IN THE COMPETITION APPEAL TRIBUNAL

Case No.: 1407/1/12/21, 1411/1/12/21-1414/1/12/21:

Salisbury Square House
8 Salisbury Square
London EC4Y 8AP

Tuesday 22nd November-Friday 23rd December 2022

Before:
The Honourable Mr Justice Marcus Smith
Professor Simon Holmes
Professor Robin Mason
(Sitting as a Tribunal in England and Wales)

BETWEEN:

Appellants

(1) ALLERGAN PLC ("Allergan")

(2) ADVANZ PHARMA CORP. LIMITED & O'RS ("Advanz")

(3) CINVEN CAPITAL MANAGEMENT (V) GENERAL PARTNER LIMITED & O'Rs ("Cinven") (4)

(4) AUDEN McKENZIE (PHARMA DIVISION) LIMITED ("Auden/Actavis")

(5) INTAS PHARMACEUTICALS LIMITED & O'RS ("Intas")

AND:

Respondents

COMPETITION AND MARKETS AUTHORITY ("The CMA")

A P P E A R AN C E S

Mark Brealey KC (On behalf of Advanz)

Daniel Jowell KC & Tim Johnston (On behalf of Allergan PLC)

Sarah Ford KC & Charlotte Thomas (On behalf of Auden/Actavis)

Robert O'Donoghue KC & Emma Mockford (On behalf of Cinven)

Robert Palmer KC, Laura Elizabeth John & Jack Williams (On behalf of Intas)

Marie Demetriou KC, Josh Holmes KC, Tristan Jones, Nikolaus Grubeck, Michael Armitage, Professor David Bailey & Daisy Mackersie (On behalf of the CMA)

Tuesday, 29 November 2022

(10.00 am)

Submissions re further witness evidence

THE PRESIDENT: Good morning. We have received some communications from the CMA regarding the suggestion made at the end of last week. We also have one other housekeeping matter to raise, but I suggest we deal with that point first. I do not know who wants to address us first on this.

MS DEMETRIOU: Sir, we have explained our position in the submissions that you have read and unless the Tribunal has any questions about those, would you like me to take you through the submissions and explain --

THE PRESIDENT: You certainly do not need to take us through the submissions. What I think you are saying is that it is on the would be nice to list, but should not derail the timetable and certainly the CMA would be wanting to cross-examine rather than examine in chief. That is what I got from this.

MS DEMETRIOU: That is certainly right sir on both of those points. So we say that it should not derail the timetable, because that would be -- that would not be desirable. That if the Tribunal compelled Mr McEwan then we say that he is not the CMA's witness. He is a hostile witness to the CMA and so we should be

permitted to cross-examine him and put our case to him in the same way that we did to Mr Beighton and Mr Sully and, on that basis, we would like the Tribunal to compel him, but it really is subject to those two provisos.

THE PRESIDENT: But you would not have a problem, I take it -- because I would not be regarding Mr McEwan, for example, as being Advanz's witness, so we would -- let us leave the mechanics out of the way at the moment. My thinking would be that this would be a case where anyone interested in his evidence would cross-examine.

MS DEMETRIOU: Sir, I am not sure that can be right, with respect, because he is somebody who has been represented by Advanz's solicitors throughout the investigation and the evidence that he gave in interview was materially the same as Mr Beighton's, so he said we did not commit the infringement and he answered the CMA's questions and he was represented throughout by Morgan Lewis. So it would not be right, with respect. So we have made our point about the adverse inference.

Our position is simple. We say he is a witness who -- unless some compelling explanation is given, he is a witness who is presumably available to Advanz. Their solicitors have represented him throughout. They haven't said, well, he is not available to us, because he refused to cooperate. We have not heard anything

like that.

So they have not called him and, as you see, we rely -- we ask the Tribunal to draw an adverse inference from that.

THE PRESIDENT: Ms Demetriou, let us park the adverse inference point, because we are quite clear that we would have to hear about that in closing, but I am not going to be drawn on the sort of inferences that we are likely or permitted to make at this stage. At this stage, all we are doing is working out whether there is sufficient need in augmenting the factual record by exceptionally using the Tribunal's powers having heard the factual evidence.

Many times one has got a situation where one can on a given point call five or six witnesses and, actually, only two will do and no one is going to be saying that three, four, five and six make any difference at all.

The point that I made on Friday was that the factual questions that we are likely to have to deal with go to the very heart of what both Mr Sully and Mr Beighton said and are, as I think Mr Sully suggested in his witness statement, depending on what findings we ultimately make, are likely to be career-ending ones, if it goes one way rather than the other.

So these are not unimportant points and, therefore,

it seemed to us appropriate that we raise this important question at a time when something could be done about it.

I am not in the business of talking about inferences. We can talk about that later on. I am not, at the moment, particularly inclined to treat Mr McEwan or anyone else as someone that Advanz could have, should have called, but did not. That may be a point for later.

So what I am saying, and we will hear what Mr Brealey says in a moment, what I am saying is that if this happens we will be neutral in how the witness is treated and it will be cross-examination for all.

Now, does that make a difference to the CMA's stance?

MS DEMETRIOU: Sir, yes, it does and may I make two points?

THE PRESIDENT: Yes, of course.

MS DEMETRIOU: I understand that you are saying you do not want to deal with the adverse inference point now and of course had this point not arisen it would be a point for closing submissions. We understand that.

THE PRESIDENT: Yes.

MS DEMETRIOU: How it is inextricably linked in my submission with what you are proposing to do in terms of cross-examination for all. Because the adverse

inference submission rests on the basis that he was Advanz's witness to call. That is how you get to an adverse inference. So if he is -- if we are right about that, then they should not be permitted to cross-examine him. So there is a point of principle that we do say would need to be grappled with now and there is also a second point, which is one of practicality which is how would it work?

Because if I am to cross-examine -- we say that we would need to cross-examine Mr McEwan in the same way that I have cross-examined Mr Sully and Mr Beighton. So if I do that, and cross-examine him and then Mr Brealey stands up and asks a bunch of leading questions in response, I do not think that is going to assist anyone and it would not be fair. We say that would not be a fair process.

It does, with respect, arise now, the substantive point and it does make a difference to us, because we say that if that were the premise, then that would not be a fair process and we would not want him to be called under those circumstances.

THE PRESIDENT: Thank you. That is very clear. Mr Brealey.

MR BREALEY: No surprise that we take issue with that. We say that it is completely unfair and prejudicial what the CMA are suggesting; that we somehow be forced to

call a witness through the Tribunal.

THE PRESIDENT: That is not going to happen.

MR BREALEY: No, well --

THE PRESIDENT: I am more interested in whether you think it assists with the process.

MR BREALEY: We are concerned it will derail, because it may well be that Mr Sully and Mr Beighton would have to be recalled. This will be new evidence and so no one has really thought that one through yet as to whether our witnesses of fact, in all fairness to them -- I hear what you have just said, sir, about Mr Sully. It would be inappropriate for someone to give evidence without Mr Sully or Mr Beighton even having seen it.

So there is an issue of due process here.

Also, we have appealed by reference to the Decision and that is what we have done and that is how it should rest in our submission. To derail the process now we say is unsatisfactory, but if he is to be called, he is to be called. He is certainly not our witness and we would want to cross-examine him. I cannot just say is this your evidence and then sit down, as I have done -- as you said, sir.

THE PRESIDENT: No, there is no evidence.

MR BREALEY: The fact that Morgan Lewis did represent Mr McEwan, well, that was in his personal capacity -- he

was not employed by the company at the time, but as you will appreciate, sir, these people go into an interview. They are told that they will be liable to prosecution if they tell stuff that is not true and, therefore, they need legal representation. But that is by the by.

This should have been raised at the PTR. This is an issue that has been raised very, very late, adverse inferences and then the question of well, if it is not going to be adverse inferences, should we call Mr McEwan?

THE PRESIDENT: Mr Brealey, let us be fair about this. The adverse inferences point has, if I may respectfully say so, been absolutely plain from very early on in this case, that there was a patchy covering of witnesses who could give evidence and it is something that, speaking entirely for myself, I have been very conscious of from the very early days of reading into this. That --

MR BREALEY: I hear what you say, but I would want to see where the CMA has said that in the Decision, because it really only came in their opening submissions.

THE PRESIDENT: We are not saying anything about what inferences should be drawn or how we should go about drawing them. These are, I think, extremely difficult questions, which, as I say, we are going to deal with in closing and Ms Demetriou, I am afraid, I am not going to

be drawn, however much you press, on the need to make any kind of finding one way or the other today about inferences.

To deal with your second point, Mr Brealey, this is late, but it isn't being raised by the CMA. It is being raised by us and it is being raised by us, having heard the factual evidence, as a suggestion to the parties to see how they react to this proposal and I summarise the CMA's position as being yes, but only if they get to cross-examine and it is your witness. That is the CMA's position.

What is your position?

MR BREALEY: Our position is we do not want the -- we should not -- he should not be forced to give evidence. We are not really saying it should not happen, but we are concerned about the due process, about derailing, about that we have appealed against the Decision. We have called two senior employees who -- one was the general counsel close to Mr McEwan. The other was Mr Beighton, the boss, both on the board of directors.

The CMA have to prove a consensus on the unwritten agreement and so we have quite reasonably said we have called two senior people on the board. If he was junior, they can put the case to these two witnesses, which they have. So we believe that -- this may be for

later submissions, but we believe that we have done what we should have done, called two senior people who are responsible for the decisions and they are relevant to the consensus. There is no doubt that the CMA rely on the evidence of Mr McEwan at length in the Decision, whether it is in the witness statement that they obtained or the interview.

So the Decision is replete with reliance on Mr McEwan. The stance that we took was that we call the two senior people and then we look at the called evidence. That is why we had the ambulatory draft, that chronology which -- I do not want to make too many submissions now, but you will see Mr McEwan is trying to expedite matters and we say that is inconsistent with their case.

So we have looked at Mr McEwan, we have looked at the documentary evidence and we have called the two senior people and we are appealing against the Decision.

So this is late, but if the Tribunal is minded to call him or Mr Patel, because obviously Mr Patel is -- is in a similar boat, we will live with it, but we were very, very concerned when we got the note last night with the suggestion that we would not be able to cross-examine if he gave evidence which was unfavourable to the company or to the two witnesses.

So the answer -- the short answer is I get the perception that it is a 'nice to have' rather than a must. The CMA are saying you can decide this by reference to the evidence that is going to be heard. We say the same, but we are certainly not shying away from it but we do say it has come very late in the day. We have done what is really expected of us, called two senior employees. We have dealt with the documentary evidence insofar as it relates to Mr McEwan and we should -- at the end of the day, as you have said so many times, sir, these are quasi-criminal proceedings with severe consequences for individuals and the notion that the CMA can just rock up at some point and say adverse inferences and then call someone after -- just before the expert evidence and say it is all our fault I think is extremely unfair.

THE PRESIDENT: As I say, that is something we will be coming to, but again in a nutshell, if I can articulate what I have gained from your very helpful submissions, it is this: you regard it very much on the 'would be nice' rather than this is something which we are for -- we are very keen to accept and press the Tribunal to go forward with this. You are not on that front. You are on the front, well, if you want to do this, it is of marginal benefit.

MR BREALEY: The issue is about consensus, whether there was an agreement, and we have called two people and should we call a third or fourth? I mean there are other people. I mean, how many do we need to call?

THE PRESIDENT: Mr Brealey, that is a slightly more proof of point, because having heard the evidence, particularly of Mr Beighton, but also Mr Sully, they both said they had less good information than Mr McEwan and that was not because of any fault of their own. It was because they came on to the scene somewhat later than he did.

MR BREALEY: Yes.

THE PRESIDENT: So that is why specifically we made the point in connection with Mr McEwan.

MR BREALEY: Yes, but that is very important, because at the end of the day, if it is the case that Mr McEwan entered into a market sharing agreement, as alleged by the CMA, what the CMA needs to put to Mr Sully and to Mr Beighton is how would it get past those two gentlemen? As you actually put to Ms Demetriou: are you saying that these men are complicit in this and so if he did make some sort of side agreement, how does that then pass through to AMCo and to the board of directors? That is a key question that the CMA would have to tease out with Mr McEwan and Mr Sully.

THE PRESIDENT: Again, questions of attribution, we will,

I am quite sure, be spending a good deal of time on, but to go back to the buttons you are pressing, this is of marginal benefit and only acceptable to your clients if there is an equality of arms, which, having heard Ms Demetriou, that is unacceptable from the CMA's standpoint. I think that is where the battle lines are drawn.

MR BREALEY: Yes, they kind of diametrically opposed red lines.

THE PRESIDENT: Yes. Mr O'Donoghue, anything to add?

MR O'DONOGHUE: Sir, if I may three very quick points. I do not want to get into a prequel of closings. Putting this as neutrally as I can, my first point is that we, Cinven, do not rely on the evidence of Mr McEwan and we do say and we will say in closings that the CMA -- there are a dozen references to Mr McEwan in the CMA's openings and it is paragraphs 13, 18, 25 and 29, in particular, extensive reference to these interview transcript. But that is for another day, but we do not rely on Mr McEwan's evidence is my first point.

Second, sir, are the practicalities. In my submission, all this has been rather dealt with glibly. I mean, if one looks at rule 22, the first thing is that -- does the Tribunal have that?

THE PRESIDENT: Yes.

MR O'DONOGHUE: So the first requirement is that the summons witnesses is given at least seven days' notice. So even if an order were made today, Mr McEwan could not appear until at the earliest next --

THE PRESIDENT: Mr O'Donoghue, rapidly moving into an area of practicality, which I was minded to address with Mr Brealey, about, if we were going down this route, how it would work.

MR O'DONOGHUE: Sir, can I just give you the composite points?

THE PRESIDENT: Of course, but you are very much dealing with something which I have in mind as in a sense the tail to the rather more important dog that we are considering, which is -- but do go on.

MR O'DONOGHUE: In my submission once one accumulates the practical points it ends up becoming the dog, a substantial part of it. Forgive me for murdering the metaphor.

So seven days' notice, that takes us to Wednesday. There is a realistic prospect that the evidence of the experts and Mr Stewart will not conclude until Thursday the 8th. Now, given what we saw of Mr Beighton and Mr Sully and given the thorny issues as to whose witness it is and who has a right to cross-examine, it is, we say, putting it neutrally, realistic to assume that

Mr Beighton's evidence could occupy up to two days of court time.

Now, that takes us at least into Friday, closings due on Saturday and there is, therefore, real concern, we say, that the remainder of the trial timetable is not simply squeezed, but is derailed in a very serious way. There may be an issue -- less of an issue for some of the evidence, but it is a significant issue for quite a number of us.

We do not accept the CMA's suggestion that one could safely put Mr McEwan at the end or after the expert evidence. At least speaking for myself, there is factual material that I would wish to put to the expert witness and one cannot exclude. In the ordinary course of events, of course, the expert evidence follows the factual evidence for a very good reason and the suggestion that this would come at the end, or substantially so, we say is unworkable.

Now, leaving aside the thorny question as to who exactly gets to cross-examine, there is a fundamental question as to what exactly is Mr McEwan's evidence-in-chief. The CMA of course is now keen to downplay his witness statement and, therefore, suggest that may not represent the full extent of his evidence. In any case, rule 22.2(a) requires a summons to make

clear upon which facts the witness is to be questioned. So that question has to be grappled with, at least on a preliminary basis, under the rules, but in my submission that still does not resolve the issue as to what exactly is his evidence-in-chief and what would Mr Brealey or Ms Demetriou or myself be effectively attacking.

Second, there is a further practical question as to a question of substantial preparation. At least speaking for myself, had Mr McEwan been a witness that I was intending to cross-examine, it would be a substantial exercise, perhaps involving many days, if not a week or two, of preparation and that all needs to be factored into the practicalities as well.

Finally, on the documents, since Mr McEwan has not been suggested until now as a witness in these proceedings, there are important questions as to whether the full extent of his documents is carefully reflected in the Opus bundle and it would be a substantial exercise to traverse the case file, for want of a better word, to make sure the Tribunal and the advocates have the material they need.

As Mr Brealey says, to the extent witness summons are ever issued, which is of course rare, they are issued well in advance of trial, precisely to allow all

parties and the Tribunal to prepare in a careful and fair manner.

Just for your note, sir, under CPR Rule 34.3, the court's permission is required if a summons is issued less than 7 days before trial. Now, I appreciate that Rule 22.1 mentions at any time, but we would suggest that it is a basic and obvious question of fairness that if this is to be done, it has to be telegraphed and choreographed well in advance of trial.

One final point, sir, again, just for the Tribunal's assistance. I mean, there are some questions of principle. The question of summonsing and whose witness is it has been addressed in a number of recent Tribunal cases. I will just give you the references. The first is Tesco, M94, and sir, in particular, 124C:

"It is not the task of an appellant nor of the tribunal to supplement the evidence relied upon by the CMA."

There is a cross-reference in that case to *Dirkin* M81.1 and of course you will remember in *PGL*, M192, 2355:

"The OFT should consider to what extent such statements are necessary and desirable in order to support those facts of appeal. It is of course not normally the role of the Tribunal to decide whether and,

if so, which witnesses should be deposed or called to give evidence by any party."

Sir, our fundamental position today is one of pragmatism. We say this 11th hour, where in effect factual evidence has concluded, to add a substantial witness at this stage would have a significant adverse effect on the fair conduct of the remainder of these proceedings.

THE PRESIDENT: Yes, thank you, Mr O'Donoghue. Ms Ford.

MS FORD: Sir, I focus my submissions on the position of Mr Amit Patel of Auden rather than Mr McEwan, but the submissions that I make about the trial timetable apply equally to both of them and even more so if they were both to be compelled to attend.

THE PRESIDENT: Yes.

MS FORD: As to Mr Patel, the CMA has invited the Tribunal to draw an adverse inference in respect of the fact that we did not call him. We say that that is not appropriate. But we are happy to park that issue for another day.

THE PRESIDENT: Yes, I do not think we have made any indication, at least I hope we have not, as to what we are going to be doing by way of inference drawing. What we have indicated, I hope, is that it is something that we are going to require the assistance of the parties

on, because it is quite clear that we have an interestingly patchy profile of evidence and that is actually peculiarly dangerous, because what one gets is colour from some witnesses, which does not colour events to which they cannot speak and so there is at any rate a mismatch in prominence which is something that I am acutely alive to which certainly affects the way in which one sees the facts. It is different looking at things on the documents to having someone speak to documents, having been there.

So it is obviously a live issue, but where it goes is something which we obviously are going to require a great deal of assistance on.

MS FORD: Sir, yes, we are very happy to address the Tribunal in due course.

THE PRESIDENT: Indeed.

MS FORD: In terms of Mr Patel, as the CMA explained in its letter which came yesterday, he attended an interview with the CMA on 26 July 2016. He provided a witness statement, dated 12 September 2016, and he also attended a second interview. That was actually on 23 May 2018. I mention that because I think there was an inadvertent error in the CMA's letter. They referred to a second interview on 28 March 2018, which was Mr Amit Patel of Waymade. So the reference for the Tribunal's assistance

to the second interview of Mr Amit Pater of Auden is {IR-H/1141/1} on the 23 May 2018.

As the CMA indicated in that letter, it relies on Mr Patel's evidence at various points in the Decision and just very briefly to give the Tribunal some examples.

If we look at {IR-A/12/628}, please.

THE PRESIDENT: There seems to be ... it looks like a connectivity failure.

MS FORD: I am hoping it may be a temporary one.

THE PRESIDENT: Yes, me too. (Pause).

MS FORD: Perhaps I can ask the Tribunal to take a look at a couple of references when it has the opportunity.

THE PRESIDENT: Yes, of course. Let us proceed with the submissions, but it does look as if we have got a connection failure rather than an Opus failure.

PROFESSOR HOLMES: It has just come up, but it does look very slow. Whether it is the Opus server or something. (Pause).

THE PRESIDENT: Okay. Do proceed, Ms Ford, anyway. We will certainly look up the references after the event.

MS FORD: I am grateful. So what one sees, if one looks at the Decision, is heavy reliance on Mr Patel's evidence and footnoted references to the witness statement where that evidence is set out.

Just to give the Tribunal a couple of references to look at. It is {IR-A/12/628}, paragraph 6258 and Ms Mockford has very kindly passed me a paper copy. What we see there for example -- and it may be about to come up -- is a finding that the timing of the price reduction set out paragraph 6256 above is claimed to be no coincidence. It occurred because once Waymade obtained a 10mg MA, Auden perceived it as a competitive threat that was worth buying off in order to avoid having to compete, which Amit (Auden) Patel explained and then there was a quote from his witness statement:

"We did not offer this price to other customers as those other customers would have been pure wholesalers, whereas Amdipharm Waymade was not only a wholesaler, but carried out a range of work including product development and product marketing and sales. We wanted to protect and maintain our volumes ordered through Tiofarma for 10mg tablets as well."

So there is a quote from his witness statement and then the footnote is to the relevant part of the statement and I had a couple of other examples of essentially reliance in the same way. There are many of the same nature and in our submission it is the CMA that bears the burden of proof in respect of any infringement and it is the CMA that is purporting to rely on the

evidence of Mr Patel contained in his witness statement and cited in the Decision.

So we say if anybody should have called Mr Patel in support of their case, it is the CMA.

But we say it is far too late now for them to seek to rectify that by means of the Tribunal's power to summon a witness. We say neither calling Mr Patel nor Mr McEwan could realistically be accommodated in the current trial timetable, still less both of them.

I gratefully adopt the submissions that Mr O'Donoghue made gave concerning the likely timing involved. It is reasonable to expect they might take the same amount of time at least as was occupied by Mr Sully and Mr Beighton. There is simply no spare room in the timetable to accommodate that and, in our submission, it is clearly imperative that the trial timetable should not be jeopardised at this late stage of the proceedings.

It is also -- again, I gratefully adopt what Mr O'Donoghue said about the need for preparation in order to be in a position to deal with unexpected witnesses.

THE PRESIDENT: Ms Ford, I did not intend any disrespect to Mr O'Donoghue when I said his points were tail rather than dog. That remains my view. I entirely accept that

there are considerable difficulties that would have to be addressed if, in principle, we were going to go down this route, but, for my part, I would rather we worked out whether it is actually in any sensible way a point that in principle we ought to be dealing with now before we deal with the difficulties.

At the moment, given what Ms Demetriou and what Mr Brealey have said, it does not seem to us to be a starter anyway.

If we get past that, then there would be a great deal of consideration to have to be given not least about, for instance, witness availability and how one can make this work, which we would have to address in order to be fair, but at the moment I do not think we are there yet. So, in a sense, I would rather have your take on the in principle question where I think your position is: although this is a suggestion emanating from the Tribunal, not the CMA, it is one that is in any event too late, whatever the reasons for it, and it is not something that the Tribunal ought to be pressing too hard of its own motion, because it is something which if it will so find important, the CMA should jolly well have thought of it long ago. I am putting it rather tendentiously. I am sure Ms Demetriou will have something to say about it. To be clear, it is not what

I think. It is what I understand you to be saying.

MS FORD: Sir, that is a fair summary. We would strongly resist any suggestion that Mr Patel should now be called for those reasons.

THE PRESIDENT: Is there anyone else who wants to say anything more about this?

MR JOHNSTON: No adverse inferences drawn as regards my clients and I will not detain -- we have the same positions.

MS DEMETRIOU: May I just reply on one point?

THE PRESIDENT: You may. Let me just -- Mr Brealey, I think if we went down this route it would be -- at least with Mr McEwan, it would be you that we would be relying upon on the mechanical details of communicating with him and drawing thereon the Tribunal doing so simply for the saving of time. Is there anything you can say on Mr O'Donoghue's practical points? In other words, if he is going to be away for the next four weeks then in a sense that answers the point anyway. Do you have-anything? If you do not I do not have any --

MR BREALEY: Can I just ask?

THE PRESIDENT: Of course. (Pause).

MR BREALEY: I am just the messenger not the piano player. Miss Murphy says we have not picked up with him yet, because of his age and he is unwell. That relates to

a point that I was -- I forget and Mr O'Donoghue kind of flagged it, but I do not think in this court we should ignore it that we have to be fair to him as well.

THE PRESIDENT: Indeed. How old is he as a matter of interest?

MR BREALEY: Age is all relative now, but late 60s, early 70s.

THE PRESIDENT: I am grateful.

MR BREALEY: It did occur to me as Mr O'Donoghue was speaking that clearly he would have to be brought up to speed with the documents and ...

THE PRESIDENT: Yes, thank you. Ms Demetriou.

MS DEMETRIOU: Sir, I totally understand and I am not seeking to persuade you otherwise that you have parked the adverse inference point until closing. So what I am about to say is not intended to persuade you that that is not the right course to follow. But I do want to make this point, that I am now apprehending, from what my learned friends are saying for the first time, they have indicated that they are going to seek to draw an adverse inference from the CMA's failure not to call Mr McEwan. That is not something that has ever been put at any point to the CMA.

We say that that is completely unfounded. I am just going to make the submission, but knowing that, sir,

that you are not going to determine it now, but it is relevant to what I am going to say next.

The cases that Mr O'Donoghue talked about which of course the Tribunal is very familiar with, Tesco and *Dirkin* and so on. *Dirkin* and *Willis* were cases where there was a leniency applicant and the question was whether the employee of the leniency applicant, which had admitted the infringement, should have been called by the OFT.

THE PRESIDENT: Ms Demetriou, you can take it -- I do not quite know them backwards, but I think I do know them very well, these cases.

MS DEMETRIOU: Yes. So, sir, the short point is that this is a very different case, because in this case the witnesses were hostile to the CMA's case that they were saying there was no infringement and, sir, you can see readily, I hope, that even if those witnesses could have been persuaded to give evidence on behalf of the CMA, which of course they would not have done, because they were not cooperating, they were there with their own lawyers giving hostile evidence in interview, then the CMA was not -- was in no position to call them, because if the CMA had called them, then the CMA would have had to have elicited evidence-in-chief which we knew from their interview transcripts was going to be unhelpful

because they were hostile witnesses.

So that simply was not on the cards. Now, if my learned friends are going to press that submission at closing, then we do, with respect, urge the Tribunal to call Mr McEwan now, because it would be grossly unfair to be in a position where it is being argued that the CMA -- an adverse inference should be drawn from the CMA's failure to call hostile witnesses. If that is the submission that is going to be advanced, understanding that you are not going to determine it now, then we very much do urge the Tribunal to take action now and, in those circumstances, we think that perhaps one practical way of overcoming some of the practical issues in terms of who cross-examines is this. That there is evidence on the transcripts that they gave, so they can be cross-examined on what they said in the interviews and, as long as we go first and can put our case first, then I do not object to Mr Brealey -- I do not object to him asking leading questions afterwards, but we need to put our case first, because they are hostile witnesses.

If that is the point that is going to be pressed, then we do urge the Tribunal to call Mr McEwan.

THE PRESIDENT: Thank you very much.

Mr Brealey, do you have anything more to say? That is a slightly new point, I think.

MR BREALEY: Not in response, but Ms Demetriou keeps on saying that Mr McEwan is a hostile witness, but yet the Decision is replete with references to his evidence upon which they rely.

So, okay, he hasn't confessed to a market sharing agreement, as I understand it, in the interview or the witness statement, but they do rely on a lot of his evidence, so ...

THE PRESIDENT: Thank you all very much.

We are going to take this away and think about it. We will give a clear indication at 2 o'clock as to whether we are going to take this matter any further, but I think the failure to press Mr O'Donoghue on the very serious practical problems he rightly highlighted gives you a flavour of where we are going on this, but we will keep you in suspense until 2 o'clock because we ought to talk about it amongst ourselves. So thank you all very much for that. At least it has, I think, indicated where the crossfire is going to lie in terms of inferences and, to that extent, it has at least been helpful.

I said we had one housekeeping matter ourselves. I am afraid it concerns an unexpected but unavoidable unavailability on the part of one of us on the morning of 6 December. There will be no problem in commencing

at 2 o'clock, but I am afraid the morning is going to be lost. We regret that. It is the Tribunal's issue. It is unfortunately unavoidable. I do not think we can debate how to deal with it now. We clearly will have to deal with it. It is in the middle of Professor Valletti's evidence and we put it out there for the parties to think about how best to address matters. We will of course look ourselves to how the Tribunal's timetable can be re-arranged to accommodate this, but, obviously, we do not want anyone to be short of time. I am very sorry that we have to raise this, but these things, I am afraid, do happen.

So we will park that on the list of problems to be addressed but not now.

Mr Brealey, I think it is your experts we are going on to now, is that right?

MR BREALEY: It is, sir, yes. So it is Dr Newton.

DR RINA NEWTON (affirmed)

Examination-in-chief by MR BREALEY

THE PRESIDENT: I think you have just been handed your report. I will hand you over to Mr Brealey who will act as a ringmaster in the first instance. Mr Brealey.

A. Thank you.

MR BREALEY: I you should have a report in front of you and it should be titled "Pharmalex", is that right?

A. That is right.
Q. It is at {IR-D2/2/1} for Opus. Can you confirm, please, to the Tribunal that this is your report?
A. It is indeed.
Q. Could you, please, go to page 23 {IR-D2/2/23} and confirm that is your signature?
A. Yes, it is.
Q. Then looking at paragraph 7 of annex 4, can you confirm that you have made clear which facts and matters referred to in the report are within your own knowledge and which are not?
A. I confirm that.
Q. Lastly, can you confirm the opinions you have expressed in the report represent your true and complete professional opinion?
A. They are.
MR BREALEY: Thank you. There will be some questions for you.

Cross-examination by MR JONES.

MR JONES: Good morning, Dr Newton. I am going to ask you some questions on behalf of the Competition and Markets Authority.

I want to start with some questions about your own background and your own expertise. Could we go, please, in this document in your this report to page 12.

{IR-D2/2/12}. What we are looking at here is the second page of your CV and we see there is a heading "Other Employment History", underneath that "Education". Now, my understanding from this is that you finished your PhD in 1996 and then at least until 2010, I think it is, you worked for various pharmaceutical companies. Is that right?

A. That is correct, yes.

Q. In those roles with the pharmaceutical companies you focused particularly on regulatory issues?

A. No, that is not necessarily true. The only true regulatory time I had was 1999-2001 as a regulatory affairs officer.

Q. I understand. So when you had, for example, 2002/2004 senior medical information pharmacist, what would that have been looking at?

A. Medical information is a function within a pharmaceutical company. It is mandatory and it is a scientific service which is responsible for answering questions which can come from members of the public, patients, health care professionals.

Q. I understand. Then if we go, please, to page 11, so this is the first page of your CV. I think we see at the top there that since March 2010 you worked with a consultancy -- I apologise -- a compliance consultancy

which again was focusing on pharmaceutical companies. Is that right?

A. That's correct, yes.

Q. To be clear, when we talk about -- when you talk about pharmaceutical companies, you mean companies which were involved in the development and manufacture of pharmaceuticals; is that a fair summary?

A. That as well as marketing. Sometimes companies distribute, yes.

Q. Also the marketing?

A. Yes.

Q. You also refer in the first paragraph on this page {IR-D2/2/11} to the ABPI Code of practice. The ABPI, that is the Association of the British Pharmaceutical Industry, yes?

A. That's correct.

Q. It is a voluntary code which applies to pharmaceutical companies which have signed up to it; is that right?

A. Nearly. It is not voluntary for ABPI members. It is mandatory, but they have a large group of non-members who voluntary adhere.

Q. Are you still employed now as the managing director of CompliMed?

A. No, since the merger I am now a consultant to Pharmalex.

Q. When would that have been then? When would you have

started being a consultant to Pharmalex?

A. June 22.

Q. Since June 22. So in that consultancy role are you still advising pharmaceutical companies?

A. I am indeed, yes.

Q. I think it is clear that when you are working in compliance, it is inevitable that you face some issues which are, as it were, at the interface between industry practice and the law. Now, would you agree with me that some of the issues you have addressed in your report have a legal dimension to them?

A. Yes, that is true. The code is -- extends and reflects the law, so that would be true.

Q. Now, in relation to these topics with, as I put it, a legal dimension, I want to make sure I understand how you would describe your own expertise. Would you say that you consider yourself to be an expert on the law or would it be fairer to say that you consider yourself an expert on how the law is understood by those in the pharmaceuticals industry?

A. I would say that I am an expert on the ABPI Code and where the code reflects the law, I am an expert on those matters as well.

THE PRESIDENT: But how do you know that it reflects the law?

A. Because all of the requirements for advertising are all contained in the code and then the code has all sorts of other things which have just come from European codes, international codes that are not in the law.

MR JONES: So if I can just pick up my second possibility that I put to you. I suggested that you might consider yourself to be an expert in how the law is understood in the pharmaceutical industry. Could I just clarify whether you think that is part of your expertise or not?

A. I would -- just to clarify that, the legal matters that pertain to the advertising of prescription only medicines, I would be an expert on, because they are contained also within the code.

Q. I understand that. I appreciate it might sound like I am dancing on the head of a pin, but I understand you say you are an expert on the legal issues as you have described them, but do you think you are also an expert on how those issues are understood more widely in the industry?

A. Sorry, sir. Could counsel just repeat that?

THE PRESIDENT: Of course.

MR JONES: Do you think that you are an expert also on how these legal issues are understood in the wider pharmaceutical industry?

A. Yes, I would say I am, because my expertise spans lots

of companies and their understanding is varied, so I would be an expert in ensuring that there is a consistent understanding of how those laws and codes apply to them.

THE PRESIDENT: I mean, carrying on the dance on the head of a pin, but I think it is quite an important pin. We do not in this jurisdiction receive expert evidence on law, because, for better or worse, the position is that we understand and decide the law and that is that. So I do not think it can be right, maybe we will come further into this, that you can purely and simply be an expert on the law. What you are doing I think is you are saying this is how in -- at the coalface, at the front line, this is how the code and the law that lies behind it is consistently applied in the industry and this is what you would expect to happen or not happen as a matter of practical practice, not as a matter of what the words in the documents say, but as a matter of what actually happens.

That is what you are assisting the Tribunal on. Would that be a fair description of what you are doing?

A. Yes.

THE PRESIDENT: Does that approach the pinhead you were dancing on or are we dancing on quite different pins?

MR JONES: Yes, thank you. When I ask you questions about

your report in a moment, I do want to probe your understanding of the law in some of these areas. I need to do that. But can I just make clear that if you think I am stepping into territory that really is outside your expertise, because it is just a legal point and outside something you would consider yourself to be an expert on, do just say, because, as the President has just explained, there is a line that we need to tread in this Tribunal.

There is one other aspect of your expertise which I want to ask you about, which is the regulation of dispensing pharmacists, because you were just talking about pharmaceutical companies and we mentioned the ABPI Code, but part of your report also talks about obligations on dispensing pharmacists. It is right, is it, that you have never worked as a dispensing pharmacist?

A. Oh, I have worked as a dispensing pharmacist. It was not substantial enough to fit into the CV so from -- during my entire PhD and up until my first job at Sanofi I was a dispensing pharmacist.

Q. When you then came to take employment following your PhD, can I clarify this point: I think you explained that you were advising -- you have always been working for or advising pharmaceutical companies. Is it right

for me to draw from that that you have not been advising dispensing pharmacists?

A. I have been -- in the capacity of being a healthcare compliance expert, I have never had to advise a dispensing pharmacy.

Q. So when in your report you talk about the obligations on dispensing pharmacists, could you help us with what you would say your expertise is? What is the basis for your expertise on that topic?

A. It comes probably from several different areas. It would be interpreting the MHRA's guidance on off label prescribing, as well as understanding where a pharma company might fit in with supporting or encouraging off label use.

Q. Thank you. I am going to move next away from your background and look then at the obligations on pharmaceutical companies. Could I just give you a sense of where we are going to go? We are going to start with obligations on pharmaceutical companies. I am then going to look at obligations on prescribers, mainly doctors here, and then on the obligations on dispensing pharmacists. So we will touch on all of those, but I am going to take it in stages, as I say, starting with pharmaceutical companies.

Could we go, please, to your report, the document

which we have here, page 3 {IR-D2/2/3}. Picking it up in paragraph 8, you explain there that under the Human Medicines Regulations 2012:

"A person may not publish an advertisement for a medical product with a marketing authorisation ... unless the advertisement complies with the particulars listed in the [SPC]."

Is that right?

A. That's correct.

Q. Then further down the page if we look, please, at paragraph 13. Actually, it is on page 4. You explain that similar things are said in the code and we can see there from the way that you have quoted it or summarised it you have introduced bold to present the obligation in two parts. Firstly, it must be in accordance with the terms of its marketing authorisation and, secondly, it must not be inconsistent with the particulars listed in the SPC. Is that right?

A. That's correct.

Q. They are broken into two parts, but in a sense they overlap because the SPC is always included in the marketing authorisation, is it not?

A. That is correct.

Q. In terms of what is covered by promotion under the code, we can see from your paragraph 14 that it has a broad

definition, including any activity undertaken by a pharmaceutical company (or with its authority), which promotes various things including the sale of its medicines, yes?

A. That's correct.

Q. Now, I want to look next at some of the SPCs which are relevant in this case. We will start with the Auden 10mg product. If you could look, please, at paragraph 24 of your statement, which is on page 6 of this document. {IR-D2/2/6}. You give the number there for the marketing authorisation of the Auden product, which is 175070097 and then you quote from it in paragraph 25.

Now, I think the quote is slightly wrong. Nothing may turn on it, but I think it is important to make sure that we have got the exact quotes and the correct references. So, for accuracy, I just want to show you the correct version. Before we go there, can I just ask you to look at 25 of your statement and do you see that you have included there essentially one sentence. You quote this indication as though it is all one sentence? Do you see that?

A. Yes.

Q. Then if we can look at the actual SPC. It is in bundle {H/35.1/1}. If we just turn to the last page, page 9

{H/35.1/9} just to show you that it has the PL number there, so that is the marketing authorisation that we are concerned with. It is the Auden one. Then if we look at the therapeutic indications, they are on page 1, could we go there, please. (Pause). You will see there under 4.1, "Therapeutic Indications", that essentially it is the same wording as you had, but they are presented as two indications there. Is that right?

A. That would be correct.

Q. So we know that Auden can promote its product for these indications, yes?

A. That is right.

Q. The next SPC I want to look at is the AMCo SPC, please. I am afraid I am, again, going to suggest some corrections to your statement. If you could look at paragraph 22 of your statement, please. It is on {D2/2/6}. You say there that during the period 2012-2016 AMCo had an MA for 10mg which was held by Amdipharm and you say its MA is 0644/0701.

Now, the first mistake I am going to suggest is that your reference to number 0701 is incorrect. Could we turn, please, to tab {H/822/1}. Just while we wait for it, can I explain that what we are about to look at here is a document provided by the MHRA in 2016 which lists all Hydrocortisone marketing authorisations. If you

look at the third row down, you will see, I think, the number on the left-hand column that you had referred to, the one ending 0701. But if you look along the row, there is another column, "Formulation Strength" you will see that that is for the 20mg product. Do you see that?

A. I do.

Q. I think the one you meant to refer to is the 10mg product on the next line, which is a similar number, but it ends 2876. Is that right?

A. For 10mg, yes, that is right.

Q. Now, the other point that I just want to correct while we are on this is that you said in your report that this was the marketing authorisation for the period 2012-2016. But if you look at this document, do you see that it was actually cancelled in 2013?

A. I can see that.

Q. Then if you go across to the "comment" row, you will see that it says it changed ownership to PL200720238. Do you see that?

A. Yes.

Q. That is the Amdipharm MA and we can see that one on the next page. Could we go to page 2. Do you see that that is the one which is highlighted in yellow on that page. {H/822/2}?

A. Yes, I see that.

Q. So that is the one which I want to focus on, that Amdipharm marketing authorisation. To look at the SPC for that particular product, could we go, please, to {H/132.2/1}. Now, this document you will see is a UKPAR. That is a public assessment report. Is that right?

A. That is right.

Q. On the first page you will see the MA number that I just showed you. Do you see that?

A. I do.

Q. Then the indications are on page 2. Could we go to page 2, please. {H/132.2/2}. You will see there the medicine is used:

"As a replacement therapy for children with congenital adrenal hyperplasia which affects your body's natural production of steroids."

Then in another bullet points:

"In an emergency to treat severe asthma and allergic reactions in adults and children."

Do you see that?

A. I do.

Q. Again, I am afraid I am just going to correct another small error in your report, because you haven't quite quoted this correctly. You have merged those two into one sentence again. Could we just look at that quickly,

please. It is {D2/2/6}, paragraph 23. Do you see that?

A. Yes.

Q. The errors which I have shown you so far are reasonably minor. But could I ask you how you think they might have crept into your report?

A. I mean, I would have probably just read them and then written it out as a single sentence. I apologise if it would have been clearer to put them as two separate bullet points.

Q. I am talking about all the ones we have looked at, so not just the bullet points, but the references to MAs and so on. Can I ask, did you write your report yourself from the documents or were you copying and pasting from material given to you by somebody else or how did it come together?

A. It was probably a combination of being given specific questions which I was to answer and being given specific documents for me to look at as well.

Q. Can we look, then, please at the next page, I think it is, of your report. I am on page 7 paragraph 30. {D2/2/7}. You are talking about promotion, but you are giving examples by reference to AMCo, so I want to look at this in light of the AMCo SPC that we just looked at. You are describing here various things which you say would constitute promotion and which AMCo therefore

cannot do.

At (a) you say they cannot proactively highlight that it is bioequivalent to the Actavis indication. I think you are saying that would be contrary to the code; is that right?

A. That is right, yes.

Q. The reason, as I understand it, why AMCo cannot say this, even if it is true, is that you would say drawing that sort of link would be a form of promotion; is that right?

A. It is not that it is a form of promotion. It is a form of off label promotion, because it would have inferred by talking about bioequivalence that it could be used in adults.

Q. Yes. Then at (b) you say they must be accurate about the licensed indications and must not mislead wholesalers into believing it has the same indications as the Auden product. Is that right?

A. That's correct.

Q. Then at (c) you say this, and I will just read this one out it says:

"As an MA holder, AMCo has responsibilities for its mid scenarios throughout its supply chain. Therefore, AMCo sales representatives MUST NOT knowingly allow any agent or other third party in the supply chain for the

AMCo medicine to claim or suggest that AMCo's reduced indication hydrocortisone tablets can be used in place of the Actavis full indication Hydrocortisone tablets."

Now, I think I understand what you are saying here, but I want to understand, or to make sure I have understood, the limits of it. I am going to give you a couple of scenarios and just test to make sure I have understood where the line is drawn.

Could we start with this scenario: assume that AMCo knows that a wholesaler is promoting AMCo's product to pharmacists as being suitable for adult adrenal insufficiency. So that is the scenario.

Just focusing on that scenario, I think what you are saying in (c) is that if that were to happen then AMCo could potentially get into trouble under the code. Is that right?

A. That is exactly right.

Q. Now, I just want to then think of a different scenario, which is a little bit more complicated. So I will build it up in stages. Mr Beighton, who was a witness here on behalf of Advanz, AMCo, told the Tribunal that AMCo thought that only 2% of patients would fall within the conditions covered by AMCo's SPC. So that is the starting point. You understand that.

Now, on the other hand, when the CMA looked at

AMCo's market share after AMCo entered the market, it went well above 2%. I just want to show you that in the Decision. Can we go, please, to bundle {A/12/388}. We are looking at figure 4.14. So could I just say, for clarity for others here, that this was one of the figures that the CMA later updated, but in a way which is not material to what I am about to put, which is why I am looking at this one.

But you will see I think looking at that, you will see that AMCo is along the bottom. It is the sort of third from last blue colour. It is a blue colour. Unfortunately, it looks the same blue as the Actavis one, but the one which is AMCo is the small blue on the graph and the numbers are not that clear, but I think you will see that, for example, around June 2017 -- I do not have the precise number but we can all look at that and see that its market share is 10% or something perhaps more than that. Do you see that?

A. I do, yes.

Q. Now, just pausing there, if Mr Beighton is right about the 2%, only 2% of patients fall within the conditions, and if this is right, that AMCo in fact acquired much more than 2% of the market, what it looks like is that these tablets are being given to patients off label, yes?

A. It does indeed.
Q. Now, I am going to come on, as I said, in due course to discuss what this means for pharmacists, but just sticking with AMCo for now, would you agree with me that AMCo would not break the code and was not breaking the code just because they knew that their products were being used off label. They would only break the code if they had actually promoted that in some way?
A. Yes, there is a difference between the retrospective tracking versus the prospective intent.
Q. Versus the?
A. If there was a prospective intent to promote off label.
Q. Yes, I see. But if the intent is just to sell to whoever puts in an order and, as it turns out, you know that these orders are going to people off label, that is not a breach of the code?
A. That is not a breach of the code.
THE PRESIDENT: To put it slightly differently, when you look after the event you see a volume of sales which just does not match the profile of permitted uses and you therefore infer that something very odd has happened in terms of strange coincidence that everyone has been buying from this one source or it is an off label purchase. So that is looking backwards. But looking forwards, when someone comes in to buy the medicament,

you do not know, necessarily, and you do not cross-examine them exactly as to the purpose. If they choose to buy it then that is that.

A. That is exactly right.

MR JONES: So the important line that cannot be crossed is, as you have described, promoting the product for use off label, yes?

A. That's correct.

Q. That line, I assume, would be well understood in the industry, would it?

A. Extremely well understood.

Q. Would you expect AMCo to understand it?

A. 100%.

Q. In your report you are referring to the 2021 version of the ABPI Code of Practice. But as far as you are aware, has this particular line that we are talking about, has it changed in the last 10 or 11 years?

A. I do not think it is changed since 1968.

Q. Thank you. The next SPC that I want to look at then is the Alissa marketing authorisation or the Alissa SPC and you say in your report -- we do not need to go there, but just -- you have it in front of you, so if you did want to check to anchor yourself in the report, it is paragraph 34. You pointed out this started out as a marketing authorisation granted to Orion and for that

reason I want to look at the Orion SPC, please. That is at bundle {H/1151/17}. This is the Orion then Alissa SPC.

Now, if we look at the first bullet point there that is telling you one indication. I apologise, I should have said, one condition and who can use it for that condition, do you agree?

A. I do.

Q. The second bullet point is telling you another condition and who can use it for that condition. Do you agree?

A. I do.

Q. The third bullet point is telling you some other conditions and who can use it for those conditions. Would you agree with that?

A. I do.

Q. Then what comes at the bottom after the bullet points is this:

"Hydrocortisone 10mg tablets are indicated in adults and children aged from 1 month to 18 years where the dose of 10mg and tablet formulation is considered appropriate."

So that last point does not identify any condition, does it?

A. No, and that is not an indication.

Q. It is a reference to the dose?

A. It is indeed.
Q. All right. That is the SPC. If we then look, please, at the leaflet which you criticise. That is at {D2/2/14}. If we could just -- could we Zoom in, please, where it says "Therapeutic Indications" and just get that corner. Thank you.
There are the therapeutic indications. Apart from the bullet points, the text is identical to the SPC that we have just looked at, is it not?
A. Apart from the bullet points, yes.
Q. Yes, and you emphasise apart from the bullet points, but even when one looks at it laid out like this, it is still clear, is it not, that that text at the bottom is not suggesting any condition, it is simply suggesting the dosage?
A. It is -- where that text is is under a title saying "Therapeutic Indications" and that fourth line is not an indication. If you look at the SPC that comes with the flyer, there are three bullet points in that, not four. So to portray the text like that in four distinct points misleads as to the fact that it looks like tablets can be used in adults.
Q. Let me take that in stages, if I may. Let us put ourselves in the position of a pharmacist reading this and they read that last one on its own. What disease do

think they it is going to treat?

A. It actually does not matter. That is -- they may well read the indications. They may not read any of the indications. They may only read that tablets are indicated in adults. The point around why I said this leaflet or flyer was misleading is because there are cases that have ruled that healthcare professionals are busy and the onus should be on the pharmaceutical company to clarify, particularly if the SPC has ambiguous wording.

Q. But if you were to look at this to understand the therapeutic indications, you are trying to understand the condition, is that right, that it is indicated for, is that why you would look at the therapeutic indications?

A. I mean -- sorry, is counsel ask asking as a dispensing pharmacist or as a prescriber or --

Q. Is there a difference?

A. Yes, there is a huge difference.

Q. Talk us through what the difference would be. Let us start with the prescribers and why you would look at the therapeutic indication?

A. As a prescriber, I would look at the indications so I know what I am going to write on my prescription the next time I see a patient with congenital adrenal

hyperplasia or with AI. As a dispensing pharmacist or an independent one, I might need to know what this medicine is licensed for in order to understand: do I stock it or not.

Q. You also mentioned the SPC. I think you are referring to the SPC on the leaflet. Did you mean the SPC on page 2 of the leaflet?

A. I did, sorry, yes.

Q. If we can just go to page 2.

A. I know.

Q. Actually, it is clinical particulars. There it is. So if we zoom in on number 4 there towards the top. But you mentioned that that has the bullet points. It does have the bullet points like the SPC and then it also has at the end of it the sentence that we have been discussing. So, again, anyone looking at this would understand that that sentence is talking about the dose, not about the conditions and populations?

A. No, anyone looking at this would understand that sentence relates to the third indication, which is adults and children.

Q. Could we look at your report, please. It is {D2/2/8}. Then do you see at paragraph 35 you say:

"The flyer promotes Alissa's reduced indication ..."

Then you set it out. But there is another error,

because do you see there that you have actually not quoted the flyer there. You have quoted the SPC with the bullet points. Can you see that?

A. So I have included bullet points that were not in the flyer.

Q. Yes, that is right.

A. Yes, that is right.

Q. Then you go on in the next paragraph to say that it is misleading. Now, can I ask you, did you know when you wrote this that the wording which you were criticising is identical to the wording in the SPC?

A. I did know that, yes.

Q. I wonder about that, Dr Newton, because you have misquoted the leaflet and then you have not highlighted the facts that the text is identical to the SPC. Do you think perhaps you just did not realise that the text on the leaflet, apart from those bullet points, is the same as the text on the SPC?

A. I am not criticising the text in the SPC. The onus on a pharmaceutical company should be about the flyer and the promotion and the words used in the claims. Just because the SPC says it and someone has copied and pasted it does not mean the flyer is not misleading.

Q. It would be quite a powerful response, would it not, if the ABPI were to try to take action against Alissa on

the basis of its flyer for Alissa to say, this is exactly what the SPC says?

A. I mean, there are cases, sorry, where that has occurred. Companies have said, oh, but it is in the SPC and the PMCPA who enforce the ABPI Code will say, but it is your responsibility to make that clear. SPCs are often ambiguous.

Q. Could I put it to you, Dr Newton, that if you did realise that this was identical do the SPC, you really should have drawn that -- as an independent expert, you should have drawn that fact to the Tribunal's attention?

A. I did not realise it was relevant as to whether the flyer, which was what my instructions were, was misleading or not.

Q. I understand that, but I assume you looked at the SPC. So for some reason you had looked to see whether it was the same as the SPC. That is why you have misquoted the SPC. So you must have thought it was relevant in some way?

A. I do not believe I have misquoted the SPC in terms of the flyer and the -- sorry, the flyer and the SPC that is page 2 of the flyer, I can see that Alissa has copied and pasted that. So I think that was appropriate. What I am saying is not that they have not copied and pasted. What I am saying is that by doing so they have misled,

because the fourth line is not a therapeutic indication. The fourth line sits with the third indication.

Q. You are not saying, I think, that the content of the SPC is irrelevant to whether or not this is misleading?

A. I am not saying the SPC is irrelevant but certainly the format of the SPC is relevant.

Q. The format of the SPC is relevant. But that is also a point which you have not made in your report because in fact what you are saying is misleading is the format on the SPC not the format on the leaflet?

A. No, sorry, I will just be clearer on that. It is the format in the SPC, which is on page 2 of the leaflet, is pretty clear. There are three indications. There are three bullet points. But the copying and pasting into the flyer has translated into four distinct points. The fourth one is not an indication. So the SPC is of course relevant but the flyer is not clear on those points.

Q. No, I understand. You are placing a lot of emphasis on the bullet points but the point which I keep coming back to is when you look at your report not only have you not made that point at paragraph 35, but you have made a completely different point because what you are actually criticising in 35 has the bullet points in it because you have misquoted it. That is the point I am

putting to you.

A. Okay.

Q. Can we look back at paragraph 13 of your report, please which is on page 4. {D2/2/4}. Just to remind ourselves of the clause that we are talking about.

"Promotion of medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in the [SPC] ..."

It is not, is it? The Alissa leaflet is in accordance with the MA and it is not inconsistent with the SPC?

A. Sorry, could counsel repeat whether the question was about the flyer.

Q. It is about the flyer.

A. So the flyer, there is intent and there is impression and the impression that the flyer leaves a reader with is that the medicine is licensed in adults which it is not, so it would be in breach of clause 11.2.

Q. Were you aware when you wrote your report that a company associated with Auden had complained to the MHRA actually about the wording in the SPC?

A. I did not know that, no.

Q. Were you given, Dr Newton, a bundle of documents, maybe yesterday or over the weekend, that we at the CMA had

put together so that you could know where we were going to. Have you had a look at those now? Are you aware of that point now?

A. I am aware of it now, yes.

Q. It is quite an intricate chain of correspondence but I will go through it and I think you should just show you the main points. Let us go through some of these letters. Can we start, please, at {H/621/1}. You will see this is an email, it is actually from someone at a company called SNS which is part of the Auden group, as I understand it, and it starts by saying essentially: we hold the full label indication.

Then if you look halfway down where it says:

"Taking the above into consideration" he says the SPC for PL27925/0078 is misleading. So he is talking there about the Orion product, yes?

A. Yes, that's correct.

Q. You will see he fastens on to the last sentence, as you have. Then if you look, please, on the next page, {H/621/2}, there is a bold paragraph at the end. You will see that what he is suggesting is:

"This problem might cause healthcare professionals to dispense the product incorrectly."

Do you see that?

A. I do.

Q. Then if we can look, please, at the MHRA response. It is at {H/645/1}. This covers a variety of issues, a number of issues including the dispensing issue which I am going to come back to later when we talk about pharmacists. But on the point about SPC all it says on page 2, if we could look at that, please, {H/645/2}. Is this:

"On the inadvertent prescribing or dispensing of a hydrocortisone tablet product that excluded the orphan-protected indication a parallel can be drawn with "usage patents" where some parts of the SmPC of the reference product are under patent protection. In that case, a generic medical product can still be authorised if the product information ... exclude the indications still covered by patent law. CMDh guidance is available and provides agreed standard text for the package leaflet in this situation ..."

You will see the text there. Then at the bottom:

"We propose to explore with the MAHs of the recently granted hydrocortisone tablet products that exclude the orphan-protected indication, the possibility of adding the above statement to the product information."

Do you see that?

A. I do.

Q. Just to continue with the chain. If we go, please, to

644. {So H/644/1}. You will see here there is an email which is essentially -- you may have read this over the weekend. I am not going to go through it in detail now. But it is essentially reiterating the same points from SNS and they are worried about the impression which may be given by the SPC. Do you see that?

A. I do, yes.

Q. Then we have the MHRA's response. It is at tab 703, please. {H/703/1}. You will see if you read -- I will not read it out, but if you look at that paragraph beginning "the MHRA's regulatory powers", the MHRA basically refused to do anything more. Do you see that? Do take your time if you want to read that paragraph. I do not mean to rush you.

A. Yes, I agree.

Q. You agree. So the MHRA obviously did not think the SPC was misleading, did they?

A. I am not sure they are saying we do not think it is misleading. I think they are saying they do not intend to require any changes.

Q. They could require changes and would you not expect them to do that if they thought it was misleading?

A. Not really, no. There are lots of SPCs of products that are ambiguous.

Q. Can we look next at the Alissa version of this, please,

which is the current version of the SPC. It is bundle {H/1293.021/1}. If you look there at the bottom of the page under "Therapeutic Indications", I think we may need to look at that and the top of the next page. Can we look at them both together? No, maybe not. If you -- the point I am going to make is a simple one. You will see that the bullet points have actually been dropped now from the SPC. Do you see that?

A. Can I just ask when the date of this SPC was?

Q. Yes, this is the current -- actually, if we go to the last page. Let us go to the last page and look at the date. This is the most up-to-date one so it is January 2022, but I should say, just for clarity, I understand there have been a couple of revisions and I do not know precisely when that bullet point change that I just pointed out to you was made. But this is the current version.

But you see that the bullet points have been dropped. Do you see that?

A. Yes.

Q. Again, the MHRA has approved writing in the SPC which actually corresponds precisely to what is in the leaflet that you criticise. Do you see that?

A. I do.

Q. Can I just put it to you again, Dr Newton, that

especially given the history of the correspondence with the MHRA that we have seen, they really would not have done that if they thought this was misleading?

A. It is not about whether they dropped the bullet points or not because of that matter or not. I am not sure why they have dropped the bullet points or where the communication is from the MHRA on why that has happened. I could show you the most recent Hydrocortisone SPCs for others on the electronic medicines compendium and they have not got those points in. Some of them have got those points in. So I do not think we can say consistently this is the MHRA's belief because the SPCs differ in this area too, I believe.

MR JONES: I understand. I think that would be a convenient moment, if it is convenient for the Tribunal, to pause.

THE PRESIDENT: Yes, thank you very much, Mr Jones.

Dr Newton, I say this to all witnesses including experts, please do not talk about your evidence to anyone. We will rise for ten minutes and resume at 20 to. Thank you very much.

(11.32 am)

(A short break)

(11.44 am)

MR JONES: Dr Newton, I want to turn next to the obligations on prescribers when they prescribe a medicine. Now,

I should say this is not a topic which is covered in your report or at least it is touched on, but it is not a particular chapter in your report as such. But it is relevant because it is the step between the marketing and the dispensing pharmacist and so, obviously, the obligations at each stage overlap to some extent. So I do want to go through this and understand your understanding of it.

Now, the guidance regarding prescribing does become a little bit complex when applied to the unusual circumstances of Hydrocortisone. So what I would like to do is to start by asking you some questions about prescribing in general terms without talking specifically about Hydrocortisone and then I will come back to talk specifically about how this works in the context of Hydrocortisone. So I hope that is clear?

A. Yes.

Q. The first point I want to address is open and closed prescriptions. Could we go, please, to the Decision which is {A/12/60}. If we can zoom in on 3.63, please. You will see there a distinction between open and closed prescriptions. I will just pause so everyone can read it, but my question is simply going to be whether that is also your understanding of the difference between those terms. (Pause).

A. That is fine.
Q. Yes.
A. Thank you, yes.
Q. Then at 3.64 do you see that it is said that prescribers are generally encouraged to write open prescriptions using a medicine's generic name, for example Hydrocortisone tablets, regardless of whether a generic product is actually available.

Do you agree with that?

A. I do, yes.
Q. Would you also agree that one reason why open prescriptions are encouraged is to save the NHS money?
A. Yes, I think that would be fair.
Q. Perhaps we could just have a quick look at the guidance at {H/1319/1}, please. This says "NICE" at the top. It is published by the National Institute Of Clinical Excellence, but, just to be clear what it is, it is the British -- in fact you can slightly see this -- "BNF" above "guidance". It is the British National Formulary, which is a joint publication of the British Medical Association and the Royal Pharmaceutical Society. So would you be aware of this document?
A. I was sent this on Friday.
Q. I see, but, more generally, the British National Formulary?

A. The BNF, absolutely, yes.
Q. If we go then to the bottom of page 4, please. Do you see the heading there "Non-proprietary Titles":
"Where non-proprietor ('generic') titles are given, they should be used in the prescribing. This will enable any suitable product to be dispensed, thereby saving delay to the patient and sometimes expense to the health service. The only exception is where there is a demonstrable difference in clinical effect between each manufacturer's version of the formulation."
So I think you had already agreed to this, but I wanted to show you the guidance, prescribers are encouraged to use generic titles where clinically appropriate, in part to save the NHS money?
A. Correct, yes.
Q. The next piece of guidance then that I want to come to is the MHRA guidance, which you discuss in your report and, again, to be clear, I want to talk about this, firstly, just in general terms. We will come back to Hydrocortisone. But {D2/2/17}. This is produced by the MHRA and you can see it refers in the title to "prescribers' responsibilities" in relation to off label use of medicines. Just pausing there. I think we agree that a medicine is used off label if it is used outside the terms of its marketing authorisation?

A. That's correct.
Q. Could I also just check this with you, please, we often see references to medicines being used outside of their licence. That is the same thing, is it not? The licence tends to be a reference to the marketing authorisation?
A. There is a lot of interchangeable terms. I think you will find unauthorised, unlicensed, off label could be the same thing.
Q. Almost the same thing. Although, again just to be clear, unlicensed, if one talks specifically about unlicensed medicines, that is normally talking about a medicine that does not have a marketing authorisation for anything, but is nonetheless available for use, would that be right?
A. Not always. I think you will find even in the GMC guidance skinny Hydrocortisone used in adults is an unlicensed product. In other areas someone will say, well, that is a licensed medicine used in an unlicensed indication. So, again, I think it just varies whoever you are talking to.
Q. I understand. In terms of off label prescribing here, we can see an example of it, please, it is on page 19. {D2/2/19} So the MHRA gives an example. The first example which they give is a medicine which is licensed

for the treatment of various cancers being used instead in an ophthalmology setting. Do you see that?

A. I do, but I believe they've changed their mind on that.

Q. That particular example -- I notice from the way they have then clarified it that it all becomes a bit complicated, but, at the high level, that is the sort of example one might think about?

A. Yes.

Q. Whether this particular example holds water any more is maybe by the by?

A. Yes.

Q. So that would be an example of off-label prescribing. The key advice that we can see at the bottom of page 19, and this I think is what you emphasise in your report, "Advice for prescribers" and then there is a list of bullet points. The one that you highlight in particular is that second one, prescribers should:

"Be satisfied that such use would better serve the patient's needs than an appropriately licensed alternative before prescribing a medicine off label."

A. Yes.

Q. I want now to turn then to how all of this works in the case of Hydrocortisone. Are you aware that the CMA found that almost all prescriptions for Hydrocortisone tablets are open prescriptions?

A. I was aware, yes.
Q. I think you are also aware that the large majority of patients are adult patients?
A. I understood that.
Q. So when a doctor writes an open prescription for Hydrocortisone tablets for an adult patient, would you call that an off-label prescription?
A. No, not at all.
Q. Doctors are able to write open prescriptions for Hydrocortisone tablets without, in your view, needing to follow these steps in the MHRA guidance that we have just looked at. They would not need to treat that as off-label.
A. Well, an open prescription for Hydrocortisone in adults there is a licensed treatment so that is not off label prescribing.
Q. Yes, but of course we will come on to the dispensing in a moment, but of course the background point being that an open prescription could be satisfied in principle by a skinny label product. So I just wanted to clarify whether that possibility would in your mind change an open prescription to being an off-label prescription and I think your answer is no, it would not?
A. I am not 100% sure of the question. If you could just repeat that, counsel, sorry.

Q. Well, the question was -- I think you have answered the main question, which was whether if a doctor writes an open prescription for Hydrocortisone tablets for adults you would not consider that to be an off-label prescription?
A. No.
Q. You would not, therefore, think that the prescribing doctor would need to follow the MHRA guidance?
A. No, the MHRA guidance does not even apply, because an open script in adults is not off-label. The MHRA guidance only applies if the doctor was saying I want to give 50mgs to a child. That would be off label.
Q. I am sorry, Dr Newton. I am being slightly slow about this. Let us go back to AMCo's SPC. It does not cover adults, you accept that?
A. Yes, that is right.
Q. So let me maybe start it this way. If a doctor wrote a prescription which was closed and specified the AMCo product for an adult that would be off label?
A. That is correct.
Q. That is correct, yes. Whereas, and I appreciate I have now asked this a couple of times, but just to expand it slightly, make sure we are on the same page, whereas if the doctor wrote for that same patient just an open prescription, you would say that is not off-label?

A. That's correct.
Q. Let us turn to the obligations on dispensing pharmacists. Now, the pharmacist is handed a prescription and we have just established that almost all prescriptions are open prescriptions, yes?
A. Correct.
Q. Now, the CMA also found that Hydrocortisone prescriptions typically do not specify the patient's condition. Would you have any reason to disagree with that?
A. No, no reason.
Q. Pharmacists are of course obliged to dispense the drug written on the prescription, I think you would agree with that?
A. I agree.
Q. In terms of patient safety, you do not have any reason to think that it would be risky or unsafe to dispense a skinny label product to an adult?
A. In terms of patient safety alone, no. They are bioequivalent so, no.
Q. But I think what you say is, doing that, when faced with an open prescription, would be contrary to this guidance. Is that right?
A. Yes, because it would not -- it is not contrary to the guidance if the guidance had been followed, you know,

prescriptively as per those bullet points. What would be contrary to the guidance was if a skinny label had been dispensed to an adult without the pharmacist checking these points.

Q. Yes, exactly. So the pharmacist, you say, would have to check these points. Can we just start with a simple point. If we go back to page 17 and the start of the guidance, please. {D2/2/17}. It is on the face of it about dispensing, is it? It is about prescribing. Do you agree with that?

A. I mean the title would imply that, yes.

Q. So if the prescriber has decided that the product which they have written on the prescription is appropriate, and the prescriber has not had to follow, in your view, the off-label guidance, then that is sufficient, is it not? There is no need for the pharmacist to second guess what the prescriber has done. They simply need to dispense the product on the prescription.

A. It is actually slightly worse, because if the prescriber does not know that the product that is being dispensed is off-label, then they have all this liability and none of the knowledge. So, actually, they could very well assume that what they have prescribed and what the patient gets dispensed is in line with the licence. They probably are not even thinking about this guidance,

because why would they think it is applicable.

Q. I am sorry. I need to go back just to make sure I have understood that exactly.

You say they have all of this liability and none of the knowledge. I am struggling to understand who would have the liability. I think we established that prescribers do not need to follow the guidance to write an open prescription. So you are not saying that doctors would have this liability, are you?

A. A doctor has the liability for knowingly prescribing a medicine off-label. What I am suggesting is that this guidance, whilst it does absolutely focus on prescribers, a lot of NHS policies etc out there reflect the same for dispensing pharmacists, and if a dispensing pharmacist knowingly dispenses a medicine that is skinny, for adults and the prescriber does not know, my suggestion is how can the prescriber be held liable for that?

Q. What would be the answer to that? Can the prescriber be held liable for that?

A. Not if they can demonstrate that they did not know that their patient was being dispensed an off-label medicine.

Q. So then we go back to the pharmacist and the pharmacist is faced with an open prescription. They have to dispense what is on the prescription. We have agreed

that these products are bioequivalent and what I am suggesting to you is that there is not -- just on the face of this guidance, there is nothing that says the prescriber then has to do the job that the -- sorry, the dispenser then has to do the job that the prescriber did not do. So it does not make sense, does it, to push these obligations on to the dispensing pharmacist?

A. I mean, bioequivalence is just one aspect. When you are fulfilling a prescription for dispensing, you check that the medicine that you are dispensing is the same as the medicine and the next thing you check is the licence, the dosage, the patient population. So there is a huge chunk that we are not talking about, which is not just bioequivalence. It is, is it, the right one licensed for that patient and all prescriptions have the age of the patient on there straightaway, so I do not really need to know the indication, because I know if it is an adult or not.

Q. So let's just think this through in practical terms. When you say you would not need to know the indication, is that important? Is that because pharmacists do not generally know the indication?

A. I think it depends on the patient management system that pharmacies use, but a lot of pharmacists would absolutely know the indication either from a summary

record or from medicines usage reviews and what have you. But in the instance I am suggesting in a very busy pharmacy where not everything is known and checked, then it might suffice just to know the age of the patient, particularly if it is a repeat prescription.

Q. But do you remember that the Alissa indication is different to the AMCo indication? I am sure you remember that. So they are both skinny label, but one is skinnier than another, if you like. The AMCo one is skinnier. So, in fact, I think in practice the only way this would work on your approach would be that pharmacists would have to work out not only the age of the patient, but the condition which it has been prescribed for. Do you agree with that?

A. I do agree.

Q. Just putting ourselves into the pharmacy, the pharmacist says to a patient -- we do not have access to the records -- is this for congenital adrenal hyperplasia or is it for adrenal insufficiency? Is that what they need to ask?

A. No, what tends to happen in practice is that they ring the doctor for that information.

Q. It would be unworkable, would it not, to require pharmacists to go through this process?

A. That is why the guidance is the guidance, because it is

ensuring someone has carefully, thoughtfully considered these very key points about safety. So it is not designed to be super easy, because otherwise it would happen a lot.

Q. Dr Newton, you say it is about safety. But is not the point here that when we have a bioequivalence generic there is not a safety issue?

A. I mean, I think the Hydrocortisone issue is very different to most generics on the market, which would be fully bioequivalent and not have orphan drug designation. It is a different point.

Q. Hang on. The difference that you are highlighting is the orphan drug designation, not a bioequivalence or safety issue?

A. From a safety perspective, a generic, two generics on the market, which have the same bioequivalence and are licensed for the same population, can quite easily be dispensed off an open script. That is not a problem.

Q. Yes, but you added in there a licence for the same indication, but I am just making the point that whatever the licence is, if they are bioequivalent and there is not a patient safety issue, it just does not make sense to require pharmacists, as you would want to require them, to apply this guidance which should apply to prescribers?

A. Which is why, in my experience, the easiest thing and the normal thing would be to ring the doctor, check that they know and then you have transferred the liability. That is what happens in practice.

Q. Are you aware that back in 2014 Auden McKenzie raised the question of dispensing off-label with various people, including the chief pharmaceutical officers in, I think, England and Scotland?

A. Yes, I saw that.

Q. You saw that in the documents. Can we look at the Auden letter, please. It is at bundle {H/418/1}. Now this says "Draft", but I think it is all that we have. So I think, I will be corrected if this is wrong, but I think this is the only version of this letter that we have got. You will see it says at the top addressed to chief pharmaceutical officers.

If you go to page 2, please H/418/2}, you will see there that they are drawing attention to some GMC guidance, not the MHRA, but it is similar, it is making similar points, and at the bottom of the page do you see where it says "We would welcome discussing with you", they are asking for a discussion about giving potentially appropriate guidance to senior pharmacists. Do you see that?

A. Yes, I do.

Q. Then if we could go, please, to the chief pharmaceutical officer's response at {H/635/1}, and you will see on page 1 he starts by saying:

"Colleagues at the MHRA have informed me that there are no material differences between the available generic immediate release and they are all bioequivalence to the brand leader."

Do you see that?

A. Yes, I do.

Q. Then on page 2, please. {H/635/2}. If you just read that, you will see he is saying he does not think there is any need to write to senior pharmacists. Do you see that?

A. I do.

Q. I then want to take you to what the chief pharmaceutical officer said to the CMA when this was discussed with him. Can we go, please, to {H/1245/1}. You will see this is a note of a call between the CMA and NHSEI, which includes, you will see there on page 1, the chief pharmaceutical officer. Do you see that?

A. Yes, I do.

Q. If we go, please, to page 3. Under the heading "Dispensing", there is a record there of what NHSEI said. You may well have had an opportunity to read this over the weekend, but I will just give you another

chance now. Could you read to yourself 5.1 actually to 5.8. So maybe if you give an indication, please, when you have read these paragraphs.

THE PRESIDENT: Ask to turn over the page when you need to. (Pause).

A. The next page, please. (Pause) Okay, thank you.

MR JONES: So could I suggest to you, Dr Newton, that the NHSEI and the chief pharmaceutical officer in England have a very different view of pharmacists' obligations to your view.

A. Yes, I agree.

Q. Can I then suggest that your understanding of the obligations on dispensing pharmacists is wrong and the correct position is that they can dispense off-label, provided they are meeting a prescription which has been written?

A. So I think this actually -- there is a degree of agreement here. So I am not contesting at all that the products are not bioequivalent or that there is any threat to patient safety. I think everyone agrees on that point. On a very specific licensing liability perspective on section 5.8, the chief pharmaceutical officer does not give an opinion and says there are matters for pharmacists to consider when they are knowingly dispensing products off-label for cost saving

rather than medical reasons and that is the point that I am saying where I believe the liability sits and I do not believe I am disagreeing. I believe they have not really given a strict opinion on that.

Q. But if you look at 5.7, the dispensing pharmacist is not obliged to establish what condition an open prescription is intended to treat "and attempting to do so may present patient confidentiality issues."

I mean that is completely inconsistent with your view, is it not?

A. It is completely inconsistent with medicine usage reviews and care quality. There is a lot of instances where a dispensing pharmacist absolutely has to know what that indication is and checks that with the prescriber.

Q. Dr Newton, just reminding ourselves of the discussion at the start about your own background and expertise. Can I put to you that you are not really an expert in the obligations on dispensing pharmacists?

A. I mean, I am a pharmacist and I have to sign up to the nine standards of care for the GPHC so, according to those standards, I know what the key principles are and they would be around all care being person centred. So the point I was trying to make by looking at 5.8 is this cost saving over and above patient care.

Q. Finally, Dr Newton, I have one last question, which I wonder whether we might agree on this one. Would you agree even if I am right about the law that pharmacists are allowed to dispense off-label, provided only that it is in accordance with the prescription, would you agree that even then there is a group of pharmacists who take a more cautious approach and for that reason would prefer to avoid if possible dispensing off-label?

A. I would not necessarily say that is the cautious approach. I would say that is the appropriate approach. It is not about whether it is unlawful or -- of course they can dispense off-label as long as the particulars in the MHRA guidance are met. It is not unlawful to prescribe or dispense off label.

MR JONES: Thank you very much, Dr Newton. I do not have any further questions, but I believe others may have some more questions.

THE PRESIDENT: Just to fully articulate that last answer. Counsel entirely appropriately characterised the difference between cautious and not so cautious. Leaving the labelling of caution or what is appropriate on one side, would you agree that there is a broad bifurcation in the market where you have got some people who are, I do not want to be tendentious to either side, more rigorous versus less rigorous in terms of off-label

prescribing? Is there a difference in practice of approach between segments of the industry?

A. In terms of pharmacies and wholesalers, there definitely is a difference and I would assume one of the reasons would be around professional liability.

THE PRESIDENT: Thank you.

MR JONES: Thank you, sir. No further questions.

THE PRESIDENT: Who has any questions for -- Mr Palmer.

Cross-examination by MR PALMER.

MR PALMER: Dr Newton, these obligations that you refer to, both in terms of prescribing and in terms of dispensing, apply equally whether the setting is typically say the GP prescribing and a community pharmacy dispensing or whether it is a hospital doctor prescribing and the hospital dispensary dispensing. Is that right?

A. That is correct.

Q. There is no difference at all?

A. In terms of the --

Q. Appropriateness of off-label dispensing?

A. Completely the same.

Q. The guidance does not distinguish between the two cases?

A. Agree.

Q. Can I just take you to the Decision of the CMA at page {A/12/343} and ask you to look at paragraph 4.128 at the bottom of that page. Do you see that?

A. Mm-hm.
Q. Just take a moment to read that paragraph to yourself, which will continue over the page. (Pause).
A. Next page, please. (Pause).
Q. Do you see that? If we just go back to the previous page, the bottom of the page again and look at the footnote which is given, 1259, right at the bottom of the page. There is reference there given to some details of the tenders. We can turn that up if necessary, but let me just run you through them.

NHS England ran a tender for Hydrocortisone tablets in respect of the period running from March 2017-February 2020 and they awarded for 10mg tablets that contract to AMCo, a skinny product, over and above the Actavis product, which was the full label product. They did so on grounds of price. That meant that all English hospitals would then dispense that AMCo Hydrocortisone tablet to patients who were prescribed Hydrocortisone tablets in hospital, does it not, over that three year period?

A. Yes.
Q. The same goes for NHS Scotland from May 2017 to April 2019, although there the contract was given to Teva, also a skinny product, and awarded on price grounds over Actavis and the same for Wales, the most

recent tender from February 18 onwards, also awarded to Teva on price grounds over Auden/Actavis.

So this means that hospitals across Great Britain would be routinely dispensing skinny products in relation to all prescriptions for Hydrocortisone tablets or at least open prescriptions for Hydrocortisone tablets, does not it?

A. Yes, that's correct, but I would assume that the guidance had been considered and when it is done at that high level, the NHS can act at public health level if they considered bioequivalence and cost.

Q. Also patient safety and of course that question is answered, is it not, by the bioequivalence?

A. Yes.

Q. So there is no consideration there that what they are doing is inconsistent with the MHRA guidance, is there?

A. No, not really. I think that MHRA guidance tends to be about very specific scenarios and in tenders it is often the case that companies win those based on price. There is very recent case for Sanofi who were then found in breach for talking about it. The NHS can do it, but the company cannot talk about it.

Q. So the company cannot promote. That is under one level of guidance, but under the MHRA guidance -- just go back to your expert report, please, at page 4 {D2/2/4}. You

see you have got that heading "Dispensing off-label". Do you see that? Which follows the section which has dealt with the promotion of a medicine. You have dealt with that quite separately quite properly.

In terms of dispensing, you have referred to the MHRA guidance and set out the provisions of that guidance which you consider relevant and that at paragraph 17 on the next page, {D2/2/5}, from that guidance you say that means:

"That pharmacists should not dispense off-label unless the specific circumstances described above exist. In summary, these are that off-label dispensing should only occur [where certain conditions are met] and the best interests of the patient... "

At the bottom of paragraph 19, you say that if skinny products were dispensed then off-label dispensing was not compliant with the MHRA guidance if that was only on cost grounds.

A. If patient care had not been considered and it was only based on cost grounds.

Q. Right. So there is no patient care issue here, is there, between full and skinny tablets in circumstances where they are bioequivalent?

A. No, there is no patient safety issue. The difference between an NHS tender and possibly the situation with

a small independent pharmacist is the recording of the reasons for buying skinny and off-labelling. That is really quite key.

Q. That can be in circumstances where they are bioequivalent, there is no patient care issue, it can just be cost, as the NHS has shown in all three of those tender exercises. That is a good and sufficient reason for providing a generic product in those circumstances, is it not?

A. That is what the tender process is about.

Q. Yes. Can we next turn to bundle {N/155/1}. I think it is just one run of documents in {N/155/1}. Sorry, I gave a different reference. I think it will be tab 17 {N/17/1}. Go to {H/822/1}. No, sorry, I have got a different reference, which is not working out. (Pause).

Sorry, {H/1251/1}. That is the document. That is a note of a call between the CMA and the MHRA. Have you seen that document before?

A. Yes.

Q. If we can turn to the next page, please. One more, paragraph 3.1. You see at 3.1 the MHRA confirming that there was no patient safety issue arising from skinny dispensed off-label, because they were bioequivalent.

That accords with your understanding as well, does

it not?

A. Yes.

Q. So at 2, 3.2, the MHRA also confirmed that there was no regulatory barrier to skinny label suppliers selling their products to UK pharmacists, as their products were licensed for supply in the UK for other indications. The success of skinny label tablets would depend on the willingness of pharmacies to stock the skinny product.

At 3.3 they confirmed that pharmacists would be able to dispense a skinny label product against an open prescription:

"If a prescription is open, the pharmacist can dispense any product that fits the description and when dispensing a skinny label product against an open prescription, the pharmacist is following the instructions on the prescription accurately."

You agree with all of that?

A. I agree in part with it. There is an element that is missing out of it and that would be when dispensing a skinny label product against an open prescription, the pharmacist is following the instructions on the prescription accurately and as per the licensed indication.

Q. Okay. Let us move on then down to the bottom of the page at 4.

You see how it says at the bottom of 4.1 it does not issue prescribing and dispensing guidance unless there are public health grounds for doing so.

Then over the page:

"The MHRA must otherwise maintain a neutral position on prescribing and dispensing decisions and it will not intervene in the marketplace. No public health concern with respect to hydrocortisone tablets because the skinny and full labels were bioequivalent and the MHRA therefore considered switching from full to skinny label hydrocortisone tablets to be a commercial decision for pharmacies to take and outside of the remit of the MHRA."

In other words, a matter of price and something which they are not concerned with, outside their remit.

Because there were no public health issues the MHRA did not need to issue guidance on the Hydrocortisone tablets.

4.2, finally:

"They also needed to remain neutral in terms of how the marketplace worked. It was not within their remit to influence commercial decisions nor to encourage switching from full to skinny label tablets because they were cheaper. They need to respect the orphan designation that had been granted. Accordingly, the

MHRA would not have considered issuing guidance to pharmacists either encouraging switching or saying that switching was not problematic."

They would just leave that to the market. Do you see all that?

A. Yes, I do.

Q. That is because the orphan designation is not something which raises any issue for the MHRA, save in terms of their separate function of regulating the contents of an SPC and, thus, the promotion of a medicine in accordance with the SPC. In terms of dispensing obligations, the orphan designation has no relevance at all, does it?

A. It sort of depends on the question they have been asked. If they had been asked about patient safety, their answer is there is no patient safety concern.

Q. So the only reason for the distinction in the case of Hydrocortisone between full label and skinny tablets is the consequence of that orphan designation?

A. That's correct and the consequences to the licensed indications.

Q. Yes, so no clinical difference between them at all. So no liability issues between them at all.

A. I think that is probably why it is an unknown, because there have not been these horrendous adverse events from switching, there has not been a need to kind of test who

exactly is liable here.

Q. It is not that it is unknown. It is said with confidence -- I will not go through all the references with you, because the Tribunal has it -- that they are bioequivalent, that there are no patient safety issues arising and, indeed, that is what the CMA found in its Decision in this case having considered all the evidence on it including from an expert consultant endocrinologist?

A. Sorry. What was counsel's question?

Q. It is not just that it is an unknown area, but there is confidence that there is no patient safety issue at all?

A. Sorry. That is not what I meant by liability. I will go back to -- sorry, just to clarify. What I mean by liability is who is liable in the event someone reports an adverse reaction from an-off label use?

Q. But that in itself is assuming that there is some relevant difference between off-label and on-label use in the specific case of Hydrocortisone and I think we are agreed there is not one?

A. So far no.

MR PALMER: Thank you very much.

THE PRESIDENT: Mr Brealey, before you start, is there anything arising out of that or anyone else have any questions of this witness?

MR JONES: No.

THE PRESIDENT: Mr Brealey.

MR BREALEY: I have no re-examination, sir, thank you.

THE PRESIDENT: No, thank you very much for attending. We are very grateful. You are released from the witness box. Thank you very much.

(The witness withdrew)

THE PRESIDENT: Mr Brealey, is there a need for musical chairs with regard to the configuration of the courtroom for Mr Holmes. I see there is.

MR JONES: Just a little bit.

THE PRESIDENT: Would it assist if we rose for a couple of minutes to enable Mr Holmes to move forward.

MR JONES: Yes.

THE PRESIDENT: We will rise for a few minutes just to allow that to happen.

(12.26 pm)

(A short break)

(12.28 pm)

MR HOLMES:

THE PRESIDENT:

MR BREALEY: Thank you. Sir, I now call Mr Holt.

MR DEREK HOLT (affirmed)

Examination-in-chief by MR BREALEY

THE PRESIDENT: Mr Holt, good afternoon. Do sit down.

MR BREALEY: Mr Holt, there should be a report just in front of you.

A. Yes.

Q. Could you just look at that. It should say AlixPartners?

A. It does.

Q. Could you and for the -- you are there in the electronic bundle. Could you just flick through that. Could you confirm to the Tribunal that this is your report?

A. It is.

Q. Then if you go to page 64 {D2/1/64}, hopefully you have a copy?

A. I see it on the screen, yes.

Q. Is that your signature?

A. It is actually blacked out on the screen, so I should probably have a look. The answer will be, yes, but I should probably look at it before I say so. Sorry, let me just get to the declaration.

Q. 64?

A. Thank you, yes.

Q. Then we need to go to another document. So this is the joint statement. I do not believe you have got that in front of you?

A. No.

Q. I think that is {IR-G1/1}.

A. Yes.
Q. So obviously you have not got it in front of you, but that is 22 July 2022. You prepared a joint statement between the experts. Is that correct?
A. That is correct.
Q. Then if you go, please, to the last page, page 53. Can you confirm that is your signature?
A. It is.
Q. In respect of both reports, can you confirm that you have made clear which facts and matters referred to are within your own knowledge and which are not?
A. Yes.
Q. Lastly, can you confirm the opinions you have expressed in both reports represent your true and complete professional opinion?
A. They do.
Q. I am obliged. The gentleman to my right, Mr Holmes, will have some questions for you.

Cross-examination by MR HOLMES.

MR HOLMES: Good afternoon, Mr Holt. Thank you for joining us today.
A. Good afternoon.
Q. To give you due notice, we are going to be splitting cross-examination between myself and Mr Jones, not Mr Grubeck. I will be dealing with market definition

and he will be dealing with the agreements part of your report.

A. Thank you.

Q. So you explain at the start of your report that you have been asked as one of the topics to consider the CMA's findings on market definition with particular reference to its findings on the relevant product market. That is right, is it not?

A. Yes, that is right.

Q. You refer at the outset of your report to the period covered by the 10mg agreement. That is 31 October 2012 to 24 June 2016 which you define as the relevant period?

A. Yes, that is right.

Q. But your consideration of product market definition is not focused in particular on that period, would you agree?

A. I think it takes into account all of the evidence that I have seen, which may include evidence beyond that date.

Q. The specific focus is on the period following independent entry in 2015 though, would you not agree?

A. That is I think the primary evidence base in terms of data, yes.

Q. That is because you are considering, in particular, whether skinny label Hydrocortisone tablets competed in

the same market as full label Hydrocortisone tablets of the same strength following entry?

A. Yes, it was to assess whether those products were exerting direct competitive pressure upon each other.

Q. Yes. In section 4 of your report you provide a helpful summary of the approach to market definition. So if we could start there, please. It is at {IR-D2/1/18}. Focusing on 4.1.1 at the top of the page, you have set out there a quotation from the European Commission's notice on market definition. That explains that market definition is a tool to identify and define the boundaries of competition between firms and that it involves systematically identifying the competitive constraints that the firms involved faced.

At its most basic level, would you agree that the objective of market definition is to identify the competitive constraints facing a firm or firms in the supply of a particular product?

A. Yes, I think that is right.

Q. At 4.1.2 you pick up the important point in a quotation from the UK guidelines that market definition is not an end in itself. It is an important step in the process of addressing other questions relevant to the application of competition law?

A. Yes.

Q. I think it must be the case, given that you have reproduced the quotation, but can I confirm that you agree that market definition is therefore an intermediate step in a wider process of assessment?
A. Yes, I think that is a fair statement.
Q. In particular, it is the usual first step in the assessment of market power or dominance for the purposes of applying the Chapter II prohibition?
A. Market definition can be used in a variety of types of competition issues, but that is one of them.
Q. Yes. You see that at the end of the quotation at 4.1.2:
"Market definition is usually the first step in the assessment of market power."
A. Yes, that is right.
Q. In the context of the Chapter I prohibition, the agreements part of the case, it may be relevant when considering whether parties are actual or potential competitors. Is that right?
A. Yes, that might be one of the reasons for which you look at it.
Q. Yes. In your reports your focus is on the market definition and you do not proceed to consider subsequent stages of the competitive assessment. Is that correct?
A. Yes, that is correct. That is effectively in line with my instructions and the scope of my report.

Q. So you do not, for example, consider the question of dominance in the post-entry period?
A. No, I do not.
Q. You do not address whether your consideration of the appropriate market definition in this case would have any implications for the analysis of the 10mg agreement?
A. I haven't carried out that particular analysis.
Q. Looking down the page at paragraph 4.1.3, you turn to consider what is meant by the competitive constraints facing a firm or firms in the supply of a particular product. You identify there that the exercise involves considering the economic substitutes for the product in question or focal product.

By substitutes you mean the other products that customers may be prepared to purchase instead of the focal product. Is that right?

A. Yes, that is right. A product substitute is essentially an alternative product that a customer may wish to purchase and the other aspect here, we may come on to it, is the matter of degree to which that constraint is effective.
Q. Yes. Indeed, that was in fact my very next question. You explain that the question of whether another product is sufficiently substitutable to serve as a competitive constrain can be approached by considering the extent to

which a customer would be -- or customers would be prepared to switch away from the focal product if there were a small permanent increase in price in the focal product relative to a potential substitute. That is correct, is it not?

A. Yes.

Q. If such switching would be enough to make the change unprofitable, the potential substitute can be viewed as a competitive constraint?

A. Yes, that is the SSNIP or hypothetical monopolist test framework.

Q. Pausing there, can we consider for a moment the types of evidence that might be of particular relevance when assessing whether there is sufficient demand side substitutability between the focal product and a potential substitute product so as to place them in the same market?

A. Yes.

Q. First, can we agree that the characteristics of each of the products will be relevant for the purposes of assessing whether they are potential substitutes from the point of view of customers?

A. They can be relevant, but only insofar as they determine the purchasing behaviour of the consumers in the market. So they could be relevant in the sense that if the

characteristics were not perceived to be substitutable, then that would be clear in the purchasing decisions, but the converse does not follow that just because the characteristics are similar that necessarily suggests that they should be in the same product market.

Q. No, indeed, we will come on to that, but nonetheless it is relevant to consider whether they are functionally substitutable, because that may shed light on whether, as a practical matter, customers are prepared to switch between them?

A. It may do. As I say, it might be that it is sort of something that you could screen out at an early stage that if they are not functional substitutes at all then you might not need to explore any of the further questions.

Q. Yes. Secondly, can we agree that the extent to which customers do in fact switch between products will also be a relevant factor to consider?

A. Yes, that can be a relevant factor when paired with the evidence in relation to the nature of the price differentials that are being examined.

Q. Indeed, so as a third point, the evidence on price trends in relation to the products will also be relevant evidence to consider?

A. It may be relevant evidence to consider.

Q. Yes. Indeed, if we could go in your report to paragraph 1.11 in the executive summary {IR-D2/1/6}, you say in the final sentence of paragraph 1.1.11 that in this case you consider that key evidence would include the extent of pharmacies switching away from full label to skinny label, the switching, and evidence on price trends for full and skinny label Hydrocortisone tablets, as well as product characteristics such as bioequivalence and dispensing practices.

A. Yes, these are all the sorts of factors that I was taking into account and then, obviously, what you then need to do is try and understand what is happening in terms of the competitive dynamics within the market, so those are all sort of inputs to the assessment.

Q. Yes, and taking those three types of evidence together, thinking in general terms rather than about this specific market which we will come to later, if the evidence showed that two products are potential substitutes for customers and that a price change in product A is followed by price or volume changes or both in product B, that would be consistent with product A acting as a competitive constraint on product B. Would you agree?

A. I am sorry. I think I missed the first part of that. Could you repeat the scenario?

Q. So taking these three types of evidence together, product characteristics, price trends and volume trends, if the evidence shows that two products are potential substitutes for customers and that a price change in product A is followed by price or volume changes or both in product B, that would be consistent with product A acting as a competitive constraint on product B?

A. I would sort of agree with that other than -- sorry, with the clarification that it could be consistent. It would not necessarily follow that they are in the same product market, but it could well be consistent with that, yes.

Q. Resuming our discussion of section 4 of your report, could we now turn a page and consider paragraph 4.1.4. That is on {IR-D2/1/19}.

You say there at the top of the page that the hypothetical monopolist framework helps to answer the question of how much substitution is required for competitive products to be in the same relevant market and you say that it is often measured through a SSNIP test?

A. Yes.

Q. So you do not consider that a SSNIP test is the only available way of arriving at a definition of the relevant product market. Is that right?

A. Well, I agree that the application in terms of the quantification of a SSNIP test is not the only way of carrying that approach out. I think at the same time I would say that it is the standard methodology that both the European Commission and the CMA or at least formerly the OFT in their guidance on market definition emphasise as the overall framework that should be (inaudible).

Q. Am I right that you are distinguishing between the framework that one uses to conceptualise how competitive constraints may arise and the formal application of the SSNIP test by means of quantitative modelling. Is that a fair distinction?

A. That is indeed the distinction. Just to be clear on that, the framework I think is a relevant one in the sense that what you are seeking to understand is the extent to which other potential products beyond the focal product may lead to a constraint on the pricing and competitive conditions of the focal product. That is essentially what the hypothetical monopolist test or the SSNIP test are seeking to do. It may be that a broader range of evidence can be used in order to apply that framework.

Q. So it is not necessary in every case to have undertaken a formal SSNIP analysis?

A. That is right.

Q. You elaborate on this point in the joint experts statement. If we could go to that, please. It is at {IR-G1/1/3}. The relevant discussion is at proposition 4 and you see starting in the first column that the proposition is that it is not necessary to apply a SSNIP test where it is possible to observe as an empirical matter how much switching occurred in practice in response to actual price changes.

Looking across at the final column where you set out your position, you explain that:

"I consider it preferable to use a data-driven approach for market definition, and the SSNIP test is one available approach. However, there are often real-world challenges with the implementation of SSNIP tests which may make it necessary to consider alternative approaches."

I think you make a similar point in paragraph 4.1.5 of your report -- we do not need to go there -- when you highlight potential drawbacks of the hypothetical monopolist tests, in particular where products are differentiated.

Can I check that -- would it be a fair summary of your position to say that market definition should ideally involve quantitative assessment by reference to

the available data, but that it need not necessarily involve the application of a SSNIP test?

A. Yes, I think that is correct. It provides an appropriate framework to identify the nature of the constraints that are relevant from a product market definition perspective. It is important to understand that the aspect of the degree to which the substitution is occurring is important. It is important to take into account the nature of the price differences which are taken into account in that calculation, but you can often apply a market definition assessment using a broader array of evidence as opposed to in every case carrying out a full SSNIP assessment.

Q. As regards the practical difficulties, can we just spend a moment considering what the formal application of a SSNIP test would involve. Can I put a series of points to you and you can tell me whether you agree that they are steps that would be involved in formal SSNIP?

A. Sure.

Q. First, you would need to assess what would be an appropriate competitive price level for the focal product?

A. Yes, yes, that is important. The reason that is important, obviously, is that if you are looking at a comparison against a benchmark and the benchmark is

too high relative to a competitive one, there is a risk of over-inclusion in the product market definition and that is something you would ideally want to correct for.

Q. That is because you might see switching away from the focal product because of its excessive price that would not be observed in a market absent that distortion?

A. Yes, although I perhaps would not use the word "excessive" given its legal connotation, but, yes.

Q. Second, you would need to hypothesise a small but significant non-transitory increase in the price of the focal product while holding the potential substitute product price unchanged. Is that right?

A. Yes, so the importance of that is essentially to understand that the degree of market power that the hypothetical monopolist is understood to be limited by these products has to be a matter of degree. So in other words, if you were just thinking about, well, could it be profitable to raise the price by 100%, for example, then that would be inappropriate, because that would give in a sense too much leeway in terms of the profitability of a very large price increase, to suggest that the substitutes are really effectively constraining it.

Q. The exercise involves holding everything else equal, but imagining that the focal product goes up by a certain

amount?

A. Well, that is one way of looking at it. I think it is fair to say and I think the European Commission's guidance on market definition emphasises the relative price difference. That is what is important. In other words, when two products, which are potential substitutes or potentially in the same product market, demonstrate a relative change in prices then that should, if they are indeed close substitutes, engender a switch in purchasing decisions. So it is not strictly necessary from an economic standpoint to hold one price absolutely constant and then move the other one. If you can observe evidence of the two moving, as long as there are relative price changes and you can observe the reaction that, then that is evidence that should be relevant.

Q. Yes, so does this come back then to the distinction between observing quantitative evidence of trends in the market where relative price changes will be relevant and the formal exercise that is involved in hypothesising a price increase in the focal product which is the typical execution of a formal SSNIP analysis?

A. Yes, I think it is perhaps one aspect. When I say that perhaps it is not always feasible to fully implement a SSNIP, but rather you use it as framework and look at

all the evidence in the round, one of the factors is that you may not have enough elasticity evidence, for example, or you may not, because you are sort of often positing a counterfactual where you have a hypothetical monopolist, then you might not have actual evidence to look at that particular situation.

So those are reasons why you need to sort of sometimes look at this as a framework and then apply the evidence in the round.

Q. To be clear, you would need the elasticity evidence because you need a demand function to understand how the price change could be expected to impact on the volumes supplied of the focal product, is that right?

A. Yes, that is fair, because the reaction, if you were to have a relative price change, then the important issue is to what extent does that relative change in prices engender switching to the extent that it might be unprofitable or (inaudible).

Q. So the third point would be then that you would need some sense of the demand elasticity to estimate how many customers would respond to the change in the competitive price level if it were sustained over a non-transitory period, typically a few months?

A. A year or so.

Q. A year?

A. That is right.
Q. Fourth, you would then need to assess whether overall the price change was profitable and that would involve a comparison of the profits lost through lost sales with the profits generated by the price increase; is that correct?
A. Yes, that is a critical also analysis type test, yes.
Q. I think it follows from your previous observations but all of this would require quite a lot of information. It would involve judgments about matters that may be uncertain and about which evidence may be lacking. I think you mention, for example, there might not be evidence as to the extent of the demand elasticity?
A. Yes, that might be something that one would need to investigate and in my report I looked at other forms of evidence including that set out in the Decision.
Q. Indeed.
A. I do not think I meant to suggest that that was the only way to do it.
Q. No.
A. And that a quantitative approach could not be appropriate.
Q. Indeed. In this case you have opted for an alternative data driven approach based on a quantitative assessment of the available market evidence. That is correct, is

it not?

A. That is correct.

Q. Just to make the point transparently clear, you have not considered it necessary to undertake any formal SSNIP assessment or critical loss analysis yourself in order to reach your conclusions in this case?

A. That is correct.

Q. Could we turn on for a moment to propositions 9 and 10?

A. Perhaps I could just, in terms of that last question, that is correct in the sense that I haven't formally carried out the quantitative aspect but what I have done is rooted my analysis in the specific framework that is identified by the very same principles of the SSNIP.

Q. Yes?

A. So I would not say I have not rooted my analysis in that underlying set of principles. I have done.

Q. No, certainly. Could we turn on for a moment to propositions 9 and 10 in the joint experts statement which are at {G1/1/7}. If you look at proposition 9 that is stated as a conclusion:

"Auden/Actavis, a monopolist of full label 10mg HT, finds it profitable to charge a price that is (substantially) more than 10% above the competitive level."

Looking across the column you see in the first

column Professor Valletti disagrees, Dr Bennett agrees and in your column you very fairly say that the point is not addressed in your report?

A. Yes.

Q. And proposition 10 states that:

"A SSNIP test, whereby the price of full label 10mg HT is increased, starting from competitive levels while holding everything else constant, has not been performed in the current case."

You see that Professor Valletti agrees, Dr Bennett disagrees, although he accepts that it is correct that the precise test set out was not performed. In your column you say again that the SSNIP test is not addressed in the scope of your report?

A. Yes.

Q. The point is a simple one. Those questions reflect the fact that you have not considered it necessary to do a formal SSNIP assessment yourself. Instead you have relied on an alternative quantitative analysis rooted in the hypothetical monopolist framework; is that fair?

A. Yes, correct.

Q. Can we go back to proposition 4 at {G1/1/3}. If we could return to the alternative data driven approach which you identify in the second paragraph, you see there:

"An alternative data-driven approach to determine whether substitution is sufficient to consider full and skinny label to be in the same market is ..."

Then you describe what particular things you have looked at.

A. Yes.

Q. We can consider the substance later, but looking at subparagraph (a) you say:

"There has been no material switching beyond 2017" despite the relative price difference in 2018 and 19.

Then at (b) you conclude from this evidence that there has been a bifurcation of the market.

Now, in a nutshell your alternative data driven approach therefore involves an examination of the evidence as to price and volume trends across full and skinny label tablets to see whether they suggest an ongoing competitive interaction; is that fair?

A. Yes, that is fair. I think my answer in that particular column probably does not represent the entirety of the evidence base on which I was relying which obviously would be difficult to claim.

Q. But it is a summary?

A. But it was one of the points amongst various others, yes.

Q. Indeed. I will come to discuss the specific analysis as

you develop it in detail.

Sir, if that is a convenient moment perhaps we could ...

THE PRESIDENT: Indeed. The only thing, Mr Holmes, I am conscious that we lost half an hour which was for evidence through debating other matters. Are you comfortable with the time? If so, then fine but if you feel that you need a bit more time, if the witness is happy, we can run on for another ten minutes now and then perhaps start a little bit early before 2 o'clock.

MR HOLMES: I think, sir, we are in pretty good shape. I am comfortable that we will be done with Mr Holt today and may very well be able to start on Dr Bennett.

THE PRESIDENT: Very good. In that case we will rise now.

Mr Holt, you no doubt heard what I said to previous witnesses. Do not speak to anyone about your evidence. I will see you again at 2 o'clock. Thank you very much.

(1.02 pm)

(Luncheon Adjournment)

(2.00 pm)

THE PRESIDENT: Mr Holmes, before you resume your questions, just to say that we will not be proceeding to consider making an order to require the attendance of any witnesses. We are not going to make any ruling, but it will no doubt form a part of our judgment to explain why

it was raised and why it was not taken any further. So we are very grateful for the parties' help this morning, but I do not think we have put anyone particularly out of their suspense because I think you saw which way the wind was blowing, but anyway that is the way the wind is blowing. We will not be making such an order.

Mr Holmes.

MR HOLMES: Thank you, sir.

So, Mr Holt, when we broke off for the short adjournment, I think we had just agreed that your alternative data-driven approach involved an examination of the evidence as to price and volume trends across full and skinny label tablets to see whether they suggested an ongoing competitive interaction.

A. Yes, albeit that I considered other evidence as well, such as the evidence the CMA provided in the Decision in relation to how pharmacies were acting in the market.

Q. Yes.

A. Amongst other things.

Q. Yes. While there are some differences, obviously, and we will come on to those, in the conclusions you reach on the evidence, you would accept that the CMA market definition exercise also involves a quantitative assessment by reference to price and sales data for full and skinny tablets?

A. Yes, I do. Well, I think it has not answered the question. I mean, perhaps -- would you like me to expand on that point a little bit?
Q. Please.
A. It obviously has referred to various price and volume trends. I do not think it has answered the question of market definition properly by asking itself what is the impact of the migration, which I think is what has happened in the initial period after skinny label entry happened. It has not asked itself the question: what is the impact of that on the focal product from a perspective of the ability to maintain prices above a competitive level, and in my view the answer to that question is quite clearcut based on the evidence which is that the hypothetical monopolist, and in this case it is Auden, is able to maintain prices above a competitive level.
Q. Yes, as I say, you differ in the conclusions that you reach, but you do not dispute that the CMA's quantitative evidence focused on price and sales data for Hydrocortisone tablets following independent entry?
A. I do not dispute that they looked at some evidence. I think I dispute that they arrived at the same -- the right finding, yes.
Q. Can we now return to paragraph 4.1.4 of your report.

That is at {IR-D2/1/19}. In the second sentence you note that in the present case the CMA started with the focal product full label Hydrocortisone tablets and then assessed the extent to which substitution of other products would be sufficient to warrant widening the relevant product market beyond the focal product?

A. Yes, that is right.

Q. You agree that the CMA was right to take full label Hydrocortisone tablets as the focal product?

A. I agree with that, yes.

Q. That is on the basis that Auden/Actavis supplied only full label tablets throughout the infringements?

A. That is not necessarily the reason in the sense that even if hypothetically there had been two providers of full label product, it may still have been relevant to look at a focal product being the full label product. So it is not necessarily following that only because Auden was a monopolist at that particular way of defining the product that you would look at it. But I do not disagree that was the right focal product.

Q. Because that was the one that Auden/Actavis was supplying?

A. Yes.

Q. You agree that the CMA was also correct to assess the sufficiency of substitution by reference to the most

likely substitute products over the period of the infringement?

A. Yes, that is right.

Q. If we could -- the passage you quote in 4.1.4 is drawn from paragraph 4.40 of the Decision. If we could look at that, please. It is at {IR-A12/311/1} and looking at 4.40 you see here the potential substitutes considered by the CMA: skinny label Hydrocortisone tablets for the period after 3 November 2011, Plenadren, other forms of Hydrocortisone and corticosteroids. You do not take that as a list of the most likely substitutes?

A. No.

Q. You do not dispute the CMA's conclusion that the potential substitutes identified in (b) to (d) of paragraph 4.40 fall outside the relevant product market?

A. I do not. I did not look at that in detail, but, yes, I do not have any reason to dispute those findings.

Q. If we could just briefly consider at a high level the evidence in relation to that. If we turn on in the Decision to page 320 {A/12/320} and look at figure 4.3, that shows the volume trends for Hydrocortisone tablets across the infringement period. The red bars are Hydrocortisone 10mg and the blue bars, very much smaller, are Hydrocortisone 20mgs. Then you also see plotted on top of that the price trends, the blue line

for 10mg and the red line for 20mg.

This shows that the volume trends for Hydrocortisone tablets remained constant, well broadly constant, despite enormous changes in price over the period considered, does not it?

A. Yes, that is what that figure seems to show, yes.

Q. You would agree that if other medicines in the treatment area had exerted a competitive constraint on Hydrocortisone tablets, you might have expected to see tablets losing volumes as prices rose during the period prior to entry?

A. That might be what you might expect, yes.

Q. Equally, as prices fell, you might have expected an increase in the volume trend as switching occurred to Hydrocortisone tablets?

A. Yes, that might be -- again, I haven't really looked at this issue in any detail, but that might well be what you would expect.

Q. As we discussed, you accept that quantitative evidence of this kind as to actual market trends can serve as a basis for defining the relevant market without the need to engage in any formal SSNIP assessment?

A. Yes, I think if you -- my only qualifier to that would be that you need to look at the wider context, not just the trends themselves, but also the other evidence that

might demonstrate what is happening in the market dynamics in which to interpret those trends.

Q. So a broader range of qualitative material which informs the quantitative assessment?

A. Exactly.

Q. So the only area of potential disagreement between yourself and the CMA relates to its conclusions on the question of whether skinny label tablets were in the same market as full label tablets following entry in 2015 by the skinny label suppliers, is that right?

A. By reference to those set of bullets that you showed me earlier, yes, that is correct.

Q. Yes. It must therefore follow that you do not dispute any aspect of the CMA's market definition prior to 2015 when the only candidate substitute products were other medicines for treating the same condition?

A. Yes, I think that is fair. I haven't examined that in detail, but, yes.

Q. Could we turn now to consider skinny label tablets. You deal with this in section 6 of your report starting at {IR-D2/1/28}. So if we could go there, please and in paragraph 6.1.2 you identify three elements of the CMA's analysis. The first is the relevance of product characteristics, prescribing practices and dispensing practices.

Just pausing there, this would be, I suppose, part of the relevant qualitative information which informs the quantitative data, would you agree?

A. Well, I think it goes beyond that. It also relates, I think, to the interpretation of the quantitative evidence.

Q. Yes.

A. In other words, these factors and, in particular, the implications of the OD status and how different pharmacies reacted to that situation I think are integral to the analysis of the market definition issue.

Q. The second is the direct constraint resulting from competition between skinny label and full label and the third is the indirect price constraint resulting from the entry of skinny label suppliers who compete on price leading to a fall in the drug tariff. Can we begin with the first of those three elements; the product characteristics, prescribing practices and dispensing practices.

You do not disagree that product characteristics are relevant for the purposes of market definition?

A. They can be, as I mentioned earlier. They can help you rule out or screen out things that are clearly not substitutable.

Q. Yes, so they shed light on whether two particular

products can be used by customers as substitutes for one another?

A. I think they let you move on to a deeper analysis of the facts.

Q. Yes.

A. They do not in themselves suggest that they are necessarily product substitutes.

Q. No, indeed, so your point is that they are not a sufficient reason in themselves, functional substitutability, to conclude that two product are in the same market. Is that right?

A. Correct, yes.

Q. I think that is the point you make at 6.2.2 of your report?

A. Yes.

Q. If we could look at the Decision at {IR-A/12/306} and look at 4.26, you see the point is made there by the CMA that:

"Functional interchangeability or similarity of characteristics will not, in themselves, provide sufficient criteria to determine whether two products are demand substitutes because the responsiveness of customers to relative changes in price may be determined by other considerations as well."

Then a quotation to that effect from the

European Commission Decision in Astra Zeneca.

So you and the CMA are in agreement that functional interchangeability is not sufficient for market definition?

A. Agreed.

Q. You do not suggest the CMA ended its analysis with product characteristics. In fact, it went on to consider the quantitative evidence about price and volume trends as well?

A. Yes, and I think that is where we diverge in our perspective.

Q. Part company?

A. Yes.

Q. As regards the product characteristics, the CMA found that full and skinny label Hydrocortisone tablets are bioequivalent. In other words, they have identical effects on the body and can be used to treat the same conditions. In fact, they are the same product with the same active ingredient in the same concentration and administered in the same form. There is no dispute as to the CMA's conclusions in that regard, is there?

A. No.

Q. You would accept that this functional substitutability shows that there is a very obvious potential in this case for them to serve as economic substitutes?

A. Subject to the dispensing practice.
Q. Yes.
A. Yes.
Q. Turning to prescribing practices, the CMA found that prescribers typically write open prescriptions for Hydrocortisone tablets rather than specifying particular brands or indications. I think you would accept that this finding is also a relevant matter to take into account as part of the market definition exercise?
A. Well, again, it allows you to move to the next stage. Essentially, all of these screening issues are past, but then you get to the more critical issue which is the dispensing practice so everything really rides on that.
Q. It shows the proper focus of selection between products is not done at the level of prescribers. It is done at the level of dispensers and so that is the appropriate place to focus the exercise?
A. That is agreed.
Q. You pick that point up in 6.2.2 where you set out a quotation from -- sorry, this is back in the Decision. Sorry, in the report at {D2/1/28}. You set out a quotation from the Decision that because scripts were open the choice was left to pharmacists to dispense full or skinny label.
Again, I think you accept the relevance of the CMA's

analysis of prescribing practice and your point is simply that it is not conclusive?

A. Yes.

Q. You would not suggest that the CMA presented it as such in the Decision?

A. No, I do not think it has done.

Q. Finally, dispensing practices, you and the CMA therefore agree that it is the pharmacists that make substitution decision between full and skinny label tablets, so one needs to focus on the choices made by pharmacists following entry. That is right, is it not?

A. Yes, I mean it is the choice of pharmacists that are relevant.

Q. So those elements together make up the first of the three parts of the CMA's analysis you identify and on this part I think we have established that there is no real disagreement between the approach which you take in your report and the approach taken by the CMA in the Decision?

A. I think that is right.

Q. Can we now consider the other two elements you identify in the CMA's analysis, namely its assessment of the direct and indirect constraints on full label tablets arising from skinny label entry.

Now, starting with the common ground, you agree that

the entry of skinny label tablets had a significant impact on Auden's volumes and its prices?

A. Yes.

Q. As regards volumes --

A. Perhaps I could qualify that. There was clearly a migration which happened which meant an impact on volumes.

Q. Yes.

A. I think there is a difference of view between myself and the CMA in relation to how one characterises the impact on Auden's prices.

Q. Yes. But you do not dispute though that it was the entry of skinny label tablets that affected the prices, because as a result of the entry the prices came down?

A. I think I would qualify that statement as follows: there was no immediate direct impact on prices when the first skinny entrant came in, I think it was in about October 2015 with Alissa. My understanding from the CMA's charts and price trends is that at that point the full price did not fall. It actually continued to rise for as many as about six months. It was only at a later stage once, in my view, the impact of the drug tariff really came into effect that the full price began to fall.

THE PRESIDENT: So I think, Mr Holt, you are drawing

a distinction, quite a clear distinction, between impact on volume and impact on prices.

A. Yes, because I think --

THE PRESIDENT: The question put to you by counsel was: tying the two together and you then said, well, you accepted the impact on volumes, but you are, I think, taking a rather different stance as regards the impact on prices.

A. Yes, my qualification relates to the characterisation of the entry of skinny as having a direct impact on volumes and a direct impact on prices. I agree that there was a direct impact on volumes, but not that there was a direct impact on prices.

THE PRESIDENT: Right.

MR HOLMES: We might tease this out in a moment, but the causal factor which led to the prices falling, there may be different constraints at work, but it was clearly the entry of the skinny label tablets which led to the prices falling by one means or another.

A. Well --

Q. Do you agree with that?

A. Indirectly, I think that is right, in the sense that the skinny prices were a factor in the drug tariff, but that was only apparent later on as the category M scheme --

Q. We will come to that, but, nonetheless, the causal

factor which led to dramatic reductions in price was the entry of skinny label producers which then triggered other constraining effects?

A. Yes, I think my qualification stands, which is that there was no direct effect, as can be seen by that first six months of evidence, ie the absence of any direct impact on price and the fact that it rose and it was only with the impact of the drug tariff that that downward effect began to take shape.

Q. We will look at that in a moment. As regards volumes, can we look together at figure 6.1 of your report, which is at {D2/1/33}. So this shows the volumes of total sales of 10mg Hydrocortisone tablets divided between full and skinny and the full label tablet sales shown in dark blue are all Auden/Actavis, because it was the only supplier of 10mg with the full label marketing authorisation. That is right, is it not?

A. Yes.

Q. The light blue shows supplies made by the various new entrants to the market who could only supply skinny. Is that right?

A. Yes.

Q. The figure starts at 2015, because the first independent entry occurred in October of that year when Alissa launched its competing 10mg Hydrocortisone tablet

product?

A. Agreed.

Q. One of the reasons why the share taken in 2015 is so small is because it was won in the space of two or three months at the end of the year, would you agree?

A. That is possible. I have to admit I haven't looked to see whether it won a much greater share than that, but it was just then sort of pro rated over a small number of months.

Q. If 2014 had been included in the figure, it would have been a 100% dark blue because Auden/Actavis had a monopoly in the supply for Hydrocortisone tablets until then that is right, is it not?

A. Yes, again, if you sort of abstract from the sales that other parties such as AMCo were making.

Q. I am so sorry.

A. Sorry, I think there were sales of full label tablets by some other parties, but they were supplied by Auden McKenzie.

Q. You would accept that this graph shows evidence of pharmacies responding to the new competitive entry of skinny label providers by substituting the new skinny products for Auden/Actavis's full label tablets, which they were previously obliged to purchase because there was no alternative independent source in the market; is

that right?

A. Yes, that is right. I think where, and I think I agree -- obviously, that is a matter of fact -- that there was that amount of substitution happening. Where I think I disagree with the CMA is how one interprets that from a perspective of market definition.

Q. Can we also agree that there is a process of competition playing out through this substitution? It is clear that a new rival product is winning business from the incumbent?

A. Yes, it has won business from the incumbent. In my view, what has happened is, as I have described it, bifurcation of the market. The market is essentially split into two. Auden McKenzie is focusing on the full label market. Alissa, and then subsequently other entrants, are focusing on the independent -- mainly independent pharmacies who were very price sensitive and there is very little competitive tension and interaction between the two and that is the main basis on which I find that they are in different markets.

Q. Leaving aside the question of whether there is an ongoing competitive constraint subsequently, the switching, that initial switching that you describe, from full to skinny label shows Auden/Actavis losing a substantial proportion of their previous demand, the

demand they previously met, to new entrant suppliers who were pricing their products more cheaply. That is correct, is it not?

A. Yes, the migration happened and their market was smaller.

Q. If that is not a competitive interaction, what is?

A. In order to understand whether that represents a competitive interaction, you need to think about what is the implication of that for the pricing strategy of the focal product, in this case the full label product.

Q. Whether there is a competitive constraint is -- ongoing competitive constraint is one question, but you would accept that there is competition to meet the customers, the ones that you describe as price sensitive, following the entry of the skinny label providers and the skinny label providers win that competition, do they not?

A. Yes, there is no doubt that the skinny label providers by offering a cheaper price won the business of the independents and essentially the price-sensitive group. That is not to say that they are necessarily in the same product market. It is possible they are. It is possible that they are not. One needs to understand what are the competitive dynamics between those two products.

Q. The ongoing competitive dynamics and whether they create

a competitive constraint?

A. That is one aspect is what is the ongoing basis of that, but even during the process of that migration, one can also look at competitive dynamics and understand whether from the focal market perspective there was any competitive reaction to that and my reading of the CMA's evidence and price trends is that there was not. In other words, rather than there being a lot of marginal consumers who were finally weighing up the advantages and disadvantages of skinny, what was happening was that you had one group who would not consider switching, and that was I think what Auden McKenzie was focusing on, and another group that did focus on price and did not worry about the full indication issue and that there were sort of competitive dynamics within that market, but there was not a significant interaction between the two, absent the drug tariff.

Q. But the 50% of demand that was previously served by Auden/Actavis, as this graph shows, is lost by Auden/Actavis --

A. Yes.

Q. -- as a result of a cheaper product in the market?

A. Yes.

Q. You would accept -- laying aside questions of market definition, would you accept that just as a matter of

ordinary language the skinny label suppliers have successfully competed for and won that portion of the market?

A. I think what is happened is that they have revealed two distinct aspects of the market. They have certainly won the price-sensitive group by bringing forward a product that was attractive to that group.

Q. Yes.

A. That again does not suggest that there was competitive interaction between the two, in the sense that from the full label provider how was it reacting to that and what was its pricing incentive to that? What were the customers that it had thinking about and were there any marginal customers, which of course after all in a part of market definition, or in many aspects of economies, it is really all about customers at the margin and rather than a situation, which could be the case, I agree, in the context of the introduction of a new product, that there was a lot of marginal customers which creates competitive tension and, therefore, disciplines the providers, theoretically in this case the full label provider. The situation and the facts in this case suggest there were not such marginal customers. They were essentially polarised or bifurcated or binary in nature.

There were very price sensitive ones who did not really care about the degree, one might say, of price savings, as long as they got price savings, and then there were other customers who did not really care that much about price at all.

Q. We will come to that in a moment, but can we first of all just consider things in this way?

A. Sure.

Q. Looking at this scenario that has played out ex ante from the perspective of Auden/Actavis in 2014, this process of switching to a cheaper alternative is one that Auden/Actavis would surely very much have preferred to avoid, would you agree?

A. I mean, that is -- the perspective of Auden in that period I haven't sort of made a lot of comment on. It may well be that it would prefer to avoid losing business. I would not disagree with that.

Q. Just as a matter of common sense and rationality, we have seen what effect this is having on its volumes. We can turn to see what effect the entry has on its prices. That is rivalry that it would for the half of the market which it has lost that it would prefer to avoid, is it not?

A. Well, again, I cannot really comment on Auden's preferences, but, yes, I think, you know, companies

rather have more market than not.

Q. Charge higher prices rather than be faced with lower prices?

A. Yes, and it is that sort of pricing incentive which is at the heart of market definition and on which I base my findings.

Q. Okay. If we could turn on to figure 6.4 in your report at {D2/1/37}. This shows the effect of competitive entry on the prices of both full and skinny label tablets. The solid red line is the 10mg full label tablet price and it declines from £70 in late 2015 to around £3 in early 2021. The dotted black line below it shows the 10mg skinny label tablet price, which also drops rapidly once there are multiple skinny providers in the market.

Again, would you accept that by one means or another the arrival of skinny label suppliers on the market had a significant constraining effect on the prices of full label, as well as skinny label tablets?

A. My interpretation of this evidence, plus the other evidence I have seen, is that there was strong competition within the skinny market and that is why you saw a very rapid reduction in skinny prices. There clearly was a downward impact on the full label prices and that sort of coincides very closely with the

downward pressure on the drug tariff. So I think I would agree with you that there was an impact, albeit indirect and via the drug tariff mechanism. Where I then I think disagree with the Commission, sorry, the CMA rather, is that that is something that is relevant from a market definition perspective and the reason for that is that a drug tariff constraint being a regulatory constraint is essentially about countervailing buyer power. It is not about the risk of switching to an alternative product which would have been relevant from a market definition perspective.

Q. So I will come on to consider with you the direct and indirect constraints arising since the skinny label tablets launched in a moment. But for now can we agree there were constraints on the pricing of full label tablets that arose by reason of the skinny label tablets launching and offering lower prices in the market.

A. Again, the qualification has to be that it is not simply that skinny entered, but it was the impact of the drug tariff. In other words, had skinny only entered alone without drug tariff, I do not expect that the trends that we observe here would have happened in that the --

Q. I understand your point about that.

A. Okay.

Q. I understand that you are suggesting that there are

a direct and indirect constraints at work and we will see what the Decision says about that as well.

A. Yes.

Q. But the direct and indirect constraints both originated and were a consequence of the entry of skinny label tablets in the market?

A. Yes, I think that is fair, because the drug tariff had an input including the skinny pricing.

Q. Just looking at the trends that are shown on figure 6.4, I think you referred specifically to the period when only one entrant was in the market. That is to say Alissa. You referred to the first six months and that is because Alissa launched in October 2015, I think, and then you had Resolution and Bristol joining the market in March 2016. That is right, is it not?

A. Yes.

Q. So that is the six month period that you referred to I think in one of your previous answers?

A. That is right.

Q. You said there was no evidence of an impact on price during that period, is that right?

A. There is no evidence of a downward impact on full price and, if anything, it appears that the full price increased to some extent during that period.

Q. Just looking at that, so this is the plateau, is it not?

Sorry, you see the start of the dotted line and there is a horizontal dotted line. You see the lower dotted line. Actually, we can see this more clearly perhaps if we go to the Decision. Why do we not take it from there. If we could go in the Decision to -- sorry, let me just find the best graph. It is K -- in corrected form it is at {K/60/2}. So if we could go to {K/60/2}, please. Just -- I think this shows it clearly. You have got the Alissa entry in October 2015. That is right, is it not? That is the vertical line, the first vertical line on the left, do you see that?

A. Yes.

Q. Then in March 2016 you have another vertical line which indicates Resolution and Bristol entry?

A. Yes.

Q. Now, we know between those two vertical lines there is no impact on the drug tariff, because Alissa is not in Scheme M. Were you aware of that?

A. Yes, I am aware of that.

Q. You see, consistent with that, that there is no sign of the drug tariff reducing during this time?

A. That is agreed.

Q. In fact, it continues to rise?

A. Yes.

Q. We see that there is only one competitor, one skinny

label competitor, during this six month period in the market and that is the brown horizontal line, which is Alissa's pricing?

A. Yes.

Q. What we see is, as you say, an attempt is made by Auden/Actavis to increase the price on the previous trend following Alissa's entry. Do you agree?

A. Yes, that appears to be the case.

Q. But it appears to stutter, does it not? It appears to be unsuccessful? It dips back down. Do you see that?

A. I see that. I am not sure how much weight you would put in in that sort of stuttering back up, because it immediately goes back up. I think in interpreting data like this you would want to sort of look at it over that period as a whole and I think it is clear from that period as a whole that it was still on an upward trend throughout, despite the fact that the skinny product had entered.

Q. The prior trend was a relentless upward march, was it not?

A. Yes, yes, it looks like it was at a steeper rate.

Q. There are so many figures and charts, but we have seen it is like the north face of the Eiger prior to the launch of Alissa's product, is it not, with the price steadily increasing?

A. Yes.
Q. Yet we see following the entry by Alissa, when there is no possibility of an indirect constraint, this stuttering effect?
A. Well, I would not -- I do not think that you could read into that that suggests that there was direct competitive pressure. Obviously, even for a monopolist, there are trade-offs to take into account in terms of pricing and it may simply have been that at that stage it had already raised prices a lot. There was a little bit further to go and then it implemented those prices.
Q. What might have changed the trade-off from the relentless upward rise during that first six month period, if not the launch of a skinny label competitive in the form of Alissa?
A. I am not sure what other factors it may have been thinking about. Obviously, the relevant question here is what might have been the price in the counterfactual and I do not think we have any evidence as to what that might have been. I think what we do have evidence on is the extent to which it was clearly trying to reduce prices in order to avoid the migration effect that we observe and clearly it did not do that. That market sort of fell away from it, in a sense unavoidably, because of the price-sensitive nature of that group of

customers and I think naturally it focused on the set of pharmacies that were focused more on the full label.

Q. Did I understand you rightly, so it was clearly trying to reduce prices, that is Auden/Actavis, is that right?

A. No.

Q. You said Auden/Actavis was trying to reduce prices?

A. No, what I think I meant -- I certainly meant to say a strategy would be that it would respond to entry by trying to avoid the loss and the migration and one strategy might have been to significantly reduce prices in order to avoid that situation happening. That might be what you might have expected had there been close product substitution within this market. In fact, what it did was the opposite. It let that other part of the market go on the basis that that was a different segment that it was not best placed to compete for.

Q. It looks as though its first instinct was to attempt to continue to increase prices. Alissa, it has to be said, is the only entrant, perhaps rationally, was not competing hard during this period. It was keeping prices static. But even that limited competitive constraint appears to have led to a reversal in the upward trend, does it not?

A. Well, no, I would not say it is a reversal, because, again, if you look at that six month period as a whole,

the price was still going up. So it may be that more or less it was operating independently within that part of the market and had already set the price more or less at the appropriate profit maximising level.

Q. I would like now to consider with you how the pharmacies viewed full and skinny label tablets. Can we look to see what the Decision has to say about this first, please. If we could go to {A/12/331} and look together at paragraphs 4.100-4.103. Looking at 4.100 first it notes that short line wholesalers explained that their customers, predominantly independent pharmacies, switched to purchasing skinny label tablets as they became aware of their availability based on their decision to purchase the cheapest product that is available to fulfil a Hydrocortisone tablet prescription.

So that is how some of the pharmacies, primarily independent pharmacies, reacted. By switching from Auden's full label product in response to the price competition introduced by the skinny label entrants. Would you agree?

A. Yes.

Q. Then at paragraph 4.101 the views and actions of some of the pharmacies contacted by the CMA demonstrate that a number of large pharmacies had no choice but to

purchase Auden/Actavis's tablets with 8 out of the 10 largest pharmacy chains indicating a requirement for full label Hydrocortisone tablets.

That is how some other pharmacies reacted by concluding that they had to purchase Auden's product, despite the lower prices offered by the skinny label entrants. Again, you would agree with that?

A. I do, and just to add that that is essentially the same evidence, albeit I have other evidence I comment on as well, which indicates to me that there had been this binary split in the market. Price sensitive group that was essentially the subject of strong competition due to skinny entry and regulatory focused or essentially not focused on price factors and they obviously stayed with Auden McKenzie.

Q. At 4.102 you see the explanation for the unwillingness of some pharmacies to switch:

"Pharmacies have explained that their reasons for dispensing only or mostly full label Hydrocortisone tablets, regardless of full and skinny label tablets being bioequivalence, are related to non-price factors such as the following:

"Believing they could not dispense off-label for regulatory reasons, and not wishing to dual stock full and skinny label tablets, in particular, for

administrative ease and to reduce the risk of errors in dispensing. This meant that those pharmacies who had no choice but to purchase Auden/Actavis's tablets would not dual stock with skinny label tablets."

Then finally at paragraph 4.103 the CMA's conclusion:

"These views show that full and skinny label Hydrocortisone tablets were perceived by some pharmacies to be interchangeable and by some other pharmacies to be differentiated products where they had no choice but to purchase full label Hydrocortisone tablets."

Now, in your report, I think, as we have just established, you agree that pharmacies can broadly speaking be divided up in this way between some who are price sensitive and will switch and some who are what you call regulatory focused who feel they cannot do so. That is right, is it not?

A. That is correct, yes.

Q. To that extent you agree that there is a degree of product differentiation between full and skinny label tablets here? That is to say, some pharmacy customers attach significance to attributes of the product other than price, namely whether they are full and skinny label?

A. I think that mischaracterises it in the sense that it

puts far too little weight on the nature of the differentiation. In other words, it is not that -- in many differentiated product markets you have a whole range of quality and price, for example, in autos and you have all sorts of customers who would be weighing up these trade-offs and, therefore, there is a whole bunch of customers who might switch if you were sort of at the mid range and tried to raise price or at the lower end of the price and tried to raise price. There are a whole range of customers who would potentially switch to a different version of these different differentiated products and that would induce an effective constraint on the behaviour of anybody.

In my view, here we do not have -- the entire basis of this part of the debate and the decision is what is the nature of this differentiation and, in my view, it is very clear cut. It is binary. There are people who focus on price and will take the best deal and there is a big group over here who do not care about price. They care about the indication. There is not much in between. There is no marginal customers who are the ones who effectively impose these sort of competitive constraints that can arise in a differentiated product.

Q. I understand that is your position. But just taking the questions as they come and one by one?

A. Sure.
Q. My question was: I think you accept and agree that there is product differentiation, because some customers attach significance to a factor other than price. Now whether that --
A. Yes.
Q. We agree about that?
A. We agree about that. I think it is just a matter of degree of importance.
Q. Insofar as there is a difference between your position and that of the CMA, it is that you view the differentiation as leading to a market bifurcation. Whereas the CMA has decided in favour of a single differentiated product market. That is right, is it not?
A. Correct.
Q. On your account, the more price sensitive pharmacies switched away from full label in response to the price competition introduced by the skinny label suppliers over the period from October 2015 to about 2017; is that right?
A. Yes, about a year, a bit more or less.
Q. As you see it, Auden/Actavis was then, after that switching, left in the case of 10mg tablets as the monopoly supplier of full label tablets with an assured

customer base of regulatory focused pharmacies to whom it could price at a substantial premium. Is that right?

A. That is correct, but I would qualify it by saying I would not characterise it, as you did, by saying only from that point, ie after 2017. That was the state of the market in the interim period as well.

Q. But I think we have also established that you accept that there is an initial competitive interaction in the sense that the skinny suppliers win business which Auden/Actavis was previously supplying?

A. Yes.

Q. Because they price more cheaply and that is what the price sensitive pharmacies are interested in?

A. Yes.

Q. You do not disagree with any of that, do you?

A. No, I do not disagree with that statement. The question is then what is the degree of competitive constraint that that fact that I think we agree on is imposing and my view is it was not imposing a competitive constraint on the pricing.

Q. Understood, and this is what you refer to as the ongoing competitive constraint?

A. I would not even characterise it that -- the ongoing is over the duration of the evidence that we observe over the much longer period. My view is that even during the

migration this point about competitive interaction on the pricing of the focal product also applies.

Q. Very good. To explore why you have reached a different view from that of the CMA on this question of bifurcation, can we just consider now the nature of the price constraints that have operated. This is to go back to the different nature of the effects resulting from the drug tariff on the one hand and from competitive constraints on the other.

Can we begin again by considering what the Decision says. If we could turn to {A/12/346} and look together at 4.133. You see that this refers to:

"The facts that it was skinny label entry that led to full label tablet prices falling (reversing the upwards trend up until that point) and that following skinny label tablet entry both full and skinny label tablet prices have followed a similar trend ..."

Now, pausing there. As we have discussed, you agree, I think, with the basic proposition that skinny label entry led to full label tablet prices falling, as well as to skinny label tablet prices falling, subject to the mechanism involved. That is correct, is it not?

A. Yes, with the qualification that it did not directly do so and as observed by the upward trend in the full price immediate upon entry but, yes.

Q. But for skinny label entry, prices of full label would not have fallen?
A. Yes, I think that may well be the case. Full pricing might have stayed at a higher level in the absence. Full label pricing --
Q. What impacted full label pricing other than the entry of skinny label?
A. Again, it is back to the impact of the drug tariff, which I think is the essential component here. Without a drug tariff, I do not think there would have been any impact, but I think we are agreed that skinny is an indirect aspect to the impact of the drug tariff.
Q. The drug tariff only changed because of skinny label entry?
A. Yes, yes.
Q. Paragraph 4.133 then observes that those facts support the CMA's conclusion that skinny label tablets have acted as a competitive constraint on full label tablets and then it state:

"These falls in price can be attributed to two factors, though the size of each effect is not clear (nor is it necessary to determine the size of each effect):

"a. Direct price competition between full and skinny label ...

(b) for 10mg tablets the indirect price constraint arising from the drug tariff mechanism whereby (lower) skinny label tablet prices progressively reduced the level of the drug tariff price."

Then at 4.134 there is a further explanation of the latter of those two constraints:

"The Drug Tariff price is calculated based on average selling prices and suppliers then set their own selling prices taking account of the drug tariff price and the need for a discount to allow for wholesaler margins. This means that lower average selling prices will, by reducing the Drug Tariff price, indirectly constrain future selling prices. Such an indirect price constraint is directly attributable to the entry of the skinny label tablet suppliers because the Department of Health did not differentiation between full and skinny label tablets and therefore took into account both full and skinny label hydrocortisone prices in setting the Drug Tariff price."

So that is what the Decision says. You agree, I think, that the CMA is right to distinguish between these two separate ways in which the full label tablets could in principle have been affected by the pricing of skinny label tablets. You agree it is important to tease out that distinction?

A. I do for the reason that one is a product substitutability question and the other is a countervailing buyer power question, which is best assessed under an assessment of dominance or assessment of market power.

Q. To see your position, can we turn to the joint expert statement at {G1/1/25} and look at proposition 39, please.

A. 39?

Q. Yes. 39. You see that the proposition is:

"It is unclear as to the extent to which the reduction in price of full label ... was caused by its link via Drug Tariff mechanism versus the direct constraint of customers switching, or both."

Going across to the final column, where you set out your views you disagree and you continue:

"In my view the evidence indicates that the correlation between full and skinny label prices is mainly driven by the indirect price constraint via the Drug Tariff rather than by a direct constraint of demand substitution between full and skinny label."

So if we were to try and capture the difference between you and the CMA on this issue, it is that you think that the price reductions are mainly driven by the indirect price constraint. Whereas the CMA considers

that the division between the direct and indirect price constraints is unclear, as we saw from the Decision. Is that fair?

A. I think the CMA has gone beyond saying it is unclear. I think they have attributed some impact to a direct effect, which I disagree with. But leaving that aside, yes, I agree that that is the main source of difference between us, ie our interpretation of which of those factors is the predominant one.

Q. Your view is that it is important to distinguish in the weight of each or the contribution of each, because you think that the indirect price constraint, which you agree existed, should not be "given the same weight" as the constraint from direct switching in the assessment of market definition. Is that right?

A. Yes, that is right and that stems from an understanding of what the purpose of market definition is in trying to identify which alternative products to a focal product may be constraints and, therefore, should be in the same product market. What that presupposes is that there is the threat of switching to that product, which is creating a competitive constraint. Whereas in the assessment of the drug tariff and the wider assessment of the facts as I have seen them in the Decision, it is not that far off constraint which is leading to a fall

in the full prices, but rather the fact that the drug tariff is coming down and that provides countervailing buying power to the -- essentially to the pharmacies dispensing full label product.

Q. But you accept that there is a separate and additional constraint that applies and that the skinny label product, and competition in relation to the skinny label product, exerts on the full label product here by reason of the drug tariff?

A. Yes, there are a number of factors that could affect the drug tariff price. One of which is the price of skinny -- sorry, the price of the skinny label product to the extent that that it is included within the drug tariff and I am not sure we have time to go into the detail, but, obviously, it is a category M drug. Some suppliers are Scheme M members and, therefore, their volumes count. So therefore a number of factors can affect the drug tariff. One is the price of skinny. One is the volume weight of skinny amongst those who are in category M, but then there are further factors as well, such as changes in time when the full price can essentially itself reinforce or have a persistent effect and then, finally, there is another factor, which is that the Department of Health sets a margin on top of the average supplier price in order to allow a margin

for the pharmacies when they dispense the drug and that can change over time as well.

Q. You are not suggesting that the factors which led the drug tariff to fall here are anything other than the results of reductions in the skinny label prices and the impact that they then had on the pricing of full label, are you?

A. I am agreeing that those are amongst the drivers. The other ones I mentioned may also have been factors, but, in any event, all of those which lead to a change in the drug tariff level are of the variety of a countervailing buyer power issue.

Q. Just taking the various factors affecting the drug tariff that you mentioned. I think you mentioned the entry of additional suppliers that that are Scheme M members?

A. Yes.

Q. Those suppliers are all suppliers of skinny label tablets, do you agree?

A. Yes, with the exception of AMCo itself, where I think some of its supplies of the Auden product were included in category M.

Q. Laying that on one side. In terms of the price reductions that have been seen since the arrival of skinny label tablets on the market, it is the skinny

label tablet suppliers whose prices have fed into the drug tariff. Do you agree with that?

A. Yes, amongst others. So, in other words, there was also some full label volumes that were taken into account in addition.

Q. The --

A. The Auden/Actavis but also the AMCo earlier in the period, the AMCo sales of the full label product.

Q. But you are not suggesting they had a downward impact on the --

A. No, they were, I think, the only value in the earlier phase of category M.

Q. So in terms of the reductions in the drug tariff, that was the result of skinny label suppliers coming in and the price competition that resulted from that skinny label entry forcing down the level of the drug tariff. That is correct, is it not?

A. Yes, I think that is right, so that was one of several factors, yes.

Q. Would you accept that this indirect constraint that applies in this case is a rather unusual feature of this product in that the drug tariff mechanism creates a link in the pricing between full label and skinny label tablets?

A. Well, unusual in the sense that it does not apply in

unregulated markets, perhaps, yes. It is a regulatory constraint. I think my point is that any two goods or services, which are linked by something like the drug tariff, will inevitably have a price correlation, ie if one is moving down, then the other one will automatically move down as well, and that is the case even if it is clear that they are not in the same product market in the sense that they are not close economic substitutes.

Q. The effect of that mechanism is to carry across the effects of price competition on skinny label tablets so as to exercise some constraint on the pricing of full label tablets. That is right, is it not?

A. Yes, yes, so I think as multiple skinny entrants came into the market, that led to some competition within the skinny segment, lower average prices and then as a result of the drug tariff falling, that imposed a further constraint, ie a constraint on Auden McKenzie, due to the countervailing buying power that the pharmacies therefore had.

Q. We are not here talking about some totally unrelated product, are we? We are here physically identical products, which are partially differentiated only by one regulatory feature, namely the orphan designation, are then connected as respects their pricing by another

regulatory feature, namely the drug tariff. That is correct, is it not?

A. Well, I would sort of suggest that that characterisation fails to capture the fundamental issue at play in a market definition exercise, which is it is not about what are the characteristics and how many of the characteristics might vary. In this case, the OD characteristic being one obvious one. But rather what is the nature of the closeness of substitutability from the perspective of the buyers or, in this case, the pharmacies who dispense.

In that case, essentially if you are a regulatory focused buyer, then price does not matter and there is no substitutability. If you are a price-sensitive pharmacy, then of course you have migrated to the cheapest product, but is there any sense in which the full prices is an ongoing constraint? I do not think so, because as long as the price of skinny is below the price of full, you would never really consider going back and it is not really a realistic scenario that any party has put forward that there be a price inversion between full and skinny label. I would discount that scenario.

Q. Sure. I will come back to the direct constraints in a moment, but we have agreed, I think at the beginning,

that the purpose of the exercise ultimately is to understand competitive constraints upon a given product, the focal product. That is correct, is it not?

A. Yes, overall, to the extent that there are other constraints that might operate on a supplier, then they are relevant to be taken into account. My point is that there is a standard framework in the European Commission notices on market definition and abuse of Article 82 and then, similarly, OFT guidance in a similar respect between market definition and assessment of market power.

Q. But we have agreed --

A. One is about product substitutability. The other is about other constraints that might apply out with product substitutability and that is what we are talking about in terms of the drug tariff.

Q. Yes. I think we have agreed that it is a rather unusual context where this regulatory mechanism creates a link between the competition -- the price determined by competition between skinny label suppliers and the price of full label tablets?

A. I mean, I do not have a comment on whether -- how unusual it is. It is obviously something that is common in the context of category M drugs whereby there are lots of drugs that might be in Scheme M. I think the

important point is there is a regulatory constraint. I think nobody is saying it has no impact on the market. I have acknowledged that and what I am saying is that the nature of that constraint is not a product substitutability one, but rather a countervailing buyer power issue.

Q. But it is a constraint?

A. It is a constraint.

Q. On a key parameter of competition, price?

A. It is a constraint on price. I would certainly agree with that.

Q. It is a real-world characteristic of the supply of this product that the drug tariff links the pricing of the full and skinny label so that competition, even in one, will have a constraining effect on the other. I think you have agreed with that, yes?

A. Yes, but in the sense that the regulatory constraint is the thing that operates and that is something that affects countervailing buyer power in the pharmacies because they can then decide -- if the pharmacies were saying, well, the drug tariff has come down, therefore, I am going to go to my full label buyer and say, you know, my margin is too low, I am going to switch to skinny, I would agree. That is a product market substitutability issue.

The evidence is that they were not doing that. What they were doing is saying, you know, the margin has come down, the drug tariff is now too low, I do not have enough margin, reduce the full label price or either I will not stock it or maybe I will exercise my leverage in terms of my wider portfolio, but it is not -- that is not a product substitution question.

Q. Yes. I understand and you view the process of market definition as narrowly confined to questions of product substitution, even where there is a constraint on a parameter of competition, like price, arising from another mechanism in the market. Is that a fair summary?

A. It is to the extent that the other constraint is not one that relates to product substitutability and that is directly taken from the European Commission guidance.

Q. Yes. You do not go so far as to suggest that that indirect constraint should be afforded no weight in the market definition exercise. You say it should be afforded different weight. Is that correct?

A. Well, yes, I put limited weight on it. I think I have described why I put limited weight on it. Obviously, if there was other evidence that suggested that there were direct implications of the drug tariff on the willingness to switch to a different product, then

I think that would be a factor. I haven't seen any evidence of that type.

Q. You do not exclude that there may have been at least some direct constraint on the price of full label tablets as a result of the price competition from skinny label suppliers. Is that fair?

A. I think that is fair in the sense that I haven't seen any evidence of it. Had there been evidence of it, I would have taken it into account. All the evidence I have seen suggests that there was no such effect and that includes the size of the price gap, the fact that even as the price gap started to narrow there was no switching back, so if there was competitive constraint it should have operated in both directions and that did not happen.

Q. In proposition 39, just to recap, you say:

"I think that the evidence indicates that the correlation between full and skinny label prices is mainly driven by the indirect price constraint via the Drug Tariff."

A. Yes.

Q. So you accept the possibility there may have been direct constraints as well?

A. The logic of the wording suggests that is the case. I have not seen any evidence that it could be anything

other than the drug tariff.

Q. Can we consider just a few examples. You recognise in your report that in tendering to purchase for hospitals the NHS did not distinguish between full and skinny label Hydrocortisone tablets. That is right, is it not?

A. Yes, I think that is right.

Q. This is discussed in the Decision at paragraph 4.128, which is at {A/12/343}. If we could just turn that up, please. Picking it up at the end of the second line, this explains:

"That the NHS did not distinguish between full and skinny label hydrocortisone tablets in its hospital tenders in England, Scotland and Wales, which included hydrocortisone tablets amongst a range of drugs."

You see that these tenders were generally won by skinny label suppliers, but turning over the page and looking at footnote 1260 at the foot of the page, it is apparent that Actavis participated in the tenders and that it won the Welsh tender for 20mg Hydrocortisone tablets but lost the others. Do you see that?

A. Actavis lost on price for 10 and -- sorry, does it not say lost on price to AMCo for 10 and then lost to Bristol for 20.

Q. There are various tenders. There is the NHS England tender. There is the NHS Scotland tender, but in Wales

it won 20mg Hydrocortisone?

A. Okay.

Q. In relation to this portion of demand, would you accept there was a process of direct price competition for the business of the customer that did not regard full and skinny as differentiated products?

A. Well, I have to admit I did not really examine the hospital part of the market. It is obviously a separate market with separate types of demand and I think the main thrust of the debate has been really on the vast majority of it going through the pharmacies, so that is really what I focused on.

Q. We looked at what proportion of the hospital pharmacy purchasing represented.

A. I do not think that the markets sort of interact, so I do not know how much goes through the NHS tender process.

Q. Were you aware that the average selling price data, which is considered in the Decision, included supplies made pursuant to these tenders?

A. I have not explicitly considered the -- which market these were going through, no.

Q. Would you accept that there may have been some pharmacies with regulatory concerns, but for whom if the price differential became too pronounced they may

have been prepared to switch perhaps generally or perhaps for dispensing specifically for use by children?

A. Well, I think those are two different sorts of issues. I think dispensing specifically for use by children is obviously not sort of skinny label in the sense that you are going off-label of off-licence. On the other hand, I think that is a minority of drugs, I think something like 5%, and my understanding of the CMA's description of the evidence is that in the main the regulatory focused pharmacies effectively in many cases did not want to sort of dual stock for various logistical reasons.

Q. Insofar as a pharmacy was prepared to consider dual sourcing, then even the regulatory focused pharmacies would have a choice, would they not, between skinny label and full label?

A. Yes, but only for the bit that they would potentially have dispensed to children. But my understanding is that that was not a sufficiently important part of the market for them to want to dual stock full and skinny label entrants -- sorry, full and skinny label products. Instead, they went and basically dispensed the full product, even in the context of children being the source of the demand.

Q. If the price differential became sufficiently

pronounced, would you accept that they might have been prepared to accept the additional cost and burden of dual stocking?

A. Well, again, the evidence I have seen is that price was not a very important consideration in that, because there were a series of regulatory and licensing and logistical reasons why they did not want to do that.

Q. If we could go, please, to a contemporaneous document that is relevant to this point. It is at {IR-H/844/1}. If we could go to the foot of the chain, please on page 2 {IR-H/844/2}. Just blow up the top half of the screen, please. You see that this is an email from a Mr RB, the marketing and business development director of Focus Pharma. Are you aware that focus is a subsidiary of AMCo?

A. Yes.

Q. That subsequently acquired a skinny MA in October 2016 and entered in the second half of 2017.

A. Yes.

Q. He is emailing GR, Mr GR, and if you go up to the foot of the first page just for a moment, you see that he is the head -- can we enlarge that, please -- of generics at Celesio?

A. Yes.

Q. Celesio is the parent company of Lloyds Pharmacy chain?

A. Yes.
Q. Also of the full line wholesaler AAH, is that right?
A. Yes.
Q. It is one of the pharmacies you identify as in the regulatory focused group. That is right, is it not?
A. Yes.
Q. If you go back to page 2, you see the purpose of Mr RB's email. So after pleasantries he explains that he wanted to check what Celesio's superintendent pharmacists' view was on the Hydrocortisone tablets indication issue. He says that he assumes that Celesio's pharmacies could not use a product unless it has the full indications.

Do you see that?

A. Yes.
Q. Then turning back to page 1, you see in the bottom half of the page Mr GR's reply. He says in the second full paragraph that the assumptions are correct.

"Need all indications to be of any use to us really."

Then:

"For sure independent pharmacies won't care but just not worth the hassle for us at the moment."

But he then adds:

"That may change if the price differential grows."

Do you see that?

A. Yes.
Q. Then at the top of the page we see the email is forwarded internally within AMCo in March 2016 as "a note from Celesio in relation to their pharmacy chains back in December ..."
A. Yes.
Q. So on its face this would tend to indicate that even some of the regulatory focused pharmacies could potentially have been tempted to switch if the price differential grew too pronounced?
A. I am not sure I would interpret that. I think what he is saying is that the regulatory focused pharmacies need all indications ie full indication to be of any use ie they would not see skinny label as a viable substitute. I think he is then saying that maybe independent pharmacies would see it differently and that is because they are more price sensitive.
Q. He says that:

"... for sure independent pharmacies won't care, but just not worth the hassle for us at the moment".

Do you see that?
A. Yes, I see that, so.
Q. Then he goes on to say -- sorry.
A. Yes, but of course AAH is, as you say, linked to Lloyds. Their main business is amongst the national chain

providers. Their main business focus is regulatory focused pharmacies. Yes, they might have a small subset of other pharmacies that they might sell to but if that is a relatively small part of their business, that business mainly being dealt with by short-line wholesalers, then I can see why it would not be a big focus for them and that it would depend on the balance of independent pharmacies that they had on their books.

Q. Look at the top of the chain, Mr Holt. The interpretation of this email within AMCo is referring not to the AAH business but to Celesio's pharmacy chains. Do you see that?

A. Yes.

Q. So they read it as referring to the willingness of Celesio's pharmacy chains to take some or to purchase some or all of their needs from skinny label suppliers, did they not?

A. I do not know what this author meant, but my reading of it is that he is accepting the distinction between the pharmacies who really are needing to be full indication and the independents who do not.

Q. But he distinguishes, does not he, between the independent pharmacies "and us". So:

"... the independent pharmacies won't care but just not worth the hassle for us at the moment.

"That may change if the price differential grows."

Is not that a sign, an indication that some of the regulatory focused pharmacies could have changed their approach if the price differential became too marked?

A. Celesio and AAH are essentially wholesalers. They are obviously vertically integrated to Lloyds and therefore a large part of their business presumably does go through Lloyds but to the extent they have some independent pharmacies, then they are buying on behalf of them. I think what he seems to be describing here is as a wholesaler he is reacting to the underlying preferences of the dispensing community ie the pharmacies, and it seems to me he is indicating the very different positions of those types of pharmacies.

Q. But why do you interpret this as relating to AAH rather than Lloyds?

A. I thought you said it was from Celesio.

Q. Celesio owns both Lloyds and AAH. They own a pharmacy chain and they own a wholesaler.

A. Yes, yes. Well, okay, well, I do not know what this person is talking about in terms of which of those two situations it is, but if he is referring to Celesio then that is obviously, as you say, both but perhaps it depends whether he is thinking about the wholesaler perspective or his retail business perspective.

Q. But would you accept that if there were some pharmacies with regulatory concerns for whom the price differential, if it became too pronounced, could have led them to switch, that would have implications for the direct competitive constraint that skinny label tablets would impose on full label?

A. Yes, I agree that if the regulatory focused pharmacies were actually closely weighing up the potential savings to be had, but further more, doing so in a context that avoids the cellophane fallacy, in other words, that we are talking about a difference in price that is reflective of competitive underlying pricing as opposed to a cellophane fallacy perspective, then I think that would be the case.

But the evidence that the CMA itself provides is that even when the price gap was I think 30 or 40 from around late 2016/2017 there was no such switching. So to the extent that this idea that there were a lot of regulatory focused pharmacies who were at the margin in weighing up these situations, that seems to be disproven by the evidence.

Q. Would you agree that insofar as direct constraints do arise it would be very difficult to unpick such effects from the constraint arising from the drug tariff?

A. I mean, I think you need to investigate a number of

issues in order to try and assess that. That is what I have done. I can see many drivers through the drug tariff which I have explained and I cannot see any drivers through the direct effect through switching or the fact that the aggregate volumes were constant despite great changes in relative prices. I think those are all indications of the sort that would lend you to make that assessment. I am not saying it is easy, but I think there is evidence to take into account.

MR HOLMES: Sir, I was going to move now to another topic. I do not know if that is a convenient moment to take a short break.

THE PRESIDENT: Yes, that would be convenient. We will resume in ten minutes at just before half past. Thank you very much.

(3.17 pm)

(A short break)

(3.27 pm)

MR HOLMES: Mr Holt, could we now turn to consider, briefly, the position in relation to 20mg Hydrocortisone tablets?

A. Yes.

Q. The easiest way to discuss this may be by reference to figure 4.11 in the Decision in its corrected form. That is at {K/60/10}. If we could just enlarge that, please. Looking first at the blue and the brown lines, the blue

line is the full label price for Auden/Actavis and the brown line is the full label price for Waymade and the dotted line is the skinny label price.

Just considering what this shows, as a first point, can we agree that full label and skinny label tablets fell following skinny label tablet entry, as in the case of 10mg Hydrocortisone tablets?

A. Yes. I should point out that I did not spend much time in my report on 20mgs.

Q. No.

A. But I am happy, obviously, to try and answer your questions on these charts, so --

Q. I am grateful. But the trend is there is a downward trajectory?

A. Yes, I agree.

Q. As a second point, can we also agree that this was not due to any indirect constraint, given that 20mg Hydrocortisone tablets were in a different category of the drug tariff, namely category A, and, therefore, were not based on weighted average ASPs of suppliers, but effectively on the list price of Auden/Actavis and its wholesalers, AAH and Alliance. Were you aware of that?

A. Yes, so I am aware this was a category A, if that is what you are getting at.

Q. One can see the lack of indirect constraint at work here

from the dashed line at the top of the page, which is the drug tariff and it remains very high until July 2019 when the calculation method changed and with no drop at all during the infringement period, which ends with that grey vertical line. Do you agree?

A. Yes.

Q. Now, as a third point, there was an added wrinkle in the case of Hydrocortisone tablets, which is that one of the entrant suppliers, Waymade, was granted its MA prior to the Plenadren orphan designation and it could therefore market full label tablets. Does that accord with your understanding?

A. Yes.

Q. It entered in July 2015 and its prices are shown by the brown line. Then two skinny label suppliers entered in March 2016 and two more joined in 2017. So in the case of 20mg there were both full and skinny label competitors in the market alongside Auden/Actavis?

A. Yes.

Q. Would you agree that it is difficult to separate out any direct constraints posed by the competition from the full label product from the direct constraint arising from skinny label product?

A. I mean, I think that is fair just looking at the trends. I think, albeit I have not focused on this market, maybe

what you could do to try and unpick those trends is look at the other underlying evidence, such as in the context of the 20mg market what were the factors that dispensing pharmacies were taking into account. I would note that it was a much, much smaller market and I think accounting for something like, is it, 4%. That sort of order of magnitude. So given that, it may be that other and different factors might have affected pharmacies dispensing practices. I do not know.

Q. Can we at least agree that the speed of decline does appear to have increased following the entry of the skinny label suppliers when the dashed line is shown?

A. Yes, I mean, obviously, again, you cannot really distinguish between when the Waymade -- its price was starting to fall quite rapidly at that point as well so it is unclear whether the average -- what were the competitive dynamics at this point. Was it primarily the two full label markets suppliers competing closely together and their trends were quite common, albeit I understand that there might have been some brand differentiation, or was it the skinny product? I have not investigated that side of the market enough to answer that question.

Q. But we can at least agree that whatever the competitive dynamics which drove the falls in the full label prices

here, they are not attributable to any indirect constraint which arose in relation to 10mg tablets?

A. That seems very likely, unless there was some sort of portfolio bundling type process going on which I am not aware of.

Q. You are not aware of anything of that nature?

A. No.

Q. One final topic and it is really going back to where we began.

A. Yes.

Q. Let us assume for the moment that you are right and that product differentiation in the case of some pharmacies is better described as having given rise to a market bifurcation following skinny label entry, rather than a differentiated product market. We have already discussed that your report focuses on this intermediate step in the competition assessment, the market definition exercise, and it does not extend to consider other stages of the analysis. But would you indulge me for a moment if we just consider what the consequences might be in terms of market power and in terms of the assessment of potential competition?

A. I am happy to try and answer your questions even though I did not address it in my report, yes.

Q. I do not think they will be particularly controversial,

because I am not asking you to reach any final assessment. As regards market power, would you agree that the effect following bifurcation would be that Auden/Actavis was a monopolist having lost a portion of its previous market to the skinny label entrants?

A. I think that follows from the product market finding that full constituted a product market, so, yes.

Q. So its market share following the bifurcation would be 100% in the case of 10mg tablet?

A. Yes.

Q. That would consist of its assured customer base of the regulatory focused pharmacy multiples. Is that right?

A. Yes.

Q. Increased market shares by volume and value in relation to 20mg tablets following exclusion of the skinny label suppliers, that would be a market of 2, a duopoly of Waymade and Auden/Actavis?

A. Well, I have not examined the underlying competitive dynamics in the 20mg market, so you are now presuming I think that full and skinny are in separate markets in that situation. I have not --

Q. You have not --

A. -- have not specifically reviewed that, but if you are suggesting that for hypothesis sake is the case, then I would agree that obviously within that market you can

identify a number of suppliers in the market share.

Q. Very good. I am happy to stick with 10mg?

A. Okay.

Q. The basis for this narrowing of the 10mg market would be that the skinny label suppliers were not capable of imposing any ongoing competitive constraint on Auden/Actavis in its supply of either 10mg or 20mg tablets. Just leave it at 10mg tablets.

A. I think it is a matter of sufficiency. So "capable" is obviously a more extreme word in that sense, but from a market definition perspective, it is about a matter of degree and, further, I note that there may be other external constraints that need to be taken into account in pricing ability or market power more generally as well and the drug tariff is one of them.

Q. But I thought your position was that they would not have a disciplining effect on price?

A. They would not have a sufficient disciplining effect on price sufficient to draw the two buyers together.

Q. So they might have some disciplining effect on price, but you think that that effect would not be sufficient that they should be regarded as falling in the same market?

A. Yes.

Q. That is all I really wanted to ask you about market

power.

Can we now consider the consequences for the analysis under Chapter I and on this issue could we go to the expert statement at {IR-G1/1/28} and just look at proposition 44. This states that:

"Exact market definition does not matter to the assessment of the 10mg Agreement."

In the final column you very fairly explain that this is not addressed in the scope of your report. So you have not considered whether your differences with the CMA's market definition have any practical implications when assessing the 10mg agreement. Is that right?

A. That is right.

Q. But can I just check on one point. It is clear, is it not, that the entrants by launching their skinny label products succeeded in winning a portion of the demand for 10mg Hydrocortisone tablets that was previously met by Auden. There is no dispute about that?

A. No, I think that -- yes, there was a migration of volumes, yes.

Q. That was because they priced more keenly and the price-sensitive pharmacies switched?

A. Yes.

Q. I am sorry.

A. Yes.
Q. When they were working to enter or were agreeing not to enter, if that is what the Tribunal finds, before they launched, they were just as surely potential competitors of Auden's for that portion of the demand, were they not they?
A. Well, they might have been, but I think all that depends on their status in that sort of pre-entry scenario in terms of the supply and demand conditions that they were perceiving in the market. So in other words, it matters what you understand the situation to be between your make or buy Decision, in the context of AMCo for example, and, also, the information you are getting from the market around the demand. So I think you are making a general statement about all skinny entrants, where I would suggest that is not necessarily the appropriate way to look at it. You need to think about the context that any given supplier is encountering in its perception of the market.
Q. Just teasing that out. If they were seeking to enter, they were doing so because they thought there would be some demand for their product?
A. Yes.
Q. Demand that was being met exclusively by Auden/Actavis prior to entry. Do you agree with that?

A. Yes, although "exclusively" is again sort of a point that needs some clarification, because there is exclusively from the own sales of Auden McKenzie and then there is exclusively in the sense that it is the supplier, but there is a supply arrangement with a different retailer.
Q. Yes. Laying that on one side, it was the only source of --
A. Yes, that is right.
Q. -- of 10mg Hydrocortisone tablets that were available prior?
A. Correct.
Q. They were seeking these potential entrants to win a portion of that volume away from Auden/Actavis, no?
A. I would presume so. Again, I have not really commented on that or looked at their intentions, but that might be what they were hoping to do.
Q. We have seen what happened subsequently. They won 50% of that demand?
A. Yes.
Q. So does it really matter the market definition to any issue in this case? They were seeking to compete to win that 50%, whether or not they were able to contest all or only a segment of Auden's monopoly prior to entry?
A. Well, I think in terms of that set of issues and

interpreting the impact of the agreement, I think you do need to understand the relative perceptions of the ability to enter and the likely impact of that entry that the different parties were perceiving in the market and that is not an issue I have explored in detail.

Q. You have not?

A. I acknowledge and I see that others have done that and I think that is a useful debate in terms of understanding what is the impact of the so-called agreement.

Q. But in terms of what you have covered, you have left it at the market definition?

A. I have.

Q. And taken it no further?

A. Yes.

Q. I am grateful, Mr Holt. There are some questions that we have in relation to the agreements.

Sir, it is Mr Jones who will be putting those. Shall we conclude our cross-examination before any of the other parties proceed or would you rather hear questions on the market definition part first?

THE PRESIDENT: Are the other parties all happy that they are so rigorously segregated that we can safely do that? I would not want there to be a confusion.

MR HOLMES: It may be better to do them in the round.

I understand there are only a short number of questions.

THE PRESIDENT: We will let Mr Jones do his worst before that happens. I just had one question on this matter and I will raise it now since -- could we bring up today's transcript. It is page 155, going to 156. Mr Holt, this is your cross-examination and you were just being asked about the process of direct competition for tenders within hospitals and you can see the question at line 11.

A. Yes.

THE PRESIDENT: You can see that there was put to you certain tenders and you say "okay" and then you see the question that is there put. Then you answered, line 19, you say:

"I have to admit I did not really examine the hospital part of the market."

It is obviously a separate market, you say, with separate types of demand.

What drew my attention was the use of the word "obviously"?

A. Yes.

THE PRESIDENT: Did you carry out any analysis to exclude this part of the market or this separate market from your market definition?

A. No, no, I did not. Perhaps I should add some context to

the use of the word "obviously". What I meant there, perhaps I should have said it, is that that it is obviously a bidding market, a tendering market, and different types of economic factors can apply in a tendering market for large scale volumes that a hospital would tend to sort of bid on and sort of take bids from a series of parties.

I guess the other point I might add is that to the extent that hospitals treated the indication issue much like the independent pharmacies, in other words, they were not concerned about that issue, they did not see any regulatory or licensing or other logistical risk associated with that, then I would clearly put them on a par with the price-sensitive segment of the market. So it might be that their volumes would have flown through the price-sensitive part of the market when looking at the volumes of sales from skinny versus full label.

THE PRESIDENT: Granted that market definition is essentially concerned with substitutability, I am talking at a high level of generality here, the fact that different purchasers may purchase in different ways does not necessarily mean you should exclude them from your market definition. You ought to be looking at all different purchasers of a given focal product in order

to work out what is going on.

A. Yes, I think that is fair that it might well have been interesting to look at them. I think my report was essentially responding to certain issues raised in the Decision and that was really a primary focus -- was the pharmacy dispensing part of the market and that was really what I was focusing on.

THE PRESIDENT: I see. So that is very fair. I think what you are saying, and do tell me if I am characterising you wrongly, is that your report is very much responsive to the Decision here under appeal in that you are taking what they have, they, the CMA have decided in the Decision and you are using that to establish the parameters of your own report in critiquing that decision.

A. That is entirely correct. So I was responding to the CMA's findings in relation to whether 10mg skinny label and full label products were in the same market and, essentially, the analysis that was the focus of that analysis in the CMA Decision was in large part focusing on the pharmacy sales as opposed to the hospital sales. I am not saying that there was not any reference to the hospital part of the market, but the overall predominance sort of basis of the evidence was in relation to pharmacies.

THE PRESIDENT: I suspect that is the answer to my next and final question, which is: you clearly have drawn a clear differentiation in terms of what you examined between 10mg Hydrocortisone tablets and 20mg Hydrocortisone tablets. If one was approaching matters with a blank sheet of paper, so leaving on one side all of the CMA's hard work, you would presumably want to satisfy yourself that there was no question of substitutability in relation to those distinct products.

A. Yes, I think that is fair. There was some commentary in the Decision on this and I think the fact that the 20mg accounted for such a small percentage of the market essentially was driven by dispensing practices and the size of the active content in 10 being effectively the right amount for subdivision for the purpose of individual patients and so forth.

So that gave a sense that there was really a quite distinct sort of set of market conditions. In addition to that, obviously, you had very different dynamics in terms of the two full indication providers, which meant that, as I think we have seen, some of the price trends might have evolved somewhat differently.

THE PRESIDENT: Thank you very much, Mr Holt.

Cross-examination by MR JONES.

THE PRESIDENT: Mr Holmes, if there is anything arising out

of that do ask.

MR HOLMES: No, further questions.

THE PRESIDENT: Thank you.

MR JONES: Thank you, sir. Good afternoon, Mr Holt. As Mr Holmes explained, I am going to be addressing the issues in table 3 of the expert report, which is the table concerning agreements. As you will know, you only comment on a couple of those points that arise there.

So my questions will be very brief and they concern section 7 of your report really, which is where you pick this up. Could we have a look at that. It is in {D2/1/45}, please. You explain there in 7.1.1 what you are looking at in this section of your report. The section is, "Was AMCo's conduct rational?" and you explain you have been asked to consider from an economic perspective concerning AMCo's conduct at three specific decision points in the period 2012 to 2016 having regard to the relevant circumstances when the decisions were taken.

Then you list there, as you put it, three decision points and you are asking whether AMCo's conduct was rational at those three decision points. Is that a fair summary?

A. Yes.

Q. I see that you were asked these particular questions so,

just to be clear, you were not asked to address whether Auden's conduct was rational?

A. No, I was not asked that.

Q. In relation to AMCo, you were just asked to address its behaviour in relation to these three decision points. Is that right?

A. That is right.

Q. You will know that there has been a debate between the experts about whether rationality is even relevant to the issues that this Tribunal has to deal with. Can I explain to you my understanding of your position and you tell me if I have understood it correctly and if not, then correct it.

Firstly, you are absolutely not saying that just because behaviour is rational that means it is not anti-competitive?

A. Correct.

Q. What you are saying, as I understand it, is that where you have two competing accounts of the facts, one of them anti-competitive, one of them, let us call it innocent, one question you can helpfully ask yourself is whether the innocent explanation taken on its own terms would be rational?

A. Yes.

Q. So it is perhaps just a more sophisticated way of asking

a question which comes up in a lot of court cases: does what this person is saying make sense?

A. Yes, I think it is just saying, I understand that the CMA's interpretation of that set of facts is that there was an anti-competitive agreement and I think this is an examination of facts to understand whether there is an alternative explanation for the decisions being made that do not rely on an anti-competitive agreement as the basis.

Q. If the -- I have called it the "innocent explanation", so an explanation which does not involve an anti-competitive agreement, if that is rational then, just to be clear, it does not mean that it is true? It is just something to put in the balance?

A. Yes, I think I have been very clear in one of my paragraphs to identify that it is obviously for the Tribunal to form its view of the interpretation of the facts and I am merely providing economic context to these facts and what the decision making factors would be in that context.

Q. I think the paragraph you are referring to is 7.1.2, which is on the page that we were looking at?

A. Yes.

Q. I think just to take that point just a step further. It is also clear from that that the facts you are focusing

on are the facts essentially as told by AMCo. That is its facts as explained in its notices of appeal and, as I understand it, you are looking at that and you are, as I said earlier, asking yourself whether if this is right, is it rational?

A. Yes, I think that is right, yes.

Q. I suppose one complication with this approach that you have adopted would be that at the end of the day this Tribunal might not agree or disagree with AMCo on everything. They might agree with some of those facts and disagree with others of those facts and if that is where the Tribunal comes to, then if it wants to ask itself the question: is this rational, it would essentially need to redo that exercise, because your report has focused on the facts as they appear to you at this moment, but would not necessarily translate; is that right?

A. I think that is the case in a matter of detail. If you were to go through all of those annexes as the Tribunal tried to form a view as to which ones are accurate and which ones are not, then you may well need to do that. I think in one sense all of this can be simplified by saying what were the demand side fact factors and what were the supply side factors that the company, in this case AMCo, was confronting at these points in time, and

were those factors significant enough that it in a sense justifies taking the agreement not for an anti-competitive reason, but because it actually enabled them to continue to serve the market, in a sense hang on for a longer period of time or to provide a launch point for a later entry should conditions change.

So I think while agreeing that there are a huge amount of facts and in principle it could be that the Tribunal agrees with some and not all, I think it boils down really to those two broader perspectives.

Q. You have not done the exercise, I think, of asking whether, if the CMA's account of the facts is true, in other words if there is an agreement, AMCo's behaviour would be rational?

A. No, I have not done that.

Q. Just to round this off, if the Tribunal were to come to the view that there are two different accounts, they are both rational on their own terms, then essentially it is just a matter for the Tribunal to decide on the evidence which one of them is true?

A. I think that is essentially what I am saying in 7.1.2.

Q. Yes. Thank you, I have no further questions, thank you.

THE PRESIDENT: Mr Holt, just to follow on from that. The big difference, it can be put variously and it is something we will have to decide, but the big difference

between the AMCo position and the CMA position is that the characterisation of the agreements as simply a purchase of a supply is incomplete and there was an unspoken, well, unwritten rider regarding entry into market.

A. Right.

THE PRESIDENT: That is something on which, quite properly, you have expressed no view. You cannot. Were you in court to hear the evidence on this?

A. I am sorry. I was not in court to hear that evidence.

THE PRESIDENT: Entirely understandable also. So the first question is a slightly cheeky one, but what is the characteristics of someone who is assessing the rationality of an agreement? Do you say that it is always irrational to enter into an unlawful agreement?

A. No, I think that was sort of more or less the question that counsel was putting before. If it is profitable and profitability is rational and leaving aside risks and deterrents and all the negative consequences, then in principle it could be rational. I am not discounting that.

What I am suggesting here is that when you take into account the supply situation that the company faced and the demand situation that it faced from its own perception, then those are potentially relevant factors

to interpret the context by which it was reaching the supply agreement.

THE PRESIDENT: It is actually quite a narrow test of rationality, because, as you have just mentioned, in considering whether it is rational to do something, it might very well be profitable provided you do not get caught and you might feed into your rationality consideration the illegal aspects of the agreement and say, well, it may well be very profitable, but I am still not going to do it because if I get caught the consequences are horrendous.

A. I think that would be a factor that a firm would take into account, yes.

THE PRESIDENT: Right. The witnesses who gave evidence in relation to this said, and I am not going to quote them, that the Auden approach to this was in some way odd and the oddity was the low price at which the supply was provided to AMCo and there was no explanation and it is not for them to give, because it is Auden's choice to provide a supply at that level, but they found it odd and not capable of explanation.

Is the oddity that one is being handed over product at a margin which is enormous and one sided something that a rational person ought to take into account even if they do not understand why it is that this largess is

being bestowed on the person buying the product?

A. I think my -- I can offer a comment on the issue of the price, albeit a limited one in that I have not investigated this in detail, as is clear from my report, but there is an issue around differential expectations by the supplier and by the prospective entrant and that could be a factor which could explain what the level of the price was.

Another factor that could explain what the level of the price was is what are the outside options from the perspective of the person taking the supply. Those are two points which I think would be factors that affect the level of the supply. It is not quite answering your question as to whether you should take into account what are the motivations of the other party when accepting something. Well, you know, it depends what is your -- you do not know what they know. You do not have the market insight that they are picking up. You have your own market insight and I think that is really what you would be focusing on.

THE PRESIDENT: So in a sense, the sheer scale of the margin that was being made by AMCo, so a purchase price of a pound or a 1.78 or so and a sale price of £38 odd, that is not something -- on one level, on the profit maximising level, leaving everything on one side that is

clearly rational. The size of the margin is not something that you fed into your rationality analysis.

A. Well, it was in the sense that -- I did sort of look at the profitability impact of taking versus not taking the supply arrangement, but I think the important consideration was, was there a realistic and extensive prospect of entry, taking into account the supply and demand situations as perceived by the company, as laid out in annexes 1-5, which I appreciate are open to some challenge perhaps or at least have been challenged. I do not know what the outcome of that will be of course.

But it was a factor that I took into account in that context when weighed up against how successful and how much product could have been brought to market on what timetable and what sort of customers were interested. All of which essentially, based on the evidence I looked at, was suggesting that there were quite severe supply side problems and quite severe demand side problems and in that context can it be an agreement not to enter if your entry prospects were so limited. I think that was really my point.

THE PRESIDENT: Yes, thank you. Mr Jones, is there anything -- no. Anyone before Mr Brealey? Yes, Mr Palmer.

MR PALMER: Yes, thank you, sir.

Cross-examination by MR PALMER.

MR PALMER: I am taking up my usual position at the fag end of the day and ask some further questions if I may.

Mr Holt, I am going to ask you some questions about really what is one of the key premises of your report that there was an assured customer base of what you call a regulatory-focused group of eight pharmacy chains or supermarkets, which was distinct from a price-sensitive group made up of independents; Day Lewis, Tesco, as we have heard just now hospitals who were tendered by the NHS England, Scotland and Wales centrally.

A. Yes.

Q. The key issue you say in your report is the extent to which pharmacies were willing and able in practice to substitute between full and skinny labels when filling in an open prescription.

The term regulatory focused group is yours and what you say defined them as a group is that they had "no choice, but to purchase Auden/Actavis Group tablets and were not able to switch". Is that a fair summary of that central premise?

A. Yes, I think I was actually -- well, that is also language used by the CMA, so I might have been in a sense paraphrasing.

Q. That is what I want to ask you. Again, you use language -- you say they were locked in. You say they were *de facto* incontestable, but my first question to you is, to what extent is that simply derived from the CMA's findings and to what extent is that the result of some independent exercise which you have gone through?

A. It is largely defined -- sorry, derived from the CMA's findings, but not just the concluding line that I have also looked at the evidence that they have relied on to get to that point, which includes the evidence that they describe from the interviews with all of them. So that is a key source of the evidence base, but it is also some other evidence that I was looking at in relation to price gaps and switching rates and market share levels being stable over time and so on.

Q. It is in your report?

A. Yes.

Q. But the existence of this regulatory focused group, that is something which you took from the finding of the CMA that they were a group who had no choice. You looked at the underlying documents which the CMA had quoted presumably in their Decision so that you could understand something about that and what was driving that, but you did not, I think, conduct a factual exercise yourself in going through absolutely everything

that was said by the pharmacies, by the wholesalers, by the suppliers in order to reach independent conclusions of your own on that factual question?

A. Well, I think that it is fair that I did not -- I do not even know what the full breadth of that potential information set would have been. I looked at the information that the CMA was relying on and I satisfied myself as to the implications of that.

Q. Was there a package or selection of evidence that was provided to you by the solicitors instructing you or how did you identify that package?

A. It was essentially through looking at the Decision and the associated documents.

Q. So you were directly referencing documents which were referred to in the Decision?

A. Yes, I think in the main, yes.

Q. But you were not looking at, for example, documents that were not referred to in the Decision?

A. I believe so, but, yes.

Q. So you took that as a starting point and really you were asking yourself, now I understand that starting point and I understand the effect of some of the underlying documents, what consequence does that have for a proper analysis of market definition. Is that a fair summary of your approach?

A. Yes, I think, again, it is the combination of the evidence that the CMA was describing and my own quantitative assessment.

Q. I think another premise which you took, which I think is not derived from the CMA's Decision, is that which you refer to at your paragraph 6.2.3. That is page 28 of your report. In fact, the top of page 29 {D2/1/29}:

"... in the same market as full label HTs is the extent to which pharmacies are willing and able in practice to substitute between these indications when filling an open prescription."

You give us footnote 99 there, which we can see at the bottom of that page is a reference to Dr Newton's expert report. You take a sort of representative quote from her report to communicate the substance and effect of her opinion that we heard earlier today?

A. Yes, yes, I see that.

Q. You took that as a given I think as well. You did not seek to go behind what Dr Newton had said?

A. No, I did not.

Q. So you took as a given that there was in fact a regulatory obstacle to dispensing skinny Hydrocortisone tablets off label?

A. I think I put it slightly differently in that I examined the evidence as to whether the factors that pharmacies

took into account, many of them described regulatory constraints, whether they existed or not almost is secondary. What really matters is what did they actually do as a matter of practice, and that was looked at both from the how did they describe what they were doing and also the evidence about things like switching and volume trends and so on.

Q. So what mattered for you in this regard was the perceived regulatory risk which those pharmacies referred to?

A. Yes.

Q. Whether or not --

A. To the extent that that is what is driving their actual Decision, then that is what is important.

Q. Whether or not that perception was accurate?

A. Yes, yes.

Q. Good, thank you.

If we turn to paragraph 6.3.8 of your report, {D2/1/32}, perhaps we could look at 7 first of all just to put this in context what you are talking about here. You are talking about the evidence which shows that all independent pharmacies, along with Day Lewis and Tesco, switched you say by November 2017, in fact many switched substantially earlier --

A. Yes.

Q. -- than that?
A. Yes.
Q. But you do not have evidence beyond that date. But you refer to the aggregate supply of data suggesting that remained consistent. Again, you distinguish between what you say is the price-sensitive category and the regulatory-focused category.

Now, I just want to explore this distinction with you, because you then say at 6.3.8:

"This again reinforces that there are two separate groups of pharmacy customer, one that is highly price sensitive and one that is not."

I am just going to suggest to you that is an unfair characterisation of the position of the group which you call the price-sensitive group. I do not think you are suggesting that those customers do not care about compliance. I think you would accept simply they had a different perception of what compliance entailed?

A. I am not really commenting on what their intention was or whether they were or were not behaving in the right way. All I am saying is that they did not see the need to sell full indication in contrast to the other group of pharmacies who did see that.
Q. If there was therefore no regulatory obstacle, then it was a perfectly rational choice, price sensitive or not,

to choose a cheaper product?

A. Yes, I think I would agree. Subject to a separate debate about whether there were any risks and consequences to doing that, and I am not suggesting there were, that wasn't my focus, then I agree they were taking the cheapest available product.

Q. If you understand, first of all, that their perception was there was no regulatory risk and, indeed, I think you were here for Dr Newton's evidence earlier today, were you?

A. I was listening in an associated room, yes.

Q. You heard Mr Jones on behalf of the CMA put it to Dr Newton that she was simply wrong about her understanding of the regulatory regime and, in fact, there was no regulatory bar to off-label dispensing. You heard that being suggested to Dr Newton?

A. Yes.

Q. So clearly, I will put it at its lowest, it is perfectly possible for a pharmacist to have taken the view, with some confidence, there is no regulatory risk here, so my decision will be determined by other factors?

A. I suppose that is what those pharmacies were doing and I am not suggesting that they were irrational in doing so.

Q. No. Taking into account the lower price would be --

THE PRESIDENT: Sorry, when you said "rational", I think you meant "irrational"; is that right?

A. I think I said I would not suggest they were being irrational.

MR PALMER: I heard "irrational".

THE PRESIDENT: I heard "irrational" too, but the [draft] transcript said "rational" so I thought we had better ...

MR PALMER: I am grateful. Of course, that on its own says nothing about their price sensitivity. What might say something about their price sensitivity is whether the mere fact that the price was lower was enough for them or the extent to which they balanced that lower price against any other advantages of the full label product security of supply, reputation of the manufacturer and so forth, whatever they may be, and how they evaluated and valued the differences and the pros and cons in that sense?

A. I agree that in principle a number of factors could be weighed up, but they themselves clearly demonstrated from their actions that full label was not a concern, but having a cheaper price was a priority.

Q. Those who went for it can be assumed, amongst other things, to have been attracted by the price. That tells us nothing about how they valued the other things which

may have been associated with a full label product?

A. It is obviously possible there are a number of other characteristics between skinny suppliers and they had to make choices between the brand, prior relationships and so on. That is all possible factors that they might have taken into account, but not relevant to the question of are they in the same market with full label.

Q. It would not be right for anyone to suggest that those who you call the price-sensitive group were not in fact equally regulatory focused in the sense of paying serious attention to their compliance responsibilities. It is just that they perceived what those responsibilities were in a different way. They arrived at a different result.

A. That is possible, but it would not affect my findings, because by regulatory focused in a sense I do not mean they were on the right side of being correct about the regulations and the others were on the wrong side of it. That may or may not be the case. The question is does their purchasing behaviour focus on the full versus skinny issue in the sense that they felt they could not or should not or would not substitute to skinny. That was what I am calling the regulatory-focused group. Whether the others fully took account of their regulatory obligations and had very good compliance

policies is simply not relevant to my assessment of what their behaviour ultimately was, which was demonstrated to be a price-sensitive focus on that issue.

Q. Thank you. So now let us concentrate on what you call a regulatory-focused group. I think we have agreed that just what defines their membership is those who if properly categorised, I am not going to argue with them, I will be submitting in due course that some of these eight who you have put in that category do not belong on that at all, but that is a matter on the facts and submission on the documents, not for you.

But for those who could properly be said to be regulatory focused in the way that you identify them to be, that you accept, I think, what is sufficient is that was their perception of what regulation required, rather than what regulation did in fact require?

A. I think that is fair. I am not really making a point about what was or was not the right regulatory approach. I am talking more about what happened in the market.

Q. Now, perceptions can change over time, can they not?

A. Potentially, yes.

Q. Particularly if your original perception is as a matter offer fact wrong?

A. Potentially, yes.

Q. You are more likely to change that perception if you are

wrong?

A. Agreed.

Q. Because it could be pointed out to you or you could learn or you could review a decision and take a different view and say, well, initially we thought there was a compliance problem here, but actually on the strength of better information we now take a different view?

A. That is possible, yes.

Q. It is perfectly possible, right. In fact, there are examples of pharmacists doing that. Did you look closely at the evidence surrounding Day Lewis, for example?

A. I mean, I commented to some extent on Day Lewis and I think that was one example which did form the view that they could sell skinny label product.

Q. Eventually they did, yes?

A. Yes.

Q. You were not here I think for Mr Beighton's evidence where he explained that when they approached Day Lewis, when what is now Advanz or AMCo approached Day Lewis in May 2014, the supervisory pharmaceutical officer was adamant that they would not touch skinny products essentially for regulatory compliance reasons?

A. I wasn't here for that, but I accept that position.

Q. So if that was the view, as Mr Beighton said it was, in May 2014, we know that by September 2016 a different view had been reached by Day Lewis?

A. Yes, I suppose that is consistent with that fact as you mentioned.

Q. In fact, we can look in your report, where you refer to Day Lewis on page 31 at paragraph 6.3.6 at (a). {D2/1/31}. You refer to some of the evidence concerning Day Lewis. I will not go through all of the evidence with you now, but do you see about eight lines down the words:

"TM confirmed it was likely that after September 2016-Day Lewis's pharmacies dispensed skinny label tablets off-label when filling open prescriptions."

A. Yes.

Q. Did you attribute any significance to that date, September 2016?

A. No, I did not.

Q. Did you wonder why after 2016 -- after September 2016 and not just in general, what the significance of those words were?

A. I did not assess that, no.

Q. What I am going to put to you, and I can show you the dispensing data if you like, is that was a marked shift

in the dispensing practice of Day Lewis when they went from dispensing almost all full label tablets to dispensing almost all skinny label tablets, but there is no change in the market, there is no change in the regulatory environment in September 2016. There is just at least by then a change in perception as to what is permitted or not. That is right, is it not?

A. Well, I mean, it is right and I have already accepted or agreed with you that the perception is an important factor. My question is really what were the actual behaviours of the different pharmacies and, obviously, you need to look at the market as a whole and there were essentially two types of -- whether it be actual regulatory policy or perceived regulatory risk and so on, but there were broadly two categories. One which thought you more or less had or should dispense full and another group that was price sensitive and did not feel that way.

I think what is happening here is that Day Lewis clearly moved from one group to the other and I am not -- I think that is the case. I am not challenging that, but it does not affect my conclusions.

Q. You see, the point I want to put to you is that your analysis of these two categories and who was in them is one which you have conducted after the event with the

benefit of the CMA's investigation, the documents that they exhibited to their Decision and which you reviewed, that includes notes of calls, interviews they had with different pharmacies, many years after the relevant events, allowing them to obtain an insight into what was happening in their minds at the time.

But if I ask you for a moment to put yourself in the shoes of Auden/Actavis, without that benefit of hindsight at the time facing skinny entry, they do not know, do they, who is going to change their perception of regulatory risk at any given time?

A. They may not. I do not know. Obviously, they will perhaps have made their own enquiries or formed their own view, but you are right, I cannot comment on what their view of how the market might have evolved.

Q. There is no evidence that they knew what was driving the purchasing decisions and, in particular, of the perception of regulatory risk and how firmly that perception was held by any one pharmacist at the time?

A. I mean, I cannot really comment on what Auden knew or did not know at any given point in time. All I can comment on is the facts and evidence that I have seen around the volume trends, the decisions, which did include, as you say, summaries of interviews and so on. Some of that might well be in retrospect but some of it

is also real time market information, ie what actual switching, what actual --

Q. Internal emails which were contemporaneous, but, again, not available to Auden/Actavis at the time?

A. Yes, that may well be the case. I have not looked at what Auden knew at the time.

Q. When I say at the time, we must not lose sight of the time we are concerned here with a spread of time. We heard from Mr Beighton that there was a serious development, a change in the market, as he described it, in April 2016 and he explained, for example, how AAH wholesalers suddenly became interested in buying skinny products, having completely ruled it out a couple of years earlier.

Again, that is a moving picture, is it not?

A. Well, I think the likely explanation there and, again, you know, I would be happy to comment if I am presented other facts, but the likely explanation there is that AAH being a wholesaler provides derived demand. In other words, what they want to supply reflects what the pharmacies want to supply. So if they had seen possibly an important client form a different view on the regulatory perception, then that would very well be a reason why they might move, at least in respect of their sales, to that particular pharmacy to acquire some

skinny product. I agree with that.

Q. If there was a new demand from pharmacies who had not expressed it before, because of a change in regulatory perception, then they may change as well?

A. Yes.

Q. Including as to the assessment of any of their own regulatory obligations which they felt they had?

A. Yes. I think just one -- briefly, one piece of colour I have commented on, which I think is relevant to all this, is the extent to which there was ongoing switching after that initial period which, as you say, was primarily within the first year and the evidence that I have seen suggests that there was fairly modest other -- basically, the market was fairly stable. So there may well have been some movement, albeit I think the September 2016 is within the year actually.

Q. As it turns out --

A. As it turns out, exactly, yes.

Q. But during that time, one thing which was becoming clearer was the attitude of regulators towards the sale of skinny products off label. Are you aware of that? Regulators gradually making their views known when asked by operators such as Auden who wrote to the MHRA, for example, and they received answers and the MHRA wrote to, amongst others, AMCo as to how their products could

be marketed and what information could be or did not need to be contained in the patient information leaflet. These were developments which were happening over time, were they not?

A. There may well have been developments happening over time. Obviously, we do see the possibility of those developments happening over time also being reflected in the volume trends and price trends and switching decisions that people have made. My additional comment on that is that even if there were such developments, I am focusing on how the pharmacies were actually taking into account all of that information and despite some of that potential change happening, you still had the -- effectively the binary decisions with very limited exceptions of people having switched a bit later on, but, essentially, the aggregate data shows that once the bifurcation had happened, that is more or less how it stayed and that is despite the fact that the pricing differential came rapidly down due to the drug tariff and, again, you would have thought that would have triggered some reverse movement back from full -- from skinny back to full and yet that does not happen either, so I do not disagree that there might have been other sort of regulatory factors that might have evolved over time, but really what I am focusing on is what was

happening in the market from a pharmacy dispensing decision perspective.

Q. What I want to put so you is that when turning to the consideration of the extent to which skinny prices formed a direct constraint on full label prices, we must remember, must we not, that Auden/Actavis at the relevant times did not have access to all the information which you have based that analysis on and they did not know how marginal their customers were at the time, did they?

A. They may have not. I am not disagreeing that -- what information they had. I do not know what information they had, but it is fair to say that at some point in time they might not have had all the information that later evolved in the market. I think that is a fair statement.

Q. Yes. If we turn to your paragraph 6.3.28 at {D2/1/39}, at the foot -- sorry, just over the page at 40 in fact. At 29 -- sorry, 28 you refer to the evidence not suggesting that:

"The threat of pharmacies switching to lower priced skinny label HTs did not provide an effective direct constraint on Actavis's price ... Instead the bifurcation of the market into a price sensitive contestable customer group and a regulatory-focused

group highlighted clearly that Actavis had an assured market that did not regard skinny label as a suitable alternative. As explained above, Actavis had the ability to increase the price of full label tablets to this group without fear of losing sales due to switching to skinny label HTs, and it appears to have acted on this to protect its high margins ..."

What I want to put to you is certainly by the time of 2017, and indeed earlier than that, when there was market competition, Auden/Actavis could not have known, nor proceeded on the basis that it need not fear that anyone would switch to skinny just because they had been buying full label tablets up to that point?

A. Well, I think the evidence was that for a significant period of time they were selling to some pharmacies, which I have characterised as regulatory focused, at a significant price premium without them switching and with them having said, albeit I appreciate what they have said was perhaps to the CMA in an interview, that there were very good reasons why they did not consider switching to skinny. Now, I do not know whether Auden McKenzie had any particular views on that. My focus is on what was happening in the market and the price trends and the switching trends.

Q. You see, up to August 2016, Auden/Actavis could have

said to them, well, Day Lewis are buying our full label products with the price premium entailed, but then suddenly they lose that business overnight?

A. Yes, that is part of the migration that I described earlier. It wasn't --

Q. Much later than you really described earlier and the point is that they tipped at that point. How is Auden/Actavis to know that no one else is going to tip? The reality is they are going to respond to the price of skinny tablets, because they want to ensure that the price differential does not increase, thus giving an incentive on people to re-evaluate their regulatory position and switch at that point.

A. The first comment is that that migration took place over about a year and that is within that same period and, secondly, the evidence that I have seen suggests that the price premium was maintained for a very long period of time without inducing any further switching. So that to me suggests that there was a product market segmentation.

Q. Can we just turn to your evidence on the suppliers as well, which you referred to at page 36. That is {D2/1/36.} That is 6.3.17. You say that your analysis is corroborated by the evidence from suppliers. I just want to take you down quickly through this. Under (a)

you refer to the position of Celesio, the parent company of AAH Lloyds. Mr Holmes took you to an email from them. If you go down four lines:

"Following contact from Actavis these two customers decided not to go forward with stocking our product as Actavis claimed that without the adult adrenal insufficiency indication our product could only be dispensed to 10% of patients taking Hydrocortisone."

That was the position that Alissa told the CMA in June 2016, is it not?

A. Yes.

Q. But things subsequently changed with AAH actually supplying a much higher percentage of skinny products to its customers than previously. Is that right?

A. I do not know to what extent -- it may have had some increase in skinny subsequently, but my understanding is perhaps you are referring to the Day Lewis switch, which I agree happened, I think, and a bit later in 2016, but by the end of the year effectively of migration there was stability.

Q. I am also now talking about sales to AAH?

A. Sales to AAH reflect what it is selling to the pharmacies. One key element of AAH pharmacy sales is its own integrated pharmacy, Lloyds. Now, it might have had others as well, but overall I think primarily

focused I believe on the national chains. It may have also had some independents, but I am not sure that the balance of its sales transitioned extensively from full to skinny.

Q. Let us look at (b). Bristol Laboratories told the CMA in April 2016 that full-line wholesalers are still evaluating the list of their skinny product, but, in fact, we know that that evaluation continued beyond April 2016 and they did start stocking skinny products.

What you have done here, Mr Holt, no doubt inadvertently, is focus on evidence which freezes the frame, April 2016, June 2016 when in fact the market was still developing and as far as Auden/Actavis knew could continue to develop thereafter?

A. This set of paragraphs focus, and you can see that there were sort of interviews happening somewhat later as well, 2017. Obviously, this is evidence about suppliers' understanding of the market, which I am only able to obtain from what the CMA was saying. I have not relied only on these points, but I actually have looked at the evidence as to what the pharmacies were talking about and also the aggregate and individual discussions around switching factors. So it is really the body of that entirety of the evidence that I am focusing on.

Q. We will be addressing the Tribunal in detail about that evidence. I will not go through it all with you --

A. Okay.

Q. -- now. Can we just see how this translates. I will not go through each of those examples. I could make similar points. If we go to your page 39, please and 6.3.26 {D2/1/39}, where you say it appears from the available evidence that Actavis did not reduce prices in order to compete directly with skinnies but rather continued to maintain high prices and margins on its assured sales to and, in fact, initially increased its price as demonstrated by and then your (a): They increased prices following the entry of Alissa, Bristol Labs and Resolution.

Can we just look in that context at the figure which Mr Holmes showed you earlier, which is at {K/60/2}. Do you remember this figure?

A. Yes.

Q. I just want to remind you you were having a debate with Mr Holmes about the effect on the blue line, the Auden/Actavis line, between October 15 and March 16, which is when Alissa was the sole skinny competitor. Do you remember that?

A. Yes.

Q. Then we get to the line, the dotted line,

marked March 2016 when Resolution and Bristol enter. Do you see after that market entry the blue line starting to go down again, turning at that point and going down?

A. Yes.

Q. Do you also see above it the drug tariff, the dashed line, also going down?

A. Yes.

Q. Let us just put that in context. I think as you explained earlier in your report, neither Alissa nor Resolution nor Bristol were Scheme M manufacturers, were they?

A. Yes, that is right.

Q. So that line going down for the drug tariff after March 2016 has not been affected directly by the entry of Alissa, Resolution and Bristol. What I mean by that it does not reflect their prices. It continues to reflect only the fact that Auden/Actavis's price is going down. That is right, is it not?

A. I think it is actually AMCo's price which went down quite a lot during that period of time.

Q. AMCo comes in in May 2016. You see that is the next dotted line. Do you see that?

A. Sorry, what I meant by that was the AMCo sales of the full product.

Q. AMCo's sale of the full product. That is the

Auden/Actavis product, is it not?

A. Yes, but there was maybe a small price differential that might have been happening there and that, I believe, was in the Scheme M.

Q. There is only that product which is being reflected by the drug tariff, is it not?

A. At that point, yes.

Q. Yet it is going down and it is turning on each occasion, because of the market entry by the skinnies, and that can be taken as evidence of a direct constraint presented by the skinnies on Auden/Actavis's processing?

A. Not necessarily, because I think obviously what you also had was a downturn in -- firstly, you can see that the main sort of downward movement of Auden took place some time after that, but, by that point, the drug tariff was having a significant impact because there were some -- by the time AMCo's entry came in, there was already significant levels of skinny competition at that level, so a volume weighting on AMCo's skinny sales in 2016 would be something that would have an important downward effect and I think that is what is shown here.

Q. Certainly, AMCo's entry has an effect on the drug tariff, as does subsequently Teva and Genesis. At that point, it becomes harder to disentangle direct from indirect constraints, but the point I am putting to you

is before AMCo's entry there must have been a direct constraint presented by skinnies on the full label product?

A. Not necessarily, it could be the direct impact of the other AMCo sales level.

Q. That is the full label product?

A. Yes, it is, but that might be where the source of competitive tension is. That was driving the drug tariff price and if that was lower, then that would have affected indirectly --

Q. You do not think that either AMCo's full label product bought from Auden/Actavis or Auden/Actavis's product, you do not think that the prices were affected at all by the entry of those skinny products which we can see on that chart?

A. That is my reading of not just this evidence, but also the way in which the CMA's findings are presented in terms of what are the pharmacies actually thinking about. It is consistent with that as well.

Q. I think you will agree with me, at this point, they did not know how all the pharmacies would react to skinny entry?

A. They may not have done. Yes, they may not have done. That is fair.

Q. Moving on lastly, to your paragraph 6.5 -- sorry, 6.4.3,

your page 41, {D2/1/41}, where you are dealing now with the indirect constraint provided by the drug tariff price. And you say six lines down:

"... wholesalers in this situation have a credible threat to delist the full label product ..."

I should put this in context with the previous sentence:

"Knowing the drug tariff price wholesalers target a required margin (which includes allowance at the retail/pharmacy level) and use this to negotiate with Actavis. Wholesalers in this situation have a credible threat to delist the full label product, because if the price of full label is too high (particularly if the price is at or above the drug tariff price), then they are better off not buying the product (as any stock purchased could not be sold to their own customers)."

That makes obvious economic sense that if they are going to lose money by selling a product they are not going to buy it in the first place.

I would just ask you to re-evaluate that. You say in that circumstance, I think you suggest over the page at 6.5.5, that they may delist Hydrocortisone tablets all together. That is at page 44, end of 6.5.5. {D2/1/44} I just want to challenge you as to how realistic that proposition is.

The reality is, is it not, Mr Holt, that if Auden/Actavis had not maintained a sufficient margin under the drug tariff that pharmacy customers even those who you put it are regulatory focused would look again at providing skinny products rather than not providing Hydrocortisone tablets at all. What do you say about that suggestion?

A. I mean, it is obviously a possible reaction that they could have had but the evidence suggests that they did not consider and would not consider skinny. There are a number of alternatives that they had which could be to continue to secure the full label product that they wanted, albeit at a lower price due to the falling drug tariff level.

One would be essentially negotiation directly with the full label supplier on the basis that they might not stock it. The other would be that they could use obviously the portfolio of products that they bought from that supplier as leverage. So those would be two clear sources of negotiating power, countervailing buyer power that they could have used to exercise in their negotiations.

Obviously it is helpful to them in those negotiations that there is a drug tariff because that removes one of the possible medication sources which is

a pass-on type argument. If actually they could have easily just passed on any increase in sales in terms of a higher downstream price, then that would have lessened their countervailing buyer power because that would have been a legitimate alternative option.

Since the drug tariff constrained that, one has to look at other sources of countervailing buyer power which are the two that I just mentioned.

Q. It is to large extent speculative but may I put this to you: would it not be precisely that scenario of trying to reduce or eliminate that margin under the drug tariff which from Auden/Actavis's point of view would be precisely the sort of thing which they would fear would lead to a re-evaluation of the regulatory risk by those pharmacies?

A. I cannot comment on whether that was a realistic proposition. The evidence seems to be that that was not -- the pricing situation was not the primary concern. It was ensuring compliance with the full label indication.

Q. They negotiated hard to retain their margin under the drug tariff, did they not?

A. The pharmacies?

Q. Yes, and wholesalers.

A. I understand that they would do and again they would

have had sources of leverage in order to enhance their bargaining position.

Q. In those negotiations efforts were successful in maintaining that margin under the drug tariff, were they not?

A. It seems so although I think the margin may have been falling just by looking at in recent years the size of the difference between the average supplier price somewhat narrows.

Q. I am looking at the infringement period for the moment. The margin did reduce as prices got lower?

A. Yes, that is right.

Q. But during the time which is said to be the infringement period the margin was essentially maintained, was it not?

A. I do not know whether it was necessarily maintained but I am sure they did their best to maintain it.

Q. We will no doubt hear about, and that is because they had that negotiating power to maintain that and from Auden/Actavis's point of view that is something which they were anxious to preserve so that they did not re-evaluate that regulatory position and make a jump to skinnies as half the market already had done?

A. Again, that sort of concern seems inconsistent with the evidence that I have seen, that those pharmacies were

not considering skinny. It was not merely a price issue. They had other non-price reasons to adopt that but nonetheless they were able to exercise some constraints on the level of price as a result of the drug tariff for the other reasons I mentioned.

Q. This is all in a context where, as you acknowledge right at the outset of your report, that these are bioequivalent products with no clinical difference and from that clinical point of view are completely substitutable. That is something which you would expect Auden/Actavis to have well in mind alongside any understanding that this regulatory risk which was perceived by some was in fact written water and could easily change overnight, as it had done with others?

A. I think the crucial thing, as I was saying earlier, is what was the perceived regulatory risk and I think the evidence suggests that a significant part of the markets perceived that that to be extensive and therefore did not wish to consider alternatives.

Q. We will make submissions on what the evidence shows about that in due course.

A. Understood.

MR PALMER: Thank you very much. That is all my questions, thank you.

THE PRESIDENT: Thank you, Mr Palmer. Mr Holmes, you have

no further questions.

MR HOLMES: Nothing arising from that, sir.

THE PRESIDENT: Mr Brealey, I see the time. I have a meeting which I am late for but I would very much want to finish this witness tonight if we can.

MR BREALEY: I have no re-examination for Mr Holt.

THE PRESIDENT: That answers that question. Thank you very much.

MR HOLMES: Sir, on timing we are well ahead of ourselves.

THE PRESIDENT: You are. I have looked at this and we did have an overrun for Mr Holt which we will not need which is very good.

It struck me that it would be helpful if only to keep him from going mad on a non-sitting day to try and finish Mr Bishop tomorrow.

MR HOLMES: We can do our best, sir.

THE PRESIDENT: We are starting at 10 o'clock. Would it assist if we tried to carve out a little bit more time or is that something we should not ...

MR HOLMES: I certainly would not favour before starting before 10. I even wonder whether a 10.30 start would be sufficient but we are in the Tribunal's hands.

THE PRESIDENT: We will stick with 10 o'clock and so until then.

Mr Holt, thank you very much for your assistance.

You are released. Thank you very much.

A. Thank you.

(The witness withdrew)

(4.50 pm)

(The hearing adjourned until Wednesday, 30 November at 10.00 am)