a robust evaluation was done of those reports, and they were of good quality.

MR KEITH: We'll come back to the issue of whether or not the data systems in primary and secondary healthcare worked well enough in terms of being able to link them, and also in terms of accessibility to the MHRA and CHM

at the end.

Can we then turn to the question of thrombotic thrombocytopenia syndrome, TTS. Blood clots.

Thrombotic events were not identified, were they, as adverse reactions, in the course of the clinical trials themselves?

A. They were not.

Q. But was thrombosis known to be a potential side effect of vaccines historically?

A. So from other vaccines, it wasn't one of the adverse events of special interest. Thrombocytopenia, which is a lowering of platelets, was one of the adverse events of special interest, but thrombosis per se was not.

Q. All right. And the system of adverse events of special interest, is that the system by which, during the clinical trial process, manufacturers and regulators require the identification of particular safety events or adverse events, which may be likely to give rise to problems in the future, because historically, they've appeared?

A. Yeah, not only during the clinical trials but post-authorisation as well.

Q. All right. Then in February 2021, the MHRA first started to receive Yellow Card reports of suspected thrombosis and associated thrombocytopenia.

Thrombocytopenia is the low platelet syndrome, isn't it?

And those reports were associated with the AstraZeneca vaccine, were they not?

A. That's right.

Q. The expert working group, on 25 February, in the CHM, presented a paper on something called immune thrombocytopenic purpura; is that correct?

A. That's correct.

Q. And was that in response to the receipt of Yellow Card reports?

A. It was related to the Yellow Card reports on that particular population, it was -- we were focusing on immune thrombocytopenic purpura, but then there were, I think, three reports at the time of the occurrence of thrombosis with thrombocytopenia which was very unusual and we highlighted that these need to be followed up in more detail and further monitored.

Q. Concurrently in Europe, from 11 March onwards, a number of not regulators but health authorities, suspended the deployment of AstraZeneca following the emergence of these reports. In particular, I think there was a lady in Denmark who had presented a very unusual clinical picture as a result of taking the AstraZeneca, or following the receipt of AstraZeneca. And so on 17 March, did you convene, or was there convened, your

vaccine benefit risk expert working group to look at what should be done about how properly to respond to these emerging reports?

A. **(Witness nodded)**

Q. We'll look at it, INQ000409517. We can see a very significant attendance list. There are a lot of people there, aren't there, Sir Munir?

A. [No audible response]

Q. "Participants present" on the left-hand side.

If we go over to page 2, some personal data is redacted, but I think if we then go over further one page, we can start seeing the introduction and announcement.

There is a reference there, isn't there, to the conflict of interest policy? At the beginning of every single meeting does the chair remind everybody present, members and participants, of their obligation to declare any financial interests, personal or non-personal, specific or not-specific, which they have or which an immediate family member has, in any of the agenda items?

A. That's right.

Q. All right. And did some people declare interests, however than tangential, in that annex?

A. Yes.

Q. If we then go, please, to paragraph 2.5 on page 6, we'll

see that the group, having looked at the data and the evidence relating to these reports of thrombosis with thrombocytopenia:

"... agreed that there was no evidence of an increased risk of peripheral venous thromboembolism. The group also agreed the evidence did not support an increased risk of thrombocytopenia alone."

Could you just explain that paragraph to us --

A. Sure.

Q. -- but in particular, was the group reaching a view on these particular conditions or was it reaching a view generally on the risk of thrombotic thrombocytopenia syndrome?

A. So you can have different clinical presentations. There were people who were reporting the occurrence of thrombosis in their legs, a deep venous thrombosis, for example, but there were other people who just had low platelets without thrombosis, and then there were people who had thrombosis together with the low platelets. And so we had to consider the three groups separately to understand whether there was an increased risk and at that time, in terms of the evidence we had, we concluded there was no evidence of increased risk of peripheral venous thromboembolism and no increased risk of thrombocytopenia alone. However, we highlighted the

unusual cases of thrombosis with thrombocytopenia and the need for further follow-up of those cases.

Q. So in relation to that particular type of condition, thrombosis with thrombocytopenia, so blood clots and low platelets, there was something to suggest a problem, an issue, which was why you said further information needs to be rapidly gathered?

A. That's right. Maybe I can add that in my career without the vaccines, I think I'd seen one case like that in the past. So this is an extremely rare condition that occurs. And so we were just wanting to know how often it was occurring and why. Was this just because of heightened awareness that these cases were being reported?

Q. Can you just, please, explain the importance of that observation about the extreme rarity of this condition in background, that is to say in normal day-to-day life? So, by comparison, if you are starting to get a number of reports temporarily following vaccination, that's got to be compared against the extreme rarity of it occurring in day-to-day life?

A. Yes. So any condition that -- unfortunately, any diseases that occurs in the human population has a background incidence. And one of the limitations that we had was that we didn't have the data resources

available in this country to be able to define what that background incidence was of thrombosis with thrombocytopenia. So that was the first issue.

The second issue is that Covid itself can cause thrombosis. Covid itself can cause thrombocytopenia. And it was likely that Covid itself could cause thrombosis and thrombocytopenia together. Again, we do not have much data on that. And so it was important to be able to understand what was going on to determine whether it was truly vaccine-related or related to the underlying disease.

Q. You're the specialist adviser on these, of course very complex but extraordinarily serious issues. Why was there not available a case definition or at least data as to what the pre-existing position in the community was in relation to this condition? I mean, isn't that the sort of data which should be always available to you so that you can make a careful and rational conclusion as to whether or not these new reports are out of the ordinary?

A. So there was no case definition available when these reports started appearing, largely because this condition is relatively rare. As I said, in 30 years of clinical practice, I've only seen one case of this in my career. So what we did, very quickly, was to get expert

haematologists together and work with them to develop that case definition, and I want to thank them for the enormous amount of help they gave the Commission of Human Medicines and the MHRA in developing that case definition very quickly.

Q. Sir Munir, this meeting was on 17 March. The first reports of suspected thrombosis and associated thrombocytopenia had first started emerging in Europe, I think in the second week in February. Why could that passage of time between February and March not have been used to try to bottom out the case definition, or to see what data there was about background incidence?

A. So as I said, the data was trickling in, and it was incomplete, and we had to keep on going back to the individual reporters, to the haematology community who were gathering more data for us, and so a case definition really needs to be robust to be able to get as much data as possible so that you can have a definition which other people can follow. If you have a case definition which is incomplete, then it will lead to a lot of noise in the system.

Q. The meeting was on 17 March. By that stage, I think a number of European member states -- I emphasise not their regulators, so the regulators weren't withdrawing authorisation, but their health authorities, and that's

Austria, Norway, Iceland, Italy, Estonia, Latvia, Luxembourg, and Lithuania, had suspended the practical deployment of AstraZeneca. If was good enough -- if the concerns in the emergence of this extremely rare condition was good enough for them to put in place a suspension of deployment, why wasn't it good enough for the United Kingdom?

A. So the vaccination practices were different in those countries, compared to the UK. They were --

Q. -- (overspeaking) -- why was it different?

A. So they were vaccinating different age groups. We were following the nine priority groups determined by the JCVI, particularly the vulnerable group and so on, whereas AstraZeneca vaccine was being more used in the younger population in some of the European countries.

Q. And so, just to make that point as clear as you can, Sir Munir, the CHM deduced that because the AstraZeneca vaccine in the United Kingdom was not being used on younger people, because we were still in the priority list of elderly people, there was less risk, because this syndrome, TTS, appeared to be more prevalent in younger people from the reports that were emerging from Europe?

A. So at that time we had some suggestion it was more prevalent in the younger population, but not good enough

data. But that was one of the reasons, then, as we were working through the nine priority groups, it was more being used in the older age groups at that time.

And also, I should say that the vaccine availability was different. So obviously in some of the EU countries which were able to stop the AstraZeneca vaccine, they will have looked at what other vaccines were available to continue the vaccination of the population.

Q. At that date, on 17 March, had the JCVI issued its phase II list, that is to say the list of people who should be offered vaccination, after phase I, the priority list, was complete?

A. I would have to check on that. I can't remember the exact date when they actually produced that.

Q. All right. There were then a number of further meetings. The expert working group met again on 23 March, the vaccine benefit risk expert working group met on 24 March. I think you convened an independent panel on 26 March. Was that of haematologists?

A. That's right.

Q. Then, on 27 March, the full CHM convened. That's INQ000409498. The minutes, again we're can see the attendees on the left-hand side the page. If we go to page 6, please, this is a Saturday -- Saturday, 27 March -- paragraph 2.11:

"The Commission concluded that while there was a temporal association between vaccination and the reported events, the mechanism had not been confirmed and thus a causal association with the AstraZeneca vaccine could not established."

Sir Munir, by now, 27 March, almost a month and three-quarters had elapsed from the time of the first reports being received from Europe. Why was it not possible to confirm the mechanism? We presume, from that, it means the data hadn't been made available that would have established one way or the other whether a causal connection was there.

A. **(Witness nodded)**

Q. I mean, more weeks had passed. Why was that data not available?

A. So the data was trickling in, as I said. It was very difficult to get that data. Also, the data linkages that were required to get that data as quickly as possible were just not available.

Q. What were they? What were those data linkages?

A. So if you consider -- some people have talked in this module about triangulation of data. Obviously if you have a vaccine in a vaccine centre, that data then is linked to the primary care record, but then if you develop a serious adverse event, that usually ends up in

hospital admission. So you need that triangulation to the hospital data.

But even within hospitals, some of the linkages just do not exist. So, for example, admission to the A&E department may be difficult to link to the laboratory data, to the imaging data. And so it was very difficult to link all that data together. And I think that linkages -- the deep linkages are going to be critical in the future for us to be able to get the best information as quickly as possible for these kind of serious, complex events.

Q. At its heart, are you concerned there with data in hospitals and in the health service?

A. That's correct. So I think the data in hospitals particularly needs to be looked at and how it can be coded appropriately, and linked to the primary care records, so that we get a whole picture of what's going on with the complex pictures -- with complex syndromes such as this.

Q. Are you aware of the review on health data done by Professor Cathie Sudlow --

A. I am. Very much, yeah.

Q. -- of November last year. Was that the field in which she was reporting, so she was focusing on data links in hospitals and at primary and secondary healthcare

levels?
A. Yeah. Data linkage is a critical, and linkages to the laboratory systems are critical, which is just not present at the moment.
Q. Paragraph 2.17 on page 7 of this document.
"The Commission discussed whether risk mitigation was needed due to the presence of an alternative vaccine where these events are not seen at the same level [bluntly, Pfizer or Moderna], [but] it was agreed that risk benefit evaluations should be made without consideration of other vaccines."
What does that mean?
A. So when we look at vaccines, we have to look at individual vaccines and the data associated with individual vaccines, rather than do comparative effectiveness secondarily. That's not within the remit of the CHM to do comparative effectiveness secondarily.
Q. In the context of looking at benefit risk, one can readily see why you need to focus on the vaccine, which is giving rise to the problem. But wasn't the possibility or the existence of an alternative vaccine highly relevant to whether you could say to the public, "All right, there's a worry about AstraZeneca, let's use Pfizer or Moderna"?
A. So the benefit-risk evaluation of each individual

vaccine showed that the benefit far exceeded the risk for each vaccine at a population level.
Q. For each of them separately?
A. Yeah, for each of the -- and, there -- you know, if you looked, there was no direct comparative trials between the Pfizer and the AstraZeneca. So it's very difficult, secondarily, to start comparing whether one is more beneficial than the other, because the different populations were studied in those two different vaccine trials.
Q. All right. By 1 April, and the next CHM meeting, the commission agreed or concluded that causality was still not established. You still couldn't show that there was a significant link. And the number of cases, whilst rising, was still at a level which showed that it was extremely rare. I think the incidence was about four in a million?
A. That's right.
Q. So four cases of TTS in a million doses.
But the commission recommended that information on the risk nevertheless be communicated to healthcare professionals and the public. Why should that risk be communicated where you've concluded you cannot agree a causative connection?
A. So it is important to make sure that people are aware of

the potential adverse effects which may be occurring so that they can make an informed choice as to whether to receive the vaccine. It is important for openness and transparency so that the public are made aware of, you know, potential adverse effects. And I think on 18 March Dame June Raine gave a, sort of, press conference with the Prime Minister, where she highlighted that we were -- MHRA was still investigating these rare cases of thrombosis and thrombocytopenia.
So at every -- whenever it was possible that -- we wanted to make sure the public was aware that these events were being investigated.
Q. As that date, 1 April and the CHM meeting, was consideration given to at least, if not -- not changing the conditions of authorisation, but at least given to making a recommendation that AstraZeneca could not be used under a certain age group?
A. So we did discuss that, particularly I think on 4 April, looking at the age cut-off and whether there were particular age groups which were more likely to get this serious adverse event. And although there does seem to be some age stratification, we, sort of, were getting, as I said, trickling -- more data was trickling in. And then we had -- a few days later we had data globally from AstraZeneca and the presentation of AstraZeneca,

which made -- it showed more holistic data, and it was difficult for us to say there was a truly an age cut-off that we could actually use based on the occurrence of the TTS.
Q. But that Sunday, 4 April, I think Easter Sunday, when the CHM had convened on Easter Sunday to look at this issue, the committee, the commission, recommended that the authorisation under, as it happens, Regulation 174, be amended to reflect the fact that that risk-benefit balance was less favourable to the individual patient if they were under 40.
That decision was taken on Sunday, the 4th, before AstraZeneca provided, I think, quite a considerable amount of data, which it did on 6 and 7 April.
Why wasn't that recommendation on age cut-off in effect made earlier, on 1 April, at that earlier CHM meeting, when you had instead decided to tell healthcare professionals about the risk and to better inform the public? Why wasn't that position reached earlier?
A. So as you can see, we were taking this particular condition very seriously and we were ramping up meetings and meeting at short notice, not only the vaccine benefit risk expert working group, but the CHM were meeting on Saturday, meeting on Sunday, as data was trickling through. And the data was coming through and,

you know, we were asking the MHRA to get more information on individual reports, to strengthen the amount of data that we had.

And so it was very, very sort of, you know, fluid situation, if you like, whereby we had to make decisions on days' notice based on amount of data that we were receiving.

Q. And so is that why, on 6 April, the CHM meeting, the commission said, "We haven't quite got there yet. We can't justify recommending or authorising -- I apologise -- recommending a change in the authorisation conditions for AstraZeneca to have vaccination only above a certain age because the data is just not there to justify that step."

Is that the nub of it?

A. Yes, so we said, I think on 6 April, that the public should pee made aware of this particular event.

Q. And then just finally on this point, on this subject, did you give a press conference on 7 April along with Professor Sir Jonathan Van-Tam, Dame June Raine, and Professor Lim?

A. We did.

Q. We'll just briefly look at that.

INQ000408460, please.

At pages 2 and 3, we can see -- it's quite hard to

spot, but on page 2 we can see references to your name. It might be further down the page. Yes:

"So Professor Sir Munir, over to you.

"... Thank you very much."

And you say:

"... I've worked with the Commission on Human Medicines and the Expert Working Group separately to thoroughly review all the cases coming in on the Oxford-AstraZeneca vaccine in the UK. We've taken into account a wide range of data sources. We've looked at information about ... usage ... updated incidents rates, and benefit-risk comparisons for different populations by age and gender."

You say both the committees -- that's presumably the CHM and the expert working group?

A. That's right.

Q. -- have spent almost 24 hours in committee reviewing these reports. You've scrutinised them and you've had independent adjudication by an expert haematologist. Is that the independent committee to which you have referred?

A. (No audible response).

Q. And:

"... we've worked with another group of haematologists to develop a case definition".

And then you give the advice for pregnant women, those persons with a history of blood disorders, and those who experience cerebral or other major blood clots after the first dose.

A. Correct.

Q. And that's where matters were left until, I think, May, when a positive recommendation was made that alternative vaccines should be used for 30 to 39-year olds in outline?

A. Yes, 7 April, I think the JCVI made an announcement of 30-year age cut-off and then on 7 May it was a 40-year age cut-off.

Q. 30 to 39 -- (overspeaking) --

A. Yeah, and that was based on benefit-risk rather than the risk itself because the benefit in the under 30-year-olds was more marginal.

Q. And is it essential, and is this what you did, to look at and to weigh up the potential benefits and harms for each age cohort?

So if we have INQ000497993, is this a diagram from somebody called the Winton Centre, which sets out in a bar chart the benefit-risk analysis for each group. And just very simply, Sir Munir, I don't suppose I'm doing the issue sufficient credit at all, but we can see that the potential benefit for a 20-year-old of

AstraZeneca vaccination is put at 0.8. The benefit for an over 60-year-old is put at 14.1, so massively greater benefit.

In relation to the potential harm, for a 60-year-old, the risk of TTS from AstraZeneca is put at 0.2, and therefore that's weighed against the massive benefit. But in relation to 20 to 29-year-olds, the potential harm is put at 1.1, which slightly exceeds the 0.8 benefit, and that's the exercise that you did?

A. That's right. And this also depended on how much the virus was circulating in the community at the moment. So the first graph shows you with low exposure risk but then if you go down the graphs and so on, there's medium exposure risk and then high exposure risk as well.

Q. So you've got to take into account incidence and transmission and risk of getting infected.

A. Absolutely.

MR KEITH: All right.

My Lady, is that a convenient moment?

LADY HALLETT: Certainly.

You were warned that we take breaks, Professor, I hope. I shall return at 3.15.

(2.58 pm)

(A short break)

(3.15 pm)

LADY HALLETT: Mr Keith.
MR KEITH: As a result of the commission's examination of the issue of TTS, did you, have you reached some views as to what lessons can be learnt in terms of making the job of the CHM easier in the future, and more efficient, in relation to, firstly, getting more information from the Yellow Card Scheme that better enables the CHM from being able to get into the reporter's medical records to find out more about the event they are reporting; and secondly, as you've described, the linkage between primary and secondary healthcare data?
A. That is correct, and the first point about getting access to the medical records and getting the detail that's required, particularly when you have a complex event. The third aspect, which I haven't mentioned, is that there should be accompanying research which allows one to be able to understand a mechanism behind that which helps in terms of determining causality. And I, as a clinician scientist, was able to develop a consortium which allowed us to be able to start looking at the underlying mechanisms of why this was happening.
Q. Now, turning to the concerns raised in the public sphere about the incidence of myocarditis and pericarditis. The Vaccine Benefit Risk Expert Working Group first

discussed that issue on 4 February 2021, Sir Munir.
Is it difficult, in general terms, to diagnose myocarditis and pericarditis?
A. Extremely difficult. It can be very heterogeneous in terms of the symptoms it presents with, and you do need laboratory tests as well as imaging, as well, of the heart, to be able to make a proper diagnosis of myocarditis.
Q. Can it be caused, can either condition be caused by viral infection, and of course, most particularly, Covid?
A. Absolutely. The most common cause is viral infections, and we often do not know which virus has caused it. But we also had evidence during the pandemic that people with Covid infection were getting myocarditis.
Q. To get some idea of the scale of myocarditis in the community, what sort of figures were there concerning admissions in England for myocarditis between 1988 and 2017?
A. So I don't have that data in front of me, but you may already have that data.
Q. Sir Munir, you are right, I do. The figure which you've provided is around about 13,000, so 13,000 admissions for myocarditis itself in England, pre-pandemic, in that period.

Following the pandemic, was there an article published concerning data from Denmark, Finland, Norway, and Sweden, in relation to myocarditis in the community?
A. That's right.
Q. And what did that article show?
A. That the data particularly from Israel was very helpful in terms of highlighting that the risk of myocarditis was higher after the second dose, and it was greater in younger men.
Q. Did the article also say something about the outcome from suffering from myocarditis, and comparing the outcome if you get myocarditis from Covid as opposed to myocarditis from vaccines?
A. Yes, most cases of myocarditis, and pericarditis, were relatively mild after the vaccine, usually resulting in hospital admission of less than two days, whereas the myocarditis that was occurring from Covid was more severe and sometimes did, unfortunately, lead to a -- fatalities.
Q. So if you happen to have Covid and then you unknowingly present for vaccination, and you get a vaccine, and you then develop myocarditis or pericarditis, from that temporal link alone, you won't know whether or not it's from the vaccine or from pre-existing Covid?
A. Absolutely. We wouldn't know because there's no clear

single test which can tell us whether it's related to the virus or due to the vaccine.
Q. The expert working groups in the commission and the commission itself looked at this issue between 4 February 2021, and 23 June 2021, and although there was no evidence to suggest any fatalities in relation to myocarditis or pericarditis linked to vaccination, you recommended that the product information be updated to include a warning to the effect that such cases have been reported with the vaccines, and also to highlight clinicians to the possible risk?
A. That is correct, and also to give the relevant advice to people who may have developed myocarditis in terms of exercise, but also what to do with regard to future vaccination as well.
Q. Have you seen the expert report from Professor Prieto-Alhambra?
A. Yes, I have, yes.
Q. You may also have seen his evidence, I don't know.
A. Yes.
Q. In his report, he quantifies, he highlights, the amount of evidence, scientific and medical evidence in the public domain, and examines it for the quality, its quality, and, in particular, whether or not that evidence bears to show an association between any of the

Covid-19 vaccines and a very long list of conditions identified in the material before the Inquiry.

We've looked at TTS and myo- and pericarditis, in relation to which he concludes that there is good evidence, good quality evidence, to show at least an association, without diving into the more complex question of whether there is a direct causative link, but at least an association?

A. Yeah, that's correct.

Q. And your evidence is to similar effect.

A. Yes.

Q. Do you also agree with what he says about the quality of the evidence establishing an association, or lack of association, in relation to Bell's palsy, Guillain-Barré syndrome, transverse myelitis, and acute disseminated encephalomyelitis?

A. So we looked at each of those conditions as the reports were coming through and we did advise the MHRA to include them in the drug label with -- the Guillain-Barré syndrome, the transverse myelitis, and ADEM, acute disseminated encephalomyelitis, in the AstraZeneca vaccine.

With regard to Bell's palsy, in fact the clinical trial with the Moderna vaccine had shown there was an imbalance between the active and the placebo arm and so

we did actually include it from the beginning in the Moderna vaccine.

Q. All right. So is it your position, and you were looking at all these conditions at the time of the pandemic, that there is good evidence to suggest at least an association, so that obviously brings some degree of support and succour to those who believe that they've suffered conditions as a result of vaccination, but you can't say whether or not they are directly causatively linked?

A. That is correct.

Q. The issue of public information -- patient information leaflets, and to a lesser extent, summary of product characteristics, has been before the Inquiry. A number of Core Participant groups have expressed concern that the patient information leaflets may not have been given to patients at the point of vaccination, or did not contain a requisite amount of detail so as to put them on guard in relation to any possible adverse event or risk associated with any vaccines.

Have you formed a view about the level of information about risks that was provided to the public in the course of the pandemic? Do you think enough information about possible side effects was put into the public domain?

A. So when the -- a vaccine is first authorised, one of the things that the CHM does in terms of its advice to the MHRA is to look at the summary product characteristics, as well as the patient information leaflet and identify whether there needs to be more information included in there, whether it's in appropriate language to be understandable. So we look at that in detail.

Obviously, as more evidence came through in terms of further adverse effects, we made suggestions or recommendations to the MHRA that the patient information leaflet should be changed to include new adverse events which were appearing.

So over time, the patient information leaflet for each individual vaccine did evolve as more information came through. So I think that was appropriate and timely in all cases.

Q. That's, of course, from the standpoint of the CHM in terms of putting the information into the public domain, period.

A. Yeah.

Q. But there is obviously the issue as to the extent to which information you put into the public domain is acknowledged or read or picked up. Were you concerned, during the pandemic, that the objective picture which you were putting into the public domain was being

crowded out by other forms of information, by social media -- well, by, just in the nature of these things, the messaging -- (overspeaking) -- taken on board --

A. Absolutely, and we did -- we did discuss this many times with CHM, that, you know, it was really important that people who were being vaccinated did get the right information at the time, but obviously the misinformation and disinformation on social media was sometimes drowning out the correct information that should have been received by people.

Q. In reality, was there anything you could do about that?

A. Not really, not from the CHM's remit at least.

Q. Now turning to therapeutics. I haven't asked you, but it's obvious, isn't it, that the CHM's remit went beyond vaccines to -- and included therapeutics, in the same way that the MHRA's does.

The picture concerning the authorisation and the putting into the public domain of relevant safety-related information is rather more complex in relation to drugs, isn't it, because you've got new drugs, you've got repurposed drugs, you've got small molecule drugs, you've got neutralising monoclonal antibodies. It's a more crowded field.

But was there any significant difference in terms of the rigour or the level of scrutiny that the CHM applied

to safety in the course of therapeutic examination as opposed to vaccine related?
A. Absolutely not. We looked at every new medicinal product, which includes vaccines and therapeutics, with the same rigour in terms of quality, safety and effectiveness.
Q. Was your role -- was your job made harder in the case of therapeutics because of a more fragmented, perhaps a less good picture, from the clinical trial processes, in terms of the degree of the quality of the science, the nature of the clinical trials, whether they were underpowered or under-resourced, or under-participated in, and also public and media reaction to the possible benefit of particular drugs?
A. Yes. So at the beginning of the pandemic there were trials which were appearing, often in pre-print servers, before they were peer-reviewed, and picked up by the press, which were of low quality, which led to a lot of information relating to the effectiveness of a drug where probably the effectiveness did not really exist. And so it was really important to do some robust trials, and obviously that mantle was taken on by RECOVERY, in terms of the hospitalised patients, and then, later, on in terms of primary care, by PRINCIPLE and PANORAMIC trials, in order to develop that robust evidence base,

which was trial-based, which allowed us to be able to determine where there was true benefit.
Q. Was the CHM asked to give its advice as to how this process of clinical trial for therapeutics be better managed, better organised and, perhaps, better delivered in terms of the provision of data and information to you and the MHRA?
A. So the CHM has got Clinical Trial Authorisation as part of its remit. The MHRA can come to us in terms of advice, and in fact many of my colleagues, particularly on the infection expert advisory group and the clinical trials expert advisory group, have spent hours looking at clinical trial protocols, at short notice, and turned them round quickly so that all these clinical trials could be authorised within two days. And I want to thank them for that and acknowledge the enormous amount of work that they undertook.

But also in terms of trials which were being undertaken, it was important that we were able to monitor what was going on if there were particular issues which were arising, it was possible for the Clinical Trials Unit at the MHRA to be able to bring them back to the MHRA for -- to the CHM, sorry, for any advice.
Q. The Inquiry is aware that Professor Sir Martin Landray

and -- who was one of the co-leads of the RECOVERY trial, along with Professor Sir Peter Horby, wrote a paper making a number of recommendations about how this process of clinical trial for therapeutics might be made a little more orderly, and he referred to things like having a clearer list of national priorities in terms of what sorts of trials should be allowed to proceed, having earlier phase II assessments so that you know earlier on whether or not a particular therapeutic is worth pursuing it, having a greater use of randomised controlled trials, and having wider diversity, in fact.

Are those all suggestions or calls with which you would agree?
A. Absolutely. I think it is important that we have a proper system to develop trials from the very beginning, phase I and phase II, right through to the phase IV trials, like RECOVERY, robustly undertaken with appropriate governance framework, monitoring safety, at all stages.

The critical issue, particularly for the early phase trials, is to try to determine what dose is important, and maybe that wasn't done as well as we could have done it until later on, when new platforms were set up, such as the AGILE platform from Liverpool.
Q. Obviously in relation to therapeutics, where you're

dealing with already-authorised therapeutics which may be open to re-purposing, you don't need to go back and re-examine, do you, the issue of safety?
A. No, there should be a good safety database for repurposed medicines. However, what you can't exclude is the possibility that that repurposed medicine may interact with the disease, which is a new disease, and somehow cause other problems so it is important to continually monitor the safety.
Q. And of course, as the pandemic rolled on and as different variants of the SARS-CoV virus emerged, that made the issue of identifying suitable therapeutics harder, because they may be less susceptible to protection against the virus, and also some of the trials were taking place before the variants had emerged so you couldn't tell whether or not the benefit would have been maintained?
A. That's particularly the case for the monoclonal antibodies.
Q. All right. We needn't run through all the therapeutics which were ultimately authorised on the advice of the CHM, but just, perhaps, to pick up one or two points.

Obviously, you gave advice on, and you reviewed and ultimately the use of molnupiravir, and nirmatrelvir and ritonavir, Paxlovid, that those were authorised by the

MHRA and they were the two oral antivirals --
A. That's right.
Q. -- of which we heard from Mr Gray.
You reviewed and ultimately this was authorised, dexamethasone? That was the highlight, perhaps, of the RECOVERY trial process of which you've spoken.
In relation to that, did the CHM become engaged in a debate with the leaders of the RECOVERY trial as to whether or not there was sufficient evidence of benefit prior to you giving advice on its authorisation?
A. So the CHM and the Covid Therapeutics Advisory Group did evaluate the role of dexamethasone, looking at data in terms of how steroids had been used previously for influenza, and the data for influenza in terms of effectiveness was not very strong in terms of whether it was helping, and what the CHM wanted to know was what evidence was the dose based on, for example, in RECOVERY? And as we've seen in terms of RECOVERY doing further studies on higher doses, you don't get the same benefit with a higher dose of dexamethasone or other steroids as you do with the 6 milligrams of dexamethasone. And so the CHM asked questions in terms of what the rationale was, not only for using dexamethasone but also for the dose that was used in the trial.

Q. And happily, RECOVERY trial proceeded, the rest is history. They produced clear evidence of benefit leading to its authorisation, and the saving of --
A. Yes, and the RECOVERY trial, as far as I recall, replied to the Covid Therapeutics Advisory Group and, you know, we were happy for the trial to continue.
Q. Evusheld was reviewed by you, and authorised, and we've heard a great deal of evidence about the process by which it wasn't ultimately made available. Could you just tell us, please, though, whether or not other regulators, other than the MHRA, did ultimately withdraw authorisation for Evusheld on the grounds of lack of apparent benefit?
A. Yes, so the FDA, Federal Drug Administration in the United States, did give it emergency use authorisation but as the variants changed and became more resistant it withdrew that emergency use authorisation.
Q. Ivermectin was the subject of a considerable amount of debate in the public sphere. The debate about the benefits of Ivermectin became, I think, politically highly polarised. Was it reviewed by the CHM in March and October 2021, and did you give advice that there was insufficient evidence as to benefit?
A. Yes, we reviewed it several times, I think about three times, in the different groups, including the CHM, and

we looked at all the data. The data was not very robust, and we felt that there was no good evidence of effectiveness and it should not be used outside of a clinical trial setting.
Q. And then finally, were there two other results from the RECOVERY trial: Ronapreve, casirivimab, imdevimab; and tocilizumab, RoActemra, which you reviewed and then authorised?
A. Absolutely, and changed the label as a result of the results from the RECOVERY trial.
Q. There was another drug or therapy, hydroxychloroquine which became, similarly to Ivermectin, highly polarised was the benefit of hydroxychloroquine and chloroquine looked at by the CHM?
A. It was, on several occasions.
Q. Was it looked at for the purposes of treatment as well as for possible prophylactic use?
A. So, yes, looked for both treatment and prophylactic use. There were trials going on both for treatment in different patient groups but also the prophylaxis as well.
Q. The Inquiry's expert, Professor White, has drawn the Inquiry's attention to the fact that there was a study published in The Lancet which apparently showed not just a lack of benefit but the possibility of harm in

relation to hydroxychloroquine and chloroquine.
As a result of that publication, did the CHM go back and specifically review clinical trial data in relation to hydroxychloroquine?
A. So that particular publication you're referring to, Mehra et al, I think, was eventually withdrawn, but that was one of the pieces of evidence we looked at initially, but also there were other trials which were smaller. The Mehra et al study which was withdrawn, was an observational study but there were other trials which had been undertaken with different doses. We looked at overall evidence in terms of benefits and safety.
Q. And was there a particular commission meeting on 21 May 2020 -- perhaps we'll look briefly at it -- INQ000409486 -- in which you looked at that article and the study which gave rise to the article in The Lancet, and you looked at other data about the risk-balance and whether or not there was a benefit, and recommended, I think, reassessment overall as to what the benefit-risk level was.
A. Yeah. So it was particularly important --
Q. Thank you.
A. -- for hydroxychloroquine to understand what the safety aspects would be in this particular group, given that patients who were particularly vulnerable to severe

effects from Covid were the elderly, vulnerable, and they maybe on other drugs. Hydroxychloroquine is known to cause effects on the heart, and other drugs which can be -- also interact with it to accentuate those effects on the heart. So it was important for the CHM to give advice to the MHRA to understand the safety aspects, how they were being monitored within the trials, and for the investigators to come back to the MHRA to reassure that the safety was being monitored appropriately. Patient safety was obviously paramount to CHM in terms of making sure that these drugs were not causing any unintended harms.

Q. And if we look at this document, I think on the following page, please, 16, we can see you looked at a number of studies, you looked at the article in The Lancet and the study which underpinned it. You looked at the issue of risk-benefit.

And then, over to page 17, you discussed what advice should be given. And you also, particularly, looked at the issue of whether or not you should speak to the investigators in the trials, or at least whether the MHRA should, to see whether or not the trial should be suspended whilst you looked further at the issue of safety?

A. Yes. So that was one of the things about pausing the

trials, and the RECOVERY came back to us with the robust justification.

We also met with the chair of the Data Safety Monitoring Committee, who came to give evidence to CHM in terms of how they were monitoring the safety, and we were happy for the RECOVERY trial to continue.

We were waiting for the responses from the other hydroxychloroquine trials but the RECOVERY trial then reported that there was no benefit, and I guess that the other investigators decided to not come back to the MHRA to restart their trials.

Q. So the position that was ultimately reached was that, I think, whilst you were actually in session, on 5 June, you received information that the clinical trials had stopped themselves, the trialists had suspended their own trials?

A. Yes.

Q. And therefore there was nothing further for you to do. And so even though the press article which had made claims against hydroxychloroquine had been withdrawn, it didn't matter in the event, because the trialists stopped their own trials anyway?

A. Yes.

Q. And told you accordingly.

A. Yeah.

Q. One of the trials was permitted to restart. Was that the COPCOV trial?

A. It was.

Q. And was that the one with which the Inquiry's expert, Professor White, is concerned?

A. That's right. I think he's a principal investigator for that. That is a prophylaxis trial to give the drug at a lower dose to people who are -- for prophylaxis who don't have Covid, to prevent occurrence of Covid.

Q. But by the time that trial had reported, things had moved on even further insofar as obviously the --

A. That's right.

Q. -- vaccine programme had reached fruition, and there were further variants out there in the public domain and, therefore, there were then further issues about benefit-risk?

A. Yes.

Q. All right.

A. So Professor White and his team did reply back to us and put some additional measures in to ensure the safety of the participants in the trial.

Q. From all that, Sir Munir, you've taken care to put into your statement a number of recommendations. I just want to highlight some of the most important ones. Obviously my Lady will be going through your statement with great

care.

In no particular order, do you feel that in the course of your commission's functions, a closer working relationship and collaboration with the European Medicines Agency would have been more helpful, given that we have, of course, as a result of Brexit, withdrawn from that system? And in particular it's the European community -- not Union -- system of EudraVigilance?

A. That is correct, irrespective to whether you're in a pandemic or outside a pandemic, it is important to get up-to-date information from regulators not only within the European Union but also outside the European Union as well, so you get the overall picture of what's going on with a particular medicine.

Q. That said, was there any shortage of communication from your international colleagues, regulators and advisers on the issue of safety? I mean it looks as if you're in touch a lot.

A. Yes, yes -- yes, we were.

Q. All right.

Better access to linked-up health data you've addressed us on. Improvements to the Yellow Card Scheme you have said something about. And finally, this issue of dis- and misinformation.

From the viewpoint of the Commission, it must be of some frustration to see your carefully honed, scientifically-based, objective information being put into the public domain and being swamped by other sources of information?

A. Very much so.

Q. In reality, is there really anything that can be done about that or do we just -- do you just have to keep on pronouncing the message?

A. I think providing the message to the public is very important, and continual reminders of the true facts of the benefits and risks of the vaccine.

MR KEITH: Thank you very much.

LADY HALLETT: Just a few more questions for you, Professor. Ms Douglas, who is that away, has a couple of questions for you.

Questions from MS DOUGLAS

MS DOUGLAS: Thank you, my Lady.

Good afternoon, Sir Munir. I act on behalf of Clinically Vulnerable Families who represent the clinically vulnerable, the clinically extremely vulnerable and the immunosuppressed. The vulnerable person that CVF represents are at a higher risk of severe outcomes from Covid-19.

We've heard a little bit this afternoon about the

various vaccines and therapeutics that were authorised on the advice of the CHM. And my question is this: would you support the development of a more diverse portfolio of vaccine formats and antivirals, both as part of future pandemic preparedness plans, and during what others have described as peacetime, to ensure that clinically vulnerable groups are adequately protected?

A. Absolutely. I think it's really important to make sure that we have good therapeutics and vaccines for the whole population, those who are clinically vulnerable as well as in different groups as well. So it is important elderly participate in these particular trials to make sure particular vaccines are, and therapeutics, are relevant for that group, particularly in Covid, that they were the most vulnerable. But if you look at other infections, such as influenza, maybe children are more vulnerable, to make sure that the relevant groups take part in trials so we develop those therapeutics and vaccines for the relevant groups.

Q. Thank you. And if I may just expand on that, why is it important to have that breadth of formats?

A. Well, if you take the vulnerable in terms of the immunosuppressed, giving -- not many were involved in the initial trials, so we did not know whether the vaccine would be effective. So we now know that the

vaccine does provide some efficacy but it is not as much efficacy as in the non-immunosuppressed, and so on. But booster doses help in terms of improving that vaccine efficacy. So it is important to ensure that we have the relevant, diverse group of people involved in the therapeutic trials and the vaccine trials to make sure that we have adequate information that covers the whole population.

Q. Thank you.

If I may, my Lady, just because it went to the question about the formats of the vaccine, the point I was getting to more was that there are obviously, as we've heard, the mRNA formats, protein-based formats, and it's whether you would support a diversity of that, of having a range of formats of vaccines and antivirals?

A. Absolutely. So, it's very, very important not just to rely on one particular platform, but to have the protein-based platforms, the adenoviral platform, the mRNA platform, plus other types of platforms that may be coming through. But also different -- as we move forward, also different ways of being able to administer vaccines. For example, the ones we have been using have been intramuscular but nasal vaccines are being developed, which is going to be important. So having a portfolio of vaccines with different routes of

administration is going to be very important in terms of preparing for the next pandemic.

MS DOUGLAS: Thank you.

Thank you, my Lady.

LADY HALLETT: Thank you, Ms Douglas.

M Morris.

Ms Morris is over that way. Please make sure your answers go into the microphone.

THE WITNESS: Okay.

LADY HALLETT: Ms Morris will understand if you don't look at her all the time.

MS MORRIS: Thank you. Thank you, my Lady.

Questions from MS MORRIS KC

Q. Sir Munir, I ask questions on behalf of the Covid Adverse Reaction and Bereaved groups. These are groups who represent those who were injured by the vaccine or lost loved ones following their acceptance of the vaccine.

In your evidence you have stressed the importance of having more healthcare data in relation to those who have suffered a suspected adverse reaction. Do you accept that having patient medical records as one of the sources of that post-authorisation safety monitoring depends largely on what is recorded in that record by the healthcare provider, as to whether the symptoms may

or may not be connected to the vaccine, for example, before you even get to the triangulation point that you made in your evidence?

A. So -- sorry, I'll just speak into the microphone. So it is really important that adequate data is entered into the medical record. So if you look at primary care data, it may be coded or it may not be coded and so one can track it easily. But as we develop new tools such as artificial-based tools, natural language processing, it may be possible to actually look at the textured data, which is unstructured data, to be able to get that adequate information.

If you look at hospital data, clearly, if a vaccine has resulted in an adverse effect which is severe enough to lead to hospital admission, then that should be recorded and coded so that we can make that linkage between the vaccine and the admission to hospital.

Q. Again, depending on what's put in, what is coded by the practitioner into the records in the first place?

A. Absolutely. And coding is getting better but it's not perfect. And I think we needed to think about how we can improve coding at -- in real time. So that we get that information quickly coming through to the regulators, to the health authorities, so that we understand whether -- the harms and benefits occurring

with new medicines as well as established medicines.

MS MORRIS: Thank you, that's helpful.

Thank you, my Lady.

LADY HALLETT: Thank you, Ms Morris.

Thank you very much indeed, Professor, extraordinarily grateful to you. You and your colleagues obviously worked extraordinarily hard to try to ensure the safety -- or monitoring of the safety of vaccines for the protection of the public. And I know we are all indebted to you.

And thank you for the help you have given to the Inquiry and for giving evidence today.

(The witness withdrew)

MR KEITH: My Lady, that concludes the evidence for today.

LADY HALLETT: Thank you. 10.00 tomorrow, please.

(3.52 pm)

(The hearing adjourned until 10.00 am the following day)

I N D E X