IN THE COMPETITION APPEAL TRIBUNAL

Case No: 1524-1525/1/12/22

Salisbury Square House
8 Salisbury Square
London EC4Y 8AP

Monday 6th November – Friday 1st December 2023

Before:

The Honourable Mr Justice Marcus Smith
Eamonn Doran
Professor Michael Waterson

(Sitting as a Tribunal in England and Wales)

BETWEEN:

Appellants

Pfizer Inc. and Pfizer Limited & Flynn Pharma Limited and Flynn Pharma (Holdings) Limited

V

Respondent

Competition & Markets Authority

A P P E A R AN C E S

Mark Brealey KC, Robert O'Donoghue KC & Tim Johnston (Instructed by Clifford Chance LLP) on behalf of Pfizer

Jemima Stratford KC, Tom Pascoe & Alastair Richardson (Instructed by Macfarlanes LLP) on behalf of Flynn

Josh Holmes KC, David Bailey, Jennifer MacLeod, Julianne Kerr Morrison & Conor McCarthy
On Behalf of the Competition & Markets Authority

Monday, 6 November 2023

(10.35 am)

THE PRESIDENT: Mr Brealey, before you begin, I will just do the standard livestream warning.

As you can see, these proceedings are being streamed live on our website. An official recording of the proceedings is being made and by my authority a transcript will be produced.

It is, however, strictly prohibited for anyone else to make a recording, whether audio, visual, to photograph, transmit or otherwise send out these proceedings and it would be a breach punishable by contempt were that to occur. I am sure it will not, but thank you very much.

Good morning, Mr Brealey.

Opening submissions by MR BREALEY

MR BREALEY: Good morning, sir.

Sir, as you know, I act for Pfizer with Mr O'Donoghue.

THE PRESIDENT: A genuine double act this time.

MR BREALEY: Well, it is a triple act, actually, because Mr O'Donoghue is going to be dealing with the QALY evidence, Mr Johnston is going to be dealing with the medical evidence and I am going to be dealing with the rest, so it is a bit like the A-Team sort of thing, you

know, Mr T, Mad Murdoch, whoever the other one is.

I wish in opening to take the Tribunal through the factual documents. I really today want to concentrate on the factual documents relating to the comparators, and I want to do that chronologically, and I would like to start off by, if we can test the system, {XJ/52/5}. What I am going to do is hand up, because I am not -- {XJ/52/5}, which is the figure in Pfizer's reply, but I think it is helpful if the Tribunal has it in hard copy because certainly -- it is on the system. It has not come up yet.

THE EPE OPERATOR: I cannot see a bundle X, I am afraid.

MR BREALEY: We need to be in the confidential file. I am going to be addressing the Tribunal by reference to the confidential documents. It is very, very important. So we should have an {XJ/52}, and that is the correspondence. I am not going to be referring to one single hard copy today, so I hope it's going to work.

THE PRESIDENT: Let us get it right. We are in the file labelled "confidential bundle" with a little red padlock on it.

MR BREALEY: {XJ/52/5}. The reason I am handing it up is because I was not sure whether you could turn it around. Is the system working at all?

THE EPE OPERATOR: It is operational. I cannot find the

confidential bundle. It does not appear to be --

MR BREALEY: It is at the top.

I do need to address the Tribunal by reference --

THE PRESIDENT: Mr Brealey, do not worry, we understand why it is important. I think we had better rise for five minutes and enable this to work.

Just to put down a marker, I am sure it will not happen here, but if it does it will not be acceptable. There have been in other cases a significant delay between Opus bringing up the documents and counsel identifying them for bringing up, which I think given the volume of documents that Mr Brealey is likely to go through is not something that we can properly deal with, and if we get this problem, then we will have to shunt over to some form of paper documents created where Mr Brealey will have to get printed out in advance the stuff, but we cannot afford the sort of delays we have had in other cases where documents take 45 seconds to come up. So let us try and solve both problems now, but we will rise for five minutes to enable that to happen.

MR BREALEY: I am obliged, thank you.

(10.40 am)

(A short break)

(10.56 am)

THE PRESIDENT: So Mr Brealey, the lunatics are in charge of

the asylum and we will get our own documents up, so do bear with us.

MR BREALEY: Okay, I will take it slowly.

We are going to rejig that chart we gave you because apparently for some reason a couple of the colours are wrong, and there is a reference wrong, so we are going to update it properly and then give it to you. I am going to skip the introduction. The introduction was going to be just some of the documents as to why the tablet and the capsule are identical, a good comparator. Obviously we will look at that, but that is almost a given, and I was also just going to explain when one compares the prices of the tablet and the capsule, you are dividing by three because of the 28 versus the 84, so I was just going to go through that.

What the chart does do, even though it is wrong, and we will replace it, I was going to start off with the October 2007 meeting.

Basically what I am going to do today is go through this chronologically, and I am going to start with the October 2007 meeting that Teva had with the Department of Health and that is on the left-hand side, and then -- and that I think is -- the colours are okay there, one knows that the green dotted line is the drug tariff and the yellow is the Teva.

Then I am going to -- so I am going to look at that meeting and the evidence around that, then I am going to deal with Wockhardt's entry in October 2009. So that is just after -- just by those two little squiggles, and they will not change. So that is the date that Wockhardt entered the market, October 2009.

Then I am going to deal with Milpharm's entry in 2012, and again, I do not think that will change in the updated graph, that is the grey dotted line, so Milpharm enter the tablet market in September 2012 which is the same time, almost the identical time, as Flynn and Pfizer entered in September 2012, and then I will finally, if I have time, just have a look at NRIM's entry and that is one of the colours that is wrong.

So that is what I am going to do today, so without further ado, I will start with the £30 drug tariff for the 100mg phenytoin sodium tablet, and I start with a meeting on 16 October 2007, and to do that we need to go to {XN1/2}. So I guess I am going to have to do that as well, am I? So {XN1/2/69} which is the Tribunal's previous judgment.

So one goes into the confidential -- I do not know whether you can find out from your headquarters whether everything is --

THE EPE OPERATOR: I have been told that there are

outstanding changes which are currently being checked, but until it can be synced to my workspace ...

THE PRESIDENT: We have a page beginning 207 paragraph number?

MR BREALEY: It is 209. This is all marked confidential, so I do not actually understand why -- I do not understand why it is confidential, but if the Tribunal could read that, please.

This is the judgment dealing with the 2007 meeting. I do not think this is confidential, I think this is just...

MR HOLMES: Sir, if it assists, those markings are not confidentiality, they are sidelining just because it is a passage that is relied on by one of the parties.

MR BREALEY: Can you go to {N1/2}? Let us see how we go for the time being, {N1/2/69}. This is the Tribunal's judgment, it should not be too difficult.

THE EPE OPERATOR: I do not have that tab either.

MR BREALEY: That is because, as I understand it -- I had the same problem -- the authorities were in the confidential bundle and not in the non-confidential.

THE EPE OPERATOR: That is why.

THE PRESIDENT: It is useful to have everything in one place.

THE EPE OPERATOR: Do you know if that decision would be

publicly available? I could search for that.

MR BREALEY: Can you go to {M/16}. Is that in the confidential bundle?

Right, if we can go to {M/16/17}. So just by way of background, sir, we were going to go to the Tribunal's judgment and look at the paragraphs that described the meeting between the Department of Health and Teva, and that is what I was going to take you to and that is what I cannot because it is in the confidential bundle.

I was now taking you to the cross-examination of Mr Beighton. So this is the transcript on Day 5 where Mr Beighton is giving evidence, and just so that you know -- so he was called by Flynn and then, as you probably -- you may know, I was allowed to ask certain questions, he was not my witness, but I was allowed to ask certain questions and then Mr Hoskins for the CMA cross-examined Mr Beighton.

So this page {M/16/17} of Day 5 of the transcript is where Mr Beighton is describing the meeting between himself and the Department of Health, because Teva's prices have gone up and the Department of Health has phoned him up, called him in and called him in for a meeting, and the relevant pages are pages {M/16/17-23}. I do not know whether the Tribunal can just read pages {M/16/17-23}.

THE PRESIDENT: Yes, of course. We will do that now. Do you want us to start at the question at line 14?

MR BREALEY: One can start at line 14. So:

"Can I now move to paragraph 5 of your witness statement ..."

Just for the record, this is me asking Mr Beighton questions about his witness statement which was quite short.

THE PRESIDENT: Okay, next page, please {M/16/18}. Thank you.

MR BREALEY: This page is where he is saying that the Department phoned him up and called him in for a meeting.

THE PRESIDENT: Next page, please {M/16/19}.

MR BREALEY: He is being phoned up and the meeting was very soon after that, actually it was on 16 October 2009. He attended with a colleague. One sees at line 21 there were two Department of Health officials whose names you will see on the confidential version, although for the life of me I do not know why they are confidential.

THE PRESIDENT: Okay, next page, page {M/16/20}.

MR BREALEY: Then we see what the tablet price had been and what it was reduced to.

THE PRESIDENT: We can go to the next page {M/16/21}.

MR BREALEY: Line 13 is where he starts giving his evidence

as to the nature of the meeting. We have two more pages after this.

THE PRESIDENT: Very good. I think we can go to {M/16/22}.

MR BREALEY: This is where he is telling the Tribunal last time round that there was a discussion and the price goes down to £30, and I ask him on line 24:

"Question: So can I just be absolutely clear on this. Your evidence is that -- and I am looking at the first line of ... just to be clear. You tabled £40 --

"Answer: Yes.

"Question: -- and the government officials, the DH officials said they wanted a phased reduction. Who was it that suggested or who fixed on £30?

"Answer: They told us it would go down to £30 in a phased reduction.

"Question: So again to be clear [this is me asking the questions], that is the price that the officials wanted?"

And the answer was:

"Answer: Yes."

So then I have no further questions, but his evidence was very clear that the Department of Health required a price reduction to £30, and I will come on to some more of the evidence in a minute.

Then I understand we have got the confidential file,

but we can go on, I think, with this.

If we go on to Mr Hoskins, so page {M/16/25}, line 12, this is now the CMA, Mr Hoskins cross-examining Mr Beighton, so page {M/16/25}, line 12, and we go to read on to page {M/16/26}, line 16. So page 25, line 12 we can pick it up.

THE PRESIDENT: Yes.

MR BREALEY: I ask the Tribunal to note line 24, reference to the Secretary of State.

THE PRESIDENT: Yes.

MR BREALEY: Then over the page {M/16/26}, he says:

"Answer: I do not remember whether they used the term 'Medicines Act'. I do remember [this is line 6] they used the term 'Secretary of State' and 'has powers to set your price'."

And so we can finish at line 16, and then lastly it is important to see what the CMA put to Mr Beighton on page {M/16/27}, line 25, right at the bottom. So this is asking questions about Scheme M. He says:

"Question: Our understanding is that Scheme M has never actually been used ..."

And he says:

"Answer: I do not know."

And he says, well, there was certainly -- basically he is saying the threat of the powers being used.

He says:

"Answer: ... it was a difficult meeting."

That is at line 13. And then at the bottom on line 25, the CMA puts it to Mr Beighton:

"Question: And a company like Teva, presumably, wants to have a good relationship with the DH. It's an important part of your business, is it not?

"Answer: Absolutely. In the UK ... effectively the single customer.

"Question: So you would not want to fall out with them. That goes without saying?

"Answer: True."

So when one looks at the evidence again, as I am sure the Tribunal will, one will see that Mr Beighton's evidence is clear, the evidence is that the Department of Health official required a price of £30, the official threatened the intervention of the Secretary of State to get the price they wanted, and even a company like Teva would not want to fall out with the DH, its only purchaser, it goes without saying, the CMA said to him.

So that is what Mr Beighton said in cross-examination. I do not know whether we can just quickly go back to the Tribunal's previous judgment at {XN1/2}, I understand we may have -- there we go, and to page {XN1/2/69}. These are the paragraphs in the

judgment, paragraphs 209 to 213 where the Tribunal records its understanding and the evidence relating to the meeting.

Again, I do not think we need to read it, but the paragraphs of Mr Beighton's witness statement are set out, 4, 5 and 6, which we have seen referred to in the cross-examination. If one goes over to page {XN1/2/70}, again the witness statement is set out.

At paragraph 210, the Tribunal records the fact that I put some questions to him.

Then to flag my next point, because I am going to come to some documents, paragraph 212, the Tribunal says:

"This specific account of the [Department's] intervention to secure a reduction in the Teva Tablet price is not confirmed by any contemporaneous note or record, and we have no direct evidence from the DH itself. However, neither the fact of the meeting nor the subsequent price reduction ... was in dispute ..."

213:

"The CMA did not seriously contest Mr Beighton's account of the meeting, although it disagreed that it meant that the [Department] was 'happy' ..."

We will come on to that in a minute:

"Mr Beighton's recollection is not

comprehensive ..."

And again, as the Tribunal again repeats:

"... we afford Mr Beighton's evidence due weight, taking into account the passage of time and the absence of contemporaneous documentation."

Now, what happened at the trial was that that was the evidence that was put, but the CMA undoubtedly sowed some seeds of doubt because there was no contemporaneous documentation.

In fact, there was highly relevant documentation relating to this meeting that was not disclosed by the CMA, and we understand it because it was not disclosed by the Department of Health to the CMA, and had the Department done its job properly, and we are going to come to it in a moment, we would not have seen anything like that that Mr Beighton's evidence, we take due account of it, but is not supported by contemporaneous documents, and I want now to come to the three or four documents that were not disclosed/withheld or whatever because they are relevant to a proper understanding of this meeting, and as the Tribunal will understand, we put great reliance on this meeting and on this figure of £30. We are going to see this figure of £30 in many, many, many contemporaneous documents as we go through the morning and the afternoon.

THE PRESIDENT: That is helpful. Can I put down a marker that we are likely to need some assistance, probably in closing, as to weight. We have discussed this at a couple of CMCs or PTRs, and we have obviously indicated that we are prepared to accord significant weight to what was listed by way of cross-examination and answer in the prior proceedings, and equally, we are going to be attaching weight to what the Tribunal said by way of factual conclusion.

I think we indicated that we were not minded to accept anything in the evidence that was binding.

MR BREALEY: No.

THE PRESIDENT: Clearly this is a very good example of something where there has been a change in the evidence such that a revisiting might be appropriate.

What we are going to do, though, is proceed on the basis that what is said in these documents is right and therefore credible, what weight we attach to the debate. If there is a factual issue, in other words, if something is controverted, I think it would be helpful for someone to stand up and say that so that we can regard it in this light. But if someone does not stand up we will regard the record as, you know, something that we ought to pay attention to as being accurate and how much weight we will attach we will place later on.

MR BREALEY: That is very helpful. There is a slight difference to what the Tribunal had -- well, there is a big difference to what it had before and what it has now. I will come on to the documents right now, but when one is looking at weight, and I have just submitted what Mr Beighton's evidence was in cross-examination, insisting on £30, threat of the Secretary of State's powers to fix £30 if you do not agree, there was an agreement; the weight, that submission is supported by the only evidence in this case today. There is nothing from the Department of Health, they still have not pitched up and gainsaid anything, disagreed with anything, and it is a submission I am going to make in a few moments, but the weight of the evidence is as I have just submitted it.

With that, can I go to -- this is a confidential document -- {XG/23}. This is the first document that the Department of Health failed to disclose. If we go to page {XG/23/3}, this appears to be some comments by a primary care trust, and as we know the primary care trusts became the CCGs, the clinical commissioning groups, and they are complaining or someone is complaining about the increase in the price of the phenytoin tablet. This email exchange is on 4 and 5 October 2007. We shall see that in a moment. So this

is prior to the meeting on 16 October.

So that is a complaint from the old CCG, the primary care trusts. If one goes to page {XG/23/2}, again, I do not know why the name has been redacted as opposed to just made confidential, but it looks like the principal -- can we just make it a little bit bigger, please? Is that possible? -- the principal pharmacist has got wind of the complaint:

"I knew it was only a matter of time -- comments?"

We see in the middle of the page on the right-hand side, the principal pharmacist is sending this to two persons, two men, whose names are in red, and I do not know whether I can call them Mr, and then initial, or we just keep it bland, but it is important to see those two names. Sometimes it is easier to call --

THE PRESIDENT: Is there any reason why we cannot refer to their names?

MR BREALEY: There are some documents where they are not redacted. I would prefer to, but I would prefer, for example, to say "Mr" and then one letter, it just makes it --

THE PRESIDENT: The trouble with that is you then need a code of letters and then you need to translate them from the transcript to the code to work out what is going on.

MR BREALEY: This is ten years -- over ten years ago, people have left the employment. It seems crazy in a court of public record that we should not be referring to these.

THE PRESIDENT: Well, there does seem to have been a practice in this case to take the view that anyone who is not presenting the document is entitled to have their name, as it were, airbrushed out of these proceedings, and unless there is a reason for that, I would rather we used their names because there is a history here, and we are going to have to set it out to the extent it matters.

Mr Holmes, is there a problem?

MR HOLMES: Sir, we hear what you say. As you say, the names of a number of Pfizer, Flynn and Department of Health individuals have been redacted, and it is true that these events happened some time ago, they are not confidential. We understand in the case of the Department of Health that there is a departmental policy of trying to keep the names of officials private, apparently for GDPR reasons.

The parties could perhaps liaise about this because it affects the names of individuals not only at the Department of Health but also at Pfizer and Flynn, and if there is any issue -- the names are redacted, unless they gave evidence.

MR BREALEY: I will say, I have just been instructed, we have no desire to have any names from Pfizer redacted, and if necessary, I will make an application that the Department of Health names are unredacted and then we can debate it.

THE PRESIDENT: I think what we will do is we will proceed on the basis that in these public proceedings you can refer to the names and I will direct that that take place. I will rely on anyone, where there is a moment of genuine sensitivity to refer us to that, but these are open proceedings, these are documents that have been disclosed. I can see no basis for the record being adjusted to airbrush these names out.

We will work out in any judgment what should and should not be said, but I do not want anyone in this room to have additional burdens placed on them, and we will say something in our judgment by way of clearer direction to the parties.

I quite understand why the CMA is dealing with this, but I am afraid, we are getting to a stage where the tail is wagging the dog and the presumption is these are documents which are open and there needs to be a good reason, and GDPR is not a good reason for ensuring that the record in a public proceeding reflects the history rather than Mr X and Mr Y when you do not really know

what Mr X and Mr Y is, and you have got a level of obscurity which is in need of justification.

So we will proceed on that basis.

MR HOLMES: Thank you, sir. That is well understood. It will make life easier going through things generally, including those relating to the applicants.

THE PRESIDENT: It will make life easier for everyone and I want to make clear that I am overriding the CMA's entirely understandable redactions and we will just not deal with it unless there is a proper reason for sensitivity, and proper reason would be where someone has behaved discreditably but in a manner that ought to be protected, that sort of thing. If they have simply featured as a name in the history, then let us have the name out there.

MR HOLMES: Yes, understood, sir.

MR BREALEY: I am obliged, thank you. I would be obliged if the CMA would give Clifford Chance the name of the principal pharmacist which has been redacted, but the principal pharmacist has written to a Mr Mat Otton-Goulder and a Mr Shanahan saying:

"I knew it was only a matter of time -- comments?"

Then if we go up this is again -- we do not know who it is from and I would be grateful if we could find out who it is from, it is from the pharmacist again. The

Tribunal can see what is said. It is addressed to Mat, that is Mat Otton-Goulder.

"Shanners has kindly volunteered you to do a few [paragraphs] ..."

Then the third paragraph beginning:

"I do not pretend to understand Category M ..."

So this is the pharmacist.

"... Shanners said he did not have the authority to do anything about this apparent anomaly (or abuse of the system?) until recently ..."

So there is an acknowledgement there that the Department of Health has the authority to do something about this. He got the authority to do it recently. Then Mr Otton-Goulder, Mat, then responds:

"The prices used in category M are formulaically derived from manufacturers' factory gate price and limited with respect to the allowed pharmacy margin."

This is something that he repeats later on, as we shall see:

"The high price of phenytoin is covered by lower prices elsewhere in the category M tariff."

Now, that is an important point because we shall see him repeating this, but it means there is this kind of waterbed effect. So when the CMA is saying that the NHS is losing out, basically what is happening is you have

got a pharmacy margin and if the price goes high on one, then the Department has the power, like a waterbed, to lower the prices on other products, and this is something we may have to tease out subsequently.

More importantly just for present purposes Mr Otton-Goulder says:

"Nonetheless we are meeting the manufacturer of phenytoin next week to discuss anomalies ..."

So this is on 5 October. We saw Mr Beighton saying that he had been called in to the Department of Health and we have seen the evidence that Mr Beighton gave about the 16 October meeting.

That takes me to the next document that was not disclosed at the previous hearing, and this is at {XG/24}. This is an email exchange, 17 October 2007.

If we go to page {XG/24/3} because we have to go upwards and can we just enlarge it a little bit.

So we see this. This is on 17 October from Mr Otton-Goulder, to his colleague, to Mr Beighton:

"Dear John,

"Very many thanks for coming to see us yesterday [that is the 16th]: we appreciate the effort you have made to help us reach a conclusion which is of value to NHS patients."

So he is recognising there that the £30 is of value

to the NHS patients.

"Just to summarise our agreement: the reimbursement price of Phenytoin sodium 100mg tablets ... will reduce to £40.00 from 1 January ... then to £35.00 ... and then to £30.00 from 1 July 2008. We will review the price together thereafter with a view to further reduction.

"Best wishes,

"Mat."

So I do emphasise that this document which was not disclosed before is an acknowledgement by the Department of Health that this £30, that this reduction, that the £30 was of value to NHS patients, and the Department refers to "our agreement".

Then we can just go on to page {XG/24/2} where Mr Beighton again, if we can enlarge it, please, at the bottom:

"Hi Mat

"It was good to see you both again.

"I am sure that we have reached an agreement on this ... Richard [that is his colleague] and I definitely remember the £30 reimbursement price kicking in on September 1st. Indeed Richard was furiously writing what you [Mat] said word for word."

So essentially that gives some corroboration to Mr Beighton writing down what Mr Otton-Goulder said

word-for-word.

THE PRESIDENT: Just to be clear, though, the £30 reimbursement price, is that a reference to the drug tariff price?

MR BREALEY: Yes.

THE PRESIDENT: Then the aim was to ensure that the price to dispensaries was lower than that so that they had a margin to recover --

MR BREALEY: We shall see that a little bit later.

THE PRESIDENT: I am grateful.

MR BREALEY: After this, Teva was quite small, but we will see lots of evidence that the £30 was the reference price for Wockhardt, Milpharm and then obviously Pfizer and Flynn. We will see the £30 being the reference price and then that leaves the margin for the wholesaler and the pharmacist and then as competition kicks in as well they go lower, but the £30 reimbursement drug tariff price, we shall see the documents, is always regarded as the list price from which you then -- you benchmark and then you price.

THE PRESIDENT: Will you be explaining to us how that list or reimbursement price was in itself calculated? In other words, the flavour we are getting here is that it is simply something that was picked out of nothing, but I am sure that is not the case.

MR BREALEY: I do not know because the £30 was a price that came from the Department of Health. They have never come to the Tribunal and explained it.

We shall see in a moment that they fixed it, they hardcoded it, because they regarded it as giving value to the NHS, and we shall also see that when Mr Otton-Goulder is asked to respond, he actually says: I will not get into the weeds of how category M was calculated.

So the straight answer is I do not know how the Department of Health calculated that £30. What I do know, and we see this from the Department of Health itself and then how the market participants saw it -- they saw the reimbursement price of £30 as what the price the Department was willing to pay because it was giving value to the NHS. But I do not know the precise calculation for it, but I do know that the whole market relied on it.

So we see there Mr Beighton saying: our recollection is that the £30 would kick in on 1 October, we were furiously writing down what you said.

Then if we go up to the top:

"Dear John,

"Clearly, I meant to say at our meeting what I expressed in my email ..."

So he is acknowledging that what he set out in his email was what was essentially agreed:

"... clearly to me, and I would point out that category M prices do not change in September.

"Nonetheless, we shall say that the reimbursement price will fall to £30 from 1 October 2008 and we will anticipate further reductions thereafter.

"And that is as far as I am prepared to go in this matter: please confirm that we have an agreement so that I may attend to some other ..."

So he is saying: that is as far as I am prepared to go in this matter, and then if one goes up I think we have Mr Beighton says: yes, we have an agreement, if we can go up {XG/24/1}:

"Many thanks for this ... I confirm that we have an agreement on the basis of:

"January 1st £40

"April 1st £35

"October 1st £30."

PROFESSOR WATERSON: Can I just ask, Mr Brealey, so he anticipates further reductions afterwards; what was the basis for that, do you know?

MR BREALEY: Again, the straight answer is I do not know. I have seen -- and we will come on to this -- a response to section 26 request, response by the Department of

Health, saying they thought it would mean that, as competition came in, the prices would go down. So they do not actually interpret that as getting an agreement to have any further reductions, the price would come down. That is one answer, but the other answer is that whether it is this gentleman, Mr Otton-Goulder, or somebody else, they fixed that £30 consciously, fixed that £30, and we will come on to the evidence of that in a moment.

So how it was going to go down we do not know. We will come on to the CMA's reference to an oversight, which in my submission is not credible when one looks at the evidence, but what we do know is after this meeting, this £30 was fixed and notes were put on the system: this is a fixed price. There was a conscious decision to do that.

THE PRESIDENT: Mr Brealey, I appreciate it is going to be corrected, but looking at your diagram {XJ/52/5}, we can see the fall to £30 in the dotted green line.

MR BREALEY: Yes.

THE PRESIDENT: And then it remains constant at £30 until around March 2016.

MR BREALEY: Yes.

THE PRESIDENT: So whatever was the intention, it certainly wasn't followed through because for the five-year period

from October 2008, we have a rate of £30 --

MR BREALEY: Yes.

THE PRESIDENT: -- which stays constant.

MR BREALEY: And that remained a price signal to the market. Undoubtedly the £30, the drug tariff price is a price signal to the market because the market benchmarks off the drug tariff.

Now, there is a factual dispute, the CMA relying on an answer by the Department of Health saying it stayed at that level because it was an oversight. We say that is not supported by the evidence, and the evidence shows that a relevant person, perhaps Mr Otton-Goulder, we do not know because the Department has never come to the Tribunal and give evidence, hardcoded it, fixed it consciously, and we will see the evidence on that in a moment.

Can I go to another document that was not disclosed which is a highly relevant document. This is not a contemporaneous document, but this is what Mr Otton-Goulder said to his colleagues when faced with a section 26 request. Mr O'Donoghue says it is eight years, not five years.

Can we go to {XG/278}. This is a section 26 request by the CMA. If one goes to page {XG/278/5}, we do not have to read it out, just to note that the CMA is asking

the Department for information about capsules, and then if one goes to page {XG/278/6} we see the CMA asking the Department some detailed questions about the tablets down at 12 and 13 because by this time, June 13, the investigation had been begun and the parties were saying: we benchmarked this by reference to the tablet. So that is the question.

If one goes to {XG/284}, if we go to page {XG/284/3}, it starts at the bottom with the OFT/CMA sending this section 26 request that we have just seen to the Department:

"As discussed with your colleagues on the telephone ... please find ... a formal Notice from the Office of Fair Trading ..."

THE PRESIDENT: So this is OFT to the OH?

MR BREALEY: Correct, yes. What we just saw, the actual request at {XG/278}, that request was -- at the bottom here, that is the request that is being sent.

Then there is a delivery failure.

Then if one goes to page {XG/284/2}, this is passed on, and it is passed on by a person called Susan Grieve who is one of the chief pharmacists, and you'll see her name in quite a few of the emails, but you will see her -- it is:

"Confidential ... request - Phenytoin Sodium

Capsules..."

And then you will see in the middle:

"Mat

"I have specifically sent to you as they ask about the tablets, we will need a contribution about your activities in 2005!"

Actually it is 2009. So he is being asked what happened about the tablet because he is the person who reduced the tablet price.

Then page {XG/284/1} gives his response. He says:

"Susan,

"Sorry, I've been distracted by other matters. I have resisted the temptation to look out the mathematical underpinning of my original category M design ..."

I do not know whether that is what he was thinking about how it was the £30, but that is:

"... the mathematical underpinning of my original category M design and simply demonstrate the inevitability of the phenytoin instability."

He then goes on -- he says:

"... I am working from memory but ... I have confidence in my recollections."

Then he goes on to give his response about the tablet, and if I just ask the Tribunal to read that and

then I will emphasise two or three matters.

THE PRESIDENT: Beginning "the department of health introduced ..."?

MR BREALEY: Correct, yes, please. (Pause)

Can I emphasise a couple of things that arise from this? First at the top he says:

"I do not have access to the relevant documents."

So he is of the view, at least at this time, there are relevant documents.

The second he is also confirming, and this is seven lines up from the bottom, where he again he is referring to this waterbed effect:

"All that was happening was increased expenditure on phenytoin was balanced by reduced reimbursement prices across the rest of category M products."

So again, when one is making a submission that the NHS has somehow -- the extra cost, the NHS has lost out, what is happening is this waterbed effect and this is again something we may have to look at.

"Nonetheless [he says], the distortion was an irritation and at a meeting with Teva it was agreed to reduce the reimbursement price over a period of several quarters. The alternative of ejecting the company from membership of Scheme M and then enforcing a maximum price by direction of the Secretary of State was

considered a less attractive option."

And in my submission that, that last sentence, the alternative of ejecting the company from membership of Scheme M and then enforcing a maximum price by direction of the Secretary of State, clearly supports what Mr Beighton told the Tribunal in the previous proceedings when he said: I distinctly remember the mention of the Secretary of State and we can fix the price that we want.

So this is all -- I am trying to put the pieces of the jigsaw together because it is sometimes said: no, no, no, no, the meeting was a bit of an informal meeting, we just agreed to it. There is some teeth to why Teva agreed to do what it did: it was basically threatened.

Now, what is lacking in this answer is his reference to his letter which is it gives value -- the £30 gives value to the NHS. He does not mention that.

I am going to run out of time, so I am going to give the Tribunal, if I can -- it will just be on the record -- I am going to give some references because I could go to some other documents but there is a lot to get through.

So after this what happens is {XG/288} we can probably go to that, I can just explain what is going

on, {XG/288}, Susan Grieve, I think, asks: can you give any more information about the tablet. He says:

"There was nothing in writing."

At the top. Well, clearly there was something in writing because we have just seen the email of 17 October.

And for the Tribunal's note, the combination of {XG/290} and {XH/21} is the Department's response, and maybe we should quickly go to that. So {XH/21/15}, and this was the Department's response to that question 13, and it comes up with:

"As Teva is a member of Scheme M, according to DH's current view ..."

Well, no one on our side has ever understood the legal position as they did not have any powers, but that is by-the-by now, that is (i).

If one goes over the page to {XH/21/16}, that is the sum of the response by the Department to the CMA, or the OFT, on the tablets.

THE PRESIDENT: So this is a response to the section 26 notice we saw earlier?

MR BREALEY: Correct. And in my respectful submission, that is woefully inadequate on such a key issue as why was the £30 tablet price fixed as it was. That is the sum of it.

THE PRESIDENT: Just so that I know Pfizer's position, when we see Scheme M and its operation as a control on price, you cannot give us any details as to how Scheme M worked in a granular way. You can obviously give us the headline prices, but in terms of how those prices were calculated, that is not something that Pfizer can assist us on?

MR BREALEY: Well, Mr Beighton came up with £40, because I think his evidence was: I still want some money out of this, and we will have a look at Teva's costs in a minute. So he came up with £30, but the Department comes up with -- insists on £30.

THE PRESIDENT: Yes.

MR BREALEY: I simply do not -- I doubt whether it is a finger in the air. I mean, these two gentlemen are charged with protecting the NHS and giving value for money as Mr Otton-Goulder says.

THE PRESIDENT: I am sure that is right, but in terms of what you can do to assist us in the granular calculation, it is nothing.

MR BREALEY: No. We could have, had we got the evidence from the Department of Health, with a witness statement, we may then have got into the weeds of what it was all about.

THE PRESIDENT: Mr Holmes, just so that we understand what

the CMA know, is it as opaque -- this is not a criticism of anyone -- to the CMA how Scheme M worked?

MR HOLMES: Sir, can I just make sure that I have understood? There are three separate things which I think one needs to separate out to make sure that we are not at risk of talking at cross-purposes.

THE PRESIDENT: Of course.

MR HOLMES: Firstly, there is the question of how the £30 was arrived at during the discussion between Teva and the Department of Health, which I think Mr Brealey referred to in his response to your question.

Now, as to that, we cannot assist you, it was something that was discussed at the meeting in 2007. Mr Beighton's evidence was not controverted by the CMA, and it was basically accepted by the Tribunal in the first judgment. So there is no real issue in relation to what Mr Beighton said about that meeting, but the figure I cannot assist you with. It was a process of reduction and as Professor Waterson noted in the contemporaneous emails, it appears as though the expectation was that prices would continue to fall from the £30 point, but they did not in fact fall because they were hardcoded into the spreadsheet as a result of what was later described, I think by the CMA, as an oversight, by DH as an oversight.

There is then the question of how Scheme M operates. Well, Scheme M is the scheme, the voluntary scheme, which generic suppliers may join. It is the analogue of the PPRS which is the voluntary scheme available to those selling branded products, and among the terms of Scheme M is an agreement to supply cost information to the Department of Health which is then used under category M of the drug tariff to calculate the drug tariff price.

As you saw from a document a little while ago, there is a degree of deliberate ambiguity in the precise mechanism whereby that price is set, as I understand it to prevent the risk of gaming, because there is, I think, some risk of gaming in the way that pricing is prepared or set by pharmaceutical companies, I can try to provide you with more detail of that.

It was something I think that Professor Waterson may recall better than I, but I think it was something that was discussed in the course of the Liothyronine trial, and I think there was a slide deck that was prepared by the Department of Health to shed a bit of further light on it which we can dig out if that would be helpful.

MR BREALEY: Can I move on because we are short of time? Thank you. Unless there is any questions on it?

THE PRESIDENT: Well, what I am getting from that is that

the £30 is an output of Scheme M, but it is an uncertain output in the sense that you know that certain costings go in but how the output price is produced is something of a black box.

MR HOLMES: The £30, to be clear, was a bespoke negotiated figure between the Department --

THE PRESIDENT: Yes.

MR HOLMES: So that £30 was not the product of the ordinary operation of category M. Category M takes data from Scheme M on a market-wide basis by generics who produce a particular product and from that is calculated the drug tariff price, and that is category M, but the £30 price was not the result of that ordinary process of calculation which applies using ASPs and data provided by Scheme M members in relation to a particular product.

THE PRESIDENT: Fair enough, but that may be a distinction without a difference if you are saying that there is a creative ambiguity in the calculation of the drug tariff price in Scheme M using category M data. If you do not know how it is done, then you might say that the £30 is produced in exactly the same way.

MR HOLMES: I understand, sir. It is not as opaque as that.

THE PRESIDENT: Right.

MR HOLMES: There is a little bit of grit, I think, in the

way that the prices are arrived at, but 6.161 of the Decision provides something of an overview. It is at {XA1/1/284}. You see at 6.161:

"During the Relevant Period, category M reimbursement prices were set on a quarterly basis using volume-weighted ASPs [the actual selling prices in the market] based on retrospective sales and volume data supplied to the DHSC by manufacturers and suppliers who were members of Scheme M."

That was the connection between category M and Scheme M.

THE PRESIDENT: So that is referring to sale prices, not cost?

MR BREALEY: Yes.

MR HOLMES: It is. Costs are also collected under the terms of Scheme M and we can show you the terms of Scheme M. I do not know if we have the reference -- the booklet which contains the principles under which Scheme M operates. I can show you, but the category M price which is, if I rightly apprehend, the one that you are interested in, the way in which that is calculated in broad fashion is set out in 6.161. The same point is made for your note in 2.162.3 of the Decision which also explains this volume weighted ASP point.

THE PRESIDENT: But if push came to shove and we were

interested in how a price -- do not worry about the time, Mr Brealey, we will make sure you can catch up -- if we were interested in a non-£30 price as something just in category M elsewhere, we said we want to know exactly how this price was calculated, that is not something which is within the CMA's understanding.

MR HOLMES: Sir, broadly speaking it is calculated by reference to retrospective sales data, ASPs and volumes, the ASPs are weighted according to volume of Scheme M members and that is the main mechanism.

There is, I think -- excuse me, can I just take instruction on one point? (Pause)

MR BREALEY: We will come on to some documents, I think.

MR HOLMES: Yes, the two points have helpfully been clarified. The first is there of course then a pharmacy margin which is added to the ASPs to take account of the amount of money which the pharmacy sector is understood to need for the purposes of distribution, and that then sets the reimbursement price, the drug tariff price which is the price that is paid -- reimbursed to pharmacies for dispensing category M medicines.

The second point is my recollection -- and we will find you chapter and verse on this -- is that there is a slight element built into the scheme to prevent a reverse -- a precise reverse-engineering of the

figures, but broadly speaking, the figures are the result of the weighted ASPs of Scheme M members, retrospective sales data.

THE PRESIDENT: To what extent -- it may not be at all, but to what extent is there a thinking that the pharmacies will be able to increase their margin by selecting between competing products within category M so that they can make use of the competitive features of a market which may or may not exist?

MR HOLMES: Yes, so again, this is my understanding and I will correct myself if I get any of this wrong, but the underlying purpose of category M is that pharmacies will buy the cheapest available product that they can of a particular type. That will bring prices down as a result of negotiation. That will be reflected in the average selling prices which will in turn lead to the drug tariff falling. So that is the sequence, if you like.

The competition to win the business, the pharmacies pulls down the ASP, the ASP data then reduced the drug tariff, which will fall subsequently, and so the NHS will benefit from that competitive process to supply pharmacies.

THE PRESIDENT: That will mean that the incentive on pharmacies to change supplier in order to get a better

price is somewhat attenuated because the drug tariff which sets the rate at which they are reimbursed will follow the market down.

MR HOLMES: But they get to keep, subject to a clawback arrangement, they get to keep the difference between the drug tariff and the actual price at which they purchase from suppliers.

THE PRESIDENT: I understand, but that will be an interim benefit because in due course the ASP, which is what they pay to the provider of the drug, would inform the drug tariff price which will then go down, thereby reducing the reimbursement rate in the future.

MR HOLMES: But their incentive is to take the best price they can now they are competing to achieve cost efficiencies.

THE PRESIDENT: Yes.

MR HOLMES: And of course where this works well over time, generic competition will produce a continuing fall in ASPs down towards efficient costs of production as generic manufacturers compete with one another to win the business of pharmacies, and so pharmacies subsequently may still be able to achieve a beneficial gap between the drug tariff and the ASP that they receive, and the general pattern is that ASP pricing of course has to be some way below the drug tariff because

pharmacies need to be able to make a profit on the difference between the ASPs they pay and the reimbursement price that they obtain.

THE PRESIDENT: But if the system is working properly, you would not want the margin of the pharmacy to vary dramatically over time. That is not the intention.

MR HOLMES: First of all, insofar as pharmacies obtain large gains as a result of this process of downward competition, there is a mechanism called the clawback whereby money can be recovered from the pharmacies by way of an adjustment to the drug tariff periodically so that over time it is hoped that there are not very large gains to the pharmacies which do not get passed on to the ultimate paying purchasers, the NHS procurement bodies, the CCGs.

THE PRESIDENT: And is that clawback referable to individual drugs, or is it referable to, as it were, a basket of drugs all of which are reimbursed under the drug tariff, so that you are looking at the margin across either the whole or a significant part of a dispensing pharmacy supply?

MR HOLMES: My understanding is that it is a fairly rough and ready mechanism that is market-wide so it applies to sales across a large number of products and equally it applies across the piece to all pharmacies. It is not

calibrated by reference to any individual benefits that particular pharmacies obtain.

Now, sir, I am conscious of the time that I am taking out of Mr -- and I apologise for that. If any of that requires further elaboration or correction perhaps I could pick it up when I come to make my submissions.

THE PRESIDENT: I am very grateful, thank you, Mr Holmes.

Mr Brealey, do not worry about the time. We are very conscious that we are learning and --

MR BREALEY: Yes, it is complicated.

THE PRESIDENT: -- you will not lose as a result, we will make sure that there is time tacked on.

MR BREALEY: A couple of documents that essentially broadly support what Mr Holmes has just said. I do not know if you want the break. I mean, we started late, I would prefer to go on --

THE PRESIDENT: Why do you not go on until you reach a natural break and then we will rise for a few minutes, but in your own time.

MR BREALEY: Let me deal with a couple of things and shall we break at 20-past?

THE PRESIDENT: That is fine.

MR BREALEY: Just while we are in the flow, if we go to {XH/152} which is a Department response dated 19 January 2021. If we go to page {XH/152/2} we see the

answer to question 3(i) and 3(ii) if you could just blow that up but keep the question.

So:

"During the period ... please explain what the DHSC would have expected to happen to the Drug Tariff price of a drug within Category M ..."

Which is I think what you were just saying, sir, and the Department's answer is:

"If the average selling prices of a product within Category M decreased over time, we would expect the reimbursement price of the product to gradually reduce to reflect the decrease in the average selling prices."

So that is how the Department essentially makes savings because prices go down.

Then 3(ii):

"If the average selling prices of a product within Category M decreased over time, but the reimbursement price did not reduce, this could be explained by an upward adjustment made to the medicine margin to deliver the agreed funding envelope under the Community Pharmacy Contractual Framework."

So it may well be that the Department does not decrease the product, the price of the product, because one is looking at the half a billion or the 800 million amount of money that is given to the pharmacists to

dispense drugs. So that just maybe explains a little bit what Mr Holmes was saying.

What I want to do, though, is to emphasise that this £30 at this time was fixed, and can we go to pages {XH/152/6-7} of this response, and this is the answer to question 6, at the bottom. So it is being asked what happened and in 6(a) the Department says:

"It is not possible to determine precisely how the fixed price of £30 was maintained, ie automated or manually. A spot check of each quarter's model from July 2010 to January 2013 confirmed the Category M calculation model had a £30 value for phenytoin ... hard-coded [into] relevant cells, plus notes specifying that phenytoin was a fixed price. This may have stayed the case if the model user updated the formulae around the cell, or if the formulae were updated in all cells and the £30 manually hard-coded back into the relevant cell in accordance with the note."

So we have the Department here, they do have -- we see here -- and this is quite important. There is a category M calculation model had a £30 value for phenytoin, so there was an acknowledgement here by the Department that there was a category M calculation model which had a £30 value for phenytoin, and then that was basically set as a fixed price, so it was an exception

to what normally happens in category M.

Then over the page:

"Once phenytoin's price had been fixed at £30 this was continued in each subsequent quarter in accordance with the notes added [the notes added] to the Excel working file by previous users that phenytoin had a fixed price. The note added by the previous user did not include explanation as to why the price was fixed ... which circumstances the price fix should be stopped or be reviewed."

To a certain extent that is not anything to do with us; that is internal to the Department who have got a calculation model. We see that that calculation model refers to a £30 value, and it is fixed. We know it has been fixed. There is now a dispute between the parties, the CMA and the appellants, as to whether it being continued to be fixed in accordance with the notes on the file was an oversight or not because the Decision, for the first time, refers to it not coming down because of an oversight. I just want to address the Tribunal on that.

The CMA skeleton labours this so-called oversight at length. Maybe we can just go to that. I had other passages to go to, but let us go to the skeleton. That is {XL/3} because repeated references are made that

the £30 is not a valid benchmark because: well, it was an oversight; it should have come down, but it was an oversight.

So go to {XL/3/16}, this is the skeleton, paragraph 29(a), we see there:

"The Tablets ... price of £30 was ... above the actual ASPs being charged ..."

There is no time given there.

"... in part due to an 'oversight' on the part of the DH."

Well, okay. Go to page {XL/3/18}, paragraph 31, the penultimate sentence:

"This £30 price was then hardcoded into Scheme M and did not fall further when selling prices fell following generic entry (as it should have done ...), due to an administrative 'oversight', until 2016."

Again, assertion as a fact this was an oversight.

Two more references --

THE PRESIDENT: Where does the quote "oversight" come from?

MR BREALEY: We will see that in a moment. It comes from a response by the Department, and it is another case, we say, of an opinion by the Department being elevated in this document to a statement of fact, but the quote is the word used by the Department, but we shall see that as a matter of fact it is incorrect to say as a matter

of fact it was an oversight. So that is 31.

Go to page {XL3/22} paragraph 43(b). Again, the skeleton labours this oversight:

"The contention is unsustainable ... the DT price remained at £30 due to an 'oversight'."

It is an assertion there that it is a fact.

Then lastly page {XL/3/23} paragraph 44(b) we see there:

"... the benchmark remained where it was due to an 'oversight'. In the circumstances, its a particularly inapt one."

Well, in my submission that is misplaced, first because it wrongly asserts the oversight as a fact, and second, the oversight is not supported by the evidence.

So where do we get this oversight from? Can we go to {XH/99} page {XH/99/7} in the middle of the page. We see this is where the oversight comes from. The question to the Department is:

"The drug tariff reimbursement price for Tablets remained stable at £30 ..."

Essentially why:

"This setting of the price was inadvertently continued for longer than originally intended due to oversight as the detailed calculation of the tariff was transferred between new ..."

So just an assertion there, due to an oversight.

If one then goes to {XH/152}, because the Department was pressed on this, page {XH/152/7}, and I will just finish this and then we can break. Blow it up a bit, if you could, page 7. You see what actually was said.

So the CMA is saying to the Department, setting out its answer:

"As per our answers ... the note added to the Excel working file about fixing phenytoin tablets' reimbursement price at £30 did not include any explanation as to why the price was fixed, when/in which circumstances the price fix should stop or be reviewed. Therefore, we expected it was inadvertently carried out for longer than the person, who initiated the price fix, intended as we would have expected the reimbursement price ..."

Now, first of all, it may be a subtle distinction, but it is an important one when it comes to evidential weight. "We expect it was an oversight" is different from a statement from any relevant official with relevant knowledge that it was an oversight.

Looking at -- basically what is being said, in our opinion looking at what happened, we expect it was an oversight. That is not the same as "it was an oversight" which is the way it is put in the skeleton,

particularly when we see there was a conscious decision to fix it on a continuous basis and people have been looking at this, looking at the notes.

So that is the first thing. There is a subtle distinction between "we expect it was", "our opinion is that it was an oversight", as compared to "it was an oversight" which is almost a statement of fact.

But secondly, it is not borne out by the material because if one goes to {XG/304}, this is a contemporaneous email again from the same Susan Grieve. If one looks in the middle where she is talking about the tablets and blow it up, that paragraph:

"That said, the current reimbursement price for these tablets is a category M product which means there is probably considerable margin being pumped into the reimbursement price over their selling price ..."

So in November 2013, the Department knows full well that there is a gap between the £30 and the ASP. So when one looks at all the evidence to say that all this was an oversight rather than some sort of conscious decision. It is inappropriate for the CMA to put forward the oversight as a statement of fact. The documents support the fact that the notes on this calculation, on this Excel, there was a conscious

decision to fix it. They knew in November 2013 it was not coming down, and the weight of the evidence is it was not an oversight, this was a conscious decision. They changed their mind in 2016, but to say that all this was an oversight, in my respectful submission, is misplaced.

We can break there.

THE PRESIDENT: Thank you, Mr Brealey. We will resume then at half past. Just so that you know, we will try to run until 1.15, give you an extra 15 minutes.

MR BREALEY: That is brilliant, thank you.

THE PRESIDENT: And perhaps people could think about whether they can bear a half-hour lunch break and we could resume then at 1.45 which would give you half an hour, but I am conscious that you are all under a lot of pressure.

MR BREALEY: We lost a bit of time, and time was extremely tight anyway.

THE PRESIDENT: I do understand. If there is a difficulty, then let us know, but we will try and claw back half an hour in that way.

MR BREALEY: Thank you.

THE PRESIDENT: Until half past.

(12.20 pm)

(A short break)

(12.37 pm)

MR BREALEY: Sir, I understand we need a 45-minute break for the transcript writer.

THE PRESIDENT: That is understood.

MR BREALEY: I have given the option and I think if we can go to quarter-past and then --

THE PRESIDENT: Resume at 2.00.

MR BREALEY: Yes.

THE PRESIDENT: And we will see how far beyond 4.30 we can go.

MR BREALEY: Of course, thank you.

I have taken things a bit more shortly.

Can I just go back to {XH/152} and then essentially we will complete this £30 drug tariff.

So just go back to pages {XH/152/6-7}. In fact it is only page {XH/152/6} actually, I think we need. At the bottom that is the answer that the Department gave. This is:

"... the Category M calculation model had a £30 value for phenytoin ... plus notes specifying that phenytoin was a fixed price."

That, we say, was a conscious decision by the Department and the Department has never put a witness statement in or anything to explain whether this was an oversight, and I add this word "oversight" only appeared

in 2020 some ten years or seven years after the investigation, but we are entitled to rely on that at face value.

Then if one goes to page {XH/152/7-8}, please, it is the answer to 8(a).

We see --

MR HOLMES: Could you look at 7(b) as well?

THE PRESIDENT: The oversight, 7(b), yes.

MR HOLMES: If the Tribunal could read that.

MR BREALEY: This is all very... :

"We believe that the oversight was first discovered in a meeting with the CMA who pointed to us that the reimbursement price of phenytoin tablets had not [charged] for years. After it was pointed out, the policy team queried it with the analytical team who explained that they were instructed to maintain it at £30 ... without any explanation as to why the price was fixed...

MR HOLMES: "... when/in which circumstances the price fix should ..."

MR BREALEY: "... should be stopped or reviewed."

So I mean, I always thought that was totally bizarre that it is the CMA saying the parties are saying this is still being -- you are still reimbursing at £30, how can that be? So there is a discussion between the CMA and

the Department, and after the CMA have pointed it out then they turn around and say: ah well, maybe, and so they have unfixed it.

Importantly, 8(a) and 8(b) on the right-hand side, we see:

"... the ... reimbursement price ... was gradually and fairly equally reduced over a year ... first the analysts would calculate what the reimbursement price would have been if phenytoin tablets were included in the usual process ..."

So the Department have analysts who would have been able to assist us how they arrived at the £30 valuation, and I emphasise the answer to 8(b) because the Department is asked: well, why did you do it gradually, and the answer is:

"This was to ensure that there were no sudden changes to the reimbursement price which could have adversely affected the market."

Now, why is that important? It is important because the market does rely on the reimbursement price. The market relies on the drug tariff price, and we will look at two instances where we see this generally and then we will come on to it specifically.

So if we go to the *Liothyronine* judgment at {XN2/28} and page {XN2/28/84}, why does this matter, this public

drug tariff price, why does it matter? We see here the CMA in the *Liothyronine* Decision and the Tribunal agreeing with the CMA, that:

"... market participants will often take the Drug Tariff as a reference point."

Very important for the context in this case:

"... market participants will often take the Drug Tariff as a reference point."

So that is what the CMA said in *Liothyronine*, we did not really get that in the last proceedings, I have to say, it is only subsequently the CMA have acknowledged this, and the Tribunal have acknowledged it.

Also go to {XG/474}, page {XG/474/2} paragraph 11.

This is the CMA, AG is the CMA asking Teva, so:

"Whilst acknowledging that generic prices would depend on prices that competitors were charging, AG asked [that is the CMA person] if, as a starting point, Teva priced its products by offering a standard discount against the drug tariff as we understood [this is the CMA understanding] other firms priced as between 10 and 12.5% below the drug tariff."

Teva says:

"... can agree to lower its price ... other times when it cannot."

I emphasise paragraph 11 though because it is the

CMA acknowledging from its investigations that firms price at between 10 and 12.5 below the drug tariff, and that is why this £30 is so important: it is a reference point.

Given the time I will now move on to when Wockhardt entered in October 2009, and if we go to {XH/144} the first point to note is that Wockhardt benchmarked, when it entered it benchmarked by reference to the £30 reimbursement price, and we see this, page {XH/144/1} paragraph 4.

So when Wockhardt entered in 2009, October 2009, what did it benchmark its price by? The £30 drug tariff for the tablet:

"DG said Wockhardt would have made a decision to offer Tablets at a price of around [drug tariff] minus 20%. That level was not a pricing rule for the generics industry, but when there are two players in the market it means there is margin for the wholesaler, retailer and Wockhardt."

If one goes to page {XH/144/3}, paragraph 19, and blow it up, we see a similar thing:

"For a unique generic product where Wockhardt was the only supplier, Wockhardt would tend to price at 15% below the [drug tariff]. If there is more than one player, Wockhardt would tend to price at 20% below the

DT price. This was a rule of thumb based on whether Wockhardt's product was a unique generic or not."

But the important point to note is that, with great respect, the CMA tries to trash the £30 drug tariff price, says it is irrelevant, and yet all the documents we are going to have a look at in the next two or three hours shows how all the market participants are having regard to the drug tariff price. They benchmark their prices by reference to the drug tariff price.

So the first point is that they benchmark by reference to the £30. Let us have a look to see how Wockhardt competed with Teva when they entered in 2009. So we can continue with {XH/144}. Just have a look at paragraphs 14 and 15, it is just up a bit {XH/144/2}:

" ... feedback from buyers would be discussed at [the] sales meeting ...

"... would have a dealing price, with some price movement possible ... for example, the dealing price could be £25 ..."

So that is essentially its pricing decisions. We see it is benchmarking by reference to the DT.

Then if one goes to page {XH/144/3} at paragraphs 21 to 33, I have not got time to read all this out, but the relevant paras are 21 to 33 where Wockhardt describes how it would compete with Teva when it entered. The

bright line points are it is highlighting short-line wholesalers, it says that the incumbent Teva was going to have to give some market share away, and at the end, Wockhardt had more diversity of accounts.

But the important point here -- and this is 2009, 2010 when it is just Wockhardt and Teva -- the important point is that Wockhardt is posing a competitive threat, clearly competed with Teva, it targeted short-line wholesalers, as well as the larger ones, and was focused on winning market share, it actually obtained 23% market share, and clearly there was switching, and importantly, as we shall see now, price was the main reason for the switching, but those paragraphs are the note of the call between the CMA and Wockhardt as to Wockhardt -- how Wockhardt competed with Teva in this early period.

Again, as we have seen from other cases, these short-line wholesalers are very price-sensitive and are far more prepared to switch than maybe other larger pharmacies who have got chief pharmacists.

But there was clearly, in my submission, a significant competitive interaction between Teva and Wockhardt in this early period, and before the break we will look at the documents.

If we can go {XG/49}, if you blow it up, I am going to refer to several documents where we see

contemporaneous evidence about how Wockhardt competed with Teva. This is a Teva email of 5 November. Sigma is a short-line wholesaler.

"I have visited Sigma today and Wockhardt are now selling Phenytoin at £26.50."

Wockhardt you will see from this is selling at £26.50, and Sigma, the short-line wholesaler, says it will make less if it continues to buy from Teva at £29.25. So we see two prices there: Wockhardt has gone in at £26.50, and Teva was at £29.25 with a short-line wholesaler.

PROFESSOR WATERSON: So Teva is actually charging a price very near to the reimbursement price there.

MR BREALEY: Yes, yes, at this time, and I do not know whether that is just to the short-line wholesalers and whether it would have a more generous price to, say, Alliance or AAH, but certainly, yes, it is a 50p -- very close to the £30 here.

Now, whether that is its list price, because it may well be that that is Teva's --

PROFESSOR WATERSON: Well:

"... if he continues to take out product at £29.25."

MR BREALEY: Yes, and I have not shown you Teva's cost of goods yet because we have not had time, we will have to do that at another time, but whether that £29.50 is --

would be discounting against that, I do not know from this document. But, yes, £29.25, that is 75p versus £26.50.

We see here he took on -- the last sentence of the main paragraph:

"He took that on board but the way I read it they do not really care too much [this is about sticking with the same brand] as price is a [great] motivator."

"Price is a [great] motivator", that is the last few words of the main sentence.

Another example {XG/50}, the next document. Blow it up, please, Teva email of 10 November 2009. Can we start at page {XG/50/3}. This concerns Lexon and Lexon, as we know, is a large regional wholesaler:

"Attached are the lines that are of concern ..."

We can read it.

Then the last sentence of the paragraph:

"I have also included the Phenytoin as Wockhardt are offering a better price and as per all my customers are not really concerned about the ethical issues here. Price is king as they say."

If we go to {XG/50/2}, this is a Teva document you remember, where the question is:

"Do you have a feel for the volume we would lose...?"

Then page {XG/50/1} the account manager -- and Lexon is a very large wholesaler. Page {XG/50/1}, again, if you can every time blow it up, please, just go down the page. He said:

"Also the Phenytoin issue of great concern as I have already been told that I will lose some, if not all eventually, to Wockhardt. Main areas for me are both Lexon and Sigma."

So these are just some of the documents that are on the file, but it is giving the Tribunal a flavour of the competitive interaction between Wockhardt and Teva at this time.

Go to {XG/52}. This is another Teva email, it is dated 3 December 2009. It concerns a company called Peak. Go to page {XG/52/2}. Do not blow it up because we do not see the whole page, I am afraid.

So this concerns Peak and December prices, and then if you go to page {XG/52/1}:

"I need to talk about this -- he does not know the customers or the market. If we carry on like this we are going to lose goodwill that I have spent years building ... and that goodwill is profit to the company."

So what has happened is basically they say: Wockhardt, who are they? They are not going to

steal a march on us. The person on the ground is saying: well, actually, I am very concerned by Wockhardt:

"If we carry on like this [not matching their price] we are going to lose goodwill that I have spent years building up..."

Again, it shows what happens when a competitor enters the market.

{XG/167} concerns another pharmacy chain Prinwest. Teva is saying:

"Phenytoin [you see there] - Need to compete with Wockhardt to gain share of the product."

Just one last one on Teva and Wockhardt {XG/165}. This is an email of 16 August 2012 where Teva is putting forward a defence plan, a defence plan. For some strange reason, the CMA seem to say that this document shows there is not workable competition or effective competition. We would say this is a prime example of Teva trying to retain/gain market share. It is a defence plan.

I am going as quickly as I can. How does the Decision describe the position? If we go to the Decision {XA1/1}, at page {XA1/1/324}, these are the paragraphs in the Decision. I am not interested in the submissions in the Decision, just the key facts at the

moment, and the relevant paragraphs are 326 to 327, so 6.326 to 6.327. Those two paragraphs are where the CMA sets out what it considers was the effect. We see at the top of that page:

"Period 2: October 2009 to August 2012 ..."

So the CMA calls this period 2 which is when Wockhardt entered, but we see the CMA acknowledging a competitive interaction. Wockhardt acquired a 23% market share. The CMA acknowledges that Teva's ASP had fallen from what we just saw, maybe £29.25, to £25.34, so it has come down to £25.34, and then £21.90 in August 2012, we see this from here, and we see that Wockhardt's ASP of £29.05 had also fallen to £1.18 but averaged out at £25.82.

So that is the effect of the competitive process in this early period.

THE PRESIDENT: We are probably going to come to it, but to what extent is the tablet competition affected by the continuity of supply question? What we see in the Decision as regards capsules is that there is a manufacturer-specific imperative, putting it a little high, to stay with the same manufactured tablets which of course are capsules, which of course is going to affect the ability to shift between one provider and another.

That seems to be of less force in the context of tablets.

MR BREALEY: No, not at all, sir.

THE PRESIDENT: Not at all; it is the same?

MR BREALEY: Remember we laboured at length. NRIM, the capsule manufacturer acquired something like a 50% market share in six or seven months, and we said that was evidence of switching, which it clearly was. So NRIM captured a very large market share, and one of the reasons the Tribunal sent it back last time was because, if one looks at the tablet market and the competitive interaction there, then you cannot necessarily say that the capsule market would have been any different, because the two are the same, the guidelines are exactly the same. That is why I was going to start off with the tablet, but maybe Mr Johnston will do it. The tablet and the capsule chemically are the same, the guidelines apply the same, and we would have the same -- we just saw price is king, short-line wholesalers do not have the same ethical issues. Everything that we see here would have applied to the capsule.

One of the things that happened to the capsule of course is that the investigation started, and the CMA -- and we put a paragraph in our notice of appeal -- the CMA accept that when an investigation starts, it

slightly mucks up the market a bit because people do not really know what to do, but the short answer to the question is there was lots of switching interaction here and there was very similar evidence in the prior proceedings regarding the capsule.

THE PRESIDENT: That is helpful. It gives rise to a further question which I think I would like the parties to think about rather than to get an immediate response, which is to what extent is non-switching between capsules embedded in the parts of the anterior decision of the CMA which we cannot look at, I am thinking particularly of markets definition which is, as I understand it, linked to manufacturer-specific capsules, and I had always understood, but that may be my mistake, that the reason the markets definition is fixed to Pfizer-manufactured capsules is because of the continuity of supply. That seems to be the only explanation why you would define the market in that way.

Now, that may be wrong, in which case the point evaporates, but there may be some form of interaction between the markets definition question which is not open for us to look at again, and the question of continuity of supply where you are saying it is the same for tablets as it is for capsules.

MR BREALEY: I do not think it really matters because why

are we looking at all this? It is to see whether the capsule price is a fair price, and we are doing it by reference to the tablet market. So that is an independent market, the CMA regards the tablet market as an independent market, and so what we are doing is we are saying: well, look, the £30 was a valid benchmark, these parties are benchmarking by reference to it, there is competition, and what I am trying to do here is look at what prices would be charged in the tablet market and then compare that to the Flynn and Pfizer prices, because this, we say, was a market which was reflective of workable competition, if it was, and it is not limited to workable competition I have to say, we have to look at this more holistically and we will debate this, but let us have a look at the prices that were charged in the tablet market, that is the basis that it was remitted back to actually have a look at everything that I have been doing today, and then you compare it to the price that Flynn and Pfizer charged on launch and on 1 January 2014 when there was a 20% reduction.

So the CMA and their economist say continuity of supply, that means there was no workable competition in this market, in the tablet market, forget the capsule for the moment, no workable competition, they say: look at what happens, there were some limitations on supply,

no workable competition, to which we say absolutely ridiculous because we see during this period Teva's price going down by 60%, and when you look at the interaction of the competition between the players in the tablet market, you see what prices were being charged, in the light of the agreed £30 tablet price, you cannot say, we say, you cannot say that the Pfizer price was unfair. That is the purpose that I am going through this, to show that we have just seen someone saying: price is king, they are not interested in the same ethical issues; there was workable competition. It is a startling proposition when one looks at the documents, the contemporaneous evidence, to come up with competition was not working.

THE PRESIDENT: In this context, the competition is to allow the dispensing pharmacies to maximise their margin by reference to a reimbursement rate that was fixed at the £30?

MR BREALEY: Well, as I understand it, basically what happens is the £30 was fixed, we say it was a conscious decision. They could have reduced it, but they did not because it was fixed. It was not an oversight, it was a conscious decision. What they were doing is they were allowing the pharmacies to obtain a decent margin. That was a conscious decision. They knew that the ASP had

gone down from 30 to 24 to 23, but it stayed fixed, and that was a conscious decision, as the documents that I showed you, the Department realised the margin was being pumped into the pharmacies.

What then happened when they decided to unfix it, we see competition between the tablet suppliers, and the drug tariff price comes down.

THE PRESIDENT: But there is competition on your hypothesis even if the drug tariff rate is fixed because you can incentivise the dispensing pharmacy to buy your tablet rather than somebody else's by ensuring that their margin is greater if you buy yours than somebody else's. On that basis, the reimbursement rate adds nothing except to ensure that it is the pharmacy rather than the CCG that gets the benefit of competition.

MR BREALEY: Correct, but with the added fact that the £30 still remains a price signal to the market. The market is still looking at that £30 and saying to itself: okay, I might have to compete, I might have to compete with Teva, but we will see when Milpharm enters what does it do? It takes the £30 as a reference point. It soon realises that it has to compete on price because it has Teva and Wockhardt, but both Wockhardt and Milpharm, when they launched took the £30 drug tariff as a reference point, and my simple point, and it will be

a point that I will reiterate again and again, if you consider that the capsule and the tablet are essentially identical, what was so unreasonable for Flynn and Pfizer to do the same?

I appreciate there was a price increase, but Milpharm, Wockhardt enter the market, and they benchmark by reference to the £30 tablet reimbursement price, then they have got to compete. When Flynn and Pfizer did the same, launched it, they did exactly the same as Milpharm and Wockhardt. They took what the Department was saying was the price which reflects value to the NHS. Then you will start having to compete and indeed on 1 January 2014 Pfizer reduced its input price to Flynn by 20% because of NRIM's competition, but that is why the appellants have always been very aggrieved by the CMA trashing the £30 drug tariff reimbursement price because it is a price signal to the market, and that is where you start and then you move on.

I will just finish by looking at what our economist says, Dr Majumdar, we will go to {XE1/5}, then we can break for lunch because he just gives some further -- so {XE1/5}. That is his second report. He gives a little more context for the price increases.

We have had a look at what the Decision does. That is RBB's second -- so go to page {XE1/5/10} at 31. We

can read 31, and then over the page, it is the bullet points I just want to emphasise, we can blow this up {XE1/5/11}. I am looking at period 2 when Wockhardt came in:

"Across the first eight months of 2012 (ie the eight months prior to Milpharm's entry) ... Teva's ASP and the market ... ASP fell considerably (by ... 14%)."

We do not really get that figure from the Decision. The CMA averages it out across the whole of the period 2, but it is important to see in 2012, the first eight months, the ASP fell by 14%.

"Teva's ASP fell from £25.35 in January 2012 to £21.90 in August 2012, while the market-wide ASP fell from £25.86 to £22.35 ...

"Therefore [he says] a process of competition (causing material price declines) had already started in the first half of 2012: competition did not suddenly emerge with the entry of Milpharm; rather that entry led to a faster reduction in prices."

The simple point is that there was a competitive interaction between Wockhardt and Teva in this period 2, and it is important to see first part of 2012 prices falling by 14% and Teva was trying to maintain volume, it was looks volume, people were switching.

THE PRESIDENT: Thank you very much, Mr Brealey. We will

resume in that case at 2.00.

We have done it in other cases, it may not be possible in this, but I suspect we may be stretching the day at either end. It may be, because I am very conscious that the efforts of transcribing these things are onerous, whether one could procure the sharing of the burden amongst two shorthand writers so that the day is shorter. I will leave that with the parties, but it may be that we can ensure that you are not unduly rushed for that reason.

I appreciate it will not be possible today, but for other days it may be a way forward.

MR BREALEY: I will do my best. I know that Mr O'Donoghue and Mr Johnston need to say a few things, but we will work it out.

THE PRESIDENT: We will work it out, but I am very anxious that no one feel under undue pressure of time. I know we are all under pressure of time, but we are assisted by this sort of exchange.

MR BREALEY: That is very fair, thank you.

THE PRESIDENT: 2.00.

(1.14 pm)

(The short adjournment)

(2.06 pm)

THE PRESIDENT: Mr Brealey.

MR BREALEY: Just for the Tribunal, can I hand up those corrected charts? They are the same charts that were -- I think Mr Holmes is happy with them.

MR HOLMES: Yes, so the Tribunal knows, the change is that previously the dashed line was indicated as the tablet weighted average ASP, and it is now correctly labelled as the NRIM ASP, the red line immediately underneath the red solid line. That is the difference.

MR BREALEY: What I am going to do is now deal with Milpharm's entry into the market, and if one looks on the first page in this chronology, Milpharm is just there in September 12, and that is exactly the same time as Flynn and Pfizer launched the generic capsule.

THE PRESIDENT: Yes.

MR BREALEY: The first point to note is that Milpharm benched its launch price by reference to the £30 drug tariff, and so if we can go to {XH/91}.

THE PRESIDENT: We do seem to have a stay on the transcript, it does not seem to be running, so I do not know if there is a problem.

MR BREALEY: Not my day.

THE EPE OPERATOR: Mine neither.

MR BREALEY: Do not worry about it.

PROFESSOR WATERSON: We have a lot of "tests". I think we might be able to get it manually. So

shall we go to {XH/91}?

MR BREALEY: {XH/91/2}.

THE PRESIDENT: Yes, so that is annex 1, starting with the (v).

MR BREALEY: I have not got anything, but it is page 2, an answer to question 3(i) where in my notes it says:

"Milpharm's pricing was based on drug tariff minus 15-25% and individually negotiated with customers on a volume and price basis."

THE PRESIDENT: It does indeed say that, Mr Brealey. Your note is correct.

MR BREALEY: So what has happened, no internet?

THE EPE OPERATOR: Yes, the internet has dropped out.

THE PRESIDENT: Do you want us to rise again?

MR BREALEY: Let us see what we can do. I have my assistant here, able assistant.

So we see there 3(i), this is Milpharm:

"Pricing was based on drug tariff minus 15-25% and individually negotiated with customers on a volume and price basis."

So can I go to {XH/119}. They are all going to be XHs, and it is page {XH/119/1}, paras (a) and (b).

THE PRESIDENT: "By way of background to the documents..."

MR BREALEY: We see there again at the bottom of (a):

"[The] approach ... will be driven by volumes/the

level of market demand ... the Drug Tariff price and prevailing market prices at the relevant time. Milpharm will then offer a price below the prevailing market price (and indeed, [the] Drug Tariff ...) to win/maintain volumes."

We see again here in (b):

"... This means that Milpharm is typically either responding to changes in the drug tariff price or the prevailing market price."

Again, I just want to emphasise that the drug tariff price is an important signal to the market.

Just for the note, we will not go through it because of the problems, they make a similar point at {XH/128} but if we go to {XH/158}, which is the note of a call, so I have bypassed {XH/128} and we will go to {XH/158} to page {XH/158/2} and paragraph 14, this is Milpharm explaining that:

"... one should consider the principles of the drug tariff and how it works ... will categorise products based on the level of competition and that if one oversimplifies it, it is essentially a formula based on average pricing."

This paragraph is important because it is referring to the new entrant. A new entrant will then ask what the drug tariff is because that will inform the price

set. It is very important that Milpharm is saying this:

"[As a new entrant] a new entrant will then ask what the drug tariff is because that will inform the price set, which for Milpharm would usually be around 15 to 20% below the drug tariff ... explained that the market dynamic will then come in through discussion with customers and adjustments based on their response. If the drug tariff changes then it can trigger a change in the generic price. If the price is based on a percentage off the drug tariff the price of the product will follow drug tariff fluctuations."

So again, this paragraph is important because it is referring to the information that a new entrant will have, so when Milpharm entered it entered at £23.63, and that is in the Decision 6.340. One can compare that with £19.84 which was the Flynn ASP, so Flynn was £4 on launch.

Now, obviously things changed, but the new entrant, looking at the 30% drug tariff, Flynn was way below the Milpharm entry price, and the Tribunal asked last time it would be relevant to know what the prices were of the tablet on launch.

So this is important, the drug tariff is used time and time again as a reference point and then obviously it will look at what the customers are saying, etc, etc.

Can I just turn to some documents now which show the competitive interaction during this three-player period, what the CMA call period 3, and just for the note -- well, actually, we are on H, so {XH/144}, can we have {XH/144}?

This is Wockhardt's description, so if we go to page {XH/144/4} we see we start at paragraph 34. So this is a note between the CMA and Wockhardt. At 34, this is where Wockhardt is talking about what Milpharm did, would have challenged its short-line which would lead to price erosion, and then I will not go through it because of the time, but I would ask the Tribunal to note the remaining paragraphs. That is paragraphs 34 to 38 where Wockhardt is describing the competitive process during this three-player period. So that is how Wockhardt describes it. Let us have a look at some contemporaneous documents. So we are going to go to the XG bundle now. So {XG/184}.

Can we go to page {XG/184/2}, please?

This is a Wockhardt email. At the bottom:

"Can you advise what strategy we are taking with the above, and what prices you will trade at when Aurobindo..."

That is the parent company of Milpharm, so that is Milpharm:

"... [at] what prices you will trade at when [Milpharm] launch their Phenytoin in few days time. I am advised that it will be launched at around £10.00 per pack."

And if we go up:

"Yes there is another player in the market. Milpharm have launched with blisters of 28 tabs. I have heard a £10 price from one account but the rest of our accounts are seeing between £20 and £25 ..."

So that is the price at which to Milpharm launched between £20 and £25, and then:

"The company launching ... at times aggressive to the point of being silly ... I would regard £10 as [being] silly. Our customers report back that they are not want to go trash a market but get share."

Then if we go up, please:

"Thanks for the information. You never know when the customers are trying to pull a fast one so it is good to hear ..."

All I say here is 27 September 2012, Milpharm have entered. This is competition working.

Can we go to {XG/194}. We see here this is a Teva email of 11 October:

"As part of our defence strategy on Phenytoin we think we need to maintain our retail volume and

1 therefore we should reduce the price by £1, hate to do
2 it but we are out on price in the market now."
3 And then the response is:
4 "... but we've already signed off on [quarter] 4..."
5 So we do not know whether it happened or not. We
6 know that the Teva price certainly did go down, but
7 again, this sense of Teva: we are out on price in the
8 market now, competition working.
9 {XG/199/3}. Some of these are interesting because
10 it shows the prices that are being quoted: Rowlands is
11 a large pharmacy chain. The best price that Teva is
12 offering at this time now is £23.50. The group price is
13 £17.60, I think that is if the pharmacy takes other
14 products under the Teva 1 scheme, but the specific
15 phenytoin price is £23.50.
16 Then if we go up, we see what has happened.
17 Rowlands have advised that the quote was matched by
18 Wockhardt, and then:
19 "Not unexpected -- by the time Rowlands respond the
20 group price would need to be around £12 ...
21 "Shall we hit them again next week?"
22 "Check if it is on the ... hit list ..."
23 Is at the top.
24 "If we never had Rowlands and they were always with
25 Wockhardt then we may not have targeted them."

Then go to page {XG/199/2}. Sorry, then go to page {XG/199/1}.

"Is Rowlands on your target list for Phenytoin?"

At the bottom.

"No it is not however they pull the stock through Phoenix [that is the wholesaler] so it won't be.

"... she has advised that we have never had [the] business.

"As we have to give Wockhardt some share, may as well leave this one with them."

In my submission that is still competition working. There is a competitive price out there, and Teva having to work out whether to match it, take the business, whatever. It is still competition working.

So they do not go after the Rowlands Phoenix, but you compare this to {XG/216}, Teva email of 29 October 2012.

This concerns Celesio who own the Lloyds Group. This is a Celesio/Lloyds price challenge:

"... challenge last week on the above ... £12.75.

This is from Wockhardt, so Wockhardt have gone in at £12.75.

"Do we already have these volumes and therefore need to defend [this price]?"

The answer is:

"Yes, we ... currently have the volume with all the Celesio accounts [that's Lloyds]...The total volume equates to 25% of our volume ... so definitely need to defend this one."

So again it is defending a price, it is clearly competition working.

I am going through these, I am not going to go through too many, but I do need to emphasise to the Tribunal that we have got these contemporaneous documents, and I am meeting a case from the CMA which says we cannot look at any of these prices because competition is not working, there is no workable competition to which I say is just not supported by the evidence.

Go to {XG/228}. This is a Teva email of 8 November 2012 concerning a pharmacy group Manichem. When one reads, this here we see Wockhardt was countering to get their business back as it looks like Teva had stolen the business. Teva had only just acquired the account from Wockhardt. Teva's decision was to let Wockhardt have the business at that price and "manage price decline somewhat". They are trying to manage the price decline somewhat in the short term best offer same as last month.

PROFESSOR WATERSON: Mr Brealey, what we have seen is that

at the start the prices are up near to the £30.

MR BREALEY: Yes.

PROFESSOR WATERSON: And then they very quickly come down.

MR BREALEY: Very quickly, yes.

PROFESSOR WATERSON: So presumably these companies are all experienced in the industry, so although they may envisage starting at £25 or whatever, they know that prices are likely to come down in the pretty near future. So if the £30 is a sort of marker, they must be discounting that significantly in terms of the longer term business.

MR BREALEY: Once they find out what the actual market price is, and of course it is chicken and egg. They start off at £25, but they are now competing, and they said: we are looking at this because we are trying to work out whether there is workable competition, and the competition is driving the price down, there is no doubt about that, and the question is at what level and over what period of time do we then have a look at these prices and say: well, let us compare those prices to the capsule price and is the capsule price so way out.

So, for example, on launch, Flynn charged a third less than the £30 drug tariff. We just saw that on launch, Flynn were £4 or £5 cheaper than Milpharm.

PROFESSOR WATERSON: So are you saying there is competition

between tablets and capsules?

MR BREALEY: No. That has gone. I don't think really ever even the last we were saying there was massive competition between capsules and tablets, but the purpose of this exercise is to look at the competition between the tablet manufacturers. That was the basis of the remittal. The remittal said: we do not know what happened to the tablet market, so what I am doing at the moment is showing the Tribunal, particularly you, sir, what happened to the --

PROFESSOR WATERSON: I remember this feature of competition, the tablet market, came very, very late in the day in the previous trial.

MR BREALEY: It did, so what I am trying to do -- we did not go through this last time.

PROFESSOR WATERSON: No.

MR BREALEY: What I am trying to do is look at the process of competition here, see what happened to the prices, and there are two things. The first is the £30 is the benchmark at the start, but then we look at what happened to the ASPs because the Tribunal was interested in what happened to the ASPs, and to cut it short I am saying you cannot criticise Pfizer for benchmarking on launch its capsule price by reference to the £30. Everybody else did, they benchmarked it.

Then the second point is actually what Pfizer did was discount its price by such a large extent, so Flynn was discounted by a large extent, the Pfizer input price was about 43% of the £30.

Then you compare the capsule price with the tablet price during this competitive process, and again, you see that the capsule price is well within a range of the tablet price, and that was the purpose --

PROFESSOR WATERSON: Your capsule?

MR BREALEY: Our capsule price, our input price and Flynn's retail price, our adjusted ASP which we will come on to one day also, but if one compares the prices at which Pfizer and Flynn launched and then on 1 January it went down by 20%, was it so out of sync with the tablet price, because we are looking at a comparator, and again, I can only repeat: you cannot criticise, in my submission, for saying you should not have benchmarked by reference to the £30 because that is exactly what the other suppliers did, and then you also go on to look at what the Pfizer price was in fact and they were 43% of that £30, the input price, and then you compare it to how the tablet prices panned out during this period and we say you are still within a range of the comparator tablet prices.

PROFESSOR WATERSON: Thank you.

MR BREALEY: The CMA say you cannot compare -- the £30 drug tariff is irrelevant, we say wrong. And they say the tablet prices are irrelevant because they are not proper comparators because there was not workable competition.

So I am meeting the case here that in my submission is an extreme case where the CMA is saying to us: comparators are -- you cannot rely on them, unlike -- and we will come on to it, I will show you a passage in a minute -- unlike the previous proceedings where Mr Hoskins said the Teva ASP was the obvious comparator if comparators were relevant, and now the CMA say: no, none of these prices give you any insight into the validity of the capsule price because they are not proper comparators. Why, they say? Why we say, they say: because this is not competition working. This is not workable competition. That is in a nutshell the case. We would justify benchmarking by reference to the £30 drug tariff, just as everybody did, and when one looks at the discount that we had off that £30, you cannot say that the capsule price was so out of sync with the tablet ASPs when you look at this procession of workable competition. This is at the end of the day a case of abusive unfairness.

Then if we go back to that chart, we look at that chart and we will see the prices over the next four to

five weeks, if we look at that chart and we have the drug tariff price in the green at the top, you see the prices at which people launched in September 2012, we see the Teva in the yellow, and then you see the CMA's cost plus -- that cost plus, the bottom red dotted line is the price that we should have entered otherwise it would be abuse and you would be fined several tens of million pounds.

We say that chart does not show a case of excessive unfair pricing, and that is why I am referring to these documents, I know it is more -- it is a lot of the same, but I am meeting a case while none of this is relevant because the tablet price is not a comparator, we say why, they say because there is no workable competition. We say, well, that is not supported by the evidence.

Just for the note, I will not go through any more, but can I give you some more references? Where were we? We were at {XG/228}. Can I for the record on the transcript, another reference is {XG/236}. Another reference is {XG/241}. Another reference is {XG/248}. Another reference is {XG/255}. We will leave it there.

Again, for the Tribunal's note, the Decision -- we do not need to go to it, but I will give you the references because I will just go to our economist -- the Decision {XA1/1} at page {XA1/1/328-329} sets out

period 3 what happened to the prices, and at page {XA1/1/330} of the Decision the CMA sets out what happened to market shares.

So the relevant bits, {XA1/1/328-330} of the Decision shows you what happened to the market shares and the prices of the three players at this time, and I would like to go to Dr Majumdar's expert report because he completes the picture that is set out in the Decision. So if we can go to {XE6/3}. That is his position paper, and go to page {XE6/3/6}. If we blow it up, the (b) and the (c). I do not think this is disputed, but this is what happened in this three-supplier period.

So as we saw:

"Prices fell considerably in 2012 ..."

We saw that earlier on, 14%. And then (c):

"Prices fell by more than 50% during the Three-Supplier Period. Following entry by Milpharm in September 2012, the Teva ASP fell by more than 50% from £21.35 ... to £9.82 ...the market-wide ASP fell from £21.97 to £9.65 ... a substantial fall of more than 50%."

We say that when one looks at the tablet ASPs and compares them to the capsule price, the capsule price is not completely out of sync with these tablet ASPs.

Quickly go to {XE1/5} which is his second report at page {XE1/5/12}, this is an important fact. If one goes to paragraph 32 and blow that up, this is me meeting a case advanced by the CMA that there is no workable competition and therefore tablet ASPs are irrelevant. So:

"A competitive process of price decline had already started in 2012 before the entry of Milpharm. Entry by Milpharm intensified this process. The outcome is that between January 2012 and July 2014 ... the market-wide ASP fell by 63% and Teva's ASP by 61%."

The economists are going to have to give evidence as to whether that is reflective of workable competition or not.

Just to flag a point which we say is an erroneous point which is advanced with respect by the CMA and their economist, they say: 60%, well, fine, but it starts off from a contaminated price. So they are using the kind of Liothyronine-type approach. It goes so high, then it is gone by 60%, so what? And the critical point to note about this is that we say it was not a contaminated price. Very important. The £30 drug tariff price is relevant for two reasons. First, the reasonableness of the parties to benchmark their price against it, but secondly, it is wrong to say it was

a contaminated price. Even their own expert, Webster, says that Teva was a constrained monopolist, constrained, but that £30 is not a monopoly price, it was a price that was insisted on by the Department of Health threatening statutory powers, and that is why I wanted to make sure the Tribunal was fully aware of the integrity of that £30 price, because it is not the same as in *Liothyronine*.

So when you take period 1 and the £30 is a constrained price, it was agreed, insisted on by the Department of Health, if you look at period 2 where Wockhardt got 23% market share, and you look at the whole period from 2012 to 2014, Teva's prices went down by 61%, and when you look at this together, we say it is inconceivable that you can say that it is not a product of workable competition.

Can I just remind the Tribunal what the CMA actually said at the last hearing. If we go to {XM/23} and go to page {XM/23/97}. Professor, you might remember this well. Page 97, line 11. This is how the case got remitted essentially. So Mr Hoskins at line 11:

"Sir, the decision does not say there is one supplier. The decision recognises there are a number of suppliers of tablet. There is a finding in the decision on that."

The CMA knew there were three. The Chairman:

"And is each of [these] suppliers in its own little dominant position ..."

Mr Hoskins:

"The point made in relation to that is tablets have -- the ... non-linear pharmacokinetics ... so there is not a formal finding of dominance ..."

Professor Waterson:

"There is also in the decision a table, and you have drawn our attention to a table of your own [that was in the closing, if we can go over] regarding the price of the tablets, and it appears to be quite interesting because it says in the decision that Teva's tablet price starting decreasing in 2013...

[Mr Hoskins:]

"Yes.

Professor:

"So an interesting question would be what was the price of the tablets at the time that the capsule was actually launched, the Flynn capsule?"

I have already given you one comparison on that.

Mr Hoskins:

"I am going to come to that actually because there is a different between the drug tariff price which was observed and the actual selling prices of the tablets.

And given that abuse is an objective concept, we say the proper comparator when you are looking at Pfizer/Flynn's ASPs is obviously to look at Teva's ASPs. not ASPs to drug tariff."

So what the CMA were saying there: do not compare the £30 to the ASPs, that is not the right comparison, but what the CMA was saying was that the Teva ASP was an obvious comparator and that submission was made and on the basis of that, there was a successful remittal, and the Tribunal has probably picked this up, but the CMA say: well, the tablet ASPs are not a good comparator because we are entitled to ignore the Teva ASP, ignore the Teva ASP, the CMA says. Why? Because it was the ex-monopolist, and yet at that time it was the obvious comparator.

It is just another instance of us having to meet a continually changing case.

Can I then quickly -- we are under a bit of time pressure -- move to the Flynn-Pfizer entry in September 2012 and a couple of documents on this. Just go to Mr Poulton. Mr Poulton gave evidence, the Professor remembers, for Pfizer. That is at {XC2/8}. So this is the witness statement. He is no longer employed by the company now.

Paragraphs 25 to 27, I will not read it out, but for

example on paragraph 28:

"The price disparity between phenytoin sodium capsules and tablets was something that was frequently referred to within Pfizer. By way of example, in my email ... I referred to this as an 'anomaly' ..."

So there was a real sense of why is the tablet at £30? And at page {XC2/2/14}, if we go to page 14 at paragraph 43:

"... I explained that I have since been informed that Teva's ... reached their highest price in 2007 ... in December ... prior to TGL's approach to Pfizer and following, an assumed intervention from the DH ... Teva reduced the price of their tablet. I am not sure at what stage I became aware of the movements in the price of the Teva tablet, however, it was certainly no later than in the course of our discussions with [Tor]. Subsequently on 3 August 2010, my explanation of Flynn's proposal states that the DH 'reduced the Category M price of phenytoin tablets in 2008 to £30. The previous price was £110. This indicates the value of the medicine to the NHS'."

Just for the note, that relevant 3 August 2010 email is at {XG/7}. All the market participants including in the Department of Health saw the £30 drug tariff as indicating value. That is the price at which the

Department is reimbursing the pharmacists.

So if I quickly go to the Tor presentation which is the first presentation that was made to Pfizer, that is at {XH/11}, in the middle. So this is the company before Flynn coming to Pfizer saying: you should have a generic capsule. We see there just above the word "proposal" the market was aware:

"The Department of Health ... last year reduced the Category M price ..."

So this is a presentation in 2009, I think:

"The Department of Health ... last year reduced the Category M price of Phenytoin tablets to £30 ... This indicates the value of this medicine to the NHS."

Now, that was Tor's market perception. It was Flynn and Pfizer's market perception the £30 reflected value to the NHS, and I remind the Tribunal of the documents we saw this morning, {XH/152/6}, where the Department itself said category M calculation model had a £30 value for phenytoin, and I lastly remind the Tribunal of {XG/24} which is Mr Otton-Goulder, at page {XG/24/3}:

" ...we appreciate the effort you have made to help us reach a conclusion which is of value to NHS patients."

We find it quite strange that the CMA would want to trash this £30 drug tariff price. We know that people

benchmark off it, but it is something that the Department of Health itself acknowledged was giving value to the NHS, and it is a price at which the market participants thought was giving value to the NHS.

PROFESSOR WATERSON: So, Mr Brealey, you will remind me, because I have forgotten, both your client and the tablet were in Scheme M.

MR BREALEY: The capsule was category C. Flynn was not in Scheme M.

PROFESSOR WATERSON: Right, no. Okay, so does that make a difference in your submission?

MR BREALEY: No. In fact, while we are doing this now, I just want to pick up on a point because -- let us do it in stages. The answer is no, but what I would like to show is how the competition from NRIM affected the capsule price and how it affected the drug tariff price and the ASP, because I do not want to sit down and let it be thought that the decrease in price as a result of competition is only relating to category M. It also applies to category C.

So in short, Flynn -- because it was category C, Flynn's price dictated what the drug tariff price was and it launched. When it launched it was £22.50, below the £30 drug tariff price, and then when NRIM came in, Pfizer and Flynn reduced their prices by £20, and that

reduced the drug tariff price to £18 because of competition.

So I do not want it to be thought that this competitive process only applies to category M. It also applies to category C if there is indeed competition.

Quickly on this, if we could just go to the supply agreement that was negotiated between Pfizer and Flynn, that is at {XG/132}, and then page {XG/132/27}, these are the prices, again, you divide by three because these are for the packs of 84, but if you look at the 100mg there, that equates to £13 which is about 43% off the reimbursement price for the tablet, but the Tribunal recognised that these were independent arm's length prices between Pfizer and Flynn.

There was, if one goes to page 14 a provision in the agreement between Pfizer and Flynn for a review of the input price. So there is an annual review, but there is a general -- there is an ability to review generally, and one of the provisions is 14.2.3 which is the parties will have a look at the input price if there is competition.

Just continuing with this theme, if one goes to {XG/175}, we have seen the input prices, this is basically at launch, and it has been asked what are Flynn's prices and you see there, this is quite

important for when one is looking at the dynamics between the two, in the middle:

"I genuinely do not know what prices they have submitted. I do know that they have been approved and that the 100mg is significantly less costly than the equivalent generic phenytoin tablets."

So the first point to note is that Pfizer did not actually know -- I do not know whether -- I am being given a suntan here.

THE PRESIDENT: The blinds.

MR BREALEY: So Pfizer did not actually know what the retail prices were of Flynn.

Can we just have a look at why there was -- there was a reduction of 20% on 1 January 2014. If one goes to {XG/322}, because there was competition in the capsule market, and the parties intended -- envisaged there would be competition in the capsule market, but this is an email from Flynn to Pfizer:

"Further to our meeting..."

This is 2014:

"We are experiencing significant competition for the 100mg in the market from (a) the NRIM ... and ... [parallel imports] mainly from Spain. We request, therefore, a 20% reduction in the current cost of goods, to be retrospectively applied to our current safety

stockholding."

So it is asking for a price reduction of 20% to meet competition and at {XG/327} that 20% is granted, and we see there that Pfizer agree to reduce its price to Flynn to £11.30, so the comparable price is £11.30, and we see there the rationale was stated to be competitive pressures and that Pfizer hoped that Flynn would reduce its prices by an equivalent amount but clearly Pfizer could not require it.

There will be lots of comparisons, I am sure, throughout the whole of the trial, but Pfizer's input price, as I say, was around 11.30, 11.40, and that is in the Decision at table 2.3, and the Teva ASP for January 2014 was £14.49, almost £14.50. So there was a £5 difference between Pfizer's input price, £11.40, and Teva's ASP in January 2014, and that is the sort of comparison that we will be making showing that actually the capsule price is not way above what the tablet manufacturers were charging.

Again --

PROFESSOR WATERSON: You are talking there about Pfizer's price and comparing it with Teva's price, are you?

MR BREALEY: I was, and I was inviting you, because you are far better at maths than me, that that £5 allowed Flynn to make a margin and to compete with Teva. I could

also --

PROFESSOR WATERSON: (inaudible) view on that.

MR BREALEY: The Flynn ASP in May 2014, was £16.31, so £2 more.

And it is -- so £2 more than the Teva on that. If one compares the May 2014 to the January 2014, there was a difference between Teva and Flynn of £2, but I was giving you the input price of £11 and explaining that the Teva retail price was £14, and, therefore, there is clearly room for Flynn to be competitive in the market, as indeed it was.

That is just one comparison, and just so you know, on the basis of our economist, on 1 January, if one wants to go there, our adjusted ASP was £12.16. So our adjusted ASP is £12.16 compared with the Teva ASP of £14.49, £14.50.

These are not prices -- and I think in my submission it will be extremely artificial to say: well, because on 15 June it is kind of out of sync and then in mid-July it is in sync, you have got to look at this more holistically to a certain extent. You cannot just pick a month in 2014 and say: ha, ha, I am going to compare the two, you have got to look at it. They are two different markets, remember. The main thing is to work out whether the prices are so different as to render the

capsule price abusive and unfair.

I have almost finished and then I will let my colleagues take over.

NRIM. We just should look at NRIM.

So that was, if you remember, Professor, the second capsule manufacturer, and in our chart, that is on the second chart in the purple dotted line, so if we look at our chart -- it is on the first chart as well -- we see the Flynn in red, NRIM just below, Teva in yellow and Pfizer's input price in blue. The drug tariff price in green and then the CMA's cost plus right at the bottom at £2.40. That is £2.40, that cost plus.

If one goes to {XH/28}, we have seen so far that Wockhardt, Milpharm, Flynn and Pfizer benchmarked off the £30 drug tariff, and then have a look at {XH/28} which is NRIM's section 26 response, this is 15 April 2014, it is the actual response, the request is March. If you go to page {XH/28/17}, the answer to question 7.2, we see there, second paragraph:

"We negotiate our prices individually with all our customers. Prices are negotiated on the basis of the price for the [best] product (here: Phenytoin Sodium capsules manufactured by Pfizer under licence ...). The NHS list price currently stands at £67.50 ..."

So you divide that by three, £22.50.

"... per pack of ...

"As we sell a generic unbranded ... our customers expect our price to be significantly below the official NHS list price."

So again, we have another player in the market saying: yes, we price to the market, but everyone is looking at discounts off, in quotes, the official NHS list price.

"... this discounted price is negotiated individually with customers and our prices depend also on the purchase volumes and availability of parallel imports."

So again, I come back to the same submission. It was not unreasonable for Pfizer and Flynn to benchmark its price by reference to the official NHS list price of £30 for the tablet, the almost identical product, in September 2012.

What happens after that depends on the competition, but the actual act of benchmarking is what all these companies do, and it is, in my submission, unreasonable to say that Pfizer was unreasonable for doing what all these other companies are doing.

Can we just have a look at {XH/37} because this makes good the point about how even in category C, competition will drive down prices and will drive down

the official NHS list price.

So we see there footnote 2, if we just go to footnote 2, this is where we get:

"The official NHS list price ... was reduced to ..."

And that is £18.

"... with effect from 1st May 2014."

If one goes to page {XH/37/4} of this document, the answer to question 5, so we look at 5, and then -- sorry, page 4, answer to question 5, right at the bottom:

"The CMA is aware that from 1 May ... Flynn Pharma ... decreased the NHS list price..."

So the CMA is aware from 1 May Flynn decreased the NHS list price for:

"a pack of 84 ... by 20% ...

"a pack of ... by 15% ...

"Please state any actions that NRIM has taken..."

Can we go over the page {XH/37/5}:

"As a generic drug manufacturer we will always try to compete with the innovator on price in order to ... maintain ... In order to compete with Flynn we have decreased our price of phenytoin sodium ... in June 2014 in order to adjust our prices to the reduction of the official NHS drug tariff, which happened as a result of

Flynn's reduction in price for the 100mg phenytoin sodium capsule product, as Flynn's product ... is used to determine the NHS drug tariff for phenytoin ..."

So all I am doing is drawing the Tribunal's attention here to there was a process of competition between Flynn and NRIM which reduced the drug tariff price, so I do not want the Tribunal to think that it is only category M that leads to a change in the drug tariff price, but we see although the drug tariff price has gone down, the official NHS list price, NRIM is still discounting off that.

So we come back to this visibility of the official NHS list price.

PROFESSOR WATERSON: Sorry, on your chart, you do not have the capsule reimbursement price.

MR BREALEY: We do not; we should do. So we can update that. So the official NHS list price for the capsule was, on launch, £22.50, so that is just above Flynn's red line, £22.50, and then because of the price reduction, the 20% price reduction we just saw, it went down to £18.

So when that red line -- so the Pfizer price went down first, and we see that, and if you -- well, we will come on to that, but we see the Pfizer input price, and Professor, if you want to compare the Pfizer adjusted

ASP, if one looks at the next chart, you see the adjusted Pfizer ASP in December 2013 as very similar to the Teva ASP, but the official list price was £22.50 reduced to £18 as we just saw.

We can see that if I can just finish, and then I do need to let Mr Johnson and Mr O'Donoghue have their say, can I just draw five main propositions from the documents that we have seen today.

First, the phenytoin sodium tablet is an ideal comparator for the capsule. That is the first proposition. The tablet is an ideal comparator for the capsule.

Second, the market participants and the Department regarded the £30 drug tariff for the tablet as an indication of value to the NHS.

PROFESSOR WATERSON: Sorry, is that a misprint there? You say first the phenytoin sodium tablet.

MR BREALEY: Well, first the tablet is an ideal comparator --

PROFESSOR WATERSON: But it is not your tablet, is it? Okay.

THE PRESIDENT: It is made of the same thing.

MR BREALEY: I am just saying they are chemically identical, same patients, same guidelines. The whole of today is about comparators and whether you can draw a comparison

between the tablet price and the capsule. So the first proposition is tablet and capsule are good comparators, prima facie they are good comparators, identically the same.

The second proposition is that the market participants, we saw that, we have seen that with Tor and all the other suppliers, and the Department, we have seen the emails from the Department, the responses, regarded the £30 drug tariff for the tablet as an indication of value to the NHS.

The third proposition is the drug tariff price is an important benchmark for suppliers when pricing their product. So the drug tariff price is an important benchmark for suppliers when pricing their product. As we have seen today, all the market participants benchmarked their prices by reference to the drug tariff: Teva, Wockhardt, Milpharm, Tor, NRIM.

Fourth, as a result, there was nothing unfair about Pfizer or Flynn doing the same and benchmarking by reference to the £30 drug tariff for the tablet. They were just doing what all normal suppliers do. That was the official NHS list for an almost identical product.

Fifth, and lastly, Flynn and Pfizer's discount off the NHS list price for the tablet was so large that even when real competition started in the tablet market, even

when real competition started in the tablet market, their capsule prices were within a reasonable range of the tablet prices.

So the capsule prices were within a reasonable range of the tablet prices, and they are not unfair when a fair comparison is made.

So those are the five key propositions that I want to draw from the documents today. Clearly we are going to examine a lot more documents. Tomorrow Ms Stratford is going to go through some of the Flynn. It may be it is a convenient break, and Mr Johnston is going to just articulate some of the key points on the use of phenytoin and then Mr O'Donoghue is going to deal with the issues on the QALY evidence. Unless there are any questions from the Tribunal to me?

THE PRESIDENT: Well, in a sense we are going to be revisiting a lot of these points, as you say.

MR BREALEY: Yes.

THE PRESIDENT: Three concepts that we are going to have to understand the inter-relationship between are cost, price and value.

Now, I think you suggested as your second proposition that the drug tariff is both a price and an indication of value, so are you in your elucidation of the relationship between those two factors saying that

price equals value?

MR BREALEY: The answer to that is for today, yes, because the price that we saw hard-coded into the Department's response says that this is a £30 value, and Mr Otton-Goulder says £30, thank you, giving value. So at the moment I am just taking the documents at face value, and I am saying: this is what the parties said, £30 represents value.

I have not gone behind that. I have not had time today to go through the costs because I can give the Tribunal the references to the costs of Teva, Milpharm and Wockhardt, so the Tribunal can see what actually the costs of the goods were for the tablet manufacturers, I can do that. The Department, as I said earlier on, have the analysts doing their calculation for the tablet, we have seen reference to their analysts, but we have not had any evidence from them, and they are in the best position, and then obviously, Mr O'Donoghue is going to give you a completely independent presentation on the QALY, which actually does give you a value to phenytoin.

But I do not have the material in front of me to say: Milpharm's costs of X, because it is confidential, compared to a £24 ASP is giving value. I am relying on what the Department said the price is, £30 is giving

value to the NHS, which I am entitled to do, but I can give the Tribunal and the Professor the references in the bundle where you will see the cost of goods for the tablet which is not that dissimilar to the capsule.

THE PRESIDENT: Well, you have broached a further area of difficulty which is the extent to which cost equates to value, and that was not, to be clear, what I was tilting at, though I quite understand why it matters. It is just that if you were articulating your second proposition as a general proposition -- I think you were not given your last answer -- if you were, then if value equals price then you have a situation where effectively you are allowed as a price-maker to price up to the value that the price-payer perceives, which leaves no surplus in the buyer at all.

Now, it may be that you are saying in this case the value was articulated by the Department of Health and they were not using value in quite that sense.

MR BREALEY: The best way to answer that is as we started off this morning, the Department of Health agreed £30 which it said was of value. That was a price that it was prepared to pay. It is not just in the old kind of school of the abuse of a dominant, any price you do pay, this is different. This is not just this is me paying to some dominant company a price that is being dictated

to me; this was a price that was dictated by the Department to Teva, so this was a price that the Department was willing to pay in the truest sense which it acknowledged at the time was giving value to the NHS, and that is the starting point.

If competition brings the prices down, as it did, the buyer then has two options. Either it brings down the official list price in line, or it continues to pay the pharmacy the margin. That is nothing to do with the suppliers in the market, that is in the gift of the Department of Health.

So it can either use the surplus -- we have now got competition going down below the £30, and that is a good thing for the Department of Health, and it either says: right, well, I am going to reduce the NHS list price and then reimburse the pharmacies at a lower price and then there will be more competition and it will go down and down, or I will keep the reimbursement price at £30 and continue to give that to the pharmacies as all part and parcel of the pharmacy margin.

So whichever way you look at it, when Pfizer and Flynn benchmarked by reference to the drug tariff price, it was entitled to believe that that was a price that was giving value to the NHS.

THE PRESIDENT: Now, as I understand it, you are relying on

the drug tariff as a comparator price.

MR BREALEY: I am relying on -- (a) as a price that the Department is saying is giving value to me, but also I am relying on it because it is reasonable for all market participants to rely on this public signal to benchmark their own supply prices.

THE PRESIDENT: Well, with that proposition I do not think I have any particular quarrel, at least at the moment, and it is what you said a few minutes ago that it is in your submission unreasonable to say that Pfizer was itself unreasonable for doing what all these other companies are doing.

MR BREALEY: Correct.

THE PRESIDENT: But that is not actually the question we have to ask ourselves when applying *United Brands* and the other tests.

As I understand it, what we are doing is we are looking at what is, in a situation of dominance, a price that is an abuse of that dominance, and we have two touchstone tests: we have excessiveness and unfairness as, as it were, touchstones that we need to look at, but in assessing whether those touchstones have or have not been breached, we look, amongst other things, to comparators.

MR BREALEY: Correct.

THE PRESIDENT: Now, one must ask oneself why one is doing that, and presumably the reason one is doing that is because we are seeking a proxy for what is a competitive market price?

MR BREALEY: Well, no. Well, yes and no. So, yes, in the sense --

THE PRESIDENT: So half right.

MR BREALEY: -- when we are looking at the ASPs, yes, not solely as a competitive price, but we are looking at valid comparator ASPs. That is a given. So, yes, when you are looking at whether it is an abusive price, whether that capsule price was an abusive price, Flynn charging two-thirds of the £30 at £20, was it abusive, well, we would say no, for two reasons, answering your question.

First, which is where I agree with you, it was that launch price was in line with the competitive prices for the tablet at the time, and continued to be, that is the first point, so applying abuse of dominant position and comparators that launch price and the subsequent prices were within the range of the tablet price, but the bit that I take issue is that this case is not just about working out what a so-called competitive tablet price is because we are -- in this case, it is quite different in this case, we have a price which the Department of

Health itself insisted on, reached agreement on, threatened statutory powers on, and acknowledged that that £30 was of value, and in my submission, in the case of an abuse of a dominant position you cannot sweep that away. Yes, you can look at competitive prices, but, no, you cannot just say that £30 is irrelevant because this case is not just about, for example, looking at Scheme M and competitive prices. We are faced with a bespoke price that was insisted on by the Department, which it said gave value to the NHS, and parties -- and they did -- parties are entitled to rely on that.

So in other words, why would it be -- put it another way: you have in 2007 Teva -- and assume that we are correct and the Department insisted that Teva reduced its price to £30. One week later, after threatening to use its powers, etc, etc, one week later, the CMA come along to Teva and say: you are abusing your dominant position, that is an unfair price. You would say: well, the Department insisted on that, said it was of value to it, used its statutory powers to achieve that price. So that £30 means something.

Take another example. Let us assume that during the three-player market, Wockhardt leave and then Teva leave as well, leaving one tablet supplier pricing at £22, so there is only one supplier now. Is that one supplier

entitled to say: well, but the drug tariff price of the tablet is £30, that was the price that the Department is reimbursing at, that is the value.

So that £30 as a bespoke price is not irrelevant to the determination.

THE PRESIDENT: Mr Brealey, do not get me wrong, I am not even coming close to debating relevance or irrelevance at this stage. What I am trying to understand is how it fits in.

You said a moment ago it is not just about working out what is the so-called competitive tablet price and certainly my questions are not directed at that; what I am really trying to understand is whether you are right in attaching to the drug tariff price the label "comparator". Now, we know why comparators matter because *United Brands* tell us that they do, one should look at comparator products in order to ascertain what might be a proxy for a competitive price in a market where by definition there is not one.

MR BREALEY: My answer to that is yes, it is a comparator. Why is it a comparator? It is because the Department of Health itself insisted on that price, agreed that price, and said to the supplier: this is of value to the NHS.

So there has not been any other case where the Department of Health has sat round a room and said: this

is the price we want. Now, then to turn round and say: this is the price we do not want and by the way it is a completely and utterly unfair and abusive price I think --

THE PRESIDENT: I see where you are coming from on the merits. I suppose what I am asking is, is the drug tariff less a price and more a price control? And if so, we are going into slightly different territory.

MR BREALEY: That is why I also referred to -- so the answer to that, it is a price control, that is why I also referred to the analysts within the Department calculating the £30 as of value, and it being a fixed price. So they hard-coded it into the system as a fixed price.

THE PRESIDENT: It is a fixed price, but it is not a fixed price as to what should be charged by the wholesaler to the dispensing pharmacy because you need to factor in the margin to the dispensing pharmacy.

MR BREALEY: Yes.

THE PRESIDENT: So you cannot call it a list price without more, without some form of qualification.

MR BREALEY: No, that is a given in this industry.

THE PRESIDENT: You have made that very clear.

MR BREALEY: The NHS list price, the drug tariff price, is always at the top and then you will charge under it.

THE PRESIDENT: And within that control there is competition for the business of the pharmacies, it being a given that the market for any pharmaceutical product is constrained by those who need it, by a fixed demand. So what you are doing is being unable to expand the market by lowering price because you will not get more people in medical need, what you do is you compete for market share --

MR BREALEY: Yes.

THE PRESIDENT: -- we have seen that in the communications you have taken us to in the course of today.

MR BREALEY: Yes.

THE PRESIDENT: But what that means is that in fact, the competition is not so much for market size. It is for the favour of the pharmacies to maximise their return when they are themselves reimbursed by reference to the drug tariff price, which is why I am thinking that the language of price control is perhaps rather more important than the language of comparative price.

MR BREALEY: I can live with price control as long as it is realised that that is a price that was controlled by the Department of Health and in this case, was a fairly unique position because it insisted on the price, and then when I offer the evidence in the case that people take that list price and generally would go 15%, 20%,

25% below it, that is how they benchmark, and then when Pfizer benchmarks at 43% below it and Flynn at 30% below it, they are accused of abusing or charging unfair prices when everybody else will do exactly the same thing.

So we have two issues here. We have the competitive ASP, which I remind the Tribunal, Pfizer and Flynn did not know about. As we said in the last proceedings, we do not know what the tablet ASPs are, that is negotiated on a private basis, but what Flynn and Pfizer do have is the visibility of the 30% drug tariff price, and the visibility was not just that it was a drug tariff price that was achieved because of competition, it was a drug tariff price which the parties all believed had been insisted on by the Department of Health, and their perception was absolutely spot on, it had been.

THE PRESIDENT: Indeed. I mean, do not get me wrong, Mr Brealey, the reason I am asking these questions is not so much to find the answer, because we will come to that in due course.

MR BREALEY: Sure, you are just probing.

THE PRESIDENT: What I am trying to understand is how assuming the label "price control" is more apt than "comparative price", how that fits into the *United Brands/Attheraces* schema for working out whether

prices are excessive. I am not expecting an answer now, it is just it may be that the relevance of a price control not being a market price at all is different to a comparative price when one is relying upon the comparative price as a means of informing or proxying what in a non-competitive market the price might be if it were competitive.

MR BREALEY: When you are being asked questions and they are shining a spotlight --

THE PRESIDENT: We will make sure the blinds are lowered in the break.

MR BREALEY: But I do come back to: we have essentially two comparators, we have advanced two comparators. The first comparator is the £30, it was a controlled price, and if one is looking at *United Brands*, whether one calls it a controlled price or a comparator I do not really think it matters because it is a price which is informing the Tribunal as to whether the Pfizer price is unfair. That is the name of the game: whether the Pfizer price is unfair. If Pfizer is charging 50% and then Flynn is charging 30% less, then that price that was insisted on by the Department of Health in my submission it is not unfair.

We then go further and whether that is a controlled price or you call it a comparator, I can see why it is

maybe not a comparator because you are not comparing it to the market, but you are identifying a price which the purchaser, of its own volition, has said is fair, and if a purchaser of its own volition, particularly using threat of statutory powers, is setting a price which it says is fair, section 18 should not be fining companies too readily for pricing at -- significantly below that fair price, that is why the £30 is so important.

The £30 is also important, as I have said, because it also informs the analysis as to whether the tablet ASPs are competitive or not.

THE PRESIDENT: Yes, I mean it may be down to nomenclature or terms, but just looking at paragraph 252 of *United Brands* which is talking about when a price is unfair, the paragraph refers to a price either unfair in itself or when compared to competing products.

Now, taking for the sake of argument tablets and capsules as competing products, one can understand that one would look at the prices of the tablets as comparators, but the price control, the ceiling above which, as a practical matter, you just cannot go above, and in fact, it will be ceiling minus margin to pharmacies that is the real ceiling so far as the wholesaler is concerned, that is a rather different question. I am not saying it is an irrelevant question,

but it is a different question to that which is being asked in *United Brands*.

MR BREALEY: All I would say to that with respect is, yes, that is what *United Brands* says. We then went through a lot of other --

THE PRESIDENT: We have a lot of other cases.

MR BREALEY: But you get to the Court of Appeal and Lord Justice Green says: there is no one single test, *United Brands* is either/or -- there is no one single test, and my first submission -- I can only repeat it -- is there is no one single test but if a purchaser insists on a price, using its statutory powers, insists on a price which it then says is fair, it would be wrong to -- the author of O'Donoghue and -- at 253 --

THE PRESIDENT: There are many ways of skinning a cat, I understand that.

MR BREALEY: So that is what Lord Justice Green was saying, other ways mean -- and in this case the ASPs are -- is the comparators, as they were, the tablets, the three suppliers, the two suppliers, but we do have a fundamental prior issue to decide which is, as I say, in circumstances where the only purchaser using statutory powers insists on a price, acknowledges that it is fair, is it so unfair for the market then to benchmark it, benchmark their prices by reference to it,

and indeed, significantly discount by reference to it?

THE PRESIDENT: Mr Brealey, please do not get me wrong, I am not saying that your submissions with regard to the drug tariff are out of court because they do not seem to me to be amounting to a comparable. What I am saying is that we need to understand in order to apply it correctly what the relevance of these particular facts are, because I get what comparables do, we discussed that. This, if it is not a comparable, we need to understand precisely why, let us assume for the sake of argument it is a price control, why that is something that matters for purposes of the *United Brands* test. Mr O'Donoghue is absolutely right, 253 says other ways may be devised and price controls are absolutely not part of the discussion in *United Brands*, nor for that matter *Attheraces*, nor for that matter very much if at all in *Pfizer* in the Court of Appeal, but you have made the point and what I am putting down a marker for is that we would, I think, be assisted in an understanding of what it is we get out of this phenomenon, to use no more than that, which you say quite understandably is constituting a benchmark for how people price, because they are clearly not going to price above it, they have obviously got to price below it to reflect dispensing pharmacy margin, and there is within that a degree of

competition. So it is a much more fluid beast than simply a comparable one.

MR BREALEY: Yes.

THE PRESIDENT: There may be a comparable element in terms of ASPs of tablets transferring over to ASPs of capsules, I accept that, but you, I think, are making something more of the point and what I am keen to do is to fit it into the way in which our test works.

MR BREALEY: Take *Humber Oil*.

THE PRESIDENT: Yes.

MR BREALEY: *Humber Oil* is a case that you referred to in *Hydrocortisone*. Now, *Humber Oil* does not readily fit into paragraph 252 and yet the Court of Appeal says you have got to be joking if it goes to arbitration or whatever and then someone says: well, this is an abuse of a dominant position.

So it is that kind of -- you are faced with a price that the purchaser insisted on, said it was fair, said if you do not agree to it we will limit it anyway using statutory powers, and then a few years later you are told, well, the fact that you used that benchmark is in some sense wholly unfair, and we will have to obviously articulate it better, but those are the two fairness benchmarks, the fact that the Department said £30 was a fair price.

Now, Mr Holmes will say the Department never said it was a fair price and said to Flynn it is not a fair price, Ms Stratford will deal with that tomorrow, to which I will say also: you hard-coded it, you fixed it at £30, and you let the market act upon it. That is the shocking thing, sir. That is the shocking thing, the £30 there is -- let the market act on it, and then when the market does act on it, then it is guilty of an abuse of a dominant position.

THE PRESIDENT: Is that a convenient moment?

MR BREALEY: It is, because I am conscious of the time.

THE PRESIDENT: I am grateful.

MR BREALEY: Anyway, we will switch over.

THE PRESIDENT: We'll re-arrange it. We will see how late we can run. I think if we can go beyond 4.30 it will be do-able, but we will obviously enquire of the shorthand writer whether that is feasible, otherwise we will find more time somewhere. We will rise for ten minutes.

(3.43 pm)

(A short break)

(3.57 pm)

THE PRESIDENT: Mr Johnston, good afternoon.

MR JOHNSTON: I am very grateful. Before I begin, members of the Tribunal, obviously there is a practical question of timing --

THE PRESIDENT: I can run until 4.55. I am very grateful to the shorthand writer to give us that time.

MR JOHNSTON: The only other alternative we had pondered on was we are already starting at 10.00 tomorrow --

THE PRESIDENT: We are.

MR JOHNSTON: -- would you rather we would sit at 9.30. Mr O'Donoghue swears blind he could sit down by 10.00, but there is a question about whether that makes other people's lives difficult.

THE PRESIDENT: That I think could work.

We also do have the afternoon. I mean, I am very grateful to the parties for enabling me to give a lecture which I was scheduled to give, but we have pencilled out the whole of the afternoon. I will be back at 3.00 at the latest.

MR JOHNSTON: I am looking to Ms Stratford because I am conscious that she obviously is going to be speaking tomorrow. Would that mean keeping the start at 10.00 if we run over this evening?

THE PRESIDENT: Well, no, I am very conscious that I do not want to impose on others. From our point of view, 9.30 is fine, but we do have other burdens.

I think let us leave it to the parties to consider.

Ms Stratford?

MS STRATFORD: My Lord, I was quickly canvassing because

this was not discussed, but I think as far as I understand, at least for counsel collectively, 9.30 would be possible. Obviously we would be keen to get as clean a start tomorrow morning as possible, but I realise everyone is making their best efforts.

THE PRESIDENT: Well, we started at 11.00 and we have had a few hitches since then.

Is 9.30 do-able? I am looking at the shorthand writer here. I am very grateful.

Well, look, we will start at 9.30, we will run until 4.55, and if you want to think about the afternoon, do, because it is at the moment a glorious blank. I have no problem in keeping it that way, but it is a usable blank.

MS STRATFORD: I am most grateful. I confess I did have that in the back of my mind but was going to very much strive only to use it in extremis.

I have got a fairly clear plan of what I need to cover, so what I will do, if it is acceptable, is see where I have got to by 12.30, and unless I think we are very behind, then I am sure everyone would appreciate a clear afternoon, including the Tribunal.

THE PRESIDENT: Very good. Thank you.

Opening submissions by MR JOHNSTON

MR JOHNSTON: I am very grateful. We will take stock when

I come to the end.

I am going to be addressing you briefly now in relation to the product itself at the heart of this case, phenytoin sodium, and I am going to be doing so under five headings.

Firstly, epilepsy; secondly, AEDs; thirdly, the AED treatment pathway; fourthly, phenytoin sodium and fifthly, briefly, continuity of supply.

The evidence in relation to these questions has largely been given by Professors Walker and Sander and we will be hearing from them both by way of teach-in and cross-examination on Monday to Tuesday of next week.

I hope, and I can be corrected as I go if this is not the case, but I hope that everything I say today will be non-contentious and will be introductory and contextual.

So coming to my first heading which is epilepsy itself. I am obviously not going to hold myself out as an expert on the mechanics or the clinical aspects of epilepsy, the Tribunal will have a teach-in and will be able to ask the experts, but the experts have described it as akin to an electrical storm in the brain, so nerve cells firing in an uncontrolled manner.

It can, but does not always, result in convulsions, loss of consciousness and various other consequences.

You will have seen from within the papers, particularly within the expert reports, there are a number of different types of epilepsy, but for the purposes of this appeal perhaps the two most important categories or two broad groups that the Tribunal will doubtless be familiar with by the end are focal seizures and generalised seizures.

As I say, there is actually a large number of different epileptic syndromes that are less common, probably less important for our purposes, but focal seizures, seizures that start in one part of the brain and then spread, they amount to roughly 60% of cases of patients with epilepsy; generalised seizures, seizures that start simultaneously in all parts of the brain. That difference is important for our purposes because different AEDs are recommended for use as regards different kinds of seizures. So when we come to the NICE guidelines we will see that the first line treatments are different as between focal and generalised seizures, so that is the importance of that category.

The effects of uncontrolled epilepsy are of course very serious indeed for patients. The experts have described uncontrolled epilepsy as like the sword of Damocles hanging over the patients. There are a number

of practical constraints. If you are not seizure-free for two years you cannot hold a driving licence. Individuals with uncontrolled epilepsy have worse employment prospects, and in practical terms they lack the freedom to go about their daily lives without fear.

Medical consequence is of course extremely serious as well. The prospect of early death or sudden unexpected death in epilepsy is around 1% to 2% of patients with uncontrolled epilepsy per year, so very substantial, and for your note rather than to take you there, that is in Professor Walker's first statement at paragraph 3.6. That is at {XE4/1/4}, and as I understand it, that is not contentious.

But as well as the risk of sudden death and all the other consequences associated with uncontrolled epilepsy, it is very widely recognised that the mental health consequences of epilepsy are particularly serious and there is a study that I will not take you to but do commend to you which is Reid et al from 2003 and for your note, Tribunal, that is at {XF4/3} and it begins at {XF4/3/50}, but in particular in relation to the mental health consequences of epilepsy at page {XF4/3/55} onwards: depression, anxiety, self-esteem, as well as in that study, the discussion of a whole series of other social consequences to do with stigma: the prospects of

being married are considerably greater if you do not have uncontrolled epilepsy. So the social, the clinical consequences are very severe, and that is why when economists model the costs of epilepsy, the largest cost factor are the indirect costs, so the costs to society, the costs from people being unable to work or being off work, the costs of people dying early, if I can put it in very bald terms.

If I can take you briefly to just the first page of a study from 2007 that modelled this in Europe, and that is at {XF4/3/57}, and here we have the first page, and if you look in the summary, I do not propose to go beyond the summary, at the bottom of the first column in the summary, you have there just some bald figures. The total cost in Europe at that point in 2007 of epilepsy was €15.5 billion, of which indirect costs were €8.6 billion, but it is also important not to lose sight of the direct healthcare costs in that model which are €2.8 billion.

So those direct healthcare costs are the costs of patients not having their epilepsy controlled. That is the cost of visiting outpatients, that is the costs of visiting A&E after they have had an epileptic fit. Very, very considerable costs. The costs of visiting individuals like Professors Walker and Sander who we

will be hearing from later in the hearing.

Also worth noting that within that model the cost of AEDs within Europe was €400 million, so the cost of AEDs by reference to the globalised costs both direct and indirect was relatively small.

That brings me to my second heading, AEDs, all of which I think will hopefully be relatively familiar and uncontroversial. They play a very, very important part in mitigating everything that I have just been addressing you in relation to: the very serious costs and consequences of uncontrolled epilepsy.

When a patient first presents with epilepsy, the first thing they will be tried on is an anti-epileptic drug, that is the first thing off the rack, as it were, or an anti-seizure medicine, and the skeletons, the expert reports, everybody moves between AED and ASM relatively seamlessly. I think when we had the hearing last time they were all AEDs, I think the term of art now is ASM, but there is sort of moving between the two of them, there is no significance to be attached to one or the other, at least as far as I am aware.

If AEDs fail, then in some cases surgery may be attempted, but it is certainly a secondary option, and even after surgery, many patients will remain on AEDs in any event.

So almost everyone who has epilepsy, controlled or uncontrolled, will take AEDs and may well be on them for a lifetime, and they are life-changing. If they work and they do not always work by any stretch, but if they work they can transform a patient's life in profound ways.

Around 30% of patients are not able to be stabilised on any combination of AEDs. To put it the other way, 70% of patients are. So 70% of patients at any one time are taking AEDs and that has placed them in a position where all of those economic and social and other costs are mitigated, but there is a significant minority who have tried everything, they have been through the substantial list of AEDs that we are going to be talking about in the course of this hearing, and they do not work, and, as I say, for them, the consequences are profound.

That leads me to my third heading which is the AED treatment pathway, and by that what I mean is the process that patients go through when they first present with epilepsy that requires treatment. As I have said, they will be tried first on an AED. There are around 25 of them now on the market, and perhaps your reference point, your mini-Bible for AEDs for the course of this hearing is appendix 2 to Professor Walker's fourth

expert report, and that is at {XF4/2} and it starts obviously at page {XF4/2/1}.

What you have in {XF4/2} is a list, and again, I do not think any of this is contentious, of all of the AEDs. If we could possibly scroll through to the next page {XF4/2/2}, then possibly even to the next page {XF4/2/3}, what you have there are all of the AEDs available in the United Kingdom. You will see that what you have is the year in which they first came to market, how they are used, information about the different drug interactions that they may have, information about side effects and some further comments as well.

So when a patient first presents with epilepsy, clinicians will go to this toolkit, if I can put it that way, for the purposes of treatment, and the process that they follow for our purposes were set out in the NICE guidelines of 2012.

So if we could turn to that now --

THE PRESIDENT: Do we have the prices of these?

MR JOHNSTON: We do not have the prices of these. These are from Professor Walker. He may know some of the prices, I do not know whether he does, but he has obviously approached it from a clinical perspective.

We do have some information about the prices of some. Dr Ridge's report contains some information on

that at the first trial. I would not say he is not with us, he is not acting for Pfizer in this second trial, but Dr Ridge does have some information about some of the prices of these products.

So if we go to {XF4/3} and turn to page {XF4/3/93}, what you have here are the NICE guidelines, as you will see from the beginning, of 2012, so right at the beginning of the relevant period for our purposes.

If we turn on into page {XF4/3/117}, please, what you have here in paragraphs 1.9.1.5 through to 8 is a very high level, if I can put it that way, description of the process or the treatment pathway. If I could encourage the Tribunal to read it rather than reading it to you.

THE PRESIDENT: Of course. (Pause) Yes.

MR JOHNSTON: So what you have described there is what you will see and hear plenty about in the coming weeks, which is first-line treatment, second-line treatment and third-line treatment. So first-line treatment will be a monotherapy, will be a single drug, that will be tried. If it either is not tolerated in the sense that the patient cannot tolerate taking it, it causes some kinds of side effects, or it is interacting with other drugs that they might be taking, then they will try a different monotherapy. Ultimately, if those

monotherapies are not successful then they will move to what is called adjunct therapy, so they will remain on the best tolerated, most effective monotherapy that they have tried and then they will add in third-line therapies at that point.

If we could turn over to page {XF4/3/119} now. So here what we have is the guidance in place at the relevant time for focal seizures. So this is taking that first-line, second-line, third-line pattern, and it is explaining by reference to focal seizures how that should work.

So paragraph 1.9.3.1, first off:

"Offer carbamazepine or lamotrigine as first-line treatment to children, young people and adults with newly diagnosed focal seizures."

Now carbamazepine and lamotrigine are drugs that we are going to be coming back to at various points as two of the drugs that you may become familiar with by the end of this process, as I say because they are the first-line treatment, so they are the first drugs that you try.

Into the next paragraph:

"Levetiracetam is not cost effective at June 2011 unit cots."

But it says:

"Offer levetiracetam, oxcarbazepine or sodium valproate ... if carbamazepine and lamotrigine are unsuitable or not tolerated. If the first AED tried is ineffective, offer an alternative from these five AEDs."

Then it says:

"Be aware of the teratogenic and developmental risks of sodium valproate..."

In very simple terms what that means do not give sodium valproate to women of child-bearing aged because the consequences to them and any child they are carrying are rather severe. We may see in a moment sodium valproate is actually the first-line treatment for generalised epilepsy.

"Consider adjunctive treatment if a second well-tolerated AED is ineffective (see [above])."

Then if we come down 1.9.3.4 what you have here are the second-line treatments and you have all of the drugs described above plus some more, so at this point you also have clobazam, gabapentin and topiramate, and then if those do not work then you get to 1.9.3.5 and that is where phenytoin comes in. So you will see:

"Other AEDs that may be considered by the tertiary epilepsy specialist [so that is Professor Walker and Professor Sander] are [this one may defeat me] eslicarbazepine acetate, lacosamide, phenobarbital,

phenytoin, pregabalin, tiagabine ..."

And in fact, some of these are those that you will have seen above. So this is the point at which phenytoin comes into the picture, if I can put it that way. It is an adjunctive treatment that is used at the point at which other drugs have not worked.

So this is the point at which you have a patient roughly 40, perhaps 50, there is different numbers in the papers, but probably 40% to 50% of patients will respond to one of those monotherapies. By the end of going through all of this process, around 70% of patients will be stabilised. So in the second line/third line process, a considerable number of additional patients are stabilised, but by no stretch all of them are stabilised.

It is probably worth just noting the last sentence of 1.9.3.5:

"Carefully consider the risk-benefit ratio when using vigabatrin because of the risk of an irreversible effect on visual fields."

So this is a drug recommended for use in the third line and it is saying: consider the cost-benefit ratio, consider the upsides and the downsides of using it. Professor Walker's evidence, and I do not think that is contested, is that around 30% of patients will have

partial or total visual loss, so they will lose their sight, from taking this treatment, and I think that in some ways captures the significance of the point that I was making earlier, which is uncontrolled epilepsy is extraordinarily serious for the patients, and that is why recommended by NICE, consider carefully the risk-benefit ratio, but nonetheless recommended by NICE is a drug that will send 30% of patients partially or completely blind.

So that brings me on to phenytoin sodium. Before I do, Mr O'Donoghue has pointed out to me page 43, in fact it might be a good time to do this now before I move on to phenytoin sodium specifically, so it is {XL/1/43}, so this is from within our skeleton argument and if we can zoom in on the table at the bottom, figure 4, so here you have -- thank you, Mr O'Donoghue, very helpful -- here you have not all of but a considerable number of the drugs that were in Professor Walker's table, and you have there average cost per daily dose.

You can see phenytoin is there as the orange line. So that gives at least some context, by no means everything that the Tribunal might be after here, but certainly helps provide a starting point.

PROFESSOR WATERSON: What is the date of this?

MR JOHNSTON: This is from 2012 as I recall because I think it is from Mr Ridge's first or second -- I think second report, but I will confirm and come back to you on that, sir, thank you.

So that brings me on to phenytoin sodium. I will not again pretend to explain to you how it works in clinical detail, but in very crude terms, it works on the sodium channels in the brain to stop the storm happening. What it does is it prevents excitation of brain cells so that you do not get that uncontrolled storm starting at either one part or throughout the brain.

It is a very old epileptic -- or anti-epileptic rather, it has been prescribed since the 1930s and in fact if you go to Professor Walker's table you will find that it is the second oldest on the list.

So we have had not much under 100 years of studying it, looking at it, examining it and understanding it, and it is a drug about which we know an enormous amount, in particular, when compared to some of the drugs that have come to the market more recently, and in fact, if you look at Professor Walker's table, one of the things that you will notice is that in particular as regards the really recent drugs, 2018, 2019, 2020, when it comes to chronic side effects, so those are the side effects

that might appear after taking it for 10, 20 or 40 years, they just say "unknown", because we do not know of course about the chronic side effects of drugs that are as new to the market as that.

I think it is not contentious to say that phenytoin is effective at treating epileptic seizures. That must be right. It follows from the fact that it has been continuously prescribed for 100 years nearly and it has been recommended by NICE in the latest two rounds of guidance on epilepsy.

Now, the use of phenytoin has declined in recent years. In the mid-1990s it was the most commonly used medication for epilepsy in this country at around 40%. It has declined by the period we are talking about to -- the best figure I have is a figure from just before in 2008, and that is at {XC4/3/209}. I do not propose to turn it up, but this is just before the start of our period, 18% of anti-epileptic drugs being consumed in the United Kingdom in 2008 were phenytoin sodium, and that is consistent with what the Decision says that there were 57,500 patients stabilised on capsules, and further patients stabilised on tablets. So on any view, a substantial cohort of persons.

Now, precisely why phenytoin's use has declined somewhat is slightly contentious, I am not going to open

it up in great detail, there are different viewpoints. Has it been replaced by more effective alternatives or has its use declined because of some of the difficulties attendant on its use? And we will return to that in cross-examination and ultimately in closing, but it is worth the Tribunal knowing that that is one of the issues on which the experts differ, at least to some extent.

Three key characteristics of phenytoin that it is important to understand at this point. Firstly, its narrow therapeutic index. What that means in practical terms is that it is effective in the blood at a relatively narrow range of concentrations, or to put it another way, the range between ineffectiveness does not work at all and toxicity is relatively narrow.

Pausing there, a considerable number of AEDs, and you will see this in Professor Walker's table, are toxic at a high dose: if you take too much of them they have acute side effects, but phenytoin, one of the features of it, it has a relatively narrow therapeutic index.

Secondly, non-linear pharmacokinetics, and I hope I am not at the end of the day blasting you with too much clinical wording. I hope I am making this simpler rather than harder, but it is a simple point: if you double the dose of phenytoin, you do not necessarily

double the concentration of it in your blood, and that is because of the way that it interacts with food, it interacts with your metabolism, and so on and so forth, so you can increase the dose from 100mg to 200mg, but you may see a very small increase in concentration or a very large one, and that is why when it is first prescribed, at least in the early stages of taking it, it is often monitored to check what the concentrations in the blood are, and that is normally done by nurses in a GP's surgery, and you take it over time, you titrate up the dose, you take 25mg extra, you go in, you have a blood test and you check what the concentration is, and that is where these smaller 25mg tablets come in. The main purpose of them is for the purpose of edging up or edging down the dose in that manner.

THE PRESIDENT: It is implicit, I think, in your submissions in regard to both non-linear pharmacokinetics and narrow therapeutic index that these are both features which are subjective to the patients, in other words, you cannot predict how it is going to apply in any given patient.

MR JOHNSTON: Precisely so, and I think it is fair to say that whilst it is right to say that -- as you say, sir, no two patients will respond in precisely the same way, and it is not in issue as a consequence that phenytoin is more difficult to use than some other AEDs on the

market that do not share those characteristics. That is not disputed. That is Professor Walker's evidence. The question, of course, is where does that go to?

The third feature to discuss briefly are the side effects of phenytoin. This is again a contentious area. It is going to need to be explored with the witnesses. We will return to it in closing. I want to make a few opening remarks just to sort of set out the terrain.

The first is how important it is to bear in mind that there are different types of side effects with all AEDs including phenytoin, and they really fall into three categories. The first are the acute side effects, those are the ones that I was talking about a moment ago. They derive from the concentration of an AED in the blood. If it gets too high it can give rise to toxic results. So in the case of phenytoin, if you have too much phenytoin in your blood, dizziness, drowsiness, nausea, double-vision and twitching.

It is also important to recognise that these can be addressed by reducing the dose. That is what one does if you have too much of any AED that is giving rise to acute side effects in the blood and when you do, they almost immediately come to an end.

It is also worth saying that the existence of this kind of side effect is by no means unique to phenytoin.

So if we can have {XF4/2/1} back up again, that is the first page of Professor Walker's table.

So if we look at the bottom drug here, which is carbamazepine, which I said is a drug you will possibly become more familiar with. This is the first-line drug for focal epilepsy. This is the very first thing that is prescribed to you if you present with focal epilepsy and if we look at the acute side effects: nausea, vomiting, diarrhoea, hyponatremia, drowsiness, dizziness, double vision, lethargy and headaches.

So, again, all of these are acute side effects, and if you present to the doctors saying: I am experiencing these acute side effects, then the response of the clinician will be to reduce your dose, or potentially if that is not effective, to say: do you know what, you are not tolerating this, let us try a different drug, but they are things that can be addressed, as I say, by stopping or reducing.

The second category, and you can see this again in Professor Walker's table, are idiosyncratic side effects and they are very different to acute side effects. These are rare but very serious side effects that are perhaps best understood as effectively an allergic reaction to the drug, and they exist in a very, very small number of patients, but because of their

seriousness, they are treated very seriously.

If we go back to carbamazepine, our first-line treatment for focal epilepsy: rashes, Stevens-Johnson Syndrome, which is an extremely serious condition which can be fatal, bone marrow suppression and aplastic anaemia.

So there we have as I say a list of idiosyncratic side effects that are very rare and are very carefully monitored to avoid these outcomes.

If we turn to page {XF4/2/5} within this document, here we have phenytoin sodium. So the idiosyncratic side effects: rashes, again we have Stevens-Johnson Syndrome, hepatic failure, dermatitis/rash, agranulocytosis, which I did Google and is a vulnerability to infections, and swelling of the lymph nodes.

Again, here you have a series of sides effects and I suppose part of the submission I wanted to make today was when looking at the evidence in relation to this issue, to recognise how important it is to put these side effects in their boxes and to understand how they are addressed and what their consequences are. These are very important but very rare and almost always, if I can put it that way, headed off.

Then you have the third category of side effects,

and these are chronic side effects. So these are the effects that come from taking an AED for 10 or 20 years, and they are the long-term consequences of taking that drug, and if you look at the chronic side effects of phenytoin sodium: osteoporosis, coarsening of facial features, gum hypertrophy, unsteadiness, Dupuytren contractures, which is a stiffening of the ligaments in your hand, and neuropathy.

Now, these are all things that are known to be the chronic side effects of phenytoin, and it is fair to say, I think, that we know a particularly large amount about the chronic side effects of phenytoin because it has been used for the best part of 100 years, and, as I say, if you look at some of the newer drugs in that table then you will see that they simply say "unknown" as regards side effects.

Now, all of these side effects of phenytoin are potentially serious to a greater or lesser degree. They are all things that are understood, they are all things that are anticipated, they are all things that can be addressed to a greater or lesser extent. So when it comes to osteoporosis, the answer is at least in part that one takes more vitamin D. When it comes to gums, good dental care, and so on and so forth. Ultimately, if they become unacceptable, any of the chronic side

effects of any of these AEDs, that may be the point at which you stop taking it.

If we could turn to page {XF4/2/6} which is the page just over, just to pick up another example, here we have valproate. I said earlier valproate is the first-line treatment for generalised epilepsy. So again this is a drug that people will expect to be taking like phenytoin potentially for decades. It is a relatively older drug, again about which we know quite a lot, and the chronic side effects are things like osteoporosis, weight gain, polycystic ovarian syndrome and you can see the acute and the idiosyncratic side effects above.

If we turn to the final page, which is the next page over {XF4/2/7} we get to vigabatrin, and this is the effect that I mentioned earlier. Chronic side effects of vigabatrin: permanent damage to vision in up to 30% of people.

It is important in the blizzard of side effects we are going to be hearing about and complex medical terminology, in my submission to recognise the boxes that they fit into, to recognise the consequences of that, and to bear that in mind when asking the question: how do we understand these by reference to the value and use of this drug.

Right, my final topic, which I can finish in

probably two minutes, I think, is to talk briefly about the guidance which covers phenytoin but other AEDs as well from November of 2013.

Now, Mr Brealey has already addressed you on the relationship between capsules and tablets in terms of price. This at least touches on that question, albeit it is a wider point.

It is agreed between the parties that one iteration of phenytoin sodium capsule, another iteration of phenytoin sodium capsule and a phenytoin sodium tablet are all chemically identical. They are all functionally identical, and that is the core essential starting point.

Nonetheless, in 2013, as you know, the MHRA recommended that patients should not be swapped between different formulations or different iterations of phenytoin sodium capsules. So if you are on the NRIM capsule you should not be swapped to the Pfizer-Flynn capsule and vice versa and for the same reason you should not be swapped between tablets and capsules, and we will find that guidance at {XG/307}. Can we zoom in on the middle beneath "Background". So:

"When a generic medicine is shown to be bioequivalent (has the same effect on the body) to the original ('reference') product, as defined by the

relevant regulations and guidelines, these products can be considered to be clinically equivalent.

"However, [cautions] about switching between different manufacturers' products of ... (AEDs) have been raised by patients and prescribers. These include switching between branded original and generic products, and between different generic products of a particular drug ...

"Following a review of the available evidence, the ... Commission on Human Medicines ... considered the characteristics of AEDs and advised that they could be classified into three categories, based on therapeutic index (a comparison of the amount of a therapeutic agent that causes the therapeutic effect to the amount that causes or toxicity) [which I think must be a typo in the MHRA guidance], solubility and absorption, to help prescribers and patients decide whether it is necessary to keep using a supply of a specific manufacturer's product."

Then it says:

"Category 1 ..."

Before we look at them, category 1:

"For these drugs, doctors are advised to ensure that their patient is maintained on a specific manufacturer's product."

So these are category 1 and within category 1 we have phenytoin, we have again, carbamazepine, so again, that is the first-line treatment for focal epilepsy, the first drug off the rack, if I can put it that way, phenobarbital and primidone.

Category 2, we then have the other first-line treatments: valproate, lamotrigine and then a whole series of other drugs. For category 2 drugs:

"... the need for continued supply of a particular manufacturer's product should be based on clinical judgment and consultation with patient and/or carer taking into account factors such as seizure frequency and treatment history."

Then in respect of category 3, there is no need to be concerned.

Now, I take you to this just to put it before you and make sure that you are familiar with it. You are going to be hearing submissions at a later point about the economic and all kinds of other consequences that might follow from that, and I am not going to be addressing you on those at all, but I did want to make sure that you had at least the right reference if I can put it that way, to the MHRA guidance, and also that you saw phenytoin in its context there alongside the other leading drugs that you will be hearing about in the

coming weeks.

THE PRESIDENT: I appreciate that you are doing no more than flagging up points of interest and I am very grateful, but there is an inconsistency, I think, between the description of category 1 products, including phenytoin, and what Mr Brealey was taking us to this morning with regard to competition between tablets by different providers, because it does seem to me that if this is to be taken at face value, doctors are advised to ensure that their patient is maintained on a specific manufacturer's product, the sort of product shifting that we saw in tablets is hard to explain.

MR JOHNSTON: Sir, I think there are two parts to the answer to that question, the first of which is to say that this is from November 2013.

THE PRESIDENT: Right.

MR JOHNSTON: So to the extent there is any shifting in the period prior to November 2013, this does not apply. So I think that is a very important part of the picture to have regard to.

THE PRESIDENT: I confess that I cannot now recall where or what timeframe Mr Brealey's examples were taken from.

MR JOHNSTON: I think all of Mr Brealey's period 2 was before November 2013 and most of Mr Brealey's period 3 was before November 2013, albeit the end of it is not,

it runs into the middle of 2014 as I recall.

So there is a period of time at which this guidance comes into place.

The reality is, and you will find this -- this was an issue that was canvassed a lot at the trial last time in relation to market definition of dominance. Professor Walker's evidence which was not controverted or gainsaid, which you have in the bundles in Walker 1, 2, 3 and 4 -- 1, 2 and 3, rather, from the previous hearing, but in particular 1 and 2, was that the reality was that clinical judgment was being used at the point of prescribing and also that pharmacists are exercising their judgment in response to open prescriptions.

So his evidence, and it is probably worth reading to give some context to this, is that there was pressure from patients for this guidance, in particular, some patients very keen for this guidance, but that his experience as a clinician was that clinical judgment was being exercised.

So I think that is consistent, as I say, at both points, both at the prescribing point and at the dispensing point, and that, I think, is consistent with Flynn losing market share to NRIM and parallel imports and various other forms of shifting and loss of market share.

You are right, and this is why I wanted to take you to it, because it is there on its face in relatively stark terms, but what we also know is that the reality is that it is not followed in this strict formulation. The reality is that probably what certainly Professor Walker's evidence is, and as I say this was not gainsaid at all previously, in the context where market definition and dominance were squarely in issue, was really that the way category 1 was treated in practice was more what looks like what we have described in category 2, which is talk about it, think about it, look at the particular circumstances of the particular patient, and so on and so forth, and that is certainly consistent with what we see both on the tablet side and on the capsule side, which is that even after this guidance has come out in practice there still is switching, there still is some switching between different providers, and that is something that you can ask the experts about. As I say, I think it is Professor Walker's second statement in particular where he addresses this in most detail.

PROFESSOR WATERSON: In that context, it would be useful to look at the equivalent quantity table to figure 1, I think, if we have it.

MR JOHNSTON: Figure 1? Oh, the quantities as opposed to

prices?

PROFESSOR WATERSON: Figure 1 that Mr Brealey brought up this morning --

MR JOHNSTON: Yes.

PROFESSOR WATERSON: -- because that tells you about prices but it does not tell you anything about quantities.

MR JOHNSTON: No, and I think that is certainly in Mr Ridge's first and second reports. Last time there was more discussion of volume of shift. I know that as regards NRIM they capture a significant market share. They have half the market not long after launching.

Mr O'Donoghue makes a very helpful point as well, which is, if we scroll down to the bottom of this page {XG/307/1} to the "Additional advice for pharmacists" and if we could zoom in, this may close the loop and also be consistent with what Professor Walker was saying, if we look at the additional advice for pharmacists:

"Usual dispensing practice can be followed when a specific product is not stated."

We know that 90 plus% of prescriptions were open at this point, so clinicians are not saying: phenytoin sodium (and you need to give them the Flynn hard capsules or you need to give them Teva tablets).

THE PRESIDENT: That is what I do not understand.

MR JOHNSTON: Sir, that may well be something to ask the clinicians about. Professor Walker's evidence was that (a) the pressure for this came from patients and (b) clinicians in practice exercised their judgment, and that it was not followed with quite the same --

THE PRESIDENT: Okay, well, let us just go back up to the category 1 definition because I think it is important that we highlight a need for explanation because the way I read this -- and I am simply looking at the language -- is that you are, as a doctor, in serious danger of disregarding this quite clear advice if you issue an open prescription. I mean "advised to ensure that their patient is maintained on a specific manufacturer's product", I mean that seems to me to be saying an open prescription needs to be very carefully justified.

Now, I have no idea what the position is because I am seeing this for the first time --

MR JOHNSTON: Yes, indeed.

THE PRESIDENT: -- but I do want the experts able to speak to this to explain how it is that a doctor post this publication could sensibly as a matter of general practice issue an open prescription.

MR JOHNSTON: Sir, that is precisely why I wanted to take you to it --

THE PRESIDENT: No, it is very helpful, Mr Johnston.

MR JOHNSTON: -- because it is an important part of the contextual backdrop, and I think the critical things as I say to know are, firstly, that a good part of the switching that you were hearing about earlier today is before this guidance comes out. Secondly, that we know that it is not outlier practice clinically, if I can put it that way, to write open prescriptions because in fact 90% -- I think it is 90 or 95% of prescriptions -- were open. So we know we are not in a position where there is a small number of outlying clinicians who are kind of going rogue, if I can put it that way. Thirdly, that is consistent with what you will find in Professor Walker's second report, I think in particular where he says continuity of supply is something which needs to not be -- was not understood and was not applied as a hard-edged rule by clinicians. That is his evidence, and, as I say, that evidence is consistent with everything else that we know because we know in practice that is what almost everybody was doing in almost all cases, and secondly we know that is consistent with what happens when NRIM comes into the market and grabs 50% of the market in almost no time at all.

Consistent with that, of course, when we come to the advice to the pharmacists is if you have an open

prescription, that is at the bottom of the page, do as you would ordinarily do, so the pharmacists are not failing to follow the --

THE PRESIDENT: The pharmacists -- we went into this in *Hydrocortisone*. The pharmacists are not to be criticised for responding to an open prescription.

MR JOHNSTON: No, no, precisely.

THE PRESIDENT: My point is that it is the doctors who are being given the advice here.

MR JOHNSTON: Precisely, sir, and that was the only point I was making. To the extent there was a question about whether the pharmacists were doing what they should be in fact, the pharmacy advice at the bottom of this page is where you have an open prescription do as you would ordinarily do. So the question, as you say, is at the clinical end.

THE PRESIDENT: You mentioned or you implied that you have data about open versus closed prescriptions for phenytoin post-2013, or is that more an anecdotal question of how these prescriptions are --

MR JOHNSTON: No, I do not think it is anecdotal at all, sir. Where I am recalling that from is the first Decision last time addressed this in considerably more detail precisely because market definition and dominance were in issue, so there was much more discussion about

switching.

I am being told paragraph 190 of the first Decision and the first judgment indeed as well making reference to this. So it is not a point that is anecdotal. It is a point that was addressed in the original Decision.

THE PRESIDENT: No, what I mean is though do we have figures for open versus closed prescriptions straddling 2013?

MR JOHNSTON: Either side of the boundary?

THE PRESIDENT: Yes.

MR JOHNSTON: I cannot recall off the top of my head. We can assist you with that tomorrow.

THE PRESIDENT: There is no rush, but I think it would be helpful to have data on that.

MR JOHNSTON: But certainly my recollection is that when this was thrashed out last time one of the foundation blocks of the discussion was almost all prescriptions are open, and it was not almost all prescriptions are open prior to 2013 and then there is some really substantial change.

So we can come back to you on that and assist you as far as we can, but I think you are likely to be assisted by the original decision and possibly by the original judgment, because, as I say, it was squarely a question -- the status of the guidance was a question of some importance when it came to market definition and

dominance.

THE PRESIDENT: Indeed. What is the exact date of this document?

MR JOHNSTON: It is November 2013.

THE PRESIDENT: Right, so given that the relevant period is defined 24 September 2012 to 7 December 2016, one would actually be expecting the market definition to change before and after the date of this document.

MR JOHNSTON: Certainly it did not change in the analysis of the CMA. If it helps paragraph 22 of the first judgment says it was common ground -- it is {XN1/2/10}. The first sentence of paragraph 22:

"It was common ground in these appeals that the vast majority of phenytoin sodium capsule prescriptions are open."

THE PRESIDENT: Yes.

MR JOHNSTON: So there was no suggestion -- I can be corrected if I am wrong -- on the part of the CMA that market definition changed at any point in this case. This was a case in which Flynn's capsule was in a market of its own from the beginning all the way through, as was Pfizer's capsule in a market of its own from the beginning all the way through.

THE PRESIDENT: That is the finding. The reason I am pressing you on this is because you have quite helpfully

and properly shown us the guidance --

MR JOHNSTON: Yes.

THE PRESIDENT: -- which is expressed in --

MR JOHNSTON: Fairly stark terms.

THE PRESIDENT: -- fairly stark terms, that is an excellent way of putting it, and yet it seems to be not having the sort of effect on doctor practice that one would expect given the way it is put, and I put it no higher than that.

MR JOHNSTON: No, and it may be that the most helpful thing that we can do overnight, or at least in the next couple of days, is look back to the original Decision, and I think there may even be some section 26 notices from the original investigation that may touch on this point, but certainly by the time we got to here last time, if I can put it that way, nobody was suggesting anything other than prescriptions are open almost all the time, and my recollection is that the figure was in the 90s of percentages, and, as I say, that was why Professor Walker was talking to this point in his expert report, and he has a section on it I think called "continuity of supply" in his second report which you may get some assistance from that.

MR HOLMES: Sir, I hesitate to interrupt, you will have it well in mind that the prescriptions were nonetheless

written by capsule or tablet by that distinction, so --

THE PRESIDENT: I am coming to the capsule/tablet question. I have a question for Mr Johnston on that.

MR DORAN: Could we just go back to the guidance for a moment?

MR JOHNSTON: Yes.

MR DORAN: Above the guidance to the pharmacist there is this advice for healthcare professionals. It says:

"If a patient should be maintained on a specific manufacturer's product, this should be prescribed ..."

So it seems to be less categoric than the guidance for doctors at the top or the guidance for pharmacists below.

MR JOHNSTON: I think that is squarely consistent with Professor Walker's evidence which was in practice, when applying this guidance, clinical judgment reigns, if I can put it that way. So clinicians are obviously conscious of the guidance, but they are themselves making an assessment about whether to write the prescription in an open or a closed fashion.

We know obviously some of the prescriptions were closed, but we also know that the majority of them were not. I think Mr O'Donoghue had another quote from the judgment that was at paragraph 190, so if I could take the Tribunal to {XN1/2/64}, this is in the middle of

paragraph 190:

"We accept that this practice was not uniform, but it was nonetheless significant, and substantial stabilisation seems to have set in after the MHRA Guidance ..."

So they are saying there was some stabilisation, there was substantial stabilisation after that, but they are saying the practice was not uniform, and I suppose there you may get some more assistance in terms of where the boundary lay after the MHRA guidance.

It was not suggested that the MHRA guidance had zero impact of any kind, but it was also clear that the MHRA guidance was not the absolute death knell of switching. Quite the contrary, because that is what the volume data told from us the market and that is what the clinical conduct was consistent with.

THE PRESIDENT: Well, Mr Johnston, this has been very, very helpful. I think I want to put down a marker for the clinicians who we are hearing on 14 November that they must cover this in their teach-in.

MR JOHNSTON: That is very helpful.

THE PRESIDENT: I do not know what the answer is, but it seems to me, rather than second-guessing matters from the judgment or other material, we should receive it from those who actually know what they are talking

about, and I say that with great respect to you and no respect to me.

MR JOHNSTON: No, I take that indication very advisedly, and as I say the prereading as regards that point is either in Walker 2 or Walker 1, I think possibly in both --

THE PRESIDENT: We will do that.

MR JOHNSTON: -- but my recollection is it is particularly in Walker 2.

Sir, I do not --

THE PRESIDENT: Well, if you are about to finish?

MR JOHNSTON: I am about to finish.

THE PRESIDENT: Then I have a question which Mr Holmes indicated which is obviously we will go into continuity of supply as we will in the future, but when one is talking about the first prescription, in other words one has a patient that is getting phenytoin for the first time, what informs the choice between tablet and capsule?

MR JOHNSTON: I do not think, unless somebody can tell me otherwise, that there is a compelling answer to that in the evidence that we have.

I do know that a number of patients were on a mixture of tablets and capsules because they wanted to be able to use the 25mg capsule, and so if you are on 100mg of tablet and you want to titrate it up a little

bit in the way I was describing earlier what one is likely to do, rather than start breaking tablets in half which people also do, actually, is add a 25mg capsule, and so some patients will be on a mixture of both. Ease of swallowing is the other factor, thank you.

PROFESSOR WATERSON: I recall that Professor Walker talked about this in the first trial, so we can certainly get assistance from him on that point.

MR JOHNSTON: Yes, and Ms Stratford reminds me that another factor is the tablets can be broken, which is advantageous, the capsules can be opened and it can then be mixed into food if there are difficulties ingesting it. So there may be a range of reasons why you would take one or the other, and as I say I do know that some patients were prescribed at various times a mixture of both.

PROFESSOR WATERSON: That never works with a cat.

MR JOHNSTON: Prescribing a mixture of both or opening and mixing into the food? We could have a fluid exchange about how to give flea treatments to dogs, but I probably should restrain myself on this subject altogether. I do not have anything further.

THE PRESIDENT: No, I am grateful. Again, I think that is something which, if the clinicians would not mind, they could just assist us on the facts that inform the

choice, because if one reads the continuity of supply literally, that choice is effectively a lifetime choice.

MR JOHNSTON: Yes, if you read it in the starkest of terms.

THE PRESIDENT: If you read it in those terms, which we will be educated on as well.

MR JOHNSTON: Yes, I am very grateful.

THE PRESIDENT: Thank you very much.

MR JOHNSTON: I am conscious of the time. Is the sensible thing to start at 9.30 tomorrow given where we are?

THE PRESIDENT: I think Mr O'Donoghue does not really need two minutes to limber up.

MR O'DONOGHUE: Even my Irish brogue will not get through what I want to say in two minutes.

THE PRESIDENT: We will resume at 9.30 tomorrow and, Ms Stratford, do consider when you are proceeding through your submissions whether the afternoon is of assistance to you.

MS STRATFORD: I am very grateful.

THE PRESIDENT: Thank you all very much. We will resume at 9.30 tomorrow.

(4.54 pm)

(The hearing adjourned until 9.30 am on Tuesday, 7 November 2023)