IN THE COMPETITION APPEAL TRIBUNAL

Case Nos. 1275/1/12/17
1276/1/12/17

Victoria House,
Bloomsbury Place,
London WC1A 2EB

2nd November 2017

Before:

PETER FREEMAN CBE QC (Hon)
(Chairman)
PAUL LOMAS
PROFESSOR MICHAEL WATERSON

(Sitting as a Tribunal in England and Wales)

BETWEEN:

FLYNN PHARMA LTD AND FLYNN PHARMA (HOLDINGS) LTD Appellant

- and -

COMPETITION AND MARKETS AUTHORITY Respondent

- and -

PFIZER INC. AND PFIZER LIMITED Appellant

- and -

COMPETITION AND MARKETS AUTHORITY Respondent

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HEARING – Day 4 - Redacted

A P P E A R AN C E S

Kelyn Bacon QC, Ronit Kreisberger and Tom Pascoe (instructed by Macfarlanes LLP)

Mark Brealey QC, Robert O'Donoghue QC and Tim Johntson (instructed by Clifford Chance LLP)

Mark Hoskins QC, David Bailey, Hugo Leith and Jennifer MacLeod (instructed by CMA)

Thursday 2nd November 2017

(10.30 am)

HOUSEKEEPING

MR HOSKINS: Good morning, sir. Before Mr Brealey calls his first witness, I just want to say a few words about how we're going to deal with confidentiality.

THE CHAIRMAN: Please do.

MR HOSKINS: I should say a lot of time has been spent by people other than me working this out, I am certainly grateful to them.

Basically the witnesses can work off the same bundles that everyone has, save in relation to certain aspects of the decision. There is a confidential version of the decision that has been prepared, so we all have the non-confidential version, everything in it, sorry, I always get it the wrong way round. The public version with material redacted, that's going to be available, the decision, with everything in it. That's going to be available.

There are a very limited number of documents, including some excerpts from the decision, there is material that's confidential but the particular witness can see, and there are some documents that fall into that category, and there are little clips that we've got for each of the witnesses that we'll hand up. I'll ask

them to refer to those, but the Tribunal will have a copy of this, but I think you can just look at your versions in the bundles and I'll give those references.

THE CHAIRMAN: Am I right that the main issue is confidentiality as between Flynn and Pfizer?

MR HOSKINS: I don't know if it's the main issue, it is certainly an important issue.

THE CHAIRMAN: An important issue. Okay. Right. Thank you.

MR HOSKINS: I should say, I've obviously tried to limit, as much as possible, any requests to go to sit in private. What I've done, certainly with Mr Poulton and Mr Walters, I've left all the questions where I'm going to ask you to sit in private until the end so that they're all in one discrete block. It means I might have to take some topics slightly out of sequence, but it seems more practical than people coming in and out throughout the morning.

THE CHAIRMAN: Okay. You must let us know when you want to go into private session.

MR HOSKINS: Of course.

THE CHAIRMAN: I don't know whether this is for you or for Mr Brealey. We did have discussion at the case management conference about the protocol for this witness examination, and I think it was agreed that

Mr Brealey would be allowed to cross-examine Mr Beighton, and before you had the opportunity of cross-examining him. We put aside the question of whether you had the right to do this, and we waited to see if there were any further requests. We've had no further requests, so am I right that that is still the position?

MR BREALEY: I still would like the ability to -- I'm not going to cross-examine Mr Beighton, but what I would like to do is ask him some questions.

THE CHAIRMAN: And they're not to be leading questions, Mr Brealey.

MR BREALEY: Yes. That's why I won't cross-examine him. I think it is better for the Tribunal if you get the words straight from his mouth. All I want to do is ask some questions for clarification and that's what I intend to do. I've never been told that I can't by the CMA.

THE CHAIRMAN: Right. We got into cricketing metaphors last time. You're not allowed to bowl him full tosses.

MR BREALEY: No, I won't. No googlies.

But I will go before Mr Hoskins.

THE CHAIRMAN: Yes. It is just Mr Beighton we're talking about?

MR BREALEY: Just Mr Beighton.

THE CHAIRMAN: Otherwise it is two parties only. Fine. Then Mr Brealey, I think.

MR BREALEY: Thank you very much indeed, sir.

MR O'DONOGHUE: Before Mr Brealey calls Mr Poulton, there have been a couple of documents added to G2 overnight and on this side of the room we have no objection.

THE CHAIRMAN: A couple of documents?

MR O'DONOGHUE: Added to bundle G2 overnight. Mr Hoskins tells me, and I accept, that he became aware of these documents on Friday evening, but from our perspective, it would be helpful if this was either not repeated or if we had a bit more notice.

THE CHAIRMAN: Just remind me what G2 is?

MR O'DONOGHUE: Well G2 is the -- well, it's a mixture of things. G1 is essentially the contemporaneous e-mails, some of which I imagine will be put to the witnesses and G2 contains some of that, as well as other documents.

The concern we have in particular is that we understand from yesterday Mr Hoskins intends to put a lot of his case in cross-examination, so if we get these things overnight and have very little time to look at them and investigate further, it isn't quite fair. So we --

THE CHAIRMAN: Your concern is that they came too late; is that right?

MR O'DONOGHUE: Yes, and there is a question of fairness. So nothing about these two particular documents, but something to watch maybe going forward.

THE CHAIRMAN: Yes. I mean, you put in some evidence fairly late last week, as I recall.

MR O'DONOGHUE: We did, and I have the Tribunal's words ringing in my ears.

THE CHAIRMAN: Good.

MR O'DONOGHUE: Something relevant won't necessarily be excluded.

THE CHAIRMAN: What is sauce for the goose is sauce for the gander.

MR O'DONOGHUE: We did this before the trial, which is slightly different.

MR HOSKINS: Sir, I'm not sitting on a pile of ammunition.

THE CHAIRMAN: You're not going to do this again and again?

MR HOSKINS: If something comes to my attention I wasn't previously aware of I will use it, but I'm not sitting on it.

THE CHAIRMAN: Does the tribunal know what these documents are?

MR HOSKINS: Two documents: one is a report from The Times newspaper which refers to Mr Beighton, and the second document is a document taken from the Concordia website, which is a set of slides that were presented at

a conference in London, and of which Mr Beighton was one of the co-authors, so it is a document actually co-authored by Mr Beighton. We found that on the Concordia website on Friday evening.

THE CHAIRMAN: We have these in our bundles?

MR HOSKINS: They're now in the bundles.

THE CHAIRMAN: Do they have a reference?

MR HOSKINS: They do, yes. I can give you that.

THE CHAIRMAN: It would be kind if we were given that.

MR HOSKINS: The Times article is at G2, 150A, and the conference slides are at G2/98A.

THE CHAIRMAN: Thank you.

MS BACON: There is one problem with the version of The Times article that has been put in, which is that it seems to be incomplete, there seem to be sections missing from it. I don't know if my learned friend has made attempts to get a complete version.

THE CHAIRMAN: Is this a downloaded version?

MR HOSKINS: I honestly -- I was shown a copy of an article from The Times -- This is not -- The Times article is not going to be hugely significant. If Ms Bacon has any concerns --

MS BACON: Sorry, The Times article is what?

MR HOSKINS: Is not going to be hugely significant. If you've got any concerns after I've asked the questions

in this further line of enquiry, we haven't held anything back. We've put in the version that I have.

THE CHAIRMAN: Thank you.

Mr Brealey? Finally.

MR BREALEY: Sir, I call Mr Poulton.

MR STEVEN MICHAEL POULTON (affirmed)

Examination in chief by MR BREALEY

THE CHAIRMAN: Thank you. Mr Poulton is going to be provided with the appropriate bundle; is that right?

MR BREALEY: Bundle B.

THE CHAIRMAN: Can that be done, please (Handed).

THE WITNESS: Thank you.

MR BREALEY: Mr Poulton, you've got bundle B. Could you go to tab 2, please? Can you just identify that is your witness statement.

A. Yes, this my witness statement.

Q. I understand you want to make two slight corrections?

A. Yes, there are two dates that are incorrect in here.

Q. I think one is at paragraph 11 --

A. One is at paragraph 11.

Q. On page 3.

A. It says: "In January I moved to a new role". I actually moved to that role in July, not January, 2012. The other is at paragraph 31.

Q. Thirty-one, page 9.

A. It's actually on page 10. On the end of the fourth line, I referred to a presentation that was made by Claude Jakob, and it says there June 2010, the presentation was made in June 2011. It is actually -- the front slide of the presentation does say "2010", but it is clear from the content of the presentation that the data is all up to the middle of 2011. So it's a typographical error on the front of the presentation which has been repeated in paragraph 31.

Q. If you could go -- thank you for that -- to the end of this statement, which is at page 24. Could you confirm to the Tribunal that is your signature?

A. Yes, that is my signature.

Q. Can you confirm to the Tribunal that the facts stated in the witness statement are true to the best of your knowledge and belief?

A. They are true to the best of my knowledge and belief.

Q. Thank you very much, Mr Poulton. Mr Hoskins is right at the end, and he'll ask you some questions.

Cross-examination by MR HOSKINS

MR HOSKINS: Good morning, Mr Poulton.

A. Good morning.

Q. We have one, as I explained at the start, a little bundle, but don't worry about that, you'll be handed it as and when you need it. I have some for the Tribunal

as well.

THE CHAIRMAN: Thank you. (Handed)

MR HOSKINS: I'd like to begin by clarifying the nature of Pfizer's business with you. You'll have to bear with me a bit because I want to show you some passages from your witness statement and then I'll ask you some questions about them. So if you still have your statement in bundle B, if we turn first to paragraph 5, you see in the first sentence you describe Pfizer as one of the world's leading innovative biopharmaceutical companies. Then at paragraph 6, you make a distinction between two types of products:

"Pfizer manages a wide range of pharmaceutical products which can broadly be divided into two categories. The first includes those products which are patent protected of a degree of market exclusivity [which you define as innovative products]. The second includes those products which have typically lost exclusivity and compete with generic alternatives - "Established products" is the definition you give to them but they're also referred to by Pfizer at times as "Essential Products". Prior to 2009, these were known as "tail" or "mature" products.

So you identify those two particular categories within Pfizer's business.

Then above paragraph 13, you have of the heading "The established products portfolio". You explain in the third sentence:

"The portfolio is made up of diverse products, many of which have a relatively small turnover and receive far less of any active promotion than innovative products".

So that's established products you're describing there. Bear with me, a couple more, and then I will ask you some questions.

Paragraph 14:

"Accordingly, while there was and is strong emphasis within Pfizer on innovative products, the commercial contribution of the tail portfolio was something that Pfizer's business development team kept under regular review."

So there you refer to the strong emphasis on innovative products.

Finally, paragraph 58, second sentence, you describe Pfizer as a "Research based pharmaceutical company" and you say:

"Because of that our regulatory department was resourced primarily to deliver submissions for new branded products and to respond to queries about existing branded products."

You go on to explain:

"We did not have people with experience of generic licensing or specifically debranding."

I hope this isn't going to be controversial given what I've just read, but it's -- obviously the case isn't at the focus of Pfizer's business, it is very much what you have called innovative products.

A. Up until 2009, that was certainly the case, so we were organised geographically as a complete business. And in those days, our innovative portfolio was something, so, in patent, branded portfolio was something like 85 per cent of our total turnover.

After 2009, the focus changed because we split into separate business units at that time. We had three business units that looked after different segments of the innovative portfolio, the in-patent portfolio, and we had one business unit that looked after all of the products that had lost patents, so what we called the established product.

So overall, yes, Pfizer is still a research based innovative company, but the focus on the tail portfolio increased significantly in the business unit that was set up to manage it after 2009.

Q. Just to clarify, if we're looking at the global Pfizer business, the majority of the resources and efforts are

focused on innovative products.

A. I'm not sure that's the case. In terms of people, I think it is pretty much split between the two, but yeah, we consider ourselves a research-based innovative pharmaceutical company. Our focus is very much on discovering and commercialising new medicines, certainly.

Q. Again, I'm looking globally, most of Pfizer's turnover is generated by innovative products, as compared to the tail products?

A. I think it's these days, it's about -- it's not 50/50 but it's probably something like 60/40. I can't remember the exact numbers.

Q. You say that is today. Has that changed over time? What was the position -- (overspeaking) --

A. Yes, it has changed. I think previously around -- you know, before 2009, the vast majority of the revenues will have come from the innovative products. The established portfolio has gained in proportion over the years.

Q. If you look at paragraph 53 of your statement, this is dealing with the deal obviously that you did with Flynn, or you were looking to do with Flynn:

"By retaining manufacturing through a supply agreement, we were able to ensure that there was no risk

for patients who were already established on the product being switched to other formulations or therapies as had been a concern in earlier discussions."

Then you say:

"As there would be no change to the manufacturing process, patients would be supplied with exactly the same product after we entered the deal with Flynn."

I wanted to clarify, after the deal with Flynn, Pfizer continued to manufacture the product, did it not?

A. That's correct, yes.

Q. As you explain, there was no change in the manufacturing arrangements. You continued to manufacture the phenytoin sodium capsules in Germany, as you had done before the deal with Flynn?

A. Yes, the active ingredient was manufactured in the US, and preparation of the capsule and the final finishing and manufacturing and packaging was done in Germany, yes.

Q. But no change as a result of the --

A. No change, no. That was really important to us that there was no change.

Q. Why was it important?

A. Because we wanted patients to have the confidence that it was the same medicine. Something we wanted all along was to maintain continuity of supply for patients to

make sure this medicine continued to be available for them so there would be no risk of them, if they were switched to alternatives.

Q. What sort of risk might there be if they were switched to alternatives?

A. I don't know. We had many discussions about this with our medical team. It's a product that has what's known as a narrow therapeutic index, which my understanding is that it means that, along with other anti-epileptic drugs, that if a patient is stabilised on this product, the best thing for that patient is to stay on it and not to be switched to a different version of the product or to a different product. So one of our key drivers throughout this was to ensure that the product was still available to patients in exactly the same form.

Q. I am going to take you now to the little blue bundle. It is tab 1 of that. Just for everyone else, it is the decision, paragraphs 3.65 and 3.66.

If you wouldn't mind, I know there are certain bits that you can't see -- I'm sorry, you can see everything on that one I'm told. Sorry. We're not allowed to read it aloud is the problem. We can't read any of the coloured parts aloud.

A. Okay.

Q. I'm going to ask you, therefore, if you wouldn't mind

reading 3.65 and 3.66 and have a look at the table. Just to let you know why I'm doing that, I'm going to ask that you can confirm that the description of the activities carried out in relation to the manufacture and sale of Phenytoin are accurate in those passages.

(Pause)

A. So the only thing I don't know here is that it says half way down here, 3.65, that very little has changed in the supply chain. The references in the supply chain to what happened prior was to us selling the product to Flynn are absolutely correct. What I don't know is what Flynn's distribution model is after it -- after we delivered the product to them.

Q. So you can confirm the position pre-the Flynn deal?

A. Correct.

Q. You can confirm the position so far as it relates to Pfizer?

A. Correct.

Q. Post-the Flynn deal, but you're not in a position to confirm what Flynn does in the supply chain after the deal that was done?

A. That's right, yes.

Q. Can we go back to your witness statement, that's bundle B. Turn to paragraph 12. It's the second sentence where you say:

"Whilst I've had some exposure to the regulatory regimes that pharmaceutical products are subject to, I do not consider myself an expert."

Just to clarify, do you have any legal training?

A. I have no legal training, no.

Q. Have you ever read scheme M?

A. I haven't read the scheme in the document, no.

Q. Can we go to bundle G1, tab 4. This is an e-mail chain, it's the one at the top of the page I'd like to look at. You'll see that this is an e-mail from you, and I understand from those names that this is an internal Pfizer e-mail; is that correct? These are all people who work for Pfizer?

A. Yes, these are all people in my team at that time, yes.

Q. It is dated 8th August 2009; you see that?

A. That's right, yes.

Q. And the title the subject is: "Epanutin Adoption Deal"?

A. Correct.

Q. And you say in that:

"Thanks, Jason. Putting aside the ethical issue for a moment, I'm not sure of the sustainability of this. The price for 28 times 100mg tablets is cat M, so presumably DH can change this whenever they want. What is to stop them changing it to 0.95 [I think that should be 95p] in the next revision of the DT after we do this?

I don't know enough about cat M to evaluate."

So in August 2009, you were recognising that you did not know much about the DH's powers under scheme M, weren't you?

A. Yes, it was one of the things that we needed to get some more understanding on.

Q. Did you try to obtain a better understanding of how scheme M works before you entered into the deal with Flynn in January 2012?

A. Yes, I spoke with our finance colleagues who were the people that interacted with the Department of Health and who were responsible for our submissions under the PPRS and for pricing. And they showed me, I think it was a briefing document that the Department of Health put out at the time, that it introduced category M, which explained the purpose behind it, and some of the mechanisms within it.

Q. We don't see a review to that in your witness statement or, I believe, in any of the contemporaneous documents, do we?

A. No, I don't think I did refer to it.

Q. Presumably the reason why that's not mentioned is because you didn't consider scheme M to be a particularly serious obstacle to the deal, it certainly didn't stop you doing the deal. Was it

a serious obstacle?

A. Yeah, it was one of the biggest concerns I had, because my understanding was that part of why the Department of Health introduced scheme M was to enable them to be able to intervene in pricing of generic medicines. Firstly, to fine-tune the sum that they gave to community pharmacy; secondly, I understand they also used it to shift funding from reimbursement of medicines to paying pharmacists for the services they wanted them to do; and there was also a mechanism in there that if they felt market mechanisms weren't working, they could intervene to set a fair price. And I think there are number of e-mails in the bundle where this whole sustainability thing was a big question, because we didn't want to just simply raise the price for a couple of years, it wasn't about getting financial benefit; it was about putting this product back on a fair sustainable basis for the longer term.

So if the Department of Health could, as we believed, intervene at any time to set the price at what it wanted to, then that would have been a barrier to us continuing the availability of this product in the UK.

Q. Your understanding was that the Department could intervene at any time in relation to category M and control the price of the Phenytoin capsules? Is that

your concern?

A. Yes, I mean any product within category M. The Department -- my understanding was the Department could choose which category it put the generics into, whether it was category A or category M. Category M was the only category that gave them the power to intervene, and we believed that they used it. There was certainly plenty of articles in the pharmacy press at the time about prices in category M being reduced.

Q. Are you talking about using scheme M to reduce the price, is what you're referring to -- to what precise power are you referring to?

A. I don't know the terminology "scheme M," category M is what we referred to it as.

Q. I mean, are you aware that membership of scheme M is voluntary?

A. My understanding was that it was the Department that chose which products went into category M.

Q. So you weren't aware that scheme M was voluntary?

A. I'm not aware what scheme M is.

Q. Are you aware that there were regulations that controlled the price of certain generic medicines? They were called the Health Service Medicines Control of Prices of specified generic medicines regulations 2000/1763". Is that something that rings a bell?

A. No, that doesn't ring a bell. My understanding was that there were two categories that the Department could put generic medicines into: category A, where the price or the reimbursement price was set according to a basket of manufacturers and wholesalers' prices; and category M, which was the one where they could choose to put certain medicines, where they could set the price independently if they wished to.

Q. Your knowledge of these powers that you believed the DH had was obtained from what, from the trade press and from speaking to your financial colleagues in the PPRS; is that right?

A. Yes, so speaking to our financial colleagues to talking to people in my team who had some experience of generic medicines.

Q. Did you ask the legal team to look at this issue?

A. I don't believe I did, no.

Q. Did you ask anyone to produce a detailed paper on this issue?

A. No, I raised the question a number of times, and -- but we didn't have a paper prepared, no.

Q. In relation to scheme M, are you aware that it establishes a dispute resolution system to resolve issues between the DH and individual scheme M members?

A. No, but that doesn't surprise me.

Q. And any fears that you may have had about DH intervention didn't stop you doing the deal with Flynn, obviously, because it happened?

A. No, I think by the time we -- by the time I -- we -- took the decision to go ahead, that was still a concern. I still believe that that could happen. Another year had passed and the Department hadn't intervened in the price of the tablets, which they clearly considered to be an acceptable price. So I thought the risk was perhaps slightly less, but I think the reason -- the main reason that persuaded us to put the project forward for approval was the increasing risk that the product would be withdrawn in the next few years. So the risk balance changed on both sides.

Q. Can we go to bundle G1, tab 31. This should be a document sort of graffiti style it says: "Established products. Epanutin proposal for UKMF, December 2010, follow-up meeting April 2011."

We see from the little logo, "Pfizer established products". I presume this was a document produced by your team, by the established products team, in Pfizer; is that correct?

A. Yes that's right.

Q. By this stage, you were negotiating with Flynn, weren't you?

A. Yes, we were.
Q. Can you just help us, what is the UKMF?
A. The UK -- so again, this is after we split into business units. So each business unit in the UK reported up through different lines. So we had no common UK organisation, but what we had was each of the heads of the main business units, plus the heads of what we called the support functions for the business, formed a management team for the whole business. And that was called the UK Management Forum. So we would meet weekly, fortnightly, to discuss issues that were of interest to the whole business, rather than those issues that were specifically relevant to our own business units.
Q. What was the purpose of this particular document?
A. This was to seek endorsement from the UK Management Forum for us to proceed to seek approval with my business unit's regional and global management to go ahead with the deal.
Q. Sorry, can you just unpack that a bit? It was endorsement to go to a different part of --
A. Sorry, yes. So because of our reporting lines, the deal needed to be approved by my direct management, which was the European Management Team for my business unit. However, because it impacted the UK business,

I considered it courteous to seek the endorsement of my colleagues in other business units, prior to -- and seeking their feedback -- prior to seeking formal approval.

Q. So this is part of the process of seeking approval from your superiors to do the deal with Flynn?

A. It was a --

Q. Is that how you're describing it?

A. It was a prerequisite step. So it wasn't part of the formal approval process, the UKMF didn't need to approve it, but I wanted to make sure they were comfortable with it, and before I took it for approval.

Q. What you were doing here was setting out, presumably, the pros and cons of the deal, the good things and the bad things? This was --

A. I was setting out the features of the deal. So that -- partly for the communication, but also to understand if they had any concerns that we needed to address. So you'll see that the proposal has two dates on the front. The December 2010 proposal was where I took them through it, and we received their feedback and the concerns they had, and then the follow-up meeting in April was where we addressed the concerns that they had.

Q. So if this was intended to make sure they didn't have any concerns, you would obviously want to raise, as

I said, potential cons of the deal and not just the pros. This is not just a sales pitch, it is an open explanation of the deal and what the good things might be and what the bad things might be; it is a neutral appraisal for their consideration?

A. Yes, it was trying to explain to them the positive and negative consequences of the deal, and the main features of it and the rationale behind it.

Q. If we go to page 3, slide three, you see the heading "Epanutin Phenytoin Capsules: Current Position"?

A. Yes.

Q. "Epanutin in the UK is economically unattractive at its current list price", and there's a reference to tablets. You then say, "Tablets and capsules are not easily interchangeable". You gave an explanation earlier about the concern to ensure that the manufacturing process didn't change. Presumably that reflects that concern; is that correct?

A. No, no, this was around -- well it is partly around that, so I think we all agreed that the best course of action for -- or, the best solution for any patient on any anti-epileptic drug is that they stay on the one they're currently at. So that in itself would mean that the patients that were already on tablets or on capsules would probably remain on those. But also, we felt that

some of the prescriptions would be written with tablets in the prescription, and some would be written with capsules in. And if that were the case, if it said, "Phenytoin tablets" then the pharmacist had to dispense tablets. If it said, "Capsules" then they had to dispense capsules. If it was open, then they could dispense either. So we felt that there was probably, from talking to my medical colleagues, probably a proportion of scripts that were written specifically as Phenytoin tablets or Phenytoin capsules as opposed to just Phenytoin 100mg.

Q. The fifth bullet point says:

"Nevertheless Phenytoin capsules must continue to be available to patients."

Why was that the case? Why did you feel that to be the case?

A. Because of this issue around maintaining patients on the same product. I mean, by this -- this was early to mid-2011. By this time, we were starting to have discussions in our head office in New York about a project that was looking at significantly reducing the number of products that we had available. We had something like 18,000 different packs that we produced globally, and we wanted to -- and many -- the bottom 9,000 of those were very low revenue products that

contributed about 2 per cent of our overall turnover. And once the Established Products Business unit was set up, there was a project set up to look at discontinuing a large number of those low revenue low-profit products. And around about the end of 2010, beginning of 2011, we were starting to get an understanding as to the magnitude of the likely withdrawals. So that was at the point where I believe there was an extremely serious threat that Epanutin in Europe would be discontinued.

So our key driver, and hence the inclusion on the slide here, was that we believed that Phenytoin capsules must continue to be available to patients across the full dose range.

Q. So you thought it should survive the cull of products?

A. I very much thought it should survive the cull, yes.

Q. Then slide four, just in passing, you say:

"We recommend that price is pitched at half the price for Phenytoin tablets initially."

I'll come back to tablets in a minute. Slide six, "Potential issues":

"Ensuring continued patient access to Phenytoin caps, pharmacopolitical damage (Pfizer), parallel trades challenges and PPRS considerations."

No mention of any intervention by the DH in respect of the price.

This was a warts and all document, neutral appraisal, and you made no mention at all of potential intervention by the DH to reduce the price.

A. Not on those slides, no.

Q. If we go to slide ten, "UKMF Key Challenges". Second bullet:

"Regulatory restrictions", none identified. So again, no mention at all -- in fact, it is not a no mention, they are mentioned, and you say there are no regulatory restrictions.

A. So that was about whether there was a restriction in our ability to debrand the product either ourselves or via a third party. That was not about pricing.

Q. So you say that's not about pricing, but then one sees in that list of key challenges no reference to any possible intervention on price by the DH. It wasn't something that you identified.

A. No, as I said, I think about round that time, we still recognised the Department of Health could intervene, it had now been 5 years since they'd intervened in the price of the tablets, so I -- our judgment was that the risk that they would intervene similarly on the capsules was reducing.

Q. And certainly not sufficiently important for you to raise it in this document with the UK MF?

A. Yeah, I mean the document was a vehicle for a discussion, and a conversation. So I'm sure we discussed it at the meeting. We certainly did with our European team when we presented it in -- a couple of months later.

Q. Can we go to G1, tab 44. It should be a document entitled "UK EP Epanutin Proposal Briefing for Albert Bourla August 2011."

A. Yes, I have it.

Q. Are you familiar with this document?

A. I am, yes.

Q. And "EP" in the title presumably refers to established products; is that correct?

A. It does, yes.

Q. And that was still your department at this time?

A. Correct.

Q. And who is Mr Albert Bourla?

A. Albert Bourla was the head of the established Business Units Product worldwide.

Q. Why were you sending this summary to him?

A. It was actually sent by my -- Albert Bourla was my boss's boss, so I reported him to the European head of established products, who I presented to in, I think it was, June 2011, and then he chose to then present it upwards to Albert Bourla, and we took the briefing note

that we prepared for Mr Scully, who was my boss, and edited it slightly so that he could send it on to his boss, Albert.

Q. Was this part of the formal approval process?

A. I don't think so. As far as I'm concerned, we got the go-ahead to proceed when we presented to my boss, the European head. I think, as a courtesy, he was -- he was presenting it to his boss.

Q. But you thought this was information he should know? You wouldn't --

A. It wasn't my decision to send this. As I say, it was my boss's decision to send it.

Q. It was your boss's decision to send it?

A. Yes. I prepared the document, or my team prepared the document for him.

Q. So your team prepared the document. There is one sentence in the document which is in bold, you'll see it stands out in the middle of the page:

"The potential revenues to Pfizer from Epanutin are estimated to increase from 2.3 million per annum up to approximately 20 million per annum."

Given that's the only point that's in bold, it's a fair inference, is it not, that that was the most important point for Pfizer in relation to this project?

A. It was a relevant point, certainly. If the only way to

maintain the product was to bring it back onto a commercial footing, the way to do that was to debrand it and launch it at a similar price to the price that the tablets had been at, and as a consequence, that meant that there would be a commercial upside. And that's what that point is describing.

Q. It wasn't merely a relevant point; it was the most important point. That's why you emphasised it in this document?

A. No, I'm not sure that's the case. I think it's not the point at the top, it's not the first point on the top.

Q. You then, at the bottom of this document, your team set out a list of potential issues.

"The following potential issues are considered in the body of this document: impact on patients, pharmacopolitical issues, manufacturing implications, parallel imports."

Again, no mention of possible intervention by the DH or any other body to lower the price of the product.

A. So that was a risk that we would have discussed during the presentation.

Q. But not --

A. This is a briefing note, it's not a business case. It is meant to give someone some contextual background and then the details would come out in the presentation that

we made.

Q. What's the purpose of an executive summary?

A. It's to give the key points and some of the key background and context.

Q. The key points. So possible intervention on price by the DH was not considered to be a key point, otherwise it would have been in the executive summary; correct?

A. So I think I explained that earlier, which was that by the time we submitted this proposal, my feeling was that although the Department of Health clearly had the powers to intervene, and had done so in the past, because they were still not intervening on the tablet price, which they must therefore accept as the fair price for the medicine, that the risk of them intervening was less. So I was picking out some of the other issues.

Q. When you say the DH had intervened in the past, are you talking about tablets only or are you -- do you have other examples in mind?

A. I'm talking about the tablet pricing. That was the benchmark that we had all through this project as the value that the DH --

Q. So that was the sole example that you were aware of the DH allegedly intervening to lower the prices?

A. It was the only relevant example in this case, certainly.

Q. You explain and you corrected it this morning that you moved to a new role in Pfizer in July 2012. And you no longer had any responsibility for the UK. Is that correct?
A. That's correct, yes.
Q. Given you're the only Pfizer witness, I'm going to show you some material that post-dates that, and if you're not in a position to help the Tribunal in relation to those documents, feel free to say so. But you understand that, given you're the Pfizer person --
A. Yes.
Q. -- I'm going to give you the chance to comment on some of this material. Can we go to bundle G2, tab 99, please.
A. What number, sorry?
Q. Ninety-nine. Now I should explain, this is a 16th November 2012 letter. It is written to [✂] at the Department of Health. If you go to the last page of it, you'll see it's from someone called Dr David Fakes who is a director. And it is sent for and on behalf of Flynn Pharma Limited. Do you know David Fakes, do you know who he is?
A. I don't, I'm afraid, no.
Q. Have you ever heard of him before?
A. I don't recall the name, no.

Q. Now, on the second page of this letter there's a heading "Cost of goods". Mr Fakes says to the Department:

"You asked us to request Pfizer's permission to disclose our cost of goods data. Their response to our request was 'As a global supplier of Phenytoin, information relating to the cost structure for a production and delivery of Phenytoin sodium Flynn hard capsules is commercially sensitive and confidential'."

Then in the penultimate paragraph, on the last page, just below the bullet points, Mr Fakes says:

"Flynn and Pfizer are fully aware of the Department and stakeholder concerns in regard to the supply and pricing of this product within the UK and continue with best efforts to pursue the strategies outlined in this letter."

Have you ever seen this letter before?

A. No, I haven't.

Q. Do you know if Pfizer was aware of Department and stakeholder concerns in regard to the supply and pricing of products in the UK as at November 2012? Is that something you've any knowledge of?

A. No, I'm afraid not. Sorry.

Q. Looking at the explanation in relation to the cost of goods, it's Flynn saying that Pfizer had said that the

information was commercially sensitive and confidential, which is clearly correct, but the DH, to whom this letter was sent, was not a competitor. Is it normal for a company such as Pfizer to refuse to supply information to a regulator when they ask for it?

A. I don't know about cost of goods. I know it's certainly information that we restrict very highly internally. It's only quite senior people in the organisation who see cost of goods. I don't know whether in the past we've disclosed cost of goods data to the Department of Health, I'm afraid.

Q. If we could go back to your witness statement, so bundle B, paragraph 43. You note there, you'll see in the first half of the document, that: "Teva had reduced the price of its tablet in December 2007." If you want to read the first sort of eight lines to refresh your memory, please do.

(Pause)

A. Okay.

Q. You then state at the bottom of page 14:

"My understanding at the time was that the reduction in price reflected the DH sanctioned price reset and therefore the revised price reflected the fair value of the Teva tablets to the NHS."

Now we know that Pfizer entered into the asset sale

agreement with Flynn in January 2012. You certainly don't suggest in your witness statement that you talked to anyone at Teva, prior to January 2012, about why they had reduced their price in December 2007. And that's the position, isn't it, you didn't talk to anyone at Teva prior to doing the deal with Flynn?

A. No, we never spoke to anyone at Teva at all.

Q. Prior to doing the agreement with Flynn in January 2012, did you or anyone in your department talk to anyone at the DH about why Teva had reduced their price in December 2007?

A. I certainly didn't. I didn't know that anyone in my department would have done. My department didn't regularly talk to the Department of Health. It was our finance group that spoke with the Department of Health about these issues. I am pretty sure they wouldn't have -- well, I can't imagine why they would have discussed another company's pricing with the Department of Health. I can't imagine the Department of Health would have entertained such a discussion.

Q. If you go to paragraph 51 of your statement, you say:

"Both parties' understanding that the tablet price was the relevant benchmark informed the discussions and negotiations. The documents contained many references to the tablet as the reference. For example, Flynn

suggested that the DH 'would be concerned if [the] price rose too much [TEVA were forced to drop [their] price from [around] £100 per pack to £30 for Phenytoin tabs."

You refer to pages 39-47 of your exhibit immediately following the quote.

If we can go to those pages of your exhibit in bundle C, tab 1, page 39 of this exhibit. You'll see at page 39 this is a Flynn Pharma document entitled "Epanutin Proposal June 2010". Have you seen this before? Clearly you have actually because it is the bit in your statement.

A. Clearly.

Q. Do you remember at the time that this was a presentation by Flynn to Pfizer?

A. Yes, I think it was -- I think we used -- I think we cut and pasted chunks of this into our internal briefing documents.

Q. And, as we saw in your witness statement, you cite from this document, and the quotes that you take or you put in your witness statement is at page 42 of the exhibit.

"DH would be concerned if price rose too much, Teva were forced to drop price from about £100 per pack to £30 for Phenytoin tablets."

This is what Flynn is telling Pfizer. You don't mention any other sources in your witness statement for

the conclusion that you state in your witness statement. Is this where you got the impression about why Teva had reduced its prices?

A. No, I think we were -- I think we'd also had discussions previously with another company that approached us around doing something similar with Epanutin and Phenytoin, and they certainly mentioned it as well. And I think, prior to that, we were aware of the price changes around the tablet, the fact that the Teva price had suddenly more than trebled and then a couple of months later was brought back down again. So I think this was confirmation of it rather than raising it with us.

Q. So the sources of your conclusion were observing the change in the tablet price, what you were told by I think we're allowed to say their name -- no, I'm told not -- by the previous suitor?

THE CHAIRMAN: Sorry, can we be clear about this?

MR HOSKINS: I am allowed to. So the complete source of information for your belief that Teva had been forced to drop prices were your observation of the price dropping, what you had been told by Tor and what you were told by Flynn.

A. Yeah, so the prime reason was our interpretation of what happened in the market. We couldn't think of any other

credible reason why Teva would treble their price and then, within a month or two, bring it back down to the price it was at before without the Department of Health intervening. And that was also clearly the opinion of both Tor and Flynn. So as I say, that was confirmation of our conclusions.

Q. Referencing the price of Epanutin to the price of tablets was a central part of the deal with Flynn, wasn't it?

A. It was the obvious benchmark. It was the thing that made this deal possible that enabled us to continue the supply. If the benefit price hadn't been there, we wouldn't have been able to do this.

Q. In paragraph 67 of your witness statement you say:

"I have already referred above to the fact that both Flynn and Pfizer understood that Flynn would benchmark its price against the reimbursement price paid by the NHS for the Teva tablet. That provided the basic starting point for negotiation of our supply price. As I explained above, we inferred that the Teva tablet price was a price that the NHS were content with."

You use the word "inferred" and that's presumably to indicate, as I think you've already confirmed this morning, was because you did not actually know whether the NHS and DH were content with the Teva tablet price.

You assumed it on the basis of facts you knew, but you didn't know as a fact that they were content.

A. Yes. I mean, the tablets had been at this price previously. They then suddenly increased in price and were then very quickly reduced back to the price that they were at before, and they remained at that price until -- until this point in time. So our inference, our conclusion, was that the Department of Health had found the trebling of the price unacceptable, had intervened with Teva to bring the price down to where it was before, the equivalent of a £90 for our 84 doses. They could have intervened to bring it down further. They didn't. Therefore, our inference was that the Department of Health was happy with the price that they were at previously, the price that they remained at, and that represented a fair value of this medicine, otherwise they would have intervened to bring it down further.

Q. Can we go to bundle G1 at tab 5, please. At the top of this chain of e-mails, it's an e-mail from you to Jason Perfitt. Jason Perfitt worked for Pfizer, didn't he?

A. He worked for me, yes.

Q. He worked for you. It is dated -- it must be the American way round -- 22nd September 2009, entitled "Epanutin Adoption Deal". You said:

"There seems to be a strong concern, reluctance as to the advisability of doing this from a patient care trust perspective. I echo these, but also have a fundamental problem with the sustainability of it. What's to stop DH changing cat M reimbursement once it hits their radar? Is there not an option to point out to DH this anomaly and how much it is costing them and getting them to reset the tablets cat M tariff in line with the cat C branded tariff, thus saving them tens of millions and allowing us a level playing field on which we should be able to win higher share."

The anomaly you're referring to there is the price of tablets, isn't it?

A. The anomaly is that normally a generic version of a medicine, the reimbursement price, is cheaper than the legacy brand. Whereas in this case, it was the other way round, the generic version of the medicine was 30 times the price of the brand. So that's the anomaly that I was referring to.

Q. So that's why tablets were an anomaly because the generic was 30 times the price of the brand?

A. Yes, which is quite different from what you would normally expect.

Q. If we go to tab 10 of this bundle, at the top there's an e-mail from Colin Frost. It is the next one I'm

interested in, which is another e-mail from you to a number of people. Again, can you confirm are these all Pfizer employees?

A. Yes, these are all Pfizer employees. These are members of my leadership team for the established products business unit in the UK. Some were my direct reports, others were representatives from the support functions who sat on my leadership team.

Q. It is dated 2nd February 2010. The subject is "Epanutin". If you go down the numbering, it is 1A I would like you to look at.

A. Mm-hm.

Q. "Other companies may enter caps at a much more attractive price (caps are generally easier and cheaper to make than tablets)."

Can you just expand upon that a bit? Can you tell us, for example, how much easier capsules are to make than tablets? How much cheaper they are to make than tablets? What are you conveying here?

A. So at the time I wrote that e-mail, that was my belief. And that was based on -- I'm not originally from the pharmaceutical industry. I joined it after having worked in a different industry. And I joined -- I worked for a different company in those days. And my first introduction was to actually go into a factory and

work in the manufacturing side. I just remembered some things that I was told by the manufacturing manager at the time, and one was, one that always stuck with me, was his belief that capsules were easier and cheaper to make than tablets. I've since checked that with colleagues, and manufacturing colleagues in Pfizer, and apparently there's not that much difference between tablets and capsules in terms of ease and price. But that was what I believed at the time.

Q. Staying in the same e-mail, turning over the page, it is the final paragraph, indeed the final sentence. You say:

"The aim being to obtain a special price increase outside of PPRS or at least get them to cut the cat M price of tabs the same as caps and prevent Teva making supernormal profits."

You might want to read the whole of that paragraph to put it in context before I ask you the question.

A. I remember the paragraph.

Q. I'm not surprised. It has had quite a lot of attention.

Can we keep that open, but go to your witness statement, paragraph 42, because you deal with that statement at paragraph 42. And about seven lines up from the bottom, paragraph 42, so the last third of that paragraph, you say:

"The implication was that if the DH believed that the loss-making capsule price was roughly appropriate for an oral dose of 100mg Phenytoin sodium, then logic dictates that they must consider Teva were making supernormal profits."

Just to clarify what you're saying it, your logic is that if the DH believed that the correct price for the 100mg capsules was the price at which Pfizer was selling prior to the deal with Flynn, then by definition, the Teva prices must be supernormal because they were so much higher.

A. Yeah, what I was doing here was trying to -- was expressing frustration over the apparent inconsistency of the Department of Health's position. So on the one hand, it was very clear to us that from their initial intervention and then subsequent acceptance of the tablet price, that that represented the value that they believed that medicine gave to the NHS. Yet at the same time, the advice I was getting from our finance team, who'd raised this subject in previous discussions with the Department, was that they would not entertain any exceptional price rise or price reset of the capsules accordingly. So what I was expressing here was that how can the Department have that inconsistent position, because if -- as you say, if they truly believed that

the Epanutin capsule price was the fair price, then they, the Department, must believe that Teva are making some sort of level of inappropriate profit.

Q. You say inappropriate profit. I just wanted to ask you, what do you mean by "supernormal"? It is not simply saying the Teva price is high. Can you put some context, why supernormal?

A. My definition of supernormal profits is one that the relevant regulator would deem inappropriate.

Q. And why inappropriate, in what sense?

A. Too high.

Q. Assume for a moment that the DH did believe that the correct price for 100mg capsules was around the price at which Pfizer was selling it prior to the Flynn deal. If Pfizer then sold its capsules at the same price as the Teva's tablets -- I know you didn't, so just bear with me -- at the same price as Teva's tablets, then applying your logic, Pfizer would also be making inappropriate or supernormal profits, wouldn't it?

A. Well, no because the Department of Health wouldn't allow us to. If the Department believed that that was excessive or inappropriate, or didn't reflect the value of the medicine, then my assumption was that they would intervene in that.

Q. So they would intervene because pricing at that level

would be inappropriate?

A. I believe the Department of Health would intervene to reset a price that they considered inappropriate compared with the value the medicine gives to patients.

Q. Did Pfizer know what the DH's position was as to the appropriate price for Phenytoin 100mg capsules in February 2010? Did you have any discussions with them in February 2010 about what they considered an appropriate price to be?

A. No, I don't believe we did.

Q. Did you have any negotiations -- sorry, discussions with them on that subject prior to entering the asset sale agreement with Flynn in January 2012?

A. No, it was an approach that we -- certainly I was -- wanted to know whether we could do that, hence my wording in the document that you've just referred to. You know, why couldn't we go to the Department of Health and point out this anomaly and say to them that this is a commercially unviable product? "You, the Department, clearly see a value in this medicine because you're quite content to reimburse it at this level in its tablet form," which is an identical bioequivalent product, why can't we have a conversation with the Department of Health to say, "Let's reset these prices to something similar to the price that you're content to

pay for the tablets?" But that would have to be excluded from the constraints of the PPRS because it's a branded medicine, it is within the PPRS that we were signed up to and the PPRS doesn't allow that level of price increase.

The advice I was getting from our team that dealt with the Department of Health was that they'd had exactly that discussion with the Department about a similar loss-making product a number of years ago, and had been told that wasn't -- that was a non-starter. They'd had similar discussions in principle, but not about specific products, in the intervening years, and again, I've been told that that was not an approach the Department would sanction.

So the advice I was given was that that's just not an approach that would be considered.

Q. So you didn't have a discussion with the Department along those lines?

A. No, we didn't.

Q. So you increased the price of Epanutin through the deal with Flynn knowing that there was a risk that the DH would consider that you had benchmarked capsules to a product that generated inappropriate or supernormal profits, didn't you?

A. No, because I didn't believe that the Department thought

that Teva were making inappropriate profits because if they did, then they would have intervened to bring the price down further. So my belief was that the Department didn't think that Teva were making supernormal profits.

Q. But it is clear that that is your inference, you did not have any direct knowledge, as you've accepted, of the DH's position --

A. Yes, that --

Q. -- on what was the appropriate price.

A. Exactly, that was the conclusion I drew from what we - actions we saw in the marketplace.

Q. I will deal with one more topic and then, if you'd like, we can break.

I'd like to show you a legal authority. Don't worry, I'm not going to ask you any legal questions. It is authorities bundle A, tab 1. It is the judgment of the Competition Appeal Tribunal, so this tribunal in a pharmaceutical case. You don't have to worry about the background. I just want to show you a finding that the tribunal made. It is at page 108, paragraph 417, it is the second sentence where the tribunal says:

"The evidence we have is that in the case of many pharmaceutical products the expiry of a patent leads to competitive often generic market entry with the

consequence that the incumbent supplier either lowers prices or loses market share or both perhaps quite rapidly."

The question I wanted to ask you was whether you agree that that is the normal position.

A. Yes, I think that is the normal position.

Q. Then if we go back to your witness statement, let's turn to paragraph 28. It's one I think we've been to already this morning. It's the final part, the final sentence. You see the last three lines. You say:

"The usual but not invariable position is that the reimbursement price for generic product is less than that of the original branded product."

I think you confirmed that already this morning, but just for the sake of the record.

A. Yes, that's usual, but there are occasional anomalies such as this and I think we had one with another one of our products as well.

Q. I wanted to compare that with paragraph 68 of your statement. At page 22 --

A. Sorry, paragraph?

Q. Paragraph 68. It begins on page 21, sorry. It continues onto page 22. The sentence at the top of page 22 says:

"Therefore it was usual for companies to increase

the price of a product following a change from branded to generic."

That just jars with what you say in paragraph 28 and what you just confirmed when I showed you the tribunal judgment. There appears to be an inconsistency. I just wondered whether you wanted to refine or clarify paragraph 68 in light of the other evidence you've given.

A. So I think this related to those examples that had been described to us by both Tor and Flynn in the case of debranding. So where the brand was discontinued and a generic was launched in its place. So the product was moved from one pricing -- one regulatory scheme, the PPRS, which covers branded products, to a different regulatory scheme. So it didn't relate to where there were brands and generics, it didn't relate to where generics were launched after patent expiry to compete with the brand. I think this -- yeah, this relates to where -- to examples that we were given where branded products had been debranded and launched as generics.

Q. So it's the same product, it is a brand, it's then genericised, and what you're saying is it is usual for the price to go up in that circumstance?

A. It may be the same product or it may be a generic equivalent product. So it may be exactly the same, as

was the case when -- for Epanutin, or it may just simply be a generic version. So the brand is discontinued, but a generic is launched.

Q. But we're not talking about generic competitors competing with a brand which is the normal situation you've described earlier. This is a specific category of a particular product being de-branded.

A. Yes. Yes, these were the examples that were quoted to us by both Flynn and Tor.

Q. You cite two examples, where price of a product was increased following a change from branded to generic, and one is hydrocortisone tablets. Are you aware that the CMA has opened an investigation and issued a statement of objections into the price of hydrocortisone tablets?

A. No I'd say that was an example that was raised to us by Tor when they did their presentation to us at the beginning of 2010. I think they used it as an example to show their expertise in the generic market.

MR HOSKINS: Sir, that's a good point to break. You probably want to give the witness the usual warning.

THE CHAIRMAN: Mr Poulton, you are still under oath and please don't talk to anybody. We'll take a break for ten minutes.

(11.45 am)

(A short break)

(11.55 am)

MR HOSKINS: Mr Poulton, can we go to paragraph 21 of your witness statement.

"I've read the CMA's decision and I note that they suggest Pfizer never seriously considered Epanutin for discontinuation. I can state from my knowledge of our overall approach to the tail portfolio that if we had not entered into the agreement with Flynn I expect that the Epanutin would have been recommended for discontinuation at some point."

Then skipping a few sentences, four lines up from the bottom, you say:

"But my view is that as profitability inevitably declined year on year, discontinuation would have become an increasing likelihood as time went by."

Just focusing on the first witness statement, "Would have been recommended for discontinuation at some point". Just to make sure I've understood your evidence, it seems clear from that you're not suggesting that if Pfizer had not entered into the agreement with Flynn in January 2012, Epanutin would have been continued there and then.

A. I don't believe it would have been discontinued in 2012. I believe it would have been discontinued as part of the

implementation of the project that I referred to earlier, and I am convinced and remain convinced that if we had not entered into that deal, it would no longer be on the market in the UK now. It would have been discontinued by now.

Q. You say at 21:

"My view is that as profitability inevitably declined year on year, discontinuation would have become an increasing likelihood as time went by."

That suggests that it may not have been discontinued at all, it just might have been more likely that it would be discontinued. It becomes more likely over time as you've described. Are you now changing your evidence to say that by today it would certainly have been discontinued? Because that's not the impression your statement gives.

A. Yeah, so at the time I didn't know the implementation timetable of this project to cull, and a large number of our products. I was convinced that sometime over the next few years from that point in time, it would have been recommended for discontinuation. I couldn't have put a time on it then.

Q. Pfizer, as you've explained, as a responsible company, was concerned about patients stabilised on Epanutin, wasn't it?

A. That's why we wanted to pursue this project: to put the product back onto a long-term sustainable commercial basis. We had the opportunity with this project -- or this product to do that because we had a market price already set for that dose of the same medicine, and by doing that we were able to ensure that the product wasn't discontinued and continued to be available, not just in the 100mg but across the full dosage range for the patients that were already stabilised on it.

Q. Even in the absence of an agreement with Flynn, any decision to discontinue Epanutin would not be taken lightly, would it, because of the patient concerns?

A. It would not. And I had had those conversations with my colleagues in New York because the main exception to a product being withdrawn as part of this project would have been if had deemed as a medically necessary product, and I wanted to explore whether Epanutin would be considered a medically necessary product. And the advice that I was given is that it probably would not, for two reasons: one is that two-thirds of the European sales were in one market, and you can't have medically necessary product with necessary one market as opposed to others, and that there were readily available alternatives on the market. So, for example, the tablets.

So I was convinced that Epanutin would not be considered a medically necessary product from -- in the context of the project so I --

Q. You finish, I'm sorry.

A. I believe that it would be recommended for discontinuation in Europe as part of that -- when that project was ready for implementation, which would have been between 2014, 2017.

Q. Between 2014 and 2017.

A. (The witness nodded)

Q. In relation to this notion of medical necessity, can I ask you to go to bundle J1, tab two, page 8. If you look first of all at the title page, you will see office of -- I have given myself the wrong reference. Bear with me a second. I'm sorry. J1, tab 2 should be on Clifford Chance notepaper:

"Investigation into the supply of Phenytoin sodium capsules, Pfizer's response to the OFT's section 26 notice."

Do you see that?

A. I do, yes.

Q. On page 8 of that document, there's a heading "Discontinuing Supply" halfway down the page, page 8?

A. Yes.

Q. "Pfizer was the only supplier of Phenytoin sodium

capsules in the UK. Phenytoin has a narrow therapeutic index, NTI, which means that great care needs to be taken in switching a patient from an ongoing therapy treatment. Given the potentially severe health and economic consequences associated with epileptic seizures, discontinuation of supply was considered not to be appropriate for the benefit of patients."

Now that's information been given by Clifford Chance on behalf of Pfizer to the CMA. Do you agree that that's an accurate statement about the likelihood of discontinuance of the product?

A. I think this doesn't talk about likelihood of discontinuation. This says discontinuation of supply was considered not to be appropriate, which is absolutely what we agreed. The best solution for any patient on any anti-epileptic drug is to stay on the one that they're stabilised on, and that was the prime driver for us pursuing this project. But I think it also says that great care needs to be taken in switching, and we recognised that as well, that if there have been times when patients have had to be switched, either to or from different anti-epileptic drugs, and that needs to be taken -- great care needs to be taken in doing that. It needs to be well managed. It's possible, it's undesirable but manageable is my

understanding.

Q. Well, of the language used by Clifford Chance on your behalf is "not appropriate for the benefit of patients"?

A. And we haven't discontinued it. We've found a way to make to -- to maintain this product on the market.

Q. If we go back to your witness statement, paragraph 33. If you want to refresh your memory, could you read the first seven lines, down to "as being unjustified".

(Pause)

A. Okay.

Q. I think it is pretty clear, isn't it, that you knew that Pfizer was going to be criticised for the price increase in the product, didn't you? You knew it was coming.

A. Yeah, we are a high profile industry and we are the -- at that time, we were the largest company in the industry. We were well recognised, and like every industry and every profession, we have our critics and detractors, and we are unfortunately used to all of our actions and decisions being criticised by people who are sometimes not aware of the full context and we were -- one of the things we try and challenge ourselves to do is to think how might our actions or inactions or decisions be perceived by people who either don't have the full context or choose to ignore the full context. So it was highly likely that people would focus solely

on a percentage price rise on top of a very low base, without putting in the context of the comparator with the tablet price, the loss-making nature, the fact that the alternative was discontinuation which would result in potential patient risk, and an even higher price to the NHS.

So that was our concern.

Q. If you go to bundle G1, tab 5, again a string of e-mails. If you could turn to the second page, just above the middle, an e-mail from you, Steve Poulton, 13th September 2009. Again, is this is an internal Pfizer e-mail?

A. Yes, this is to my colleagues on the UK Management Forum.

Q. And you say:

"We have an attractive commercial opportunity to increase revenue significantly due to an anomaly in the drug tariff."

Then the second bullet point you say:

"Whilst legal, this would increase the price of phenytoin capsules to the NHS significantly. How does that fit with our trust initiative?"

Can you just explain what you mean by "trust initiative"?

A. Yes, the trust initiative was an initiative that was

started in our New York office probably a year or two prior to this. It recognised the desire to close the perception gap between how our industry operates and sometimes how it's perceived to operate. So it challenged us to be more transparent and to engage more with customers, with regulators, such that they understood the full context of the decisions that we made. I mean, in the past, you know, we're a company that invests significantly in intellectual property, so many of our dealings are commercially sensitive, but I think in -- what we were trying to challenge ourselves to do was to be as transparent as we could with our regulators, with our customers, and that was -- so what I'm asking myself here is, clearly there would be an increase of the capsule prices, no payer in any context likes prices to be increased. So we need to make sure that we're doing the right thing, and that we were able to explain the rationale behind it.

I think when we had the discussion at the UK Management Forum, we came to the conclusion that this did fit very well with our trust initiative, because the easy thing to have done would have been to withdraw this product. It is a loss-making product, to withdraw it. We felt that what we did was the responsible thing, which was to find a way to maintain the product on the

market, to return it to profitability on a sustainable basis, so that it wouldn't limp on year on year under the threat of withdrawal.

Q. As a business, you took criticism very seriously, indeed sufficiently seriously that New York implemented this trust initiative?

A. Yes, we take criticism very seriously. We believe that we act in -- you know, we bring good value to patients, and to healthcare systems, but we recognise it's a fact of life, as with all other industries, that we will get criticism from time to time. And we would always -- what the -- what this trust initiative challenged us to do all the time was to always think about how could our actions or our decisions be perceived by people who I say either didn't have or chose to ignore the full context of what we did.

Q. So if we, on that theme, go to tab 10 of this bundle, top of the page is the Colin Frost e-mail. We've seen the one from you below already in a different context, Steve Poulton, 2nd February 2010. It is number 3 I'd like to look at now. You see the heading "Trust"?

A. Mm-hm.

Q. You said:

"We need to work out how we can position this as 'no change' with patients & physicians; and at the same time

'change' with DH and payers without being accused of hypocrisy by pursuing a trust agenda, yet taking the opportunity to fleece the NHS in time of funding crisis."

So you were anticipating what the criticism would be. You knew that Pfizer would be rightly or wrongly criticised for fleecing the NHS, didn't you?

A. We knew that that would be the position that people would take if they didn't understand the full context and just focused on something like a percentage increase. And the first half of that sentence is no different to the positioning that any generic company would make in launching the generic of a brand, or indeed the positioning that we made when we launched generic versions of our own brands. On the one hand, it's the same product, but it's commercialised through a different channel. So that was no different.

Q. And you wanted to mitigate the inevitable criticism, didn't you?

A. Didn't want to mitigate it, we just knew it would occur and we wanted to try to make sure we could -- we had the ability to put the whole picture across to people.

Q. So you wanted to put Pfizer's side of the story, you wanted to manage the public perception of what had been done?

A. We wanted to be able to react accordingly so that if people were in order giving the full picture and the full context, we wanted to be able to explain it.
Q. If you go to tab 17 of this bundle, this is a June 2010 proposal by Flynn to Pfizer. Yes?
A. I can't see the date on it, but ... oh, yes, sorry.
Q. It is in the index as well, it is 1st July 2010.
A. Yes, it does say that on the third slide, yes.
Q. At page 7, there's a heading "Potential Issues". One of the issues identified is pharmacopolitical damage, Pfizer. So presumably, what that is referring to is precisely the sort of criticism you've seen, or we've seen, in some of the e-mails we've looked at, Pfizer might be accused of fleecing the NHS. That was one of the potential issues, wasn't it, with this deal?
A. I guess my interpretation of the word "pharmacopolitical" is reputational damage, yes.
Q. Then over the page, the eighth page of this document, "Strategic Options":

"Pfizer uses Flynn Pharma as the MA holder to avoid pharmacopolitical damage."

What Flynn was suggesting to you was that by doing a deal with them, that would help mitigate or manage the reputational risk to Pfizer. That's what they were suggesting to you, wasn't it?

A. Yes, it was the same point that Tor had also made to us.
Q. Can we go to tab 39 in this bundle. It's the second e-mail on that page, again it's an e-mail from you, 7th June 2011 to Christopher Scully and Christian Isler already. Can you tell us who Christopher Scully was?
A. Yes, Christopher Scully was my boss, he headed up the established products business unit in Europe. Unfortunately, the e-mail address there has his previous job within it, but he was -- he headed up the established products business unit in Europe.
Q. And Christian Isler, who was he?
A. He was his assistant.
Q. What involvement did they have in the deal with Flynn?
A. They would -- Chris Scully was my boss, he had to approve the deal.
Q. In the e-mail you say, "Chris and Chris" and then in the fourth paragraph you say:

"There are potentially significant pharmacopolitical and reputational consequences which would rule out Pfizer doing this on our own rather than through a third-party."

So what you're doing is you're telling your boss that doing the deal through a third party would provide some reputational protection to Pfizer; is that correct?
A. No, what I'm doing is raising an issue here that had

been raised both by Tor and Flynn. Personally I didn't believe it. Some of my colleagues did, so I thought it was a relevant factor to put into an initial note prior to having the discussion with them.

Q. So you didn't believe it, but some of your colleagues did believe that doing the deal through a third party would provide some protection?

A. I think some of my colleagues might have agreed with that, yes. Personally I didn't. I didn't think it was credible that an organisation the size of Pfizer under the spotlight would have -- would escape any criticism, and neither did we want to escape the criticism. You know, if we spent two and a half years deciding that this was the most appropriate thing to do for this product, and for patients, and we wouldn't have wanted to try and hide behind another company in doing it.

Q. So your personal view was this wouldn't provide protection, but some colleagues thought it would provide protection?

A. I --

Q. -- can I finish the question, sorry?

A. Certainly, sorry.

Q. You thought that the views of your colleagues were sufficiently important to raise with your boss?

A. It wasn't so much that. It was also that, plus also the

fact that it was a factor that had been raised by both companies that we'd spoken to on this, so I thought it was relevant to include it.

Q. Can we go to tab 81 of this bundle. There is an e-mail exchange here between Jason Perfitt and Joseph Byrne, we've come across Jason Perfitt before, but Jason Perfitt was the head of Customer and Channel Marketing, wasn't he?

A. Yes, Jason Perfitt worked for me, he was, in effect, my marketing lead, yes.

Q. Marketing, that was his responsibility?

A. Customer and channel management, yes.

Q. And Joe Byrne was the Commercial Development Manager Established Products; what was his role?

A. So he was -- he would negotiate contracts with a -- with hospitals within a certain region. I think Joe was in charge of London and the southeast, I think.

Q. There is a reference to London in his e-mail at the top of the page, if that helps.

A. Okay.

Q. Looking at the e-mail at the bottom of the page, Jason Perfitt to a large number of people, and the title is:

"Important information and action, Epanutin divestment."

Again there are an awful lot of names there, but is

this an internal Pfizer e-mail that Mr Perfitt is sending?

A. I don't recognise all of the names on that list, but I recognise most of them and all the ones that I can see there are internal Pfizer people, yes.

Q. Over the page, you see the content of that e-mail is:

"Dear all,

"Please see the information in the two attached PDF documents which contain communication messages regarding the divestment of Epanutin."

Do you see that?

A. I do, yes.

Q. Then, if we go back to the first page, it is Mr Byrne's response to Jason Perfitt, and he reports on a meeting with NHS London Procurement. You see that at the first couple of lines; yes?

A. I do, yes.

Q. Then the table sets out the Epanutin Flynn price increase; do you see that, the Pfizer old price Flynn Pharma price?

A. Yes.

Q. Then what Mr Byrne said was:

"The impression from the NHS is that we are linked to this. I stated that this was now a Flynn product and not Pfizer, and any pricing issues should be referred to

them. I assume this is all we can say."

Do you see that?

A. I do.

Q. Then just to complete this part of the story, if you can go to tab 78, there's a series of e-mails between Jason Perfitt and Howard Tebby. Do you know what Howard Tebby's position was at that time?

A. Howard Tebby would have been Joe Byrne's boss. Howard Tebby was the manager of our team of commercial managers who dealt with hospitals, for our hospital products.

Q. The exchange, as usual, these things run upwards, if I can pick it up from Howard's Tebby's e-mail at the bottom of the e-mail 2012, he says:

"Thanks Jason, whilst I fully recognise that the list charge that Pfizer prices is outside the control of Pfizer, it would be useful to know what list price they will be publishing. Thanks, Howard."

To which Jason Perfitt says:

"I genuinely do not know what prices they have submitted. I will let you know more when I know."

But then he says:

"We still need to be clear that the pricing of another company's product is nothing to do with Pfizer."

Howard Tebby then says:

"Thanks Jason, I would reiterate the point about it

not being anything to do with Pfizer at today's field managers meeting."

What was the field managers meeting.

A. I don't know who the field managers are who were referred to in there. It would be our commercial managers and possibly some of our sales managers. It could have been any grouping of them, I don't know which particular ones.

Q. But what was Howard Tebby's responsibility? Was it UK wide or was it regional?

A. No, Howard was UK wide. He was responsible for our team of commercial managers who sold our hospital products. So it could have been a meeting of just his team, or it could have been a meeting of his team with our commercial managers that sold our products to pharmacies. I don't know.

Q. It is a UK-wide meeting, you think?

A. Or it might have been a meeting of just the field managers in a part of the country. I don't know.

Q. What these e-mails show is that certainly Mr Perfitt, who you say was responsible for marketing in the EP division, was pursuing an active strategy of seeking to use Flynn as a means to try to deflect criticism from Pfizer, wasn't he?

A. No, I think what he's saying is that we had no input

or -- into what price Flynn chose to sell the product at or what level of discounts it chose to offer to its customers. I think it's very clear, it's about Flynn's price.

Q. Indeed. You're putting the blame on Flynn. You're saying that: "Flynn price is entirely to do with Flynn, nothing to do with us, therefore if you're going to criticise anyone, criticise Flynn, not Pfizer."

That's the clear strategic from these e-mails?

A. No, I don't think so. I think what we're saying is that we entered into an arrangement to sell this product to Flynn, we set our supply price to Flynn, according to our methodology. What Flynn then chose to sell it on to their customers at was entirely up to Flynn. Nothing more than that. We were very clear that we should not get engaged in having conversations about Flynn's pricing, or having any influence or input into Flynn's pricing.

Q. So if the NHS wanted to complain about the prices that Flynn was charging, it should complain to Flynn?

A. If they wanted to raise issues around any commercial aspects of the sale of this product, it was Flynn, certainly. If they wanted to raise issues around the divestment, then they would criticise us, as they did.

Q. Go to tab 25 of this bundle. It is a document entitled

"Epanutin Proposal October 2010". Although it doesn't say in it, our understanding is this is a document produced by Flynn. Then if one goes to section 6.5, you see the heading "Parallel Imports"?

A. Yes, I do.

Q. It says:

"A price increase in the UK would lead to potential parallel imports from other EU markets, subject to local availability. Assignment of the trademark to Flynn in the UK would mean that parallel imports would risk infringing Flynn's trademark. In any event, some parallel importing would reduce but not remove the attractiveness of the strategy to Pfizer."

So you see that Flynn believed that whilst there was some risk from parallel imports, this would not remove the attractiveness of the deal to Pfizer. Was that also your position in relation to the risks from parallel imports?

A. My belief was that parallel imports would certainly increase. Parallel imports are -- the nature of us operating in the European market, we have to take account of them. I'm not sure -- sorry, I'm not sure what your question is.

Q. It wasn't a significant obstacle to doing the deal with Flynn, was it? It was a possibility that parallel

imports would reduce the attractiveness, but it was not a serious --

A. I think that would depend on the level of parallel imports.

Q. But this --

A. With a significantly increased price differential, one could expect a significant increase in parallel import volumes.

Q. Certainly, at this stage, Flynn were not anticipating that that eventuality would happen, because they are looking forward, and they are not saying, "We expect parallel imports to increase to such an extent this will be a problem." They're actually saying the opposite. They're not anticipating that problem.

A. I think you'll have to ask Flynn why they wrote that.

Q. Well, let's see what Pfizer wrote. That's tab 31 of this bundle. It's a document we've seen before, the established products for the UKMF. So if we can look at page 8, this is Pfizer's internal document.

"How much could parallel imports impact sales?

There should be no impact on 25mg, 50mg and 300mgs in the UK. These alone could be worth £15 million. Even if 50 per cent of sales of 100mg were lost to parallel imports, the upside would still be greater than 20 million."

Actually it is quite clear, isn't it, that Pfizer agreed with Flynn that any risk from parallel imports was not sufficient to undermine the commercial attractiveness of the deal with Flynn to any material extent?

A. Yeah, we wanted to -- we always take into account what we think will be the likely impact of parallel trade, so what we wanted to ensure was that if there was a significant increase in parallel trade, that this still meant the product was commercially viable, because if it wasn't, we would go back to the same situation that we were trying to clear, which is that the product would end up being discontinued.

So 50 per cent of sales lost to parallel imports is significant, and that could have been easily achievable by the volumes that were being supplied in other markets. But it is only on the 100mg. It was only 100mg that was available in other EU countries, or other EU countries that were priced lower than the UK.

THE CHAIRMAN: Mr Hoskins, just before you -- could I just ask a question, Mr Poulton?

On that slide, the one that refers to parallel imports, there's a third bullet point which says, "Parallel trade will increase, managing through European trade group." Could you explain what that means?

A. Yes, our European trade group were responsible for trying to identify the in-market demand in every country. So what was needed to satisfy the local demand. And then we ensured that we supplied into each market that level of product, plus a tolerance, to make sure that we were supplying sufficient for the local market needs.

THE CHAIRMAN: So if you detected an increase in demand in that market which you thought was going to parallel trade, you would manage that; is that right?

A. Yeah, we wanted to make sure that we were supplying sufficient into the market for local market demand. Clearly, we could not influence how much of that was diverted by wholesalers and pharmacists into the export trade, but we wanted to ensure that we were supplying sufficient for the local market.

THE CHAIRMAN: So that would include making up the difference, as it were, would it?

A. We wouldn't necessarily make up the difference. We will obviously try to impress upon local pharmacists and local wholesalers that these products were meant for their local patients, that's why they were in their local language packs.

MR HOSKINS: I need to go to the decision now, and I'm told you need to go to the non-confidential version of the

decision, which is -- I'll just check you're being handed the right version.

A. Okay. (Handed)

Q. This is the CMA's decision, and it says:

"Flynn then set out whether its proposal" --

THE CHAIRMAN: Sorry, could you give us a paragraph?

MR HOSKINS: I'm so sorry. Page 123, paragraph 3.280. So the bottom of page 123. The decision says:

"Flynn then set out whether its proposal, in particular the proposed price increase, would encourage parallel imports."

THE CHAIRMAN: Sorry, I'm --

MR HOSKINS: You've got a different page number, I'm sorry. So paragraph number 3.280.

THE CHAIRMAN: Okay.

MR HOSKINS: Sorry about that.

"Flynn then set out whether its proposal, in particular the proposed price increase, would encourage parallel imports. Flynn considered that parallel imports would naturally be limited by the stock available."

Then there is a quote emanating from Flynn saying:

"There is currently a level of parallel imports which is limited by the availability of stock. No more stock would be available to importers."

Do you agree with that view expressed by Flynn in relation to the availability of parallel imports?

A. Yes, the UK supplied volume of Epanutin in Europe was about just over half, 50 per cent, 53, 54 per cent, with parallel imports into the UK market meant the demand level of volume was about two-thirds. But it meant that there was about 45 per cent of what we supplied into Europe would have been available for parallel import because the majority of that was in lower price markets. So it was limited by that. So 45 per cent of our European volume could have been parallel imported into the UK, but it was -- that was the limit.

Q. What Flynn is actually saying is that there appears to be some constraint on the level of parallel imports due to the availability of stock. Can you shed any light on that? Flynn seems to be going a little bit further than you've just suggested or described.

A. My understanding is that it is limited by the amount of stock that we supply in the other markets.

Q. So you --

A. As I say, that was about 45 per cent of the European volume. Now, some of that, a small percentage of that, would be in higher price markets like Sweden and Ireland, but the majority of that was in lower price markets like Spain and Greece. So all of that would

have been available for PI.

Q. However, it would also be used to supply patients in the local markets?

A. It should be used to supply patients in the local markets, but clearly that wasn't the case. We had many examples of shortages in the exporting markets where patients suddenly had to be switched to other -- either other Phenytoin sodium products or other AEDs. And it was a real concern for our colleagues in those markets.

Ironically, withdrawal of that -- of Epanutin in those markets would probably have been an easier solution.

Q. I go back to your witness statement, paragraph 50. You say:

"When we were considering the level of supply price to negotiate with Flynn, it was clear to us that Flynn would pitch its price by reference to the tablet benchmark. Accordingly, our supply price was a matter of negotiation with Flynn. We did not consider nor intend that it would in any way drive Flynn's pricing."

Is it fair to say that your negotiations with Flynn proceeded on the assumption that both you and Flynn would be making a profit from your respective sales of Epanutin? Flynn wanted to make a profit, that's why it wanted the deal, didn't it?

A. Yes, we expected that both companies would make a profit, certainly.

Q. If you go to paragraph 19 of your statement, it's the final sentence at paragraph 19, you say:

"Epanutin capsules have been either unprofitable or marginally profitable for many years."

So unprofitable or marginally profitable.

Then if we go to bundle G1, tab 23, at the top of the page, again an e-mail from you, 3rd August 2010. Is this again an internal Pfizer e-mail?

A. Yes, that's an e-mail to my colleagues on the UK Management Forum.

Q. Under the heading "Situation" you said:

"Currently Epanutin Phenytoin sodium capsules are sold at a rate marginally above [I think that should be COGs rather than GOGs]"?

A. It should be, yes.

Q. I'm relieved because otherwise I would have to take a lesson in gogs.

"This makes it borderline commercially viable".

Now cost of goods are direct costs attributable to the cost of the goods sold by a company; is that fair?

A. We had different measures for cost of goods, but the one that we referred to here was, in effect, the price to bring a pack of medicine into the UK. In other words,

it was the price that was charged to our profit and loss account. So it is the cost of manufacture, plus the cost of freight from the factory to the UK, plus any duty, tax, import. Plus -- yeah.

Q. The capsules were being sold at a rate marginally above that measure of COGs. So why was it said to be loss-making? Where did the losses come --

A. Because that doesn't include all of the costs. So on top of that we had the distribution costs, and we had other costs that were incurred in the UK market to sell and market that product and to maintain it.

Q. But I think it's quite clear, isn't it, from the two documents I've just shown you, Epanutin wasn't making heavy losses, it was, at best, borderline loss-making. That's the language you use here, and you used the words "unprofitable" and "marginally unprofitable" in your own statement.

A. The only table I can remember, and I -- is in the case bundle somewhere -- where it quantifies the overall margin on the product in the UK to be minus 27 per cent. So in other words, for every £100 of revenue we made, it cost us £127 to do it. Unfortunately, I don't know the reference to that offhand.

Q. We have the information on that. We can look at it.

A. Cost of goods changed every year. Every year our

manufacturing organisation would publish what the cost of goods were, and those changed year on year. And of course they changed according to exchange rates as well.

Q. Can we go to tab 5 of this bundle.

Second page, over the page, an e-mail from you, 13th September 2009. Again, this is an internal Pfizer e-mail, is it?

A. Again, this is an e-mail to my colleagues on the UK Management Forum.

Q. Actually we've seen this one before as well, I'm sorry. You remember we looked at the trust initiative reference in the second bullet?

A. Yes.

Q. It is the first sentence I want to look at this time:

"We have an attractive commercial opportunity to increase revenues significantly due to an anomaly in the drug tariff."

So a commercial opportunity to increase revenues significantly.

If we can go to tab 10, there's an e-mail from you, 2nd February 2010, again that is one we've seen before, in a different context, in relation to caps being generally cheaper and easier to make than tablets. Again, I want to focus now on the first paragraph, where you say:

"Following the presentation at Friday's EPLT we need to progress this. The potential upside is huge - and we are already behind budget on our two main growth engines; Fragmin and Growth Initiatives. This means we cannot afford to dismiss this lightly. However there are still Qs in my mind that Friday did not resolve, and an additional one that Friday created."

So the potential upside is huge, and attractive commercial opportunity to increase revenues significantly.

The position is, is it not, that the deal you did with Flynn, including the prices you agreed with them, means that you didn't simply make Epanutin commercially viable, you made and make significant profits from the deal, do you not?

A. So these are at two different periods in time. I can address each of them separately, if you wish me to.

Q. I'm actually asking a question about what happened after this, because these two documents are looking forward, and the question I'm asking you is that post-deal, the deal you did with Flynn actually meant not simply that the product became commercially viable, but it became an extremely profitable product for Pfizer.

A. So we didn't look at the profitability. We had -- we were looking at price, and the reason why this project

was able to even be considered was because we had an established benchmark price in the market for the same medicine. If that price benchmark hadn't been there, we couldn't have done this. We would have had no justification. We had a market price that had been set, that had been accepted by the Department of Health, and it was very clear that that was the price that the Department of Health felt, offered, or reflected the value that that medicine gave to patients and the NHS. It was broadly in line with what the NHS was paying for other anti-epileptic drugs. So we considered that was the justification.

We talk about upside is huge, because the price that we were previously getting for this medicine was hugely undervalued. So the consequence -- not the consequence, the necessary consequence of us maintaining this product back to profitability was that there was an upside.

Q. Mr Poulton, with respect, that's a politician's answer, because you didn't answer my question.

A. Sorry.

Q. The question was, the prices you agreed with Flynn didn't simply make this product commercially viable; they have enabled Pfizer to make significant profits well beyond what were needed for mere commercial viability. You can answer that question "Yes" or "No".

I appreciate it if you did and then, if you want to clarify it, you can, but it deserves and merits a "Yes" or "No" answer.

A. Yes, certainly. The price increase that was necessary to bring it in line with the tablets meant that it was significantly more profitable. It was unprofitable previously and the only way we could be to maintain it would be to bring it to a level of profitability that would be sustainable. As I said, we focused on the price because we had a benchmark price in the market.

MR HOSKINS: Sir, there is now -- I'm getting to the end of my questions, but there is a section where I need to go, or ask you to sit in private because there's Pfizer confidential information and I can't deal with it simply by sort of a nod or a wink, we're just not in that territory.

THE CHAIRMAN: Before you do that, I wonder if there are questions from my colleagues that are not confidential?

MR LOMAS: I have two questions, if I may.

Questions by the PANEL

MR LOMAS: The first is going back to document 5 in bundle G1.

In fact, before we get there, my understanding at this time is that Pfizer's revenue from Epanutin was about 1.8 million a year. Is that a figure that

resonates with you?

A. From memory, I believe it was between 2 and 2.5.

MR LOMAS: If we go to G1/23, so the documents you have the in front of you, page 23, which is an e-mail that Mr Hoskins took you to a few moments ago, which is your e-mail, I think, of the 8th March or 3rd August.

A. I think it is 3rd August. I think these are switched, yes.

MR LOMAS: If you just look down under "Situation", it says:

"We sell about 8.1 million of Epanutin capsules a year."

A. I think it was by the time we did the deal that it was --

MR LOMAS: Okay, that's what it was.

If you go back to document 5, and essentially it is picking up a point that Mr Hoskins was asking you, document 5, on page 2, which is where we were, your e-mail of 13th September to your UK Management Forum, said:

"We have an attractive commercial opportunity."

I then want to look at the first bullet point, which I don't think you were taken to, which is:

"It would still increase our EP revenues and IBA by more than 6 million (and I have a significant shortfall to find in 2010)."

Can you just explain what that's about?

A. Yes, so this was at -- this e-mail was dated at the end of September, so we were putting together our budget for the following financial year. And as with every year, we were always challenged to increase our numbers, and clearly, if we were able to reset the capsule price to the -- to what we considered to be a justifiable and fair price for the medicine, then that would give us the -- some revenue upside which would contribute towards our budget for the following year.

MR LOMAS: And that's a revenue upside of greater than 6 million?

A. So IBA there is an internal profit measure. It's --

MR LOMAS: So it is a profit measure, not a revenue measure?

A. Yes.

MR LOMAS: So profit goes up by 6 million and helps to fill the shortfall?

A. It would have done if we'd been able to achieve it, but clearly we didn't, so I had to find other ways to make up that shortfall.

MR LOMAS: Thank you.

The second question is a question relating to Europe, although not quite to transfer pricing. My understanding is that Pfizer was selling the product in Sweden, Belgium, Greece and Spain, amongst others, but

certainly those four.

A. Yes.

MR LOMAS: Were you making a profit on the sales in those countries?

A. I have no idea, I'm afraid.

MR LOMAS: Because your responsibility is with the UK?

A. Yes, I don't know what the cost of goods they were charged, I don't know what discounts they paid. Sorry.

MR LOMAS: Those are my two questions.

PROFESSOR WATERSON: Just one question, we've talked about discontinuance versus continuing on a different basis. Was there a consideration ever given to discontinuing some of the formulation?

A. No I --

PROFESSOR WATERSON: Only 100mg --

A. No, we wanted to maintain the full dose range because our understanding was that even for patients who were being prescribed the tablets, because the tablets were only available in 100mg, if a patient was on a dose of 150, then they needed an adjunct from a 50mg capsule. So we -- one of the important things for us was to maintain the full dose range as well.

PROFESSOR WATERSON: Thank you.

THE CHAIRMAN: I think my only question, Mr Poulton, is in somebody else's witness statement, not yours, there's

a reference to a Pfizer AED called Zarontin, which I think it was said was discontinued.

A. Yes.

THE CHAIRMAN: Is there anything you can tell us about that?

A. This is from memory, so Zarontin was an anti-epileptic product that we discontinued in the early 2000s. It was a product that was having some significant quality -- it was again an old product that was having some significant quality problems. It required a significant investment in order to -- or would have required a serious investment in order to resolve those issues, even if that were possible. And the decision was taken to discontinue it.

THE CHAIRMAN: So it is not quite the same situation as faced you with Epanutin?

A. No.

THE CHAIRMAN: From your memory.

A. No. But again, there wasn't the opportunity -- well, we couldn't produce the tablets to the -- capsules, I think, to the required quality without a large investment. So -- but again, we recognised that because it was an anti-epileptic drug, we had to manage the withdrawal very carefully, so I think we gave a year's notice, and, you know, we worked very closely with the patient groups in order to manage that. I think there

was a generic available, from memory, but I am not 100 per cent sure.

THE CHAIRMAN: Thank you very much.

Right, then I think we should move to in camera. So could everybody who is not in the confidentiality ring please leave the tribunal.

MR HOSKINS: I can say Pfizer people can stay, because it's Pfizer confidential.

THE CHAIRMAN: Yes, I should have said. Everybody apart from Pfizer people. If you are not in the confidentiality ring, please leave the tribunal.

[REDACTED IN CAMERA SESSION]

(12.59 pm)

(The Short Adjournment)

(2.00 pm)

MS KREISBERGER: Thank you, sir. I call Mr Walters.

DAVID EDWARD WALTERS (called)

Examination-in-chief by MS KREISBERGER

MS KREISBERGER: Mr Walters, you should have a bundle that looks like that, making its way up to you, that says bundle B on it. If I could ask you to turn to tab 4, in that bundle, you see there it says, "Witness statement of David Edward Walters". If I could ask you to turn to the back page of that document, which is page 20. Mr Walters, is that your signature?

A. Yes, it is.
Q. If you could turn to the next tab, tab 5, and you see there it says, "Second witness statement of David Edward Walters"?
A. Yes.
Q. If you could again turn to the last page of that document; is that your signature, Mr Walters?
A. Yes, it is.
Q. Mr Walters, you've told me that you'd like to make two minor corrections to your first statement.
A. Yes.
Q. I think the first one is at paragraph 10?
A. Yes, it is, yes. This is actually for clarification, it suggests there that we acquired the marketing authorisations in September 2012. That's actually when we launched the product. So I would suggest that we insert "which we launched in September 2012", for clarification. The actual dates of acquisition are, I think, set out in our notice of appeal.
Q. Just so the Tribunal has it, after the word "Epanutin, which it launched in September 2012".
Mr Walters, if you could take us to paragraph 52, which is on page 17, I think you have another clarification.
A. Yes, that's correct. Yeah, it is a clarification. It

is on line 4:

"Where there is just one generic competitor, are very different to those where there are two or three more generic competitors".

That is in addition to the original originator products.

THE CHAIRMAN: So what do you want us to add?

A. "In addition to the" --

MS KREISBERGER: We had discussed just to clarify the fourth sentence, which begins:

"Competition for market share tends to be much more fierce where there are two or more competitors in addition to the first entrant."

A. Yes.

Q. That should be clear --

THE CHAIRMAN: That will do it, will it?

MS KREISBERGER:

It doesn't change the meaning, it just clarifies it.

THE CHAIRMAN: Okay.

MS KREISBERGER: Mr Walters, subject to those two clarifications, does the evidence in these two statements remain your evidence to the best of your knowledge and belief?

A. Yes, that's right, yes.

MS KREISBERGER: I will hand over to Mr Hoskins, who has

some questions for you.

Cross-examination by MR HOSKINS

MR HOSKINS: Good afternoon, Mr Walters.

A. Good afternoon.

Q. Just to first of all clarify your qualifications; do you have any legal qualifications?

A. No, I don't.

Q. Do you have any economics qualifications?

A. No, I don't.

Q. Can we go to paragraph 64 in your first statement, that's tab 4. You say in the middle of that paragraph:

"... Flynn incurs large common costs including its administrative costs and few product-specific costs."

So you seem to be saying there lots of common costs not any direct costs; have I understood that correctly?

A. Sorry, there are lots of common costs?

Q. I take from that you seem to be saying in Flynn's business predominantly the costs are common costs and there are relatively few direct costs; have I understood that correctly?

A. Yes. We have some direct costs associated with the brands, but not so much with the generics.

Q. Can I ask you to look in bundle F, tab 5. This is something called a joint statement. It was produced by Mr Williams, who I'm sure you're familiar with.

A. Yes.
Q. He is an expert accountant, he is instructed on behalf of Flynn, and Mr Harman who is instructed on behalf of the CMA. Have you seen this document before?
A. Yes, I have, yes.
Q. Can you go to question or point 4.2, which is on page 21. We both have to be a bit careful here because the actual figures, the pounds figures, are confidential, so neither of us should say them out loud. I'll take you to them, but we have to be careful not to say them out loud.

What Mr Williams says is that Flynn's common costs are around the figure, if you go to the last page at page 22, you'll see there's a figure in the penultimate line: "Lower cost pool" then in brackets there is a figure in pounds, "And the lower ROS 6 per cent without MOT."

Do you see the figure I'm referring to?
A. Yes.
Q. So he has obviously looked at Flynn's figures and he has come up with that as your common costs figure.
A. Mm.
Q. In relation to your direct costs, the figure that he has come up with is, if you go back to page 21, the second paragraph begins:

"The costs in question which principally relate to sales and marketing expenses on Flynn's non-phenytoin brands amount to ..." and you'll see a figure?

A. Yes.

Q. You'll see that the figures are relatively similar, if I can put it like that.

A. Yes they are, but those sales and marketing expenses, as I said, they relate to the brands. We don't have many direct costs when it comes to generics.

Q. So the distinction you're making in paragraph 64 of your statement is intended to be limited to what, because it seems to be couched in very general terms. Do you need to clarify that? It seems to say Flynn's business generally large common costs, few product-specific costs, but if Mr Williams is right, and he is an accountant, neither you nor I are, that wouldn't seem to be quite accurate?

A. I think for the overall business, obviously Mr Williams has identified the actual numbers. As I say, for the generics, our direct costs related to promotion, for example, are quite limited.

Q. In general terms, when we're number crunching, is it generally safer for us to look to Mr Williams, or your reports?

A. Oh, I would imagine that Mr Williams knows --

understands the numbers far better than I do, yes.

Q. Now in relation to the launch of Phenytoin sodium capsules, Flynn prepared a communication plan. Can we go to the decision, and I think you should go to the non-confidential version of the decision.

Paragraph 3.355. Sorry, I don't have a page number, but it should be in the middle of the page there's a "G":

"The MHRA's approval of Flynn's communication plan. The MHRA approved Flynn's communication plan on 19th July 2012."

This was a document that you prepared for submission to the MHRA; is that correct?

A. Yes, we did.

Q. Indeed, as is recorded here, it is correct it was approved by the MHRA; correct?

A. Yes.

Q. Presumably, given that you were preparing this to seek the MHRA's approval of it, you took considerable care in drafting that document; is that correct?

A. Yes, we did.

Q. The plan itself is in bundle G1, tab 75. It should be a document "Flynn Pharma communication plan for the introduction of Phenytoin sodium Flynn hard capsules"?

Do you have that?

A. Yes, I do, yes.
Q. If you turn to page 2 of this document, you'll see the heading "INTRODUCTION & OBJECTIVES."
Presumably that is something you've seen before; is that correct?
A. Yes, I think I wrote most of it.
Q. Is that something you have looked at recently?
A. No.
Q. Can I ask you then to read to yourself the section "Introduction and objectives". If you wouldn't mind just refreshing your memory on that. (Pause)
What Flynn is saying in this communication plan is there are concerns around patients changing product and what you are doing in this communication plan is you're assuring the audience it is aimed at -- and we'll see that in a minute -- that there's no cause for concern here because the product will remain exactly the same.
A. At that moment in time. At the launch of our product, yes.
Q. Then, if we go to the next page, page 3, section 3.1, it says:
"Flynn intends to send a letter to all UK general practitioners, secondary care based epilepsy and urology clinics, announcing the change and advertising the availability of the freephone helpline. The letter is

shown in appendix 1."

If we turn then through to appendix 1, you'll see on page 8 of 14, appendix 1: "Letter to prescribers", it says:

"Dear Doctor, IMPORTANT ANNOUNCEMENT."

If I can pick it up in the middle of the draft letter or the letter that's to be sent:

"Phenytoin is a drug with a narrow therapeutic index (NTI) and as such there may be concerns among prescribers and patients regarding any change to the product. Please be assured that the Flynn Pharma product is identical to Epanutin and there are no differences in formulation and the site of manufacturer remains unchanged. The capsules continue to contain the same identical markings as Epanutin, including the word Epanutin. Prescriptions should be written as Phenytoin sodium Flynn xMG hard capsules. It is essential that the prescription contains the name of the Marketing Authorisation Holder, (ie, Flynn) to ensure the correct product is dispensed."

So what this letter that you were to send, I imagine you did send it to all prescribers; is that right?

A. Yes. Well as far as the extent of the mailing lists that were available, yes, we did.

Q. What you are saying to prescribers is effectively they

should write closed prescriptions because of the concerns about any switching away from Epanutin; is that correct?

A. To ensure that the correct product is dispensed. If they wanted the Flynn product, they needed to prescribe it as the Flynn product.

Q. The reason you suggest they would want to prescribe the Flynn product is precisely the reasons we've seen you give in this communication plan, which is because of the NTI, there may be concerns in relation to any change of product for the patient; correct?

A. There may be concerns, yes. It doesn't mean that there are always concerns. I mean, we did spend some considerable time with Pfizer going round the patient support groups in the UK to actually validate the concerns that patients have, and it's quite clear that some patients, not all patients, but some patients are concerned about any change, any change. So at the time when the product's name was being changed, it was felt really important to make sure there were no other changes at that moment in time.

Q. If we can go through to appendix 5, page 13, this is retail pharmacy mailings, so this is a letter to be sent to retail pharmacists; correct?

A. Yes.

Q. "Changes to the prescribing and availability of Epanutin."

"Dear pharmacists" and I pick it up halfway down again, it's a very similar text:

"Phenytoin is a drug with a very narrow therapeutic index (NTI) and as such there may be concerns among patients and prescribers regarding any change to the product. Please assure patients that the Flynn Pharma product is identical to Epanutin, there are no differences in formulation and the site of manufacture remains unchanged.

The capsules contain the same identical markings as Epanutin. Prescriptions should be written as Phenytoin sodium Flynn XMG hard capsules."

What we see from these letters was that Flynn was concerned to ensure that patients who were stabilised on Epanutin should continue to receive the Phenytoin sodium Flynn hard capsules product; is that correct?

A. Where there may be concerns amongst the patients and prescribers, yes.

Q. What you were also concerned to say is that they should have the Pfizer-Flynn product, not the NRIM product?

A. The NRIM product, was it -- yes, it was available. Yes, if they had concerns and they wanted the Epanutin product, they should prescribe Flynn, not NRIM.

Q. And the retail pharmacists --
A. Not NRIM.
Q. -- should dispense Flynn.
A. Yeah. I mean, if a doctor actually writes a prescription for the Flynn product, then they are obliged to dispense the Flynn product, not the NRIM product.
Q. That was also attractive to you commercially, obviously?
A. It was a consideration, yes.
Q. This whole principle we're looking at is sometimes referred to as continuity of supply. You're familiar with that as a term?
A. I'm familiar that the term has come into use, yes. I think when we launched it was not necessarily a widely used term, but yes, it was -- it is a concern amongst some prescribers, and you have to recognise that.
Q. Can we go back to your witness statement, that's bundle B, first witness statement, so that's tab 4, paragraph 52 this time. It's the last two sentences. You say:

"In this case, Flynn knows, as is common knowledge in the industry, that NRIM's commercial strategy is not generally to start a race to the bottom on price, but rather to build up a 30-50 per cent share of the market. This is exactly what happened in the case of Phenytoin

capsules."

When you say NRIM's commercial strategy is not generally to start a race to the bottom on price, can you explain what you mean by that?

A. Well, this really comes back to competitor intelligence, and it's -- if you observed the behaviour of a company like NRIM, they know that once they've achieved a certain level of market penetration, if they then continue in a price war, which is effectively what you're suggesting that they should do, then basically ultimately the drug tariff would be affected and their income would also be affected. So generally, as a policy, it's not something that they do. As -- it's very different when NRIM itself was acquired because it went to a company who operated in a different way. This simply comes back to knowing your competitors. It's simple market intelligence.

Q. In relation to continuity of supply it's correct, isn't it, that Boots and Lloyds didn't always respect continuity of supply in respect of Phenytoin sodium capsules?

A. No, they didn't. I wouldn't say didn't always respect, they didn't respect it very much at all, actually.

Q. What they actually did was dispense NRIM capsules to patients who had been stabilised on Flynn's product,

didn't they?

A. Yes, they did.

Q. They only stopped doing that when the MHRA issued its guidance in November 2013, didn't they?

A. Oh no, they didn't. Oh no, they didn't. No, if you refer to the mystery shopping exercise that you dismissed yesterday, or whenever it was, as being one website application, it wasn't. It was a series of visits to pharmacies throughout 2013 and 2014, into 2014. So it was post the guidance being published, and it was a long time after the guidance was actually circulated to such companies for a consultation. So they knew full well what was coming, long before we did, and our mystery shopping exercise clearly shows that when presented with a prescription for the Flynn products, patients were quite often being diverted onto the NRIM product. Quite often.

Q. You say when prescriptions for the Flynn product, but you are aware that 90 per cent of prescriptions were actually open, aren't you?

A. Well, they are now. I mean, they haven't always been.

Q. We're told that they were during the period that the infringement is alleged to have taken place; are you aware of that?

A. Back when we started looking at the potential for this

project, the level of branded prescribing was actually much higher.

Q. For Phenytoin sodium capsules?

A. For Epanutin.

Q. When do you think that that ceased to be the case or over what period do you think that changed --

A. -- (overspeaking) -- I don't know, I haven't tracked it over time.

Q. At the period when the infringement started, or at the period when you did the deal with Pfizer? Let's take that. The period you did the deal with Pfizer, you were saying that the percentage of prescriptions for Epanutin was what, more than 50 per cent were closed? What are you saying?

A. I think the last figures we'd had -- I mean, I don't know if they were at that moment in time, but certainly when we had our first meeting with the Department of Health, we actually talked about the fact that we would be happier with it being retained as a brand because it would give us greater protection of our market share. So we very firmly believed -- I think history has shown us to have been wrong in that because everyone has actually started to write the products generically, it seems, which kind of suggests that maybe the MHRA themselves should have had a better communications plan,

because if they were genuinely concerned about it, they didn't make a very good job of implementing it.

Q. Let's look at what Flynn understood by continuity of supply and what Flynn did about it. Because Flynn wasn't happy about Boots and Lloyds dispensing NRIM capsules, was it?

A. Well no.

Q. And you had correspondence with Boots. David Fakes is the Chief Executive Officer of Flynn; is that correct?

A. He is now, yes.

Q. Can we go to bundle G2, tab 143. There's a number of e-mails behind this. I should explain to the Tribunal, we're in a rather odd situation because Boots have claimed confidentiality over the names of individuals, which means that even when I'm going to show Mr Walters a letter that he wrote to a person at Boots, the name of that person has been redacted. Hopefully we'll manage between us, but it's not our fault that we're in this rather bizarre situation.

THE CHAIRMAN: It's not the only odd thing about this case, Mr Hoskins.

MR HOSKINS: I'm sure that's right, but this is a particularly strange one.

Mr Walters, I hope you understand it is slightly odd, I am going to show you correspondence you had with

individuals -- and I'm not allowed to tell you the individual's name -- but you'll see what position they had within Boots.

A. Okay.

Q. You'll have to bear with me on that. You have a clip of documents. I'm afraid we're going to have to do some counting together, unless yours have been numbered. You have to count in. It is the 25th page, so for example, the first one has a -- I almost said the name. You see the heading "David Walters", that's page 1 and then the back side is page 2. I need you to just count through the pages 1, 2, 3, 4.

A. To the letter?

Q. Yes, I want you to go to page 25 of this bundle. That should be the 13th page if you're counting whole pages; 25 if you're counting both sides.

There should be a heading "David Fakes" when you get to the right page. So it should be "David Fakes", then there's an individual at Boots whose name has been redacted. 17th January 2014 is the time; is that the one you have?

A. Yes, I have.

Q. Good. If you can look at the e-mail at the bottom of the page, so it is from David Fakes on 10th January 2014; do you have that?

A. Yes, I do.

Q. I can tell you, it's sent to and copied to individuals at Boots. The first person is the Pharmacists Professional Support Manager, I'm told. You see the subject is:

"AED guidance and recent correspondence between Flynn Pharma ..."

And I'm allowed to say it is Boots, but I'm not allowed to say their name. So this is an e-mail that David Fakes sent to people at Boots. He says:

"Dear [X] thank you for your e-mail in response to our e-mail of 6th January. I'm pleased that we agree that the intent of the MHRA guidance on AEDs is to ensure that patients should be supplied consistently with the same brand. The keyword or message is consistency. However, in regard to the Boots internal advice to pharmacists, I note that in regard to category 1 AEDs the pharmacists should take steps to ensure the patient is supplied with a product that has been supplied previously."

Then you can read the next sentence to yourself. I'll pick it up at:

"As I have said previously, we have good reason to believe that practice or policy changes were made affecting the period from late September 2013 up until

possibly the current time, and most likely to include October and November 2013, the net effect of which was to result in the preferential dispensing of the NRIM product in response to an open generic prescription. It is our firm view that this was and would continue to be expressly contrary to the intent of the MHRA guidance."

So you refer to the practice of the Boots prior to the MHRA guidance of dispensing the NRIM product instead of the Flynn product, and you say that this was and would continue to be expressly contrary to the MHRA guidance.

Do you agree that was Flynn's view?

A. Yes, it was -- yes, it was, yes.

Q. Then picking it up at the next full paragraph:

"It may well be that the default or preferred supply of the NRIM product was not directly as a consequence of internal policy changes within Boots, but it could alternatively or additionally be the result of a policy change at wholesale level to supply the NRIM product by default, in response to orders or requests from Boots pharmacies. However, the net effect remains that consistency of patient supply has been interrupted and thereby patient safety is potentially compromised."

Again that's confirming what we've already seen: Flynn's view is that if consistency of supply was

interrupted, patient safety is potentially compromised. Do you agree with that?

A. Yes, we are basically drawing their attention to the guidance. It is up to them if they actually follow the guidance, but yes, that's what we were doing.

Q. Then in the next paragraph, I am going to skip the first two sentences and pick it up at the third:

"I might add additionally that the direction to ensure consistency of supply and the reasoning behind it are not new to the profession. The reality is that these measures do no more than to reinforce NICE clinical guidance that already existed. I reproduce an extract of that NICE guidance below. In short, it has been since the application of NICE guidance in 2012 considered good practice to ensure consistency of supply. Indeed, the scientific and clinical literature are replete with reports cautioning against unintentional switching for narrow therapeutic index drugs (NTIs) for many years previous. If one accepts this position and it is hard at face value to understand the clinical and scientific basis for systematic or significant change in products supplied by a wholesaler or accepted and dispensed by the pharmacist."

What again Flynn is saying is that even before the MHRA guidance in November 2013, continuity of supply was

well established; is that correct?

A. Yes, in the UK, that's true.

Q. What we see is that Flynn had quite a long correspondence with Boots following this. You'll be relieved to hear -- and I'm sure the Tribunal -- that I'm not going to take you to all of that correspondence, but I want to take you to certain parts of it.

The next one I'd like you to look at is still in this clip, but you'd need to go on to page 31. It should be a letter on a Boots' letterhead saying: "Dear Mr Fakes".

"I am writing further to your e-mail dated 15th January."

Do you have that?

A. Yes.

Q. You will see -- again I'm not allowed to say the individual's name -- the person who sent it was the Director of Professional Standards and Superintendent Pharmacist at Boots. And he says -- I'll skip the first couple of paragraphs:

"I have reviewed the message that was issued to our pharmacy teams on 13th November in response to new MHRA guidance on anti-epileptic drugs and I remain of the view that the advice is appropriate. You have highlighted the advice to dispense the brand that has

been supplied previously, implying that this is not correct. The guidance from the MHRA is to ensure that patients are maintained on a specific manufacturer's product and it is difficult to know how else this can be done, other than to identify the brand that the patient has taken most recently.

Our clear guidance is to identify and dispense the brand that had been supplied previously, and if the brand in question is NRIM, this brand will be dispensed, and if it is Flynn, then your company's product will be supplied."

What Boots are saying in this letter is that they do intend to supply with their view of continuity of supply following the MHRA guidance; do you agree with that?

A. That's what they're saying, yes.

Q. But the problem was that the view, Boots's view, of what continuity of supply required and Flynn's view of what is required were different, because Flynn was unhappy that patients who had been given NRIM capsules, even though they'd been previously stabilised on Epanutin or Flynn capsules, were going to carry on the continuity of supply having NRIM capsules. That's correct, isn't it? That was the nature of the dispute between yourself and Boots?

A. There was a disagreement between the two techies,

basically. They're both pharmacists, both qualified pharmacists, and they had a different view, because some of those patients may have received only just one prescription for the NRIM product. Others may have been on it for months. So is it right to continue them on the NRIM products, or put them back to the product they had been on for years and years? And that's where this particular aspect of the dispute was, it was just a disagreement between two experts in the field.

Q. Just a technical dispute?

A. It was a technical dispute, yes.

Q. Well, let's see what Flynn did about the dispute. If we go next to -- you need to turn backwards in this -- to page 16 of this clip of documents. So it should be a letter on Flynn Pharma headed notepaper dated 7th February 2014.

A. Okay.

Q. If you go to the third page of that letter, you'll see it is again a letter from Dr David Fakes. It's sent to the individual at Boots, it's the same one we've seen before, Director of Professional Standards and Superintendent Pharmacist. Mr Fakes says:

"I'm writing again further to our teleconference with yourself and [X] of last Friday and to set out again the detail of our concerns that still remain, and

finally to ask if Boots has reconsidered its position and taken any further action."

He says:

"Up until around March 2013, there were no alternatives to Phenytoin sodium Flynn capsules other than spasmodic supplies of parallel imports from a number of countries, and most notably Spain."

Do you agree with Mr Fakes that supplies of parallel imports were spasmodic up until around March 2013.

A. Supplies of parallel imports are by nature spasmodic. It depends on the availability of stock in the country of origin.

Q. Then he continues at the bottom of the page:

"Notwithstanding the MHRA advice of November 2013, we have, as you know, in recent months become aware of further confusion and concerns at patient level, including examples of loss of seizure control and incorrect advice being given to patients, the aggregate effect of which is to challenge the continuity of supply principle.

Can you help us with how did you find out about the examples of loss of seizure control?

A. We had contacts, both through the freephone service that we set up as part of the communications strategy that was agreed, and through our med info from patients that

were being told things that were basically untrue. They were being told things like the Flynn product is not available --

Q. So I'm asking you to --

A. In some pharmacies --

Q. -- focus on a different issue, which is you say -- or, sorry, Dr Fakes said in this letter that Flynn had examples of loss of seizure control?

A. Yes, yes, that's correct.

Q. Can you give us some more information on those, please, the actual examples of loss of seizure control?

A. Well, basically patients have found they've been switched from what was the Flynn product to the NRIM product, and they then had a resultant seizure, because what this relates to is the reason that you're looking at not switching to a different formulation is that there may result in a loss of seizure/control, which is actually, for the patient, in many ways is worse than the side effects. Because if you're an epileptic, it usually means you lose your driving licence, and possibly even your job. This is the basis for concerns that patients have.

And Boots, through their stock policies, were clearly not just ignoring the guidance, they were taking measures that went beyond that. They were actually

giving patients the impression that the Flynn product was not available. And this again was also confirmed in our mystery shopping exercises which the CMA has chosen to ignore.

Q. Can I go onto the top of the next page, Dr Fakes says:

"You might also wish to take soundings of the patient advocacy groups to explore their levels of concern. As recently as February 3, Professor Ley Sander, Medical Director at Epilepsy Society, has articulated further continued concern and expressed the view that it is essential for anyone with epilepsy to maintain a consistent supply of the same version of their AEDs. The Epilepsy Society website also provides examples of patient testimonies including one dated 29th September 2013."

Then he sets it out.

"I used to get Pfizer Phenytoin, then when it was taken over by Flynn, last month the pharmacist that usually gives me my drugs wasn't on, and I was issued a different brand. As I was taken into hospital and they just used the new brand my mum packed, I have had breakthrough seizures."

This is a specific example of a loss of seizure control that Flynn was aware of and you were telling Boots about it; yes?

A. It's an example. But it wasn't the only example. And we were actually told in our discussions with Boots by the buyers, who were themselves pharmacists, that they didn't actually agree that the guidance was worth very much, that when a previous anti-epileptic drug had been genericised, they switched all the patients over to the generic form without any problems whatsoever, which, to us, was absolutely astounding.

Q. Why was it absolutely astounding?

A. Well, because if there's guidance out there, I mean, yes, the MHRA could have made it into a directive if they wanted to enforce it more, but if there's guidance out there, you kind of think that it's there for, you know, for a reason. And in certain circumstances where the doctor or the patient has concerns over continuity of supply, they should follow the guidance.

Q. And as you --

A. It's not in every case, but that's what it says. It's basically if you have concerns, and you feel that continuity of supply is important, then prescribe by brand.

Q. If you go back to the letter and pick it up at the next paragraph, it is the third paragraph on page 17.

"As we made clear in our call, the MHRA advice is not in reality new. It builds on albeit with a degree

of confusion if not contradiction, the NICE CG137 January 2012. The NICE guidance itself in this regard only builds on and reconfirms earlier authoritative advice from SIGN 70 (2003) and SIGN 81 (2005), and in the body of earlier published literature cautioning against assumptions of therapeutic equivalence for brands and generics for agents such as Phenytoin. I remain at a loss to see [X]'s argument that the Boots purchasing decision was ever consistent with guidance or best practice. It was not."

So again you're making the point that this principle of continuity of supply in relation to Phenytoin sodium capsules was well established, not just before NICE CG137 January 2012, but for many years before that; is that correct?

A. As you yourself said in your opening statements, yes. And the fact is that -- you were looking yesterday, or the day before, even, I'm not sure -- as to whether the guidance has been followed post issuing the guidance, or whether the continuity of supply has been followed. And the numbers clearly say that it hasn't been. And if you look at the growth of the NRIM products, you would look at the sales graphs and say it's at least flat in a market that is declining by an average 6 per cent per annum. Which tells you that automatically,

1 therefore, the market share is going up. Because --
2 I mean, they may be getting it from parallel imports,
3 and they may be getting it from the Flynn products. If
4 it's either of those two, it's a product that is
5 equivalent at the moment, we believe, to Epanutin, not
6 to NRIM. So for the market share to continue to rise,
7 and if the sales are flat and it's declining at
8 6 per cent per annum, let's say you start off with
9 33 per cent market share, after two years your market
10 share is now 40 per cent. So it is continuing to
11 increase, and that can only be people switching from the
12 original Epanutin formulation to NRIM.
13 Q. And Flynn was -- it wasn't simply a technical dispute
14 with Boots. Flynn, as we see from this chain of
15 correspondence, was very annoyed about the Boots
16 position --
17 A. I don't deny, actually, that yes, of course David was
18 applying some pressure, because of course it's in our
19 commercial interest to try and get Boots to correct
20 their ways.
21 Q. But you're not suggesting that what is said in the
22 letters was inaccurate or incorrect or misleading in any
23 way, are you?
24 A. No I'm not saying it's inaccurate, because we're in
25 cases where the healthcare professional believes, or the

patient believes, that continuity of supply is important, they should be doing what they weren't doing.

Q. Indeed, you thought this was a sufficiently important issue that you yourself wrote a letter to the managing director of Boots, didn't you?

A. Oh mine was a much wider letter, actually.

Q. Well, we can see it. It's this bundle, tab 142.

A. 142, okay.

Q. You'll see it's to the managing director, 25th February 2014. If you look at the end of the letter you'll see your name and signature.

A. Yes.

Q. "We wish to make a series of complaints. Number 1, that Boots's purchasing and/or dispensing policies in relation to Phenytoin sodium hard capsules 100mg since July 2013, if not earlier, to date have been contrary to patient interest and safety in failing to give full and proper regard to relevant best practice guidance including, but not limited to ..."

Then you refer to the various guidance 2003, 2005, 2012, 2013.

You make points we've seen before at the top of the second page about the guidance, and how well established it is. Indeed, you repeat some of the points that Dr Fakes has made. Then, on the second page, point 2:

"Through an exchange of correspondence and a teleconference with the Director of Professional Standards at Boots, we've been advised of Boots's view, based on your expert internal and external advice, to the effect that if a patient has been switched to the NRIM formulation, they will continue to be supplied this product. We do not agree that this should be the case. In contrast, we submit that it flies in the face of pre-existing authoritative guidance and extensive published literature. We regard this as compounding and repeating the error. At the very least we believe that the situation should be discussed with the patient prescriber."

So what has happened is that Boots has not followed continuity of supply, they have put people on the NRIM product. And you're saying that they were wrong to do that, and following the MHRA guidance in November 2013, what you're pushing Boots to do is actually in relation to those patients who had been given NRIM instead of the Pfizer-Flynn product put back on the Pfizer-Flynn product, because you believed that was what was required by the continuity of supply.

A. That was the dispute that I referred to earlier, the difference of opinion between our pharmacists, our technical expert, and Boots pharmacists. That's exactly

what -- that same dispute. But you'll see that the letter was much wider than that. It was -- I mean, basically what was going on in Boots -- in fairness to the Chief Superintendent Pharmacist, when we had our telephone conversation, and he had his buyers there with him, I don't think he knew what was going on. I got the impression from his responses that he really did not know that what was happening, and I don't think he approved at all.

For us, it was very disheartening because, you know, we don't -- we don't want to fall out with Boots, I mean, they're an important customer to us, and we have a relationship with them, because not everything is done on price. We also have a relationship with them. And they not only did not actually tell us that they were doing these things, but they actively hid the information. Their staff were told not to discuss this with Flynn, which is very, very disappointing. Again, I don't think this reflects Boots's policy, I'm sure that the senior management would have been quite horrified, actually, as I'm sure that the Chief Superintendent Pharmacist was. But of course, their letters did not admit to anything like that, and they basically just carried on.

Q. You had a similar chain of correspondence with Lloyds

and Celesio, didn't you?

A. We did, yes. Again, this reflects the practices of initially NRIM with Celesio and Lloyds. And then secondly, Auden McKenzie, when NRIM started supplying their products to Auden McKenzie. Then ultimately, of course, they sold the product to Auden McKenzie. And the buyer at Boots had actually changed the purchase policy, was actually given a job at Auden McKenzie.

So the whole thing was a little bit underhand and that's why it was so disappointing to us and that's why we fought back with every tool that was available to us, in order to protect our market share.

Q. Again, I'm not going to take you to all the Lloyds and Celesio material, the same points are made to them, but I would like to show you one of them. Tab 144 of this bundle. If you could turn right to the end, again there's a clip of documents. If you go right to the end of tab 144, and you should have an end of an e-mail chain and it's the facing page I want to look at which has David Fakes at the top from David Fakes to David Walters "Re Celesio follow-up"; is that the page you have?

A. Yes.

Q. What David Fakes says to you in that e-mail is:

"Before we make contact, we need to know if [X] is

or is not the Superintendent Pharmacist for Lloyds, this is where the issue lies. The issue is one of professional practice and guidance at pharmacy level, and not a regulatory one."

What is Dr Fakes referring to when he says, "The issue is at a pharmacy level and not a regulatory one"?

A. Again, if someone is actually presented with a script for the Flynn products and they are diverted onto the NRIM product, that's a professional standards issue.

Q. So what --

A. That is potentially a very serious professional standards issue.

Q. Why is it a serious professional standards issue?

A. Because professional standards say that they must dispense if the -- a certain brand is nominated by the prescriber. And to actually -- and even to then mislead people to believe that the Flynn product is not available, is actually a professional standards -- potentially a professional standards issue.

Q. From what you've said, is it fair to say --

A. And pharmacies can, in the -- you know, if they break professional standards in a serious manner, they can ultimately be closed down. It's that serious.

Q. What is clear from this and from your answers, I think, you tell me if I've got this right, is that what really

matters to Flynn -- and it is understandable -- because what matters to you commercially is what individual pharmacists actually dispensed. That's the key to you, isn't it?

A. It's important to us, yes. I mean, we are a commercial organisation, I make no apology for looking to protect our market share, but that doesn't actually mean that we don't have regard for patient safety and --

Q. I'm simply talking about this continuity of supply principle.

A. Yes, well that's related.

Q. What the absolute crux of continuity of supply is --

A. That's related to patient safety.

Q. -- is what product does an individual patient get? Is that correct?

A. Yes, it can do.

THE CHAIRMAN: Don't talk over each other.

MR HOSKINS: We're both being told off.

A. Okay, sorry.

THE CHAIRMAN: By me as well.

THE WITNESS: Sorry, sir.

MR HOSKINS: Can I go back to your witness statement. So that's bundle B. It's the first one I want to look at, that's right tab 4, bundle B, that's paragraph 56. You say in opening:

"Flynn's pricing decisions are also affected by hospital tenders."

Then a few lines down you say:

"Hospital tenders represent a not insignificant proportion of Flynn's sales and it is therefore important that Flynn is able to complete effectively against competing products."

You may want to keep that paragraph open, but I'd like you now to look at bundle J2, tab 70. Again the figures I'm going to show you are confidential, so we can look at them, but we can't say them out loud.

The document is entitled "Phenytoin Sales by Month" and we see the data comes from UDG. Can you just explain what role UDG plays in Flynn's distribution?

A. UDG is our pre-wholesaler. They also deliver direct to hospitals. So generally, they deliver to wholesalers for the retail sector, but for hospitals, they do deliver direct. The wholesalers may also deliver to hospitals.

Q. Now this is obviously a snapshot that you see the heading "2016", then there are two tables beside each other, one January '16, one February '16. If you look across, you take the rows:

"Presentation PHENYTOIN SOD FYNN 25MG HARD CAPS x 28".

Then there is a figure for hospital and there's a figure for wholesaler. You'll see the hospital figure is, I think -- well you see the relationship it has to the wholesaler figure.

A. Yeah, I mean, generally the hospital sector will account for around 5 per cent in total, because the figures you're looking at there, that's the UDG deliveries to hospital, there will be some from the wholesalers as well, as I explained earlier.

Q. So it is fair to say that these figures, albeit just for a couple of months in January, February, 2016, are reasonably representative of the general position throughout the period?

A. Yeah, I'd say it's around 5 per cent, which as we said is not insignificant. I was just going to say that the hospital sales, yeah, it could be for patients on their routine follow-ups with neurologists, but it's also likely to represent any new patients that had been put onto Phenytoin. So you are obviously competing with the NRIM products in that environment.

Q. Can I ask you to go to bundle G1, tab 53.

G1, tab 53. This is a document I'm sure you're well familiar with because it is the exclusive supply agreement that Flynn signed with Pfizer, as we see on 17th April 2012.

A. Yes.
Q. If you can go to clause 14.2 of the agreement, you'll see the side heading "Annual price review":
"The effective prices for the products will be reviewed and adjusted annually on or before November 30th of each year for the next calendar year, annual price review, and/or on agreement between both parties, it may be deemed necessary outside of the annual price review whereby should agreement not be met the effective price will be maintained."
We see there that the supply agreement provided for an annual price review to take place on or before November each year; correct?
A. Yes.
Q. Can we go to bundle G2, tab 132. At the bottom of that page there is an e-mail from you to Alison Wheeler. Can you just tell me who Alison Wheeler was?
A. I believe -- I mean, you'd have to confirm this with Pfizer, but Alison, I believe, joined Steve Poulton's group -- or actually Steve might have left by then -- when Jason Perfitt and Steve had been moved into other positions, she became our primary contact, our initial contact, with Pfizer.
Q. Your e-mail which is at the bottom of the page, 9th December 2013, says:

"Dear Alison, we are now a couple of months and we're beyond the contractually scheduled review. I wonder if we can organise this meeting before Christmas."

I think it is fairly obvious from that that no review had taken place before 30th November 2013.

A. No, I was a little bit frustrated trying to get a -- with all due respect to Pfizer, I was a little bit frustrated trying to get meetings organised at times.

Q. Flynn and Pfizer actually met to discuss pricing on 16th December 2013; is that right?

A. I don't actually know off hand. Are there minutes of the meetings?

Q. We'll come to some material that relates to that.

Keep bundle G2 there, if we can just skip back to your first witness statement again for a moment, bundle B, paragraph 24. You might just want to cast your eye over paragraph 24, but I want to pick it up in the final few lines, five up from the bottom:

"At launch, in the end we had to persuade Pfizer to produce a further loss-making batch of Epanutin capsules in order to ensure that patients continued to be supplied during this period. This step was taken at Flynn's expense because in order to compensate Pfizer for the additional branded stock, Flynn --"

I'm sorry I'm not allowed to read the next bit. You can read it to yourself.

The position was that Flynn had agreed to do what is seen in the confidential bit that we've read but I'm not allowed to say out loud. So it is in the final one and a half lines; do you understand what I'm referring to?

A. Yes, I do, yeah.

Q. That had been agreed, and the understanding was that after 12 months, the price would be reduced; is that correct?

A. Yes, that's correct.

Q. Then if we go back to G2, at 133. Tab 133. At the bottom, there is an e-mail from Alison Wheeler to you, David Fakes and some others, and the subject is "Today's meeting"; do you see that?

A. Yes, I do, yeah.

Q. It says:

"Dear all, many thanks for today. Please find a summary attached."

A. Yes.

Q. That's where I get the date that there was a meeting between Pfizer and Flynn on 16th December 2013. Does that help jog your memory?

A. Well, it does appear that there was, yes. It's not in

my memory as to what date it was, but yes, that would appear to be as you suggest.

Q. Then if we go to 138, tab 138, again, I'm afraid we have this sort of -- this clip of documents. If you can turn through, it's page 13. If you can just work through until you come to something with the title "Pfizer-Flynn meeting Monday 16th December 2013."

I can tell you that this is the summary that Ms Wheeler prepared of the meeting and sent to you. Do you recognise this document? Does it ring any bells?

A. Yes, I've seen this document, yes.

Q. And we'll see from this that a range of issues were discussed, and the final bullet is: "Price reduction requested". You'll see it says:

"A change backdated to September 2013 to account for level stock currently held."

Then there are some initials.

Am I right in assuming that the initials are the people who are responsible for these action points? Is that your understanding?

A. Well, those are Pfizer initials.

Q. Those are Pfizer initials?

A. Yeah. I believe they are, anyway.

Q. Why did Flynn want a price reduction to account for level stock currently held? What was the issue there?

A. Because it was 1 year after the supply agreement started. And they'd said that they would -- the bit that we couldn't read applied for one year, which actually was September '13. So we said okay, I mean, they agreed to make the change that was necessary, and we pointed out to them that this was meant to have happened since September '13, so we asked to them to apply it to the stocks that we'd purchased since September 13.

Q. Then your e-mail in reply, she sends you this summary, and your reply, if we go back to 133, it should be an e-mail from you to Alison Wheeler, 18th December 2013, you say:

"Dear Alison, your summary looks fine."

Then you add some additional points below. There is no reference in these documents to competition from NRIM, is there?

A. There's not in these documents, no.

Q. The decision to seek a price review in December 2013 was not triggered by fear of competition from NRIM, was it?

A. The decision to seek the price change was related to the agreement for the additional year, and not specifically to NRIM. It doesn't mean that we didn't discuss the markets and the way the intelligence we had regarding NRIM's shares. But as I mentioned earlier, we weren't

particularly concerned about NRIM. We expected to lose some market share to them, and our intelligence told us that they -- their usual habit was to take it to a certain level, and then basically desist. And their target was one of the two largest retail chains in the country. And they were successful.

Q. We know from paragraph 57 of your first witness statement, that Flynn and Pfizer agreed to a price reduction on February 2014.

A. Yes.

Q. That's correct, isn't it? Then if we go back to G2, tab 139, this is a letter from effectively an agreement, actually, it's signed by Paula Tully Director of Pfizer and by David Fakes on behalf of Flynn Pharma.

"Amendment to the pricing terms."

"This letter sets out an amendment to the pricing terms. Pfizer hereby confirms ..."

MR LOMAS: (inaudible).

MR HOSKINS: I'm sorry, I didn't realise, it is G2, tab 139.

PROFESSOR WATERSON: I've got it over here.

MR HOSKINS: That's fine.

This letter then sets out the price agreement to the table, and then it says halfway down:

"As agreed, the product price for the 50mg dosage now reflects the original price envisaged in the supply

agreement following a temporary uplift in price to compensate for a delay in the launch of the product in April 2012."

Then it says:

"Reductions in the supply price for the 100mg and 300mg doses reflect the need to respond to competitive pricing pressures in the marketplace which we described in detail at our meeting."

But you have just told us that you're not particularly concerned about the competition from NRIM when this negotiation was taking place.

A. In September '13.

Q. Well, I'm sorry, I took you to the meeting in December --

A. Sorry, in December --

Q. December 2013.

A. December.

Q. You accepted there was no reference in any of that material to competition from NRIM.

A. Mm.

Q. I took you to the summary of the meeting --

A. Yeah.

Q. -- for which you accepted that the reason for seeking the price reduction was nothing to do with competition. The agreement was made in January, and this is just

simply recording the meeting that's made. So I appreciate that it was 2013, 2014, but this is part of the same story and you've just told the Tribunal that NRIM was not a significant concern to you in these negotiations.

A. That's correct, yeah, yeah. But it became obvious to us in that period, interim period, which is a couple of months, basically, that we were beginning to lose more sales, and once we investigated it thoroughly, this started to relate to the deal that was done with Auden McKenzie. So this was the start of our problems with Boots.

Q. Something else had happened which is the CMA had begun its investigation into Pfizer and Flynn in May 2013, hadn't it?

A. Yeah.

Q. You knew you were being investigated?

A. Yeah.

Q. Both Pfizer and Flynn were aware by then that it would be advantageous to them to be able to refer to competition from NRIM, weren't they?

A. That's not something we discussed.

Q. You weren't aware of that at all? Saying there was competition with NRIM --

A. I don't remember it was anything that we ever

considered. But what you're saying is we basically were manipulating it to answer to the CMA. We didn't have a clue where the CMA were going at that stage.

Q. Had you engaged lawyers by this stage.

A. Yes, we had, yeah.

Q. Still in this letter -- sorry, agreement -- it's just above the table. It says:

"Pfizer hereby confirms that it shall offer Flynn the following revised supply prices with effect from 1st January 2014."

A. Yes.

Q. We see there that Pfizer agreed to backdate price reductions to Flynn until 1st January 2014; correct?

A. That is correct, yes.

Q. Flynn reduced its own list prices to its customers on 1st April 2014; correct?

A. Yes, that's correct.

Q. Can we look now, please, at bundle J1, tab 23.

I understand that all these figures are claimed to be confidential. There have been references to Flynn's prices in open court in some of the opening submissions, but unless anyone tells me otherwise, I'm going to treat them as confidential. So you understand, Mr Walters, that we can read them, but we cannot say them out loud. Have you got me on that?

A. Okay.
Q. So what we see in this is it's titled "Phenytoin sales March-August 2014", and this was a response that Flynn gave to the CMA when the CMA sent one of its formal section 26 notices. So this is information provided by Flynn to the CMA. And it's quite hard to read, but you'll see in blue under "Product Phenytoin 25mgs"; do you have that?
A. Yes.
Q. We're interested here in the wholesaler situation. So you'll see the wholesaler price in March '14 for 25mgs; do you see that?
A. Yes.
Q. You see that it drops slightly in April '14?
A. Yes.
Q. Then it actually increases materially in May '14.
A. Yes.
Q. Similarly, the price is maintained in June '14, increases a bit in July '14 and effectively stays at the same level in August '14. So what we see here is a small reduction for 25mg in the April that following that, in the immediate following months, an actual increase in the price for 25mg?
A. Yes.
Q. Then if we again track for 50mg prices, phenytoin 50mg,

again I'm looking at the wholesaler figures. You'll see the average selling price March '14, you'll see there is a reduction in April 2014, but you'll see then an increase in May '14 to actually greater than the price that had been applied in March '14; yes? Price is maintained in June '14, increases July '14, increases slightly in August '14. So again we see a drop for 1 month, but then an increase thereafter.

100 mg, wholesaler prices. You'll see average selling price March '14, we see a fairly substantial reduction in April '14. A further reduction in May '14. Price is maintained in June '14. Slight reduction July '14, and then a substantial increase again in August '14; yes? There we see a slightly different pattern: a drop in April '14, price stays quite low but then it's increased again in August '14; yes?

A. Yes.

Q. There's a similar pattern, 300mg wholesaler, you see the March '14 figure, you see the reduction in April '14, you see a further reduction, May '14, price maintained June '14 and then an increase comes in July '14 and a further increase in August '14?

A. Yes.

Q. Can I go to your second witness statement, so that's bundle B, tab 5.

THE CHAIRMAN: Mr Hoskins, what is your plan for the afternoon in terms of time?

MR HOSKINS: I'm going to stop in the next five minutes and we can have our break if that suits.

THE CHAIRMAN: And after that?

MR HOSKINS: I'm going to carry on, but I think we'll struggle to finish by 4.30. We will struggle. We won't finish by 4.30.

THE CHAIRMAN: Yes, well we're slightly in your hands on this.

MR HOSKINS: I understand.

THE CHAIRMAN: Carry on.

MR HOSKINS: We can discuss at the end of the day, but the position then is if we run over, Monday we said we'd be non-sitting because I think Mr Ridyard and one other expert weren't available. So perhaps the parties can consider whether they want to come back on Monday to finish the factual witnesses, or whether they'd prefer to carry on on Tuesday with the factual witnesses. I'll throw that out for consideration. They can maybe take soundings during the break and obviously we're in the Tribunal's hands, but what suits you.

THE CHAIRMAN: Perhaps you'll take soundings. In the meantime, crack on.

MR HOSKINS: Paragraph 6 of your second statement. Flynn

began the process to move to RWM in 2013. That's the reduced wholesaler model, isn't it?

A. That's correct.

Q. "Flynn met and negotiated with three different wholesalers and this process began prior and was not linked to the price reduction for phenytoin. It was a purely commercial decision, and the move to RWM was intended to cut costs across Flynn's entire portfolio, not just phenytoin, by reducing wholesalers' margins from approximately [I won't say the figures X to Y and Z]. As explained in the excerpt above, by May 2014, most pharmaceutical suppliers had moved to RWM and Flynn was an exception for not having to do so."

So what happened was that Flynn reduced the number of wholesalers it supplied to; is that correct?

A. Directly, yes.

Q. But it increased the wholesale price that Flynn charged to those wholesalers?

A. Across the entire product range, yes.

MR HOSKINS: Sir, I can take a break now.

THE CHAIRMAN: Thank you. Ten minutes. Mr Walters, you're under oath. Please don't discuss the case.

(3.15 pm)

(A short break)

(3.25 pm)

THE CHAIRMAN: Mr Hoskins, we've taken soundings amongst ourselves, our very strong preference will be to finish with these three witnesses today. That was the original plan.

MR HOSKINS: I understand.

THE CHAIRMAN: We will sit late, if necessary.

MR HOSKINS: I'm happy.

THE CHAIRMAN: In the meantime, perhaps speed up a bit.

MR HOSKINS: Well I will, I think you have to say that to both of us to be fair.

THE CHAIRMAN: I'll say it to both of you, but you're in charge of the cross-examination and it is for you to set the pace.

MR HOSKINS: I am. But you'll be aware, I don't want to interrupt the witness or cut him off.

THE CHAIRMAN: No, or talk over him. Absolutely. All understood.

MR HOSKINS: I will do my best.

THE CHAIRMAN: So you know how we're thinking. Is that acceptable to you all?

MR HOSKINS: It is to me.

THE CHAIRMAN: I think bringing Mr Beighton back on Monday or Tuesday is not really very fair.

MR HOSKINS: I understand. If we go to bundle G1, tab 21, please. This should be a document: "Flynn Pharma

Limited Draft Heads of Terms." If you can flick through 5 pages, there should be a document entitled: "Epanutin proposal October 2010". This, I understand, is a proposal by Flynn to Pfizer made in the -- the date is October 2010; is that correct?

A. That's correct.

Q. And then if we can look at page 7, you'll see the heading "FAQs", and then 6(a) at the bottom of the page:

"Would any price increase encourage parallel imports? There is currently a level of parallel imports which is limited by the availability of stock. No more would be available to importers."

What is Flynn saying in this document?

A. Well, no more than the current levels, basically. The markets for the three presentations other than the 100mg are very limited. So I think, I mean, Pfizer will correct me, but I think it is basically Ireland, which is small compared to the UK, so the quantities are limited. And the 100mg, it's predominantly coming in from Spain and Greece. So basically there would be no reasons to why those supplies into Spain and Greece would be increased by Pfizer.

Q. As a generic company, presumably you keep a close eye on parallel imports, that's one of your main competitive threats potentially, isn't it? I'm not just talking

about Phenytoin, I mean generally.

A. I mean, within the context of a small company and we don't have huge resources, we're not Pfizer, we do try and keep an eye on competitors, yes.

Q. Can we go next to bundle J1, tab 14. It should have a heading "Phenytoin: the Market and Developments"; do you have that?

A. Yes, I do.

Q. This is a document that Flynn provided to the CMA on 7th April 2014. Do you recognise this document?

A. Not off hand, no.

Q. Is it one you'll have seen before, do you think?

A. I will have seen it, I'm sure, yeah.

Q. If you go to the second page of that document, you'll see the heading "PI":

"PI licences have been under increase lately with now over 15 licences in operation for the 100mg alone sourcing product from Spain. Initially, the pricing for the PI had been very competitive, but due to more licences being granted but not the stock available, stock was effectively put up for auction on a monthly basis. Pricing is now between [X] and [X] off list price in the open market."

So is it a fair summary of what Flynn is saying there, that whilst the number of parallel imports

licence holders has increased, the number of licences has increased, the supplies have been limited?

A. Well, by the -- what it's actually saying is that the Spanish wholesalers, for example, recognise that there was a big profit gap, and so they had an opportunity, so instead of selling it at the Spanish prices, they started to sell it effectively by auction, to the highest bidders. That's all it's saying.

Q. So it's not that there was an increase in stock, it was simply that the manner in which the stock was directed to parallel imports was being done by auction, so that the Spanish wholesalers could increase their profits; is that a fair --

A. Yeah, that's basically it. Of course, in some cases though, Spanish wholesalers are owned by UK wholesalers.

Q. Can we go to bundle G1, tab 21. This is a clip we've seen before very recently, "Flynn Pharma Draft Heads of Terms." It's page 9 of this document, so if you can go through, there's a presentation, Flynn paper: "A speciality care pharma company."

A. Yeah.

Q. Then you have to go through, it is page 20 of this bundle. A slide, it says, "How much would PIs impact sales?" Tell me when you've got to that.

"How much would PIs impact sales? There should be

no impact on 25, 50, 300mgs in the UK. These alone could be worth 15 million."

Why is Flynn saying no impact on 25, 50 and 300?

A. Well, because of the reasons that I mentioned before. It's -- those -- not necessarily the 300, but the 25 and 50mg, I think it's only Ireland that actually sells them outside the UK. So the volumes that are available to parallel traders were going to be limited, as they always had been.

Q. Then you say:

"Even if 50 per cent of sales of 100mg were lost."

Flynn isn't saying that it was expecting 50 per cent of sales to be lost to PI, is it?

A. No, this was basically -- I mean, this is a very early document. This is when we're selling the concept to Pfizer, but there was a place for Flynn in this -- in this arrangement, and basically we were just showing them that, you know, even if you did lose 50 per cent, you would still be making more profit. So it's still attractive to you. That's all we were saying.

Q. But there was no expectation that they would lose 50 per cent. This is almost a worst-case scenario, even if this happens, you still make --

A. Well we don't actually control the sale of Pfizer products anywhere, and we don't have, as you know, post

the asset sale agreement and our launch, we don't actually market the product in any other market in Europe. So this is not something that was within our control. It's -- this is something in any sense, I mean, this is something that basically comes down to how Pfizer are actually managing their stocks within the European markets.

Q. If we can go to tab 29 in this bundle, this is a bit later on, this is December 2010, there's an exchange of e-mails between yourself and Nick Foster, who was Nick Foster, what role did he have?

A. He worked for us at Flynn.

Q. What was his position?

A. Business development and, I mean, we have to do everything at Flynn, so he was also involved in the relationships with the UK wholesalers and retailers and of course changing lightbulbs, as we all do.

Q. You say to him in the e-mail, in the middle of the page:

"We can discuss on Monday the approach to parallel imports. I think we just need to emphasise the need to do the deal, wait and see if parallels become a problem and then address it through senior Pfizer management. It is better for them to make a decision to sell the other markets to Flynn once they start seeing profits rolling in from the UK."

Nick Foster replies after the chat:

"I agree, I really think that PI should not be a major hurdle. Even if they lost 75 per cent to PIs, they would still be considerably better off."

So Flynn's view of the PI threat was that it was certainly not one that anyone should be overly concerned about; is that correct?

A. Not overly concerned in the sense that they're still going to make decent profits if they lost those sort of levels of sales. It doesn't mean they wouldn't be concerned about them, but it's not something that would necessarily be a deal breaker.

Q. Then if we can go to --

A. This is all before we did the deal, of course. This is all before then.

Q. Can we go to G2, tab 113. These are Flynn board meeting minutes, 5th March 2013. We see you were present; do you see that?

A. Yes, I was, yeah.

Q. Then on the second page, under the heading "Business update Phenytoin," and towards the end of that, three lines from the bottom of that little bullet:

"The budget for 2014 assumes a 20 per cent decline in volume on a 100mg strength only that could be the subject of PI. However, the prices have been maintained

at the same level as launch."

Is that Flynn saying, "We don't consider it necessary to introduce any reduction in our prices because of competition from parallel imports"?

A. Well, as I've already mentioned, I mean, we would -- there's really not very much that we could do against PI. The sort of thing that we are able to do, obviously, is to look at the -- talk to our retailers, offer some rebates to some of the important ones, which are not shown in the selling prices from the UDG or from the wholesalers, and obviously they are buying more than just one strength of product from us. And lots of other products, too. So there are things that you can do in a general sense, but in terms of just simply reducing the price of the 100mg isn't necessarily the right approach to it.

Q. So you decided, for setting the budget for 2014, to maintain your own prices on 100mg?

A. And to assume that we'd be affected by a 20 per cent decline in volume.

Q. Can I go --

A. Oh that were true, actually.

Q. Can I go to your first witness statement, please. That's back to bundle B. So B, tab 4, paragraphs 22-34. It's where -- it actually begins at paragraph 20.

"Flynn's discussions with the Department of Health".

A. Yes.

Q. Then at paragraph 21 you say under the heading "18th July 2012 meeting":

"Flynn first contacted the Department of Health (DH) on 3rd July 2012 to request an early meeting to discuss its proposed increase in the price of Phenytoin sodium capsules."

Then at paragraph 25, under the heading "6th November 2012 meeting", four lines down there's a paragraph that begins:

"In fact, each meeting which Flynn has held with the DH was requested by Flynn. The DH never initiated any of our discussions about price."

Can I take you to bundle G1, 59.

Sorry, this has to be done in the small clip. This was not, I imagine, a document certainly -- you wouldn't have seen it at the time, because at the bottom of the page --

A. Which tab?

Q. I'm sorry, it's tab 59. In the little bundle, tab 1. I'm so sorry. It's G1, 59 in the main bundles.

At the bottom of the page, you'll see "[✂], [✂], MHRA"; do you see that?

THE CHAIRMAN: We are keeping names of officials out, unless

they are senior civil servants.

MR HOSKINS: I'm so sorry, that's my mistake. I'm sorry.

You'll see the name of an MHRA employee and you'll see it's sent to a DOH employee, it's dated 25th June 2012.

A. Yes.

Q. You see what he says.

"Thank you for the feedback, [✂]. [✂][and I won't say his name, but you'll see from the top that [✂] is also at the MHRA] [✂] and I had an interesting phone call with Flynn Pharma this afternoon. They are playing hardball on this one. And although the MHRA do not agree with the name change, Flynn effectively threatened to stop the product if they do not get the generic name approved."

Then the final paragraph:

"We have told them that if they wished to press ahead with the change, then the next stage is to supply us, including DoH, with their proposed healthcare professional communications."

Then in this bundle at tab 63, G1/63. You see this is an e-mail from Martyn Bain, who was your Finance Director. We see that from the bottom of the page; yes?

A. Yes.

Q. And it is to a person at the DH; do you see that?

A. Yes.

Q. It says:

"Dear [X] your contact details were given to us by [✂] of the MHRA."

Then the penultimate paragraph:

"We request an early meeting with the DH to discuss these issues."

THE CHAIRMAN: Mr Hoskins, names, please. You just mentioned the name.

MR HOSKINS: I read out -- did I? I'm so sorry.

THE CHAIRMAN: Otherwise we're going to change the way we're working.

MR HOSKINS: I'm not doing it on purpose.

THE CHAIRMAN: I'm sure you're not.

MR HOSKINS: I'm very sorry.

THE CHAIRMAN: I'm not picking you up on purpose.

MR HOSKINS: You're just pointing out the mistakes I keep making.

"We request an early meeting with the DH to discuss these issues, and to ensure that the DH perspective and remit is considered in parallel with the MHRA review, and to more importantly ensure there is no interruption to supply, and there are no concerns to patient healthcare professional arising in the short to medium term."

What these e-mails show is that it wasn't actually Flynn's idea to contact the DH in the first place. The reason why Flynn contacted the DH was because the MHRA asked it to do so; is that correct?

A. It is a slightly different issue. If I can explain, what we said is that yes, we did actually ask the DH for a meeting, because the meeting that we had with the MHRA put us into a bit of a corner, as we explained. They were insisting for the first time that the product had to be a brand, and we explained to them that if it were a brand, it would be subject to PPRS, and there was nothing that we could see in the PPRS regulations that would allow us to increase the price to make it viable. And they basically said, "Well actually that's something you're going to have to discuss with the Department of Health."

And so we asked them who they thought it would be best to discuss it with, because this also had impact on our ability to continue to supply products, that was the key, these hold-ups were threatening the continuity of supply, and basically the first -- the one that this is actually addressed to, who I won't name, at the DH, my understanding is he is mostly to do with supply. He's the guy that we have to contact if we have any threat to our continuity of supply.

So this was written to him, but we said that we were obviously in this box and we would like a meeting with the DH. We were not approached by the DH.

Q. No, you weren't approached by the DH.

A. No.

Q. But the reason you approached the DH was because the MHRA has raised an issue at which you -- and then asked you to approach the DH. It was MHRA that asked you.

A. They didn't ask us to approach them, they said, "We suggest that, you know, this is nothing to do with us. We are the regulator in terms of the product licence." But this particular issue of pricing is not within our remit and we suggest that you go and talk to the DH about it."

That's exactly what we did.

Q. Then if we go back to your second witness statement, paragraph 10. You say there:

"The CMA says that Flynn does not claim to have been constrained by fear of the DH's powers to intervene on the pricing of Phenytoin. That is just not true."

Are you saying that the level of Flynn's prices for the Phenytoin sodium capsules would actually have been higher if it hadn't been for this fear of the DH's powers to intervene? You would have priced them higher.

A. No not at all. They wouldn't have been higher because

we, as we have said all along, we benchmarked them against the tablet price. And we had every reason to believe that the tablet price, every reason, was accepted by the DH as being fair. Everything available to us told us that the price had been set by the Department of Health. Everything. The drug tariff definition of a category M product says specifically that the Secretary of State determines the price based on the information from the suppliers.

We also alerted the CMA to another NHS website which says much the same thing, and the -- I always get this the wrong way round -- the pricing -- no, the pharmaceuticals of PSNC, the Pharmaceutical Services Negotiating Committee, their website also says under category M that the price is determined by the Department of Health. So if there was any suspicion that this product, you know, on our part, could have been excessive, I mean, how would we know that? If it's excessive then basically it means that the Secretary of State or the Department of Health are culpable.

So we compared it with the closest thing on the market, you know, Phenytoin sodium, one's a tablet, one's a capsule. The price had been agreed with the Department of Health.

MR LOMAS: I think Mr Hoskins was asking you a slightly

different question. If you hadn't had a concern about DOH's powers to intervene, you would have priced the capsules even higher. Why would you have bothered with the reference price for tablets if you were free from that concern?

A. Well, because, you know, we're not trying to fleece the NHS. We actually believe that that is a fair comparator. And if you ask the general managers of products across the pharmaceutical industry, you know, how do you price products? This is a -- I believe this is a similar approach to the approach that any of them would have had taken. You look at comparators in the market. Because that does reflect what the DH is recognising as fair value today.

MR HOSKINS: So fear of the DH didn't have any constraining effect on the price you actually set for your product?

A. Well -- the last thing I want to do is upset our only customer for this product. And, you know, we made every effort to discuss this with the Department of Health, they chose not to negotiate, despite the titles on their business cards, and, you know, we would actually have welcomed a negotiation on the product because basically it would have been the right thing for them to do, just as they'd done with Teva before them, and Teva was exactly the same situation as us. They didn't develop

their product, they acquired it. They ramped the price up to actually over £40 million per year, and then through intervention by the Department of Health, which they subsequently claim they never made --

Q. I'm going to come onto the -- I just want to focus on the particular point again, and Mr Lomas raised it. If I can just tell you, at the start of this question I asked you the question: "Are you saying that the level of Flynn's prices for the Phenytoin sodium capsules would actually have been higher if it hadn't been for this fear of the DH's powers to intervene, you'd have priced them higher?"

And your answer was: "No not at all. They wouldn't have been higher because we, as we've said all along, we benchmarked them against the tablet price."

A. Mm-hm.

Q. So the particular point I'm asking you to confirm, it seems to follow from that, that fear of the DH played no part in constraining the level of the price you set for your product?

A. We weren't fearful, because we believed that it was fair, because it was set against an identical product for which they had agreed a price. Our product was 25 per cent lower, and then subsequently it was reduced even more, to the point where their product became

66 per cent higher price. And even today, after we've been directed to reduce our prices, the tablet is still about three or four times the price of the capsules.

Q. Can we go to bundle G2, tab 92. It's over the page. Top right it says, "from Warren Roiter" who appears to be warren@woodbury-associates.com, 1st November 2012 to David Fakes, David Walters and himself.

This is dated 1st November 2012, so just to put this in a timeframe. This is just before Flynn's meeting with the DH on 6th November 2012, ie the second meeting; do you see that?

A. Yes.

Q. At the time Mr Roiter was employed by Woodbury & Associates, who were Woodbury & Associates? What relationship did they have with Flynn?

A. Well, the only thing that's important here is that Warren is actually one of our board members. He's a director of the company.

Q. Was he at the time he sent this e-mail?

A. Yes, yes, he was.

Q. So this is one of your board members?

A. Yes.

Q. Is it right he's a solicitor?

A. Yes, he is a former lawyer, a law firm that he used to run.

Q. And he says:

"Flynn is not a member of scheme M so not directly affected by the attached. If we had been members then we could have increased the price, but the starting point would have been the Pfizer brand product price and generally not higher; is that correct? The ultimate power of the Secretary of State to regulate prices seems quite useless here as they cannot force us to sell the product. This must be all about negotiation. The NHS needs the product. We want to sell the product but do not have to, and we need to make a reasonable profit. Somewhere between these positions will be the final price to be agreed."

You replied the same day, so we need to turn backwards to the front of this tab. You see it is at the bottom of the page from David Walters, 1st November, to Warren Roiter:

"Hi Warren, I'm not sure about whether or not the brand price would have come into it had we been members, but other than that, I agree with you."

You agreed with his statement that:

"The ultimate power of the Secretary of State to regulate prices seems quite useless here as they cannot force us to sell the product. This must be all about negotiation, the NHS needs the product, we want to sell

the product, but do not have to and we need to make a reasonable profit. Somewhere between these positions will be the final price to be agreed."

Is it correct that you believed that was an accurate summary of where you stood with the DH?

A. Well, basically, yes. I mean, he's just saying that, you know, nobody can make us sell the products. So we can if we wish, we can discontinue the product. But that's the ultimate power, of the Secretary of State, could be to make us reduce the price to a level that we simply cannot see as being viable. I mean, it was mentioned yesterday that perhaps our real rate of return, you actually said should have been 1 per cent. I'm sorry, I can get more than that by putting the money in the bank without any risk at all. So why would I invest in a product with a return on sales of 1 per cent?

Q. Can we go to your first witness statement at paragraph 26. You see the heading towards the middle of page 8 "6th November 2012 meeting".

A. Yes.

Q. Then paragraph 26 at the top of page 9:

"We confirmed that the price of our capsules had been set by reference to the price of tablets. The DH said for the very first time it did not consider the

tablets to be a relevant comparator."

You say for the very first time, but it's right, isn't it, you'd only had one previous meeting with the DH and that was on 18th July, 2012?

A. We'd had one previous meeting. We made it very clear to them at that meeting that we were benchmarking against the tablet. They had every opportunity to come back to us between July and November to say that if they believed it, you shouldn't be comparing to the tablet. It's not a valid benchmark. They didn't.

Q. But they did at the second meeting, as we'll see?

A. Well, they did, but they did not consider it to be a relevant comparator. So, you know, why didn't they tell us that before? They knew our plans pre-launch.

Q. So paragraph 30 of this statement:

"in the decision, the CMA criticises Flynn for making misleading statements regarding its costs at the 6th November meeting. I disagree and our own record of the meeting, which was drafted very shortly after the meeting, is very different to the DH's note on this point."

So is it fair to say that you are confident that Flynn's note of the meeting is an accurate record?

A. Well, it is what it is. It's the record from that moment in time. And we -- I was horrified to think that

they thought we'd been misleading them when they deliberately misled us to say that they never negotiated the price of that product.

Q. G2, tab 94. I have to be careful not to read out the names, I admonish myself at the start? It is:

"FILE NOTE OF MEETING WITH DH RE PHENYTOIN 6TH NOVEMBER 2012."

This is the Flynn note of the meeting; is that correct?

A. I believe these were, yeah, Martyn Bain's note of the meetings.

Q. If you can turn over to the second page of it, you'll see "II" and II was one of the DH officials in attendance. I'm not allowed to say the name.

"[II] noted that tablets were only about 20 per cent of the market so wasn't true competition."

[✂], who is also a DH official, stated that:

"Scheme M relies on competition which as there is no direct competition for capsules currently in the market does not apply to this product. Phenytoin sodium capsules therefore fall outside PPRS and scheme M. In [✂] view the product falls between the two schemes as do others not named. They do not know our costs breakdown and DH currently have no justification of value of money that they need from us. [✂] unless they

can understand it, the DH has to go away and see what powers are available to do something bit.

"We advise [that's Flynn] we could not disclose our cost of goods that we pay Pfizer under our supply agreement as this would breach our confidentiality agreement with them. [✂] confirmed they recognised the need for some increase in prices, but needed to be able to justify the large increases value for money.

"DW [you] advised we might have to discontinue the product if we didn't make sufficient margin. [✂] advised that we need to give a breakdown of all our costs or they would have to review what options were available to DH to enforce any powers they had noting that nothing had been invoked since schedule M was introduced.

"[DW] stated that the main element of our cost was the cost of the finished product we supplied. We felt that the discussion with DH PPRS on price at launch was sanctioned by default as it went unchallenged. [✂] stated that this could not be the case as PPRS had no remit on pricing of generic products, and that scheme M was not a pressing approval. We should not in [✂] view assume that the DH and NHS are happy with the price of tablets."

So I think you've already accepted you knew very clearly, as a result of that meeting, that the DH had

concerns about benchmarking your price to tablets, didn't you?

A. We were told for the first time that we should not, in [✂] view, assume that the DH and the NHS were happy with the price of the tablets. We pointed out in the meeting that they should be because they negotiated them. To which we were then told we did not negotiate the price of the tablets. That's how the conversation went.

And it was then taken off of the table for discussion, because it was -- it involved someone else's product. So, you know, she quite rightly said we shouldn't really discuss what happened between those -- themselves and the other party, as Mr Poulton said this morning, the DH just shouldn't do that.

Q. The DH, you were aware they were not happy with using tablets as a benchmark, and you --

A. Well, from that meeting onwards.

Q. From that meeting onwards?

A. Yeah.

Q. And you were also aware that the DH's view was that they had not negotiated a tablet price with Teva?

A. That's what they said, yes.

Q. You also knew very clearly as a result of that meeting that the DH had concerns about your price for capsules,

didn't you?

A. Well, the main reason for the meeting, again, we asked them if we could meet, because we were concerned that the level of criticism that was being aimed, not just at us but also at the DH, because of the price increase. Now, that's basically what had happened, and so, yeah, we were aware, and nobody likes price increases, nobody, even on products where the price has probably not moved since -- well, for decades.

Q. What the DH asked you to do at that meeting was provide costs information, they said, "Without costs information we simply can't evaluate whether these levels of increase are justified or not". We see that from your note, don't we?

A. We also had some discussions. I actually thought at one point we were beginning to get somewhere because they did accept, they did accept that we needed to make a profit. They also accepted that our contracts manufacturer, ie Pfizer, needed to make a profit, and it looked as though we were moving towards a negotiation, actually.

We were asked to provide, on the spot, because this had just been thrown at us, we were asked to provide what, you know, what added value we brought to the product. Of course, the biggest one of all was simply

that we've given it a new home with an experienced company, one that is used to managing products through their end of life. And we know exactly what the issues are going to be, as the volumes decline and decline, and we are used to making the transition to new producers.

So basically we were actually under the impression that this was the beginning of a negotiation process, and as we said at the end of the letter we sent to them outlining the various areas, we would welcome further discussion on these matters.

Q. Can we go back to your note, it's the sixth paragraph up from the bottom:

"[✂]confirmed they recognised the need for some increase in prices."

I've just read this, but Flynn's note of the meeting says, "[✂]advised that Flynn need to give a breakdown of all their costs or the DH would have to review what options were available."

That's accurate, isn't it? That's what you were told. They wanted the breakdown of all your costs?

A. Yeah, that's not referring specifically to cost of goods.

Q. No, they wanted a breakdown of all your costs?

A. Yeah, this is where we had a discussion on what it was going to cost us in the future to transition the product

to new manufacturers, which we, in the decision, subsequently comes out that apparently we never intended to do that, which is staggering.

Q. As you say, you were taken by surprise by this approach. At the top of page 3 there's little heading "Added value" and there's some entries there that you have put in. But you said -- and we've seen it on page 2 -- you stated:

"The main element of our costs was the cost of the finished product we are supplied."

So the main element of the cost was actually the cost of the goods, and that's correct, isn't it? The cost of goods for Phenytoin far outweighs any other potential costs that you identified to the DH.

A. At that moment in time, yeah.

Q. Can we keep G2 handy, your first witness statement, paragraph 31. You say:

"Following the 6th November meeting Flynn sent a follow-up letter to DH on 16th November 2012."

We see that in G2, tab 100. First document behind tab 100 is the covering e-mail, and then you get the letter itself, 16th November 2012. Again, careful not to say the names.

Page 2, "Cost of Goods." Do you see the heading?

"You asked us to request Pfizer's permission to

disclose our cost of goods data. Their response to our request was 'As a global supplier of Phenytoin, information relating to the cost structure for production and delivery of Phenytoin sodium Flynn hard capsules is commercially sensitive and confidential'."

So you were saying to them "Very sorry we can't give you the cost of goods information because Pfizer won't let us"?

A. That's correct.

Q. Then, on page 3, there's a heading "Supply chain resilience", and what you do there is provide a narrative description of various elements of your supply chain, but don't provide any figures, do you? You don't put any actual figures on these elements?

A. Well, as we've said, we -- in terms of the existing supply chain, we weren't allowed to by Pfizer. In terms of the future, we had already discussed the sorts of numbers that may be involved in identifying additional suppliers or alternate suppliers, both the active and the finished products.

Q. In relation to cost of goods, Pfizer said no.

A. Yeah.

Q. We'll come on to potential future costs to Flynn.

In relation to present cost to Flynn, because you presumably had some, we know that, you don't give any

figures; correct?

A. Correct -- sorry, can you just say that again?

Q. Okay. There are number of elements to the cost of this. There's the cost of goods that you pay to Pfizer, and you say: "You can't have those because Pfizer said we can't tell you them."

A. Mm-hm.

Q. You referred to some potential future cost to Flynn which we'll come to in a minute?

A. Yeah, yeah, yeah.

Q. Flynn had some existing costs --

A. Yes, we did.

Q. -- dealing with the product?

A. Yeah.

Q. But you don't give any figures for those costs in this letter, do you?

A. Not in this letter, no.

Q. Then back in your witness statement, paragraph 32, you say:

"The DH never followed up on this response, and did not attempt to engage with Flynn on pricing issues at any other point."

A bit further down:

"As the DH successful intervention to reduce the price of Teva tablet shows, the DH has very substantial

purchasing power and drug companies are almost always cooperative when the DH makes demands on them."

But Flynn wasn't cooperative because DH asked for a breakdown of costs and you gave them nothing on costs, save for the narrative we've seen.

A. We did exactly as they asked. We asked Pfizer if we could give them the cost of goods and they said no. It didn't stop them from actually approaching Pfizer, I don't know if they did or not, but that was not for us to be involved in.

Q. Did you tell Pfizer that the DH had asked -- presumably you had, because you asked Pfizer --

A. Of course.

Q. -- did you tell Pfizer why you were asking Pfizer for permission to give these costs of goods details to the DH?

A. I don't remember. I mean, we certainly told them that we'd had a meeting with the DH and they'd asked to --

Q. But you must have done because you wouldn't simply have gone to Pfizer and said, "We want to reveal cost of goods to the DH", you would have told them why you wanted to reveal costs of goods to the DH, clearly you would have done?

A. Well, as I say, I don't actually remember.

Q. But it's very likely that you --

A. It's likely, yeah.

Q. Paragraph 32, going back to your statement. At the bottom of page 10, you say:

"Flynn expected to have a proper commercial negotiation with the DH about pricing, but this never occurred because the DH simply did not engage. Flynn took this to mean that the DH considered that its pricing of Phenytoin was justifiable."

How on earth can you say that that was your impression given the meeting you had with the DH on 6th November 2012 where they told you "We don't accept you can benchmark the tablets", they told you "We are not happy with the price of your capsules", they told you "If you want us to be happy about the price of capsules, you must give us costs information, all your costs information", and you go back with no costs information. It's simply not credible to say that you came away from that series of events to say, "We thought the DH was happy that our price was justifiable", is it?

A. Well, I believe it is, actually, because the fact is that this isn't the first time that we've made an offer to start a negotiation. We offered in our first meeting with the DH to keep the product within PPRS in return for a price increase to make the product viable. That's clear.

In this instance, as I said, we were misled as to the reason that they were unhappy with using the tablet as a benchmark. So there was a lot of bluff going on. I mean, we actually, within a week, we knew that that was not the case because we checked it out. We actually checked it out had there been a negotiation.

Basically the fact that they didn't come back to us, and even worse than that, it turned out they'd already complained to the CMA. They'd handed it over to the CMA. I don't think they ever intended to have that negotiation.

THE CHAIRMAN: Mr Walters, I do understand that you want to get your story across, but it's probably going to help if you answer the questions that are asked you.

A. Okay, sorry, sir.

THE CHAIRMAN: If you can keep to the past. Thank you.

MR HOSKINS: Can we go to bundle J1, tab 3.

This is a note of a meeting between the OFT and Flynn on the 16th July 2013. Again, we see that you were present. You're listed under the attendees of Flynn. If we go to paragraph 35 of this note, let's begin at 34:

"On 6th November 2012, Flynn asked for a further meeting with the DH because Flynn wanted to know how it could be accused of abusing a monopoly. DW said that

during this meeting with the generics group at the DH [I won't say the names] on 6th November 2012, the DH used the word 'ridiculous' to describe the allegation of abusing the monopoly. DH noted that the DH was still very unhappy seeing this as an unacceptably large price increase in the absence of any additional value added to the product."

That is an accurate reflection of what you believe the DH's state of mind was following the meeting on 6th November 2012, isn't it?

A. That's correct. They were focused on the price increase.

Q. They were very unhappy?

A. With the increase, yeah.

Q. Can we go to your second witness statement at paragraph 10. Bundle B, tab 5. Heading "Flynn believed the DH could intervene in its prices". Then five lines down, sorry, do you have it, paragraph 10?

A. Yes, I do, yeah.

Q. Five lines down, there's a sentence begins:

"Flynn had benchmarked its price to Teva's Phenytoin tablets." Do you have that?

A. Yes, I do.

Q. "Flynn had benchmarked its price to Teva's Phenytoin tablets in the belief that the DH had the power to

control the price of category M products and in the knowledge that the Teva tablets were a category M product, and in particular following a dramatic reduction of the price of tablets between 2007 and 2008."

Then in paragraph 12 you see at the bottom:

"I can say that if the DH had invited Flynn to join scheme M, Flynn is very likely to have accepted."

Now, when the DH made it clear to you that it had serious concerns with the price of Phenytoin capsules, why didn't you suggest at that stage that you'd be willing to join scheme M?

A. At that stage, I mean, they didn't suggest it. We didn't suggest it.

Q. I mean, if you were scared --

A. -- (overspeaking) -- there's no reason for that.

Q. Sorry, you carry on?

A. No, it's just there's no reason for it. It was never discussed.

Q. When the CMA began its investigation into your pricing, why didn't you offer to join scheme M as a means of trying to resolve the issue?

A. Well, we tried to resolve the issue with the CMA at one point and we were told that they would only discuss any form of settlement if we accepted the guilt in the

matter.

Q. You didn't offer to join scheme M at any stage, did you?

A. No, we didn't. We didn't offer, no, and nor were we asked to.

Q. Membership of scheme M is voluntary, isn't it?

A. I believe so.

Q. The DH couldn't force you to join scheme M, could it?

A. They could have asked us.

Q. They couldn't force you to join scheme M, could they?

A. They couldn't force us to -- no, they couldn't force us to. But I'm not sure why they would think that we wouldn't do it.

Q. Back to your first witness statement, paragraph 36. First Walters paragraph 36:

"It is certainly fair to say that Flynn made it clear to the DH and the MHRA that unless a price rise was implemented, it was not commercially viable to supply the product."

Then paragraph 37:

"It is neither fair nor accurate for the MHRA and the DH, or indeed the CMA, to accuse Flynn of using discontinuance as a threat."

A. That is correct.

Q. So you told them that you might have to stop supplying the product if you couldn't get a price you were happy

with, but you didn't threaten them at any stage.

A. We did -- we didn't threaten them, we were basically outlining the facts. You know, we could not sell the product if we could not make a profit on it. That's fact. It's not a threat. A threat is where you say "unless you do this, we're going to do that." We didn't use it as a threat at all, and we never would do. Our intention throughout this entire process was to keep the product on the market.

Q. Can we go to G1, tab 59, it is a document we've already seen. I want to look at it in this context. I'm sorry, it's in the blue bundle, first tab. So we've seen this before and I'll not make the same mistake by mentioning the names this time.

An e-mail from someone at the MHRA to someone at the DOH. Tab 59, the bottom of the page. I'm sorry, tab 1 in yours, the bottom of the page.

So we've seen this before; do you remember?

A. Yes, I do, yeah.

Q. And the text "[R] and [I] had an interesting phone call with Flynn Pharma this afternoon. They are playing hardball on this one. And although the MHRA do not agree with the name change, Flynn effectively threatened to stop the product if they do not get the generic name approved."

A. Yeah.
Q. So you might not have thought it was a threat, but the chap at the MHRA certainly perceived it as a threat, didn't he?
A. If I could actually draw your attention to the e-mail from [✂] -- sorry, I must not mention the name. From Mr T, on this matter, which was in June as well, he also used the phrase that we effectively threatened to stop the product.
Q. Let's look at that. I was going to take you there. That's tab 61 in the main bundle, if you want to look at it. Sorry, tab 61. There's a number of e-mails, it is on page 2 at the bottom, from -- let's call him R. "Minutes of our telephone conference call"; is that the one you're referring to?
A. Yes, I believe, it is, yes.
Q. So R's take on the same exchange with you was:

"As brief summary, Flynn ... bought the MA for Epanutin Capsules from Pfizer. Pfizer agreed to ... manufacture. In a very difficult [telephone conversation] Flynn effectively said 'Allow us this name change or we'll cease to manufacture Epanutin'. It is a commercial decision - pricing versus for Epanutin versus generic is a nonsense - so Flynn see this name change as an angle to charge more. However, this name

change has been preceded with absolutely no communication strategy whatsoever."

So the people who were on the call with you both received themselves as receiving a threat from you.

A. It is actually an interpretation. Both of them used the phrase that we "effectively said." "Effectively said." In this particular e-mail, it also goes on, as you just read:

"However this name change has been preceded with absolutely no communication strategy whatsoever."

We also discussed that and he obviously wasn't listening very carefully when we discussed that either because of -- yes, we did have a communication strategy, and yes, we did tell them that.

Q. So those two individuals thought a threat had been issued. Let's look at a further document --

A. They were in same meeting.

Q. We're going to look at another incident now, J2, tab 64. Your tab 2 in the little blue file. This is a note of a meeting between the CMA and the DH.

Sir, I am not sure if you will have seen this before, but let's just see how other people perceived Flynn. Paragraph 25.

"Flynn told the DH that it would not be changing how it was pricing its Phenytoin product, and if it could

not price at the level it wished, it would consider discontinuing the product. The DH said it took this threat very seriously. The DH had seen products discontinued where a company no longer believed that it was economically viable to continue to supply it."

Then paragraphs 36 to 37:

"DH explained that Teva, including its senior managers, personally had received a lot of criticism about the price of its tablet product at the time. DH said that it had attempted to have similar discussions with Flynn regarding the price of Flynn's Phenytoin sodium capsules, but as described above, Flynn had refused to reduce its prices and had said that it would consider discontinuing the product if it could not maintain its prices."

A. This is not actually a contemporaneous document.

Q. It's not, no.

A. This is, you know, February 2016. This is someone looking back, and effectively putting their own spin on things several years later.

Q. You say spin, Mr Walters, but let's be honest, there's no smoke without fire --

A. No, no, no, no --

Q. Let me finish the question, please.

A. Yes, by all means.

Q. On a number of occasions, people you have been discussing with have formed a very clear view that you were issuing a threat that unless you were able to price at the levels you had chosen, you would discontinue the product. That's the clear impression that was formed of you, wasn't it?

A. If we gave that impression, then I do apologise, but actually, I don't think it's the impression that they should have taken from it, because, as I've said in the witness statement, it's certainly fair to say that we made it clear to the DH and the MHRA that unless we could implement a pricing increase, it was not commercially viable to supply the product. We've also indicated through these statements that we were open to negotiation. We'd already offered to keep it in PPRS. Already offered.

Q. Can we go to your first witness statement again, please. Bundle B, tab 4, paragraphs 10-19. You deal with the possibility that Pfizer might have discontinued the production of Epanutin entirely if it had been unable to enter into an agreement with a company such as Flynn. You remember that, don't you?

A. Sorry, entirely --

Q. That's what you say in your statement, yes?

A. Right.

Q. Do you agree?
A. That they would have had to have discontinued it --
Q. Entirely --
A. Entirely.
Q. -- if it hadn't been for Flynn doing the deal -- Flynn or someone else doing this sort of deal with them?
A. That's basically, yes, that's correct.
Q. Then paragraph 14 you say:

"I was aware at the time of the negotiations that Pfizer had previously discontinued another anti-epileptic drug, Zarontin, in similar circumstances in 2005. Like Phenytoin sodium, Zarontin was a mature product experiencing declining sales volumes. In fact, Flynn had approached Pfizer around this time to discuss entering into a commercial arrangement to rescue Zarontin. In that case, Pfizer decided not to pursue a collaboration with Flynn and instead stopped producing the product altogether and discontinued it."

Were you involved in the approach to Pfizer about Zarontin?

A. Yes, I was, yes.
Q. So you will be aware that Zarontin is a category three AED without any continuity of supply issues?
A. It is now, it wasn't then. There was no categorisation in those days.

Q. But you're aware that any continuity of supply issues in relation to Zarontin are less serious than they are in relation to Phenytoin sodium.
A. Under the current guidance, yes, under the guidance that existed at that time, that's not necessarily the case, no.
Q. Do you accept that the continuity of supply principle was less important for Zarontin than it was for Phenytoin sodium capsules --
A. I accept that that is what the current MHRA guidance says.
Q. -- I didn't finish the question. At the time that the approach was made to Pfizer in around 2005?
A. Do I accept that it was less important?
Q. Yes.
A. At the time? No, I don't, no.
Q. Because?
A. Because, as I just said, the categorisation didn't come until the MHRA guidance in 2013.
Q. In 2005, continuity of supply was of great importance for all AEDs?
A. Well, according to the NICE guidance, yes.
Q. Fairly, at paragraph 19 of your statement, you say in the middle of that paragraph:
"I obviously cannot speak for Pfizer" and that's

obviously right, isn't it, the decision whether or not to continue producing Epanutin was Pfizer and Pfizer's alone?

A. Yes. But we've heard obviously from Mr Poulton today that it was a very real possibility --

Q. Well we've heard his evidence, we don't need you to summarise it for us.

THE CHAIRMAN: How are you doing for time, Mr Hoskins?

MR HOSKINS: I will finish within 30 minutes.

THE CHAIRMAN: I don't see how we're going to do Mr Beighton, if you are finishing in 30 minutes. I thought that was the understanding.

MR HOSKINS: I can't cut the questions, sir. If I don't put these points, I'll be told I haven't put the points.

THE CHAIRMAN: How are the transcribers doing?

MR HOSKINS: I apologise, it's --

THE CHAIRMAN: I mean, my view is that you had the management of this day and it's taken longer than you --

MR HOSKINS: It has taken longer than anticipated, yes, and I apologise.

THE CHAIRMAN: Not entirely due to the witnesses, either.

MR HOSKINS: I'm sorry.

THE CHAIRMAN: Does anybody else have any suggestions as to resolving this?

MR BREALEY: That's going to take us to five. I mean, I do

need to ask Mr Beighton some questions, and I think that will be 20 minutes.

THE CHAIRMAN: How long do you anticipate with Mr Beighton?

MR HOSKINS: About a similar amount of time.

THE CHAIRMAN: How long have you got now?

MR HOSKINS: I think this will be another 30 minutes.

MR BREALEY: As I understand it, Mr Beighton can be available on Tuesday.

THE CHAIRMAN: Well, you were going to consult when we were out of the room; have you done so?

MR BREALEY: He can be available on Tuesday morning.

THE CHAIRMAN: Right.

MR BREALEY: That would mean then that Mr Hoskins can finish at five, and there can be re-examination, if necessary. I appreciate it is unfortunate, but, if we have an hour on Tuesday morning, I'm sure we'll catch up.

THE CHAIRMAN: Yes. Right. We were going to discuss when we started on Tuesday morning. It sounds like we're going to start at ten o'clock.

MR BREALEY: I think Ms Bacon would like us to. The answer is yes, if it's possible, I think we should start at ten.

THE CHAIRMAN: How is the transcript writer? We'd all rather carry on, then.

MR HOSKINS: I apologise, I'll try my best. I have

tried to speed up, and I'll carry on doing my best.

Q. You need to go now into the blue bundle at tab 3. For everyone else it is the decision, paragraph 3.66. Let me just check the confidentiality on this. Nothing in here.

Can I ask you to read paragraph 3.65 to yourself, then 3.66, and then to have a look at the table, please.

We're not allowed to say out loud any of the names in 3.65, we're not allowed to say out loud the last sentence of 3.65. Can you tell me whether you agree that 3.65, 3.66 and the table are accurate? Are there any errors there that you can see?

A. Well -- sorry, three-point -- the table actually defines the activities, it obviously doesn't reflect the responsibilities.

Q. No, but are there any crosses which are in the wrong columns?

A. No, I'm reasonably happy with that one, yeah.

Q. Can we go to paragraph 40 of your first statement. There's some confidentiality here in the figures:

"As regards the buffer stock, in September 2012 Flynn set out to develop a safety stockholding policy to provide a buffer against supply interruptions. To this end it built up stocks equivalent to [X] market requirements with the consequential carrying cost to

Flynn of approximately [Y]."

Now, if needs be, you could and did sell that reserve stock, didn't you? It's not a sunk cost, it's not money that's wasted.

A. No, no, it's a cash flow issue. There is obviously a risk in holding stock.

Q. Can we go now to paragraph 41 of the statement.

"As a further dimension to its supply chain strategy, Flynn took preliminary steps to identify a second API supplier as early as October 2012."

A. Yes.

Q. Then 49(a):

"Contrary to the CMA's suggestion, it was not necessary for Flynn to obtain Pfizer's approval in order to appoint a new API supplier. Although Pfizer's cooperation would have been required if a new supplier had been appointed as an alternative source of API, rather than a full replacement."

First of all, why would Pfizer's cooperation have been required if a new supplier had been appointed as an alternative source of API rather than a full replacement?

A. Well, our agreement for supply with Pfizer was time limited. If we wanted them to continue with the secondary manufacture but not the API supply, then we

would have had to -- it would have been better with Pfizer's cooperation.

Q. Better why?

A. Well, basically because they handled the product, they -- it would obviously mean that if it was a second source of API, that the quantities of API that they themselves were producing would be lessened. Because you can't just sign someone up as an API supplier without giving them some business.

Q. Can we go to G1, tab 53. We've seen this before. It is the exclusive supply agreement between Pfizer and Flynn. Can you look at clause 2.2.

"Purchaser agrees not to purchase the product or any products substantially similar to the product from any other source."

Now I know you're not a lawyer, but do you agree that Flynn would have been in breach of contract if it had set up a second API source without Pfizer's permission?

A. During the term of the agreement, yes.

Q. Yes. Flynn actually did try and obtain Pfizer's agreement for a second API source, didn't it?

A. Yes, we did, yes.

Q. Pfizer didn't agree, did they?

A. I'm not sure that that's the case at all, actually.

Q. Did they give their approval?
A. No, they didn't give their approval nor did they deny that it would be necessarily a good thing. They were very receptive to the idea, because they themselves had had a major batch failure shortly after we launched the Flynn product which related to API, that's why we identified that as an area of risk.
Q. Let's see what Pfizer did say. G2, tab 138. I'm afraid we're going to have to count through the pages again. It's tab 138. If you flick through the pages you'll come to a handwritten document, it is dated 13th January 2014. You see this is a meeting note that you attended. You see your name, Flynn, David Walters, at the top left of the page.
A. Yes.
Q. And --
A. I'm not sure I've ever seen this document before, actually. Sorry, I have seen it before today, but not until this disclosure was made.
Q. Fine. The second bullet point says:
"Flynn wants second source of API and packaging."
Then miss a sentence, next sentence.
"P [which is Pfizer] can investigate the feasibility of second source, but don't normally do this, so very unlikely."

A. Mm-hm.
Q. Pfizer's position was that this was very unlikely that they would ever agree to it; correct?
A. Well, that's what this says, but we were not told that. We were actually told the opposite: that they thought this could be a good idea.
Q. So you're saying this was a meeting note that was never provided to you, this was just an internal Pfizer note of the meeting --
A. This is --
Q. -- and they didn't tell you in the meeting that it was very unlikely?
A. No. Quite the opposite, I went, as the records show, I went to Freiburg myself actually to discuss it with the manufacturing unit, and they thought that that could be a good idea. We just had this bad experience with the Kalamazoo product. They also said that they themselves had previously worked with Rekordati and also in that meeting they said that it's quite possible that we're still even using Rekordati product for other markets in the world. That's what they said at that meeting. So there was clearly no resistance to the concept of getting in a second supplier of API.
Q. Well, no resistance that they told you, but we see from the meeting note that in fact, internally, it was very

unlikely?

A. Yeah, I can see that in these particular individuals, it did actually record that, yes.

Q. If you would turn over the page, there is another note of the same meeting. Item 2, "Second source API packaging and safety stock:

"Pfizer do not normally provide second sources because the network is so large. If second sources were added, the capacity would be greater than we could manage. We have confidence in our supply and safety margins. Additional third-party arrangements are not catered for."

So the truth is, whatever the impression you were given, this was never going to happen, was it?

A. From this, it would suggest that it probably wouldn't have done. I mean it didn't actually happen, but there were other factors involved in that, I'm sure, because we had other meetings relating -- we had other comment from Ms T -- from Pfizer -- that again told us that if we were going to progress second source of manufacture, that could actually be very useful to them in the future.

PROFESSOR WATERSON: I'm confused. Whose note is this? Do we know?

MR HOSKINS: I don't think we know specifically. I think

these --

A. It's Pfizer, it's --

MR HOSKINS: They're called Pfizer notes, but we don't know the individual.

MR LOMAS: Can I clarify one very basic question. If you'd found an alternative source of API, does that chemical, do the molecules flow into Pfizer, who then make the capsules and then sell it on, or do you buy capsules in a finished form from another supplier?

A. No, no, you can do either.

MR LOMAS: Or either?

A. Yeah, you can actually have a new source of API, but you can also have a new source of finished products.

MR LOMAS: Right, so the exclusivity clause in 2.22, "The purchaser agrees not to purchase the product or any products substantially similar to the product from another source", only applies to the second version of that, in other words where you get the finished product from someone else, not where the API goes into Pfizer?

A. Yeah, I mean, as I say, the duration of the agreement was very limited anyway, and so this would not happen quickly, under any circumstances. You know, you've basically got to go through all the work that's required to show that this -- you'd end up with a product that is essentially similar.

MR LOMAS: Okay.

A. You know, you'd add a second source to the licence, but of course, as long as we wanted Pfizer to maintain production, then of course it made absolute sense to discuss it with them openly, and given the major problem that we'd both experienced in October 2012, less than a month after we launched, you know, we both at that time could see the sense in it. I mean, it's --

MR LOMAS: I don't want to take up time.

A. I'm sorry. Sorry.

MR HOSKINS: If we go back to your first witness statement, paragraph 48, you say:

"Ultimately Flynn has not yet been able to implement its plan to identify a second API source."

You attribute that to the uncertainty created by the CMA's investigation. Then you go on to say:

"The cost of taking this step was estimated by Flynn to be approximately [X]."

But the truth is that money has never been spent, has it, for the reasons we've seen; you just haven't taken that forward?

A. No, we haven't. No, we haven't. And as we said, it's because the uncertainty created by this case. Who's going to invest that amount of money not knowing what your final price is going to be? It's logical, isn't

it?

MR HOSKINS: Sir, I'm now very close to the end. I need to go in camera now, because there's some confidential material that I can't refer to.

Questions from the PANEL

THE CHAIRMAN: Any other questions you want to ask?

PROFESSOR WATERSON: Yes, one I think you can help me with. Typically, there are wholesalers who sell on to pharmacies?

A. Yes.

PROFESSOR WATERSON: And a typical pharmacy, will they deal with just one wholesaler, or several?

A. No, a typical pharmacy will have several wholesalers and they get deliveries usually at least twice a day.

PROFESSOR WATERSON: Right.

A. So, you know, it's unlikely that they're going to keep a lot of stock.

PROFESSOR WATERSON: Yes. So they could deal with one wholesaler for NRIM product and another wholesaler for your product?

A. Oh absolutely, yes.

PROFESSOR WATERSON: Thank you.

THE CHAIRMAN: I have one question. We were talking earlier about parallel imports, and I didn't raise it then because I wasn't sure where it was going. Has Flynn

taken any action to prevent parallel imports itself, other than relying on --

A. No, sir.

THE CHAIRMAN: None?

A. None.

THE CHAIRMAN: Thank you.

MR HOSKINS: In terms of going into camera, this is obviously Flynn confidential information, so Flynn people can stay in, but everyone else outside the confidentiality ring has to leave.

THE CHAIRMAN: Right. Don't go too far, because you may have to come back.

[REDACTED IN CAMERA SESSION]

Re-examination by MS KREISBERGER

MS KREISBERGER: Just one question. Or at least a question on one point. Very brief, you'll be pleased to hear.

Mr Walters, the chairman asked you a question about parallel imports, whether you'd taken any action to impede parallel imports. And you may well have had commercial conduct, conduct in the market in mind. I just wanted to ask you whether you're aware of any legal action that Flynn has taken in --

A. Oh yes. Yes we have. That wasn't to impede parallel imports; that was to impede the use of our trademark. It was a simple trademark case which was judged in our

favour.

Q. And the distinction --

THE CHAIRMAN: I'm not sure I quite grasp the distinction.

A. Well, basically --

THE CHAIRMAN: -- between a simple trademark case and a case that has -- (overspeaking) --

A. Basically one of the importers was using our name, Flynn, bringing in Epanutin, which is not our product, and we have no control over the manufacture of Epanutin as we do with the Flynn product, and they wanted to put our name on it, so they were using, or proposing to use, our trademark. And so we took them to court and we won the case. They appealed, and we won the case.

THE CHAIRMAN: So the --

A. But it didn't --

THE CHAIRMAN: The misuse of the trademark, as you put it, was in relation to parallel imports?

A. Sorry, it was in relation to, but it didn't actually restrict parallel imports. And the products that were brought in could still be sold. They could be sold as, you know, Phenytoin sodium capsules with their name on. They could be sold as Epanutin, over-labelled, as they do. What they couldn't do was actually use our trademark, because our rights had not been exhausted. And basically, if there'd been any quality problems with

the Epanutin that was being brought in and sold under Flynn, that was not considered to be fair or right.

THE CHAIRMAN: Okay, I think that's a helpful clarification. Thank you.

MS KREISBERGER: That's all from us. No further questions.

THE CHAIRMAN: Right. Any questions from us? In that case I think you may stand down, Mr Walters.

(The witness withdrew)

HOUSEKEEPING

THE CHAIRMAN: I think that concludes the proceedings for today, so we shall therefore start on Tuesday at ten o'clock, and you will be calling Mr Beighton.

Just one moment. You were going to give us a couple of documents. Well, no, you were going to give us some regression lines, and you were going to give us some pointers to some paragraphs. Any chance of those?

MR HOSKINS: Absolutely. You'll understand we've been occupied. We'll work on it tomorrow and aim to get it to you by the close of play tomorrow.

THE CHAIRMAN: It will be helpful to have them by the weekend, please.

MR HOSKINS: We'll get them to you tomorrow.

THE CHAIRMAN: Anything else?

MS BACON: Yes, I can confirm we're speaking to our economists about the regression line, we had an initial

discussion with them yesterday. Obviously we've been otherwise engaged in the court today but likewise we'll progress that tomorrow.

THE CHAIRMAN: Okay. Right, okay. Thank you very much everybody.

(5.07 pm)

(The hearing adjourned until 10.00 am on Tuesday, 7th November 2017)

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