Thursday, 23 September 2021

(10.00 am)

Presentation by Counsel to the Inquiry on the Pharmaceutical Companies

SIR BRIAN LANGSTAFF: Yes, Mr Hill.

MR HILL: Today, sir, we move on to the presentations from counsel to the Inquiry on the pharmaceutical companies. That will be the pattern of work for the next couple of weeks. Before turning to the individual companies, we thought it would be helpful to present an overview of the licensing regime as it stood in the 1970s and the 1980s in particular. This is an attempt to assist everybody in understanding what is coming next. It is not a comprehensive discussion of all aspects of licensing. That would take many days and perhaps wouldn't be of such great assistance. Instead, this is intended just to give a neutral overview to assist in understanding the presentations and the evidence that is going to follow in the next couple of days and weeks.

Further evidence about the licensing regime is going to be heard by you later in this Inquiry and this presentation is not intended in any way to pre-empt that evidence. It may be that things that you hear subsequently change your view of what we are

saying today.

A helpful overview of the regime was provided in the evidence of Lord Fowler and in his witness statement. Lord Fowler said in his statement that he was drawing on the findings of the BSE Inquiry, and particularly volume 7, chapter 2. That described the position in 1988 to 1989. Lord Fowler's understanding was that, in broad terms, that was an accurate summation of the situation before that as well, and that is also our understanding.

So as to avoid reinventing the wheel, I'm going to read from that statement to provide the initial overview, then we'll go through in a little bit more detail some of the points.

So, Soumik, could we have on the screen, please, WITN0771001, page 35.

So this is the evidence of Lord Fowler in his written statement. What he says about the regime is this:

"(1) The licensing regime was established by the Medicines Act 1968.

"(2) In essence, a medicinal product could not be sold unless it had been granted a 'product licence' by the Licensing Authority. The Licensing Authority was in principle the relevant Minister, although in

practice his or her functions were delegated to officials in the Medicines Division of [the Department of Health] (medicines for human use). They received advice from a number of committees of experts set up under Section 4 of the Medicines Act, known as the 'Section 4 committees'.

"(3) Responsibility for the granting, renewal, variation, suspension and revocation of licences was given by the Medicines Act to the 'Licensing Authority'. Under the Act 'the Health Ministers' and 'the Agriculture Ministers', ie the Secretary of State for Health, the Minister of Agriculture, Fisheries and Food and the corresponding Ministers in Northern Ireland, Scotland and Wales, comprised the Licensing Authority, although any one of them acting alone was permitted to perform its functions. In practice, the functions of the Licensing Authority in relation to medicines for human use in the UK were, throughout the period of 1985-96, performed by the Secretary of State for Health."

I will come back to that date. I think that is just an artefact of a report, and is something which also applied up to the earlier period as well.

"(4) Although formally the Secretary of State for Health acted as the Licensing Authority for human

medicines, in practice his or her functions were delegated to officials working in the Medicines Division of [the Department of Health] (and, after April 1989, officials working for the Medicines Control Agency (MCA)), subject to the normal legal principles relating to the extent to which ministerial functions may be delegated.

"(5) The arrangements meant that product licences were physically granted by officials, not by the Minister, although I remained accountable for them.

"The Medicines Act 1968 required that Ministers establish a Medicines Commission, made up of professionals with 'wide and recent experience' in the practice of medicine and pharmacy. The Commission was required to advise the Ministers making up the Licensing Authority on matters relating to the execution of the Act and on medicines generally where the Commission considered it expedient or when requested by Ministers. It also acted as an appeal body in respect of advice given to the Licensing Authority by the Section 4 committees.

"(7) The Committee on the Review of Medicines (CRM) was established to review the safety, quality and efficacy of medicines that had been on the market

before the Medicines Act introduced licensing requirements. At that time these products were granted licences of right.

"(8) The Committee on Dental and Surgical Materials (CDSM) advised on questions of the safety, quality and efficacy of dental and surgical materials.

"(9) The Committee on the Safety of Medicines (CSM) advised on questions of the safety, quality and efficacy of human medicines that fell outside the remit of the CDSM and the CRM. The Biologicals Sub-Committee was one of the Sub-Committees reporting to the CSM.

"(10) The Licensing Authority was required to consult the relevant section committee (or if there was none, the Medicines Commission) in certain circumstances, for example, when it was minded to refuse an application for a product licence or suspend, vary or revoke a licence. Otherwise, officials had a discretion whether to seek advice from the Section 4 committees in relation to any particular product.

"(11) The licensing regime for human and medicinal products was operated by officials in the Medicines Division in [the Department of Health and Social Security]. This Division was organised in

three parallel structures: medical staff, pharmaceutical staff and administrative staff. Responsibility for staff and these structures was essentially divided along professional/administrative lines. The professional staff reported to the Senior Principal Medical Officer (SPMO) or the Chief Pharmaceutical Officer and the administrative staff reported to the Under Secretary.

"(12) The National Institute for Biological Standards and Control (NIBSC) was established under the Biological Standards Act 1975 in order to secure high standards of quality, safety and efficacy and consistency of biological substances used in medicines. In fulfilling this role it devised standards for the quality, purity and potency of biological substances, tested batches of biological products on behalf of DHSS, carried out research and advised a number of bodies, including Medicines Division of DHSS and its Section 4 committees. NIBSC staff were members of the BSC [and the] CSM.

"(13) EC regulation of human medicinal products was introduced with the adoption of Council Directive 65/65/EEC."

That was introduced on 26 January 1965, so before the United Kingdom entered what was then the

European Economic Community.

"Its framework was similar to that of the Medicines Act: it was based on the grant of a 'marketing authorisation' by the competent authority of the Member State in question (ie a decentralised system). No product within the scope of the Directive can be placed on the market in a Member State unless an authorisation had been issued by the competent authority of that Member State. No new legislation was introduced to implement Directive 65/65/EEC."

I take that to mean no new legislation within the United Kingdom.

"The competent authority of the [United Kingdom] for the purposes of the Directive was the Licensing Authority. Additional measures were introduced in 1975, including mechanisms for the recognition by all member states of product licences granted by an individual state. The Committee for Proprietary Medicinal Products (CPMP), a scientific committee, was also established; this advised the Commission ..."

Pause there to note that that's the European Commission:

"... on issues of safety, quality and efficacy in much the same way as the CSM advised the Licensing Authority in the UK.

"(14) This Chapter of the BSE report goes on to refer to the Evans-Cunliffe report commissioned in 1987 ..."

That is something, sir, that we will come back to shortly.

That, sir, is where I leave Lord Fowler's evidence. The key points that we take from that evidence on the structures are these: first, products were licensed by the Licensing Authority, in particular that was a reference to the Secretary of State for Health, but also other Ministers. In practice, the function was delegated to officials working within the Medicines Division of the DHSS. From 1989, the functions were undertaken by the Medicines Control Agency, following a reform of the Medicines Division. The Medicines Control Agency was a self-financing agency within the Department of Health.

Those officials to whom that function was delegated could take advice from what we'll refer to as the Section 4 committees, they were listed in Lord Fowler's evidence but, for our purposes, the key ones are the Committee on the Safety of Medicines and the subcommittee, which is the Biologicals Subcommittee of the Committee on the Safety of

Medicines.
SIR BRIAN LANGSTAFF: The Biologicals Subcommittee was a subcommittee of the CSM?
MR HILL: That's right.
SIR BRIAN LANGSTAFF: So it would give its advice or recommendation to the CSM and the CSM would, as a Section 4 committee, give its advice to the Licensing Authority; is that correct?
MR HILL: That is correct, sir. We will come on to a little bit of evidence from Sir Joseph Smith shortly that describes that in practice.

There was also a body called the Medicines Commission. This also provided advice, including on how to set up the Section 4 committees and what they should be doing and how they should be constituted. It also acted as a de facto appeals body: if the CSM or the CSM(B) advice was to reject an application the company could then appeal to the Medicines Commission.

In addition to those bodies --
SIR BRIAN LANGSTAFF: What was the effect if it allowed an appeal?
MR HILL: The effect would be that its advice to the minister would be that, for example, a product licence should be granted, but ultimately the Licensing

Authority would be the one that was taking --
SIR BRIAN LANGSTAFF: So ultimately the minister -- or the Licensing Authority, all the ministers who composed that authority, would have to make a decision?
MR HILL: That's right, sir.
SIR BRIAN LANGSTAFF: Did it ever happen?
MR HILL: There were certainly appeals to the Medicines Commission. I don't -- I can't say off the top of my head how many of those were successful or what the outcome of those was. As it was advisory, it would not necessarily be a firm appeal allowed or appeal dismissed; it may be our advice is that further information needs to be gained on this particular topic. But if that information is gained then we would recommend that a licence be given. So it's not a judicial body, as it were, saying yes or no, instead it's got a wider remit.

In addition to those bodies there is the National Institute for Biological Standards and Control. This was established under a separate Act but it carried out certain functions which are relevant to licensing. It provided advice to the CSM and the CSM(B). The staff from the NIBSC might sit on some of the Section 4 committees, and it would also carry out testing, for example, as part of the

licensing process.

That, sir, is the outline. I would like now to just go into a little bit more detail about some of the provisions of the Medicines Act 1968, and you'll be pleased to hear, and I'm sure everybody will be pleased to hear, that I don't intend to go through every one of the 300 pages of it, but we will just pick up a few of the points from it.

First, the question of what factors were relevant to determining the application for a licence. Second 19 of the Act provides a non-exhaustive list, and the three key themes are safety, efficacy and quality, and you will have heard those mentioned in Lord Fowler's evidence.

That's found in Section 19(1). Those are also the three areas on which the Section 4 committees were permitted to advise. That is, Section 4(3)(a).

For imported products, the Licensing Authority would also consider, and I quote:

"... the methods, standards and conditions of manufacture of those products ..."

That's Section 19(3).

The manufacturer's operation, premises, equipment and the qualification of its staff and of its recordkeeping were also to be considered.

That's Section 19 (5). That is, as I say, a non-exhaustive list. There isn't a single checklist which the Licensing Authority had to go through, but those are matters that the legislation said that it should consider when fulfilling its functions.

The Act also specified certain factors that the Licensing Authority should not take into account. Section 22, that's 20(2), provided that the Licensing Authority could not refuse a licence on the grounds of price, and cannot make a licence provisional on the product being sold at a particular price.

So it is not the function of the Licensing Authority to try to regulate the price of the medicines.

Section 19(2) provided that when assessing how efficacious a product is -- "efficacious" is the word used in the Act; I take it to mean how effective the product was at doing what the product should be doing, so how effective the indigestion pill is at getting rid of indigestion.

When assessing how efficacious the product is, the Licensing Authority should not take into account whether or not another product is equally or more efficacious, although when it's discussing or considering the safety of a product, it could take

into account the fact that a safer product was just as effective or was more effective.

So the Licensing Authority is not there to say: we're not going to licence this product because there is another one that does the same thing just as well. But if there is a safety concern, that is a matter that it can take into account.

The next point that I would turn to is something that was mentioned by Lord Fowler, that the Licensing Authority shall not refuse a licence on grounds of safety, quality and efficacy, without consulting the relevant Section 4 committee, or if there wasn't time, the Medicines Commission.

Now, that's in Section 20(3). That meant that the Medicines Division could grant a licence without consulting the Section 4 committees, but it couldn't refuse one. That may be of some relevance to something that comes up later in the presentations.

The Licensing Authority can make a licence provisional on undertakings from a manufacturer of an imported product, and some of the types of undertaking that could be sought were given in Section 19(3) of the Act. They are things like the licence won't be granted unless the manufacturer of the product gives an undertaking to permit inspection of the

manufacturer's premises by or on behalf of the Licensing Authority. The undertaking could be to comply with certain prescribed conditions that are part of the licence, but, as we've seen, you can't use that to get around the prohibition on setting the price of the product.

The undertaking might be to give a declaration that the product complies with the laws of the country in which it is manufactured.

The length of time that the licence lasts was set by Section 24 of the Act. The rule was that a licence granted under the Act would last for five years. The licence holder could apply for it to be renewed. Where an application under the Act for renewal had been made, then the licence, and I quote:

"... shall not cease to be in force ... before the licensing authority have determined the application."

That's section 24(6).

The Inquiry's understanding of these provisions is that if a product was granted a licence in, say, 1975, that licence would run until 1980. If, before 1980, the licence holder applied for a renewal, then the product would continue to be licensed until that application was considered and decided, even if that

ran past 1980.

In such circumstances -- and we will see this in some of the papers that we look at shortly -- the renewed licence would run from the time of the expiry of the old licence, rather than the time that the decision was made.

As I say, sir, that is our understanding. There may be further evidence that you hear on this which changes that understanding. At present, that is how we understand the process to have worked.

There was a power to suspend, vary or revoke a licence subject to the procedures set out in the Act, and that power and those procedures are found at Sections 28 to 30.

A licence could be suspended, varied or revoked on a number of grounds, including that the application for the licence was false or incomplete, Section 28(3)(a); that there had been a material breach of a provision of the licence, section 28(3)(b); and, and I quote here:

"... that medicinal products of any description to which the licence relates can no longer be regarded as products which can safely be administered for the purposes indicated in the licence, or can no longer be regarded as efficacious for those purposes."

That's section 28(3)(g).

I also note, sir, that appropriate ministers were given powers to make regulations governing product labelling and packaging, and those powers were backed by a criminal sanction for some breaches. That's at sections 85 to 91.

That is the overview of how products would be licensed under the Act, but it's important to note that there are exemptions which are contained in the Medicines Act 1968 as well.

The position was that, without a licence, a company was, in effect, prohibited from selling, supplying, exporting or importing a product, unless one of these exemptions applied, and prohibition is found in Section 7. For the Inquiry's purposes, two exemptions are of particular relevance. The first is the named patient basis, and the second is for clinical trials exemption. We turn first to the named patient basis.

The Act allowed doctors and dentists -- there is also some provisions for pharmacists as well, but for the purposes of simplicity, sir, I'm just going to refer to doctors during this presentation.

Sir, the Act allows doctors to import a medicinal product to his order, and I quote "for

administration to a particular patient of his".

That's at Section 9(1) and a similar provision is at section 13(1).

So the doctor can import a product without a licence if it's to be administered to one of his patients -- the gender is expressed in the Act.

So that was the basic position as set out in the 1968 Act.

In November 1978, certain restrictions were introduced on products imported under a named patient basis by the Medicines (Exemption from Licences) (Importation) Order 1978. That is SI 1978-1461.

In brief, those restrictions were: the importer of the product had to inform the Licensing Authority within 21 days of the first receipt of a product.

That's Article 3(a).

The second restriction was that no advertising or representation was allowed for such products. They could only be provided, and I quote the statutory instruments:

"... in response to a bona fide unsolicited [offer]."

The third restriction is that written records should be kept and maintained, and would be made available to the Licensing Authority on request.

So that is, 1978, 10 years after the initial Act. You see the introduction of this order to put in place those provisions.

From June 1984, further restrictions were introduced in the form of The Medicines (Exemption from Licences) (Importation) Order 1984.

It might be helpful to have this onscreen, please, Soumik. It's PRSE0000177.

If we look, sir, first at the top of the statutory instrument, you can see its title. You can see that it was made on 14 May 1984, it was laid before Parliament on 16 May 1984, and it came into operation on 6 June 1984.

Then you can see underneath the various ministers who have been involved in the implementation of this legislation and, as per Lord Fowler's statement, the first reference is:

"The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by ... the

Medicines Act ..."

Have made the order that follows.

Further work, sir, will be undertaken on trying to understand how the Act operated in practice across the four countries of the United Kingdom, but it can be seen here that there is a joint and a central approach to this piece of legislation, and it is our understanding that most licensing decisions were taken centrally, most were taken within the Department of Health, and we will look to see whether or not there was any variation over the course of the evidence that we hear.

If we turn, please, Soumik, to the second page. We can see that this is referring back to -- it is a statutory language and it refers back to the previous articles within this order, and indeed to the Act, and it's talking about the exemption on the named patient basis.

The first point that I would draw out is that you can see in 4(1)(a) that there is now a requirement that in order to make use of the named person exemption:

"... the person importing a medicinal product which is the subject of that exemption has given or sent to the licensing authority, prior to each such

importation, a notice in writing which states his intention to import that medicinal product for sale or supply in the circumstances specified ..."

So whereas previously the requirement was to let the Licensing Authority know once you have received the product, now you have to give prior notice.

We can see, in 4(1)(a)(i), (ii), (iii) and (iv), some of the information that you needed to provide when giving that prior notice: the name of a product, each active constituent -- then at point (iii), this is important because it's introduced by this Act for the first time, the quantity of that medicinal product which is to be imported. Then the name and the address of the manufacturer.

Then on to (4)(b):

"the person importing a medicinal product which is the subject of that exemption has given or sent to the licensing authority, together with the notice referred to in paragraph 1(a) an undertaking in writing

"(i) [that the] quantity of that medicinal product which is imported in accordance with the notice referred to in paragraph 1(a), does not exceed such quantity as will be sufficient for 25 single administrations or for 25 courses of treatment not

exceeding 3 months."

Again, sir, this is a new provision which is introduced in the Act, and you can see that the effect is to limit the amount of product that can be imported on a named-patient basis. Our understanding --

SIR BRIAN LANGSTAFF: On one occasion?

MR HILL: Precisely, sir. Our understanding of that is that it is 25 courses of treatment for that named patient, so if you have two named patients, then you can have another 25.

SIR BRIAN LANGSTAFF: But is there anything to stop the clinician concerned, as he gets towards the end of the three months, saying, "I'm going to do this for another three months"?

MR HILL: No, but I would require --

SIR BRIAN LANGSTAFF: Further communication?

MR HILL: Yes, yes.

SIR BRIAN LANGSTAFF: So it requires further writing of letters?

MR HILL: Yes, but what it does allow, for the first time, is for the Department to be aware, if it is able to trace through those letters, of the quantity of material that is being imported on the named patient basis. So far as I'm aware, the previous legislation, primary and secondary, didn't allow for that.

The next provision is that the person seeking the exemption:

"... will inform the Licensing Authority forthwith of any matter coming to his attention which might reasonably cause the licensing authority to believe that the medicinal product can no longer be regarded either as a product which can be safely administered to human beings or as a product which is of satisfactory quality for such administration ..."

Again, sir, that is a new provision, and you will see that it echos, not precisely, but it echos the wording of the 1968 Act about when you can revoke or vary or suspend a licence.

The next provision, and this is an updating of the provision that was in the 1978 order, and I quote:

"he will not at any time issue or cause another person to issue any advertisements or make any representation in respect of that medicinal product and that he will sell or supply that medicinal product only in response to a bona fide unsolicited [offer] ..."

Then the next provision is about written records and you can see it goes into more detail than the 1978 Act does about what those records should contain and includes the name and quantity of a medicinal product,

the name and address of the manufacturer, and if different the supplier, assembler:

"in respect of [a supply or sale] of that medicinal product, specifying the name and address of the person to whom that medicinal product is sold or supplied, the quantity and the date of such sale or supply ..."

There is also a provision that follows that those records should be kept for five years.

The next Article to which I will draw your attention, sir, is 4(c). Then is again a requirement in order to get the exemption, and for the exemption to hold, and I quote:

"the licensing authority have not, before the end of the specified period, given or sent to the person proposing to import that medicinal product a notice in writing stating that the provisions of this Order shall not apply to anything which the said person proposes to do which consists of importing or selling or supplying that medicinal product because --

"(i) any conditions specified in the preceding sub-paragraphs of this paragraph is not satisfied, or

"(ii) the licensing authority have reasonable cause to believe that that medicinal product cannot be regarded as a product which can safely be administered

to human beings or is not a product which is of satisfactory quality for such administration."

SIR BRIAN LANGSTAFF: So this is the teeth which the Authority has in respect of prior notice? So instead of telling the authority you've brought the product in and may well have used it, you now have to say, "I'm going to do it", and the authority can say, "Well, sorry, this order doesn't apply". If the order doesn't apply, you don't have exemption; you don't have exemption, you can't do it.

MR HILL: That's correct, sir.

SIR BRIAN LANGSTAFF: Right.

MR HILL: Though the following provision is that the specified period means 28 days. So the person seeking the exemption provides the notice, if within that 28 days the Licensing Authority doesn't do what you have just said, then the exemption will apply. So it's not a case that you have to wait for the Licensing Authority to say yes.

SIR BRIAN LANGSTAFF: They've got to act fairly quickly?

MR HILL: Yes.

Sir, the final point I would draw your attention to, paragraph -- Article 6 of the order, right at the end. You can see:

"The Medicines (Exemption from

Licences)(Importation) Order 1978 is revoked."

That was the previous order that we were talking about, so this supplanted it. We will see that it is signed by Kenneth Clarke, Minister of State for the Department of Health and Social Security and the Secretary of State for Wales, Nicholas Edwards, George Younger, Secretary of State for Scotland, Michael Jopling, Minister of Agriculture, Fisheries and Food, the Permanent Secretary of the Department of Health and Social Services for Northern Ireland, and the Department of Agriculture for Northern Ireland, Under-Secretary. So that, sir, then is the 1984 order.

You may feel, sir, that in the --

SIR BRIAN LANGSTAFF: Do we have any information as to why it was only six years after the earlier order that this was introduced?

MR HILL: It is something, sir, that we will be exploring, a theme to explore during the presentations that we're about to embark into.

SIR BRIAN LANGSTAFF: I mean, it gives rise to a suspicion that the Department thought that there might be good reason to control the named-person exemption, because it had led, in some cases, it was thought or suspected, to unsafe products being used.

MR HILL: I would agree with all of that, sir, save for the question about whether or not unsafe products were used. There may be a feeling that it has been used to circumvent the licensing procedure too much. That could give rise to the use of unsafe products, or it could just be a concern that there is a potential or a risk of products which haven't gone through the same checks for safety, efficacy and quality of being imported into the UK market.

SIR BRIAN LANGSTAFF: I wasn't suggesting it was an inference that could be drawn.

MR HILL: No.

SIR BRIAN LANGSTAFF: But I was suggesting that at least it opened your eyes to the possibility that that might have been in the minds of those who were proposing this order.

MR HILL: Certainly, sir, and there is evidence that you will hear in the coming days which I think supports that. Obviously, others will have their own view of that evidence but it will be my submission that there is evidence that supports it.

SIR BRIAN LANGSTAFF: Thank you.

MR HILL: If we turn away from the named-patient exemption to the second exemption, and that is clinical trials. The 1968 Act set out at section 31 and sections 35 to

39 a regime in which a clinical trial could be undertaken. These were supplemented over time by various orders made by ministers, including the medicines exemption from licences, clinical trials order of 1974, which is SI1974/298.

I won't try, sir, to take you through all of the relevant provisions but the initial position under the 1968 Act was that a product licence -- a product could be used in a clinical trial if, firstly, a product licence authorised its use in that trial, so there was an actual licence which said it could be done. That's section 31(4)(a), or if a clinical trial certificate -- sometimes referred to as a CTC -- was issued, so that's section 31(4)(b), so if a person who is seeking to include a product in a trial applies for a certificate rather than a licence.

Sections 31(5) and 31(6), in our understanding, allow a product to be used in a clinical trial on a named-patient basis. So if you're importing the product on the named-patient basis, that patient can be entered into a clinical trial.

Under Article 2(4) of the 1974 order, if a person intending to sell, supply or import the product notified the Licensing Authority of a proposed clinical trial and provided details of it, and the

Licensing Authority had agreed to that exemption, then the product could be used as well. So that's not a certificate, it's not a licence, it's a notification and agreement procedure.

In March 1981, the regime was changed by the Medicines Exemptions from Licences Clinical Trials Order of 1981. That introduced a clinical trials exemption scheme, sometimes referred to in the papers as a CTX, whereby the Licensing Authority could exempt a supplier from a product from a need to hold a clinical trial certificate for three years if certain undertakings were given, Articles 3 to 5 of the 1981 order.

The supplier would apply for the exemption providing details of the product and for trial, together with a certificate signed by a doctor, that's article 4. There would be a period of 35 days in which the Licensing Authority could inform the supplier that the scheme did not apply and, at the end of that period, the exemption would take effect. That's Article 4. So, again a similar negative consent procedure, rather than positive asset.

The supplier was required to inform the Licensing Authority of any adverse reactions or other matters that might reasonably cause the Licensing

Authority to think that the product was not safe or satisfactory. That's Article 4(1)(c). Again, similar to the 1984 order that we have just looked at.

SIR BRIAN LANGSTAFF: In advance or in retrospect?

MR HILL: Well, the adverse reactions obviously has to be in retrospect but any other matter that might reasonably cause the Licensing Authority to think that the product was not safe or satisfactory, that would seem to be an ongoing obligation.

The Licensing Authority had powers to terminate the exemption, including on grounds of safety. That's Article 5(2). So you may feel, sir, that, in contrast to the named-patient basis, where we see a tightening of restrictions there is a greater degree of flexibility which is introduced by these orders over time, in terms of the clinical trials process.

So those were the legislative provisions, sir. I'm now going to turn to a little evidence about how the process operated in practice. It's intended to provide an introduction about the general structures and processes, further evidence is going to be called in due course and you will, of course, sir, want to consider all that before making any findings. This is really just by way of introduction.

The first bit of evidence, please, Soumik, is

WITN5281001. This is the written statement of Sir Joseph Smith dated 25 June 2021. This version, sir, is the unsigned but approved evidence that we disclosed prior to witnesses giving evidence in the summer. For these purposes, I don't think it matters, sir, I don't think this evidence is in any way contentious, it is merely Sir Joseph discussing some aspects of how the licensing process works.

If we could turn first, please, Soumik, to page 3, and paragraph 0.2. We can see, Sir Joseph setting out the positions that he held. He was the director of the National Institute for Biological Standards and Control, that's NIBSC, from 1976 to August 1985. He was the Director of the Public Health Laboratory Service from August 1985 to 1992. He sat on the Committee on the Safety of Medicines from 1978 to 1986, and he was the Chairman of the Committee on the Safety of Medicines Subcommittee on Biological Products from 1981 to 1986.

You have heard evidence, sir, of the meeting of 13 July 1983 of the Committee on the Safety of Medicines Biologicals Subcommittee and it was Sir Joseph who was in the chair at that meeting where the steps in response to AIDS were discussed.

If we could turn to paragraph 2.7, which is --

forgive me, Soumik -- it's on page 8. Sir Joseph describes the way in which the work of the NIBSC was divided. We go down to 2.9 on the same page, he talks about:

"The wide variety of different biological products necessitated a corresponding range of scientific disciplines at the NIBSC. During my time as Director, the Institute had five scientific Divisions ..."

He lists them. For our purposes the important one is blood products.

He then goes on, at the bottom of that paragraph and the next page, to talk about how the work of that Department can be broadly divided into three areas: standardisation, control and research. For today's purposes it is the controlled work of the NIBSC which is of interest to us. That is at 2.11. I read from his statement, he says:

"The control work of the NIBSC included the evaluation of medicinal products before and after licensing, and advice was given to the Licensing Authority and the Committee on the Safety of Medicines on applications for product licences and clinical trials certificates for biological products. The NIBSC also had a part to play in the batch release

process, which was applied by the Licensing Authority of the DHSS to manufacturers of certain biological products and required them to submit to the NIBSC, on a batch-to-batch basis, protocols describing the results of in-process tests made during the manufacture, and, in the majority of cases, samples of all such batches. The samples could include, in addition to the finished product, bulk and in-process materials, the control of which is essential to ensure the quality and safety of biological medicinal products. A batch release order could require that marketing or supply of any batch shall not take place without the issue of a formal release certificate by the Board on behalf of the Licensing Authority. This type of order was known as a 'full stop order'. Such orders were usually judged to be necessary for new biological products, and sometimes remained in force permanently, as in the case of potentially hazardous products, such as live virus vaccines. In other cases, satisfactory control could be maintained by scrutiny of protocols only. Once satisfactory evidence had been provided for the manufacture produced a product of consistently acceptable quality and related safety, a batch release order might have been partially relaxed or completely withdrawn.

"The testing carried out by NIBSC on biological products used in human medicines included testing against the appropriate biological standard the potency of submitted batches of biological products which were the subject of a UK product licence or clinical trials certificate application in the United Kingdom, but may also have included other tests relating to the purity and potency of the product ..."

He addresses those in paragraph 2.20, which I won't take you to yet.

Paragraph 2.15, please, Soumik, on the next page. This is about the Blood Products Division. Sir Joseph Joseph said this:

"The Blood Products Division was established as a separate entity within the NIBSC on 1 October 1976, with the appointment of Dr Duncan Thomas as its Head and the transfer of scientific and technical staff from the former Division of Hormones and Blood Products, which until then had been responsible for the control of haematological materials. When I was Director, the Blood Products Division was responsible for controlling certain blood products, for preparing International and British Standards, and for carrying out related research."

I'll turn now to paragraph 2.20, to which

Sir Joseph Joseph made an earlier reference. This is again about the work of the Blood Products Division. What he says is this:

"Apart from testing for purity and potency of samples of blood products examined by the NIBSC, tests for thrombogenicity (the tendency of a material to generate blood clotting and/or thrombus, when in contact with the blood) could be carried out, as well as tests for certain blood borne infections where these were available. For example, when I was Director, samples were tested for hepatitis B antigen, and later, when a test became available, for HTLV III. It appears from the NIBSC report for April 1984 to March 1985, that samples were being tested for HTLV III by this time ..."

There is -- it follows a quotation from the report which says:

"A total of 124 batches of manufacturers' products was submitted, a slight fall from last year, which was probably mainly due to the switch by manufacturers at the end of 1984 to Factor VIII preparations subjected to heat treatment ... The batches included 18 from the Blood Products Laboratory, Elstree, and 10 batches from the Protein Fractionation Centre, Edinburgh. Tests at NIBSC on

these materials gave negative results for HTLV III and hepatitis B."

Turning to the remit functions and activities of the Committee on the Safety of Medicines and the Biologicals Subcommittee and his roles on those committees, Sir Joseph says this:

"The CSM's primary role was to consider questions relating to medicines licensing. The CSM would regularly consider applications for product licences and clinical trial certificates made by drug manufacturers. These applications, including applications to vary existing product licences as well as applications for product licences for new products, were referred to the CSM by the Licensing Authority strictly speaking the Secretary of State, but in practice the Medicines Division of the DHSS. Applications for consideration by the CSM went in the first instance to the Secretariat of the CSM and would then be presented to the appropriate sub-committee. The main sub-committee dealing with most pharmaceutical products and a second sub-committee dealing with biological products (the CSM(B)).

"As explained above ... biological products were products which could not be assessed by physical and chemical means alone, and required biological

standards against which to measure their potency. This would include vaccines, certain antibiotics, hormones and blood products. The CSM(B) was composed of senior members of expertise appropriate to its work out, that of assessing the safety of biological medicines and their risk-benefit balance. They were experienced in assessing the necessary biological, clinical and epidemiological evidence contained in the cases submitted for their consideration. Their expertise included clinical infectious diseases, clinical and experimental virology and bacteriology, haematology, endocrinology, epidemiology and the production of biological medicines. The Sub-Committee's evaluations also benefited from the assessments made by the medical and scientific staff of the Medicines Division of the DHSS as well as the views of the professional staff of the NIBSC. The advice of the administrative and legal staff of the Medicines Division could also be taken into account, particularly regarding the requirements of the Medicines Act, for example the need for confidentiality.

"The conclusions and recommendations of the CSM(B) would accompany the application papers when they were considered by the CSM. The CSM would in

turn make recommendations to the Licensing Authority."

That is, sir, as we discussed earlier. I would also draw your attention, sir, to a little later in the statement, paragraph 3.53 at page 44, please, Soumik. This is a further comment that Sir Joseph Smith makes. This in the context of the 13 July 1983 meeting, but from the way the evidence is presented I think that it has a wider relevance as well.

Paragraph 3.52:

"I am asked at question 12(b) ..."

That is a Rule 9 request that we sent him.

SIR BRIAN LANGSTAFF: We're on the wrong -- thank you.

MR HILL: Thank you.

"I am asked at question 12(b), what, if any, discussion there was at the CSM of the CSM(B) conclusions and, if there was any discussion, whether there is any reason why it was not recorded in the minutes."

As I say, sir, that relates to the 13 July meeting:

"I cannot recall there being much discussion on this occasion, or indeed on other occasions when the CSM(B) presented recommendations to the CSM, although the CSM would have read carefully any written information provided, CSM members generally agreed

with the CSM(B) in relation to its recommendations."

SIR BRIAN LANGSTAFF: So, in effect, it was a nodding through type process?

MR HILL: After consideration of the papers, yes.

SIR BRIAN LANGSTAFF: Yes, they'd read the papers.

MR HILL: They'd read the papers.

SIR BRIAN LANGSTAFF: Or had the papers to read anyway.

MR HILL: You will have further evidence, sir, from people who worked both on the CSM(B) and worked with the CSM(B), which will, we hope, provide more information about how things worked in practice. That is the evidence that we have from Sir Joseph at this point.

The final piece of evidence that I would draw your attention to, sir, at this stage, is the Evans-Cunliffe report, which was mentioned in Lord Fowler's evidence.

Soumik, can we have, please, WITN0771006. This is the front page of the report, and you can see it is by Dr Evans and PW Cunliffe, published in December 1987.

If we go to page 10, please, Soumik.

We can see the context of the report. I will read from it:

"Introduction.

"In the spring of 1987, the Medicines Act 1968

was almost 20 years old, and the Medicines Division of the DHSS (which is the government department charged with implementation of licensing of medicines under the Act) was showing signs of overload. We were asked by Ministers to study the arrangements for the control of medicines, with the following terms of reference:

"'To examine the issues for DHSS arising from the continued increase in licence applications and other work under the Medicines Act and to recommend ways of dealing expeditiously with this work, while maintaining adequate standards for the safety, efficacy and quality of human medicines in the United Kingdom.'"

So that, sir, is what they were asked to do, and why they were asked to do it.

If we could turn, please, to paragraph 2.2. This gives a little insight into the size of the Medicines Division at the time -- sorry, page 11. Thank you, Soumik.

Paragraph 2.2 says:

"In all these activities, the greater part of the work in assessing applications and in issuing licences on behalf of Ministers is done in Medicines Division of DHSS, assisted by the Medicines Commission and a number of expert statutory committees ('the

Section 4 Committees') of which the Committee on Safety of Medicines is probably the best known. Medicines Division comprises some 300 civil servants including 165 administrators, 97 pharmaceutical staff (mainly pharmacists) and 24 doctors, the most senior being two Grade 3 officers namely a Senior Principal Medical Officer and the administrative Under-Secretary."

I don't go to it now, sir, but table 3 at page 54 of this report contains more of a breakdown of how the size of the Medicines Division changed over the years.

A little further down page 11 we can see that the problem that had given rise to this report. This paragraph, sir, is also instructive in terms of the different types of licences that could be applied for. It's not a case that there was simply one form of application.

What the report says is this:

"There has been a progressive increase in the number of applications. Analysis is complicated by several factors, viz:

"i) different kinds of application impose quite different burdens upon the Division. The assessment of a novel kind of medicine (a 'New Active Substance')

usually requires much more work than does that of the simpler ('Abridged') application for a medicine based on a familiar active ingredient; Clinical Trials Certificate and Exemption Certificates, Variations and Notifications are different again."

I'll pause there, sir, just to point out some of that terminology: the abridged application and the applications to vary an existing licence; two different matters to a new active substance licence which requires consideration from scratch.

If we go over to subparagraph (iii) on the next page, please, Soumik. Further evidence of the complexity, the report says:

"iii) even within one category -- say, Abridged applications -- there are marked differences in the complexity of the professional work needed in the Division. Such differences are hard to quantify, but the industry and DHSS staff agree that both New Active Substance and major Abridged applications are steadily becoming more complex. For example, medicines produced by recombinant DNA techniques present the assessors with quite new kinds of problem to solve."

Reading on, the report authors say:

"Table 2 shows DHSS figures for the numbers of applications received each year from 1976 to 1987,

without attempting any correction for this increase in complexity. The growth overall approximates to 5% per year. Table 3 shows how the Division's staff increased over the same period, with a commendable increase in efficiency."

I won't take you to those tables, sir, but they're for everybody to see if they wish to:

"The growing workload has brought problems. In particular, the time taken to deal with an application, measured from its receipt to the grant of licence, has grown to embarrassing dimensions ..."

A further table is given to show that:

"These times currently considerably exceed the period stipulated in EHC directives yet they are not necessary for the careful scrutiny of the data submitted nor do they contribute to its rigorous assessment; indeed, the public is the loser because new medicines take so long to get in the patients' hands. The delays are also commercially detrimental to the applicant companies; when it is remembered that a fairly run-of-the-mill new medicine might earn 1 million a year, and a very successful new active substance perhaps 50 million per year during its short patent life, it can be seen that each additional month's delay in issuing licences is costing companies

thousands, even millions, of pounds annually. And, of course, the taxpayer has an interest in a thriving UK pharmaceutical industry."

Paragraph 2.6 makes the point that delays of this kind are not confined to the UK but also found elsewhere.

Then if we go, please, to chapter -- to the following page, page 13, which is the chapter on "Complaints & Findings". I'm not going to go through all of the findings of the report or all of its recommendations, but this does, sir, I think, help to show a snapshot of what people were thinking about some aspects of the licensing system at the time when this report was being prepared in about 1987.

Paragraph 3.1:

"In this and the following chapter we summarise the current problems in relation to the control of medicines as perceived by those we consulted ..."

Pause there to say, sir, that there is a list of those who were consulted at the back of the report:

"... and discuss our own findings and conclusion about the strengths and weaknesses of the existing arrangements. Many of these conclusions are critical. Necessarily, we give the criticisms full weight and space, for they are the foundation on which we have

built our recommendations for improvement: but it is important to remember when reading them that the overall record of medicines control in the UK is a good one, and its reputation stands deservedly high. All countries have problems with delays and bureaucracy, and notwithstanding their complaints the consensus of those we consulted was that the UK system is still one of the best in the world -- it is by no means the slowest, and its record in protecting the public without inhibiting therapeutic innovation and progress is second to none. What follows, then, is intended as constructive criticism to help make a good system better.

"3.2. The principal complaints and difficulties made known to us were:-

"3.2.1 -- by senior management of DHSS.

": increasing workload is causing overload and delays

": too many applications are incomplete, slovenly or premature imposed constraints (eg the Treasury headcount) forbid taking on necessary staff

": difficulty in recruiting suitably experienced professional assessors

": appeals against licence refusals are very time-consuming."

So that's what the senior management of the DHSS said.

The "consumer interests", so-called, said that the:

": legislation was more favourable to the health of the pharmaceutical industry than to health of the consumer

": more medicines are approved than are needed

": undue secrecy about the nature and working of the medicine control process

":undue secrecy about the grounds on which licensing decisions are taken

":flaccid enforcement of the legal powers re premotion and advertising"

The complaints by the industry were of:

": delays

": over-formalised procedures with too little informal communication

": over-zealous pursuit of unnecessary detail ('nit-picking')

": professional assessors lack experience.

": frequent errors in documentation."

The principal complaints and difficulties from the staff of the Medicines Division were the:

": poor quality of many applications

": lack of secretarial and other support for professional staff

": inadequate computing and unreliable database

": structure of the division impedes good working and effective management."

Finally, on the following page, principal complaints by "others":

": the scope of the legislation should be extended to bring additional items under control."

Then if we go to paragraph 3.4, the report's authors talk about where there weren't complaints:

"Rather to our surprise there were two significant omissions from the list of criticisms. Even though we gave ample opportunity for the issue to be raised, those we consulted did not particularly condemn the amount of data required in support of licence applications, for new drugs. And we found that although many of those we consulted would like to see the Medicines Act 1968 changed in one respect or another (some favouring tightening its provisions, others the reverse) there was almost universal reluctance to see its amendment lest more be lost than was gained by disturbing the present balance of conflicting interests."

Those then, sir, are the times of criticisms

that the report's authors received during their work. I stress this is from 1987, so it is a snapshot in time, and it may not apply earlier, it may not apply later. I also stress that this is a report into the licensing of medicinal products broadly, across the board, and not just blood products.

Finally, sir, if we could go to pages 6 and 7 -- please, Soumik. Could we have page 7 on the split screen with it, please.

I won't go through all these, sir, but these are a summary of the recommendations that were made. You can see that they are divided into organisational recommendations, new technology, staffing and personnel, improved procedures.

Then if we go -- I won't ask for it to be brought up, but there are also recommendations about expert drug reaction monitoring, expert advisory committees, appeals and finance.

So that is the series of recommendations that the report made. I confess I haven't followed through precisely how they were implemented, but I do note that it was a couple of years later that the Medicines Control Agency took effect within the Department of Health, taking on the work that had previously been done by the Medicines Division.

That, sir, concludes the presentation that I'm giving now on licensing, the overview. Much more can and, I'm sure, will be said on licensing during the course of the evidence that you hear, and on the other functions of some of the bodies that we have mentioned. But, for now, I will leave it there.

I note the time, sir, and we'll be moving on to the pharmaceutical companies shortly.

SIR BRIAN LANGSTAFF: Yes, well we'll take a break until 11.45.

MR HILL: Thank you, sir.

(11.10 am)

(A short break)

(11.45 am)

MR HILL: Sir, we turn then to the presentations from your team on the pharmaceutical companies, and these will take place over the next two weeks. Perhaps it will help if I say a word about what will and will not be covered in that time, and about the approach that we have taken.

The first phase of these presentations will be a company-by-company approach, looking at the main importers of blood products to the UK market in the 1970s and the 1980s in particular. Those being Immuno, Hyland, Armour, Air Cutter and Abbott Alpha.

There will also be a presentation on the UK-based company, Speywood, which is a slightly different category.

The focus of these presentations will be on the following matters. First, the UK licensing of the products, and the use of the products within the UK; second, communication of risk in respect of those products, particularly within the UK; third, the donors whose plasma was used to produce the products; and fourth, other contacts and communication between the companies and people, organisations, within the UK.

That is a general outline of the structure to help give some shape to it. There is obviously a lot of overlap between those areas, and so there is not a clear delineation, but those are the types of areas that we will be considering.

Due to the materials that are available to us, we are able to say more about some companies than we are about others and we are able to say more about some areas for some companies than we are for others. To give an example, Immuno, who we will be talking about today, we have quite a lot of documentation about the licensing process, so it is a good way of exploring that process through the Immuno documents.

For Hyland, we have a little more about donors, so it is not a case that we will be able to say exactly the same sets of things about the different companies. But we hope to cover the ground fairly expeditiously and, we hope, without too much repetition. The going will be slow at first but we hope we will be able to pick up the pace as we go on.

In November, there will be a further presentation, and that presentation will be about the response of those companies -- not so much Speywood, but the five companies that I mentioned before -- the response of them to the growing knowledge of the risk of infection from the use of their products and, in particular, infection with AIDS.

That presentation will be a cumulative one, drawing on materials from all of the countries. We think that is a better way of reflecting the narrative of the events and it avoids repeating certain meetings, certain documents, again and again.

In this first set of presentations, which, as I said, concentrate very much on the UK picture, we will touch upon the corporate structures of these companies but we do so for two main reasons. The first is to help explain what companies were doing at different times, which company was doing what at

a particular point in time and, in particular, we would invite everybody to keep in mind the distinction to be made between the parent company, based in these instances in the United States -- or in the case of Immuno, in Vienna -- and a UK-based subsidiary or a company that is connected with the parent company, which is based in the United Kingdom, and the interaction between those different entities will be of some interest.

The UK-based companies, as we will see from the papers, were often reliant on the parent company not just for the product but also for the data that was used in the licensing process and for the packaging and for the labelling.

The second reason why we will touch upon the corporate structures is to explain where and why the Inquiry has sought materials from particular sources, what lawyers call "the disclosure exercise". It helps to understand what has been looked for, what has been found, and how we have approached that process. The picture is invariably complex and it will not be something that we go into in detail in the oral presentations, but witness statements will be disclosed to help people to understand where it is that we have looked and why we have looked there.

That is all part of the transparency that is fundamental to this Inquiry's work.

So those are the reasons why we will touch upon the corporate structure. The companies, over time, were carved up, they were sold, they were resold, and we are not seeking to give you a corporate history of those companies. We are not making any submissions to you on which company, if any, has inherited any liability or culpability, legal or otherwise. That is no part of these presentations.

A word, sir, of the sources that we have used. They are voluminous but they are incomplete. The Core Participants will be aware that there is a documentary on relativity connected with all these presentations where the documents have been placed and there are many thousands of documents which have been placed on it.

Where material is located overseas, you have no powers of compulsion under the Inquiry's Act 2005, you have relied on the cooperation of the organisations involved. It has not always been possible to identify all of the documents that we would have liked to have seen. That is inevitable after 40-plus years. Some documents are missing, some documents may have been destroyed, some documents your Inquiry team may have,

but we have been unable to locate the specific facts from 1978 that we are looking for, because it's somewhere within this vast mass of materials that we've had. I can say that it is not for want of trying.

If we say that we can't identify a document, we mean just that: that we haven't been able to find it. We're not implying anything untoward about the reasons why we haven't been able to find it.

Our approach to the documents has been to bring our independent analysis as your counsel to it, we have sought to identify material and themes that will assist you in discharging the terms of reference of the Inquiry. It's not an exhaustive process and I should say that myself and Ms Richards are indebted to the work that has been done of the wider Inquiry legal team in making these presentations.

Others may disagree with our analysis. They may identify other documents, other themes that they consider to be important, and we welcome those being brought to our attention. We also note that the Core Participants will have an opportunity to make their own submissions. You will also hear further evidence from witnesses who are connected to these areas. We do not seek to pre-empt that evidence in these

presentations, and all should keep in mind that a witness may come along and give an explanation about a document which hasn't occurred to us.

You, sir, I'm sure, will consider all of the evidence that is presented to you, both by us, the submissions of others and by the witnesses. The fact that in these presentations a document is referred to doesn't give it a special status, and the fact that a document is not included doesn't mean that it is not important. You will consider it all, sir, and it will be a matter for you as to which conclusions you draw from them.

With that presentation complete, sir, I'd like to turn to the first of the companies that we're going to look at. That is a company called Immuno. Those present here today will have seen that on the timetable we have grouped together Immuno and Hyland and Travenol. The reason for that is that, in later years, a single entity was involved in owning all three of those companies. That didn't happen until the 1990s, there is then some further splitting of the companies, which I don't need to go into now. It is important to note that for the key periods in which we are interested in these presentations, that is to say the 1970s and the 1980s, these companies were

competitors and they were not part of the same group. So Hyland was competing directly against Immuno in selling factor products.

In terms of the corporate structure for Immuno, all I will say is this, very briefly. A company called Immuno International AG was founded in 1960, and its principal place of business was Vienna, so this is an Austrian company. It was the parent company of a UK-based company which was originally called Serological Products Ltd. That was incorporated on 27 January 1972. That company later changed its name to Immuno Ltd, and that was 31 December 1976. Both in this presentation and in others the fact that a company is called "X Ltd" is an indication that that is a UK-based company. As I have said, there is a distinction always to be kept in mind between the international company and the UK-based one.

The first managing director of Immuno Ltd was a man called Norman Berry. He later became the chair of the company, the chairman, from 1984, and the managing director from that time was Peter Coombes. He had previously been a marketing manager. One other name that comes up in the documents that I raise now is Robert Nicholson, who, in the mid-'80s had taken

Mr Coombes' former role of being the marketing manager of Immuno Ltd, all of these men within the UK-based company.

For Immuno AG, some of the names that we see in the documents coming up are Dr Otto Schwarz, who was managing director, production for Immuno AG, the Vienna-based company; Dr H Eibl -- I hope you will excuse the pronunciation -- the director of research and development at Immuno AG, the Vienna-based company; and also a Mrs Diernhofer, who we understand headed the licensing and registration department of Immuno AG.

Those are names that we will see as we go through.

The company -- at points I will refer to "Immuno" generally to try to encapture work that was done by both Immuno AG and Immuno Ltd. Trying to break it up every single time that but I say the word will perhaps be a little repetitious, so at points I will refer to "Immuno".

Immuno provided three main products to the UK market that we're going to consider in the coming presentation. They were Kryobulin, which was a Factor VIII concentrate; Prothromplex, which was a Factor IX concentrate, it also contained Factor II

and Factor X, but it was predominantly used for Factor IX concentrate; and a product called FEIBA, which was used for inhibitor patients.

FEIBA stands for Factor VIII Inhibitor Bypass -- I forget the "A", sir, forgive me, it will come back to me as we go along.

So those are the three main products but within those products, over different times, different variants of them are presented to the UK market and presented to the licensers. There are generally three-phases. The first phase is the original product, so Kryobulin or Prothromplex, in a non-heat-treated form.

The second stage is a dry heat-treated form of the product. Dry heat treatment refers to the way in which the product was heated in order to try to get -- to encourage viral inactivation, so the second phase is of dry heat product.

The third phase is of a steam or vapour heated product, and we will come on to the distinction between those terms in due course. That is a different method of heating those products, which, as the name suggests, uses a wet or moist heat from steam or vapour, rather than the dry heat of an oven.

Those are the three distinct phases, but to add

a further layer of complexity, there are different methods within each of those phases for heat treating the product. Immuno referred to products by -- with the preface "TIM", which I think stands for Thermal Inactivation Method, and so a -- you may see a reference to Kryobulin as TIM 2, as opposed to Kryobulin TIM 4. Now TIM 2 is for the second method of dry heating Kryobulin, and method 4 would be the fourth method of dry heating Kryobulin.

But then you will have Kryobulin also referred to as Kryobulin Neo TIM 2 or Neo TIM 4, sometimes S-TIM 2 or S-TIM 4, and that is the second method of steam heat and activation of the product. So you get different variants even within the different types of heating.

For that reason, sir, it gets somewhat complex, and at points I will stop, and I'm sure that you will interrupt, and ask to clarify exactly which product that we are talking about. Usually it is possible to tell, not always.

But the overall structure is of unheated products, dry-heated products and then steam or vapour-heated products, as time progresses through the '70s and into the '80s.

With that introduction, sir, I turn to the way

in which products were licensed by Immuno, starting with Kryobulin, the Factor VIII product.

As I go through, sir, I will give references to documents. I'm not going to bring them all-up because there are an awful lot of them, but I will place on the record the references so that people can go and check on relativity and see the documents to which we're referring.

Immuno AG began producing Kryobulin, which was formerly known as Kryobulin Human Antihaemophilic Fraction in 1965. Initially it was sold to on the Austrian market but the product was exported and sold abroad from 1969 onwards. The reference for that is SHPL0000071_181, page 39.

The sales figures indicate that Kryobulin was available in the United Kingdom, albeit in the small supply, from 1970. If we could bring this up, please, Soumik, its SHPL0000071_185, and first of all page 4, please. We can see many of the documents are in German, of course, and this is sales of Kryobulin, 1970, and we can see the first entry is for Heidelberg, but the second entry is Crown Agents London, the 100, 250 and 500, that's for different size of the products which are being sold. Six units sold to Crown Agents, and then also --

SIR BRIAN LANGSTAFF: You say six units, you mean six bottles of the 500, whatever it is, or --

MR HILL: That is my best understanding, sir.

SIR BRIAN LANGSTAFF: Because, at this stage, I don't think the international unit had yet been introduced, had it?

MR HILL: That's right, there is a standardisation, that comes later.

SIR BRIAN LANGSTAFF: About 1971, I think it was, but I may be wrong.

MR HILL: Somewhere around there but, here, my best understanding of this is that this is six bottles or six vials of the 500 sized Kryobulin.

SIR BRIAN LANGSTAFF: Presumably this would have been on a named-patient basis, would it?

MR HILL: There was certainly no licence by this stage, 1968 --

SIR BRIAN LANGSTAFF: So it would have to be?

MR HILL: Unless it was clinical trials.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: But one of the exemptions would have to have applied.

So we can see Crown Agents have bought that, and then underneath what I think is a Dr Mibachan in London, one unit, whatever that may be, a vial, it may

be a bottle.

If we go to, Soumik, to page 1, that's 1970, that's the first time we have them appearing on the sheets and we do have some earlier sheets as well.

1971 we can see the Crown Agents have now bought three of the 500 sized units, Mr Newcession in London has bought two. If we could just expand that page a little, please, we can see that is being sold also in Milan and Pisa and we can also see Dr Mannucci's name in Milan, further down the list as well.

Then page 6, please, Soumik. This is 1972, and we can see now it being sold to St Thomas' hospital and to the Crown Agents, to the Royal Free Hospital. Now, that's -- the Royal Free are buying a different product called Bebulin, which I understand to be an immunoglobulin but the Crown Agents and St Thomas' are buying Kryobulin.

Again, we can see it also being sold in Madrid, in Warsaw and in Pisa.

Thank you, Soumik, if we could have the next document, please MHRA0033323_003. This is a letter dated 22 December 1972. You can see it is sent to Mr Berry, who is the managing director of Immuno Ltd, the UK-based company and it comes from Duncan Thomas, who was mentioned in Sir Joseph Smith's evidence too

subsequently becomes head of blood products at NIBSC. What he says is:

"Dear Mr Berry,

"Thank you for your letter of December 20th, 1972. There is no objection to you supplying Dr Biggs with Kryobulin for the treatment of named haemophiliac patients."

So going back to your earlier question, sir, this seems to be the product being supplied on a named-patient basis. I suspect Dr Biggs might be an error for Dr Briggs.

SIR BRIAN LANGSTAFF: It may be Dr Rosemary Biggs, mightn't it?

MR HILL: Sorry, yes, I've written her as Briggs, but yes, Dr Rosemary Biggs, at the Oxford Haemophilia Centre.

Now, that's from December 1972 and in the same month we have the first application for a product licence for Kryobulin. If we could have on the screen, please, Soumik, MHRA0033325_002.

This, I show you, sir, to show what an application looks like, as of 1972. You can see the application is made by Serological Products Ltd, that's the company of which Mr Berry was the managing director, the UK-based company. So it's the UK-based company that makes the application but, as we will see

from the documents, relies on material from the Vienna-based company.

You can see the contents there of what is provided with the application, there is a summary of the particulars of the product, the specimens of the inner labels, of the solvent labels, of the outer labels, the draft directions circular is the leaflet that goes with the document, and then some scientific evidence about the methods of manufacture or the methods of analysis, stability report, and copies of various studies.

If we could go over, please, to the next page, Soumik. You can see this is the -- if we could expand that, please -- summary of the particulars of a product, and it includes the fact that the licence is sought for five years, which is the time stipulated by the 1968 report.

Then onto the next page, please, Soumik. These are the various details that accompanied the application, what the licence is required to authorise, the product, and you can see the different sizes 100 units, 250 units, 500 units, the pharmaceutical form, the description of the product, and its composition.

Then onto the next page, please, Soumik. You

can see for the different sized units of the products it gives directions about how it should be reconstituted with water, so that you can then apply and inject the product.

If we could turn, please, to page 6, Soumik. We have the physical characteristics, which is a description of the product, and then the clinical use and the recommended clinical use is including:

"Treatment of bleeding caused by Factor VIII deficiency in patients with:

"-- Haemophilia A.

"-- von Willebrand's Disease.

"-- Haemophilia caused by Factor VIII inhibitors", and so forth.

We then turn on the next page to the clinical recommendations on the route of administration through injection and recommended dosages. Over the following pages you have the dosages for different situations for bruising, for heavy bleeding into muscles, for haematuria, for major surgery, and so forth.

If we could turn, please, to page 10, Soumik, recommendations there for flow rates for injections, and details of how the product is manufactured and assembled. This, I hasten to add, is a summary and -- though it is backed by far more documentation, as we

saw from the contents page .

Page 11, please, Soumik. The summary of how quality control is exercised, and you will see there at 14(a) it says:

"A detailed report on analyses carried out will be given in Part 3, Section B."

So these are the detailed reports that follow on from the summary.

Page 12, please, Soumik. A description of the containers and of the labelling and, again, reference is made to the documents supporting the application where these are set out. We will be looking in some detail at the labelling in due course.

Then, finally, please, Soumik, page 13. We see "Method of sale and supply":

"The product will be made available [at]:

"Hospitals, and Haemophilia Treatment Centres."

The application is signed by Norman Berry, the managing director of Serological Products Ltd, dated 1 December 1972. We know from a covering letter that it was sent to the Department on 8 December 1972. I don't ask for that to be brought up but the reference is MHRA0003323_009.

I won't go through all of the supporting documentation that accompanied the application but

there are a couple of features within it that I wish to draw your attention to.

Can we have onscreen, please, Soumik, SHPL0000071_181.

We can see from the first page this is Mr Berry sending to Mrs Diernhofer of Immuno AG, who was in charge of their licensing department, a replacement copy of the admissions that went with the Kryobulin application.

If we could turn, please, to page 25. The section on "Manufacture and composition". It's said here, this is part of the application, and -- sorry, Soumik, if we could just expand it; my fault. We can see this is enclosure number 4 and it's the draft of the circular, so that's the leaflet that accompanies the document and provides details, to those who read it, about the document -- about the product, sorry.

The section on the "Manufacture and composition" says this:

"Kryobulin is prepared from pooled plasma of healthy donors and freeze-dried for stabilisation. All donors, whose plasma is used for the production of Kryobulin, are tested at each donation for their GPT level and the absence of AU/SH/HA antigens (Hepatitis Associated Antigen). Any donor, who has a history of

a pathological transaminase level or a positive AU/SH/HA antigen test, is permanently excluded from the donor programme. Despite these precautions, the risk of transmission of homologous serum hepatitis can only be diminished, and not completely eliminated."

SIR BRIAN LANGSTAFF: Just so that we can follow, when it's AU/SH/HA, those are acronyms, are they?

MR HILL: Yes. We understand them to mean Australian Antigen, Serum Hepatitis Antigen and Hepatitis Associated Antigen.

SIR BRIAN LANGSTAFF: Yes. Thank you.

MR HILL: Actually, I should add that that is our understanding, rather than something we have taken from the document.

SIR BRIAN LANGSTAFF: Well, it seems reasonable. They're all examples or all different ways of expressing the same thing, pretty much, that it's something in the blood which indicates the presence of hepatitis.

MR HILL: That's right, sir.

If we could turn to page 29 now, please, Soumik. This is part of the same document, the draft circular. This is the section on the side effects. It says that:

"Side effects are rarely observed during treatment with Kryobulin, though the following

reactions may occur ..."

The first is an allergic reaction. Then if we go over to the next page, the second point listed, and I quote:

"Despite the precautions taken in the selection of donors, the risk of transmission of homologous serum hepatitis cannot be entirely excluded when administering human coagulation factors."

The application was considered by the Committee on the Safety of Medicines' Subcommittee on Biologics in January 1973, and a report was prepared for that committee by Dr Duncan Thomas. That report is at MHRA0033322_060. I don't ask for it to be brought up.

In the report, Dr Thomas notes that the pool size, was 1,000 donors between the ages of 18 and 65, with plasma obtained via plasmapheresis from six centres in Austria and Germany. So a pool size of 1,000 donors, based in Austria and Germany.

In his medical comment, Dr Thomas wrote that the submission was, and I quote, "deficient in certain respects", that's the end of the quotation, including minimal information regarding manufacturing process and little clinical evidence of effectiveness. However, he considered the donors to have been, and I quote, "well screened."

Dr Thomas' report recommended that a product licence be deferred pending further information being provided.

One of the members of the Subcommittee was Dr William Maycock, who was, among other things, the director of BPL at the time, later Sir William Maycock, Dr Lane's predecessor. But he wrote to Dr Thomas on 4 January 1973. That letter is at DHSC0100026_163, expressing general agreement with Dr Thomas' report.

I won't go further into that letter, because we also have another document, which I'll ask Soumik to bring up, which is MHRA0033322_057. We can see in the top left corner this is described as Dr Maycock's comments and we know from his letter to Dr Thomas that Dr Maycock was unable to attend of the CSM(B) in person, so it appears that he sent his comments through ahead of time.

On the labels and leaflet he says this:

"The manner in which advice regarding treatment is presented is unacceptable. Any advice about the use of this preparation for preventing and controlling haemorrhage in haemophilia should be in general terms. The advice in the first two paragraphs (pp 30 and 31) is acceptable and can be expanded in certain respects.

The advice about treatment in certain specific circumstances should be omitted; some of the statements, eg that about haematuria, are in absolute terms and will sooner or later prove to be misleading."

So that is, as we understand it, a criticism of the way that the labels were produced in terms of the effectiveness of the product. Unfortunately, and perhaps inevitably, page 30 and 31 don't translate into the documents that we have, so we can't see exactly what it is that he is talking about there.

A little further down the document:

"Hepatitis: The pool size in terms of donors is small that that used in the preparation of Hemofil but a residual of icterogenicity, after the exclusion of HBAg positive donors, will remain. It does not necessarily follow that this risk will be less than that attached to Hemofil."

So that is a risk of something that could cause hepatitis. The reference to Hemofil we will no doubt come on to tomorrow, but, as Dr Maycock indicates, it was made with a larger pool of donors. Dr Maycock saying here that doesn't necessarily mean that there isn't a risk of a smaller pool of donors that the Immuno product was using.

SIR BRIAN LANGSTAFF: He is drawing specific attention to the pool size being smaller, and that being related to the risk of becoming jaundiced.

MR HILL: Yes. Yes, he is.

SIR BRIAN LANGSTAFF: So he does show a clear awareness -- I would expect it anyway from what we've heard thus far in relation to risk -- that the pool size is related to risk.

MR HILL: Yes, he does, sir. But his conclusion being that it doesn't necessarily follow that the risk will be less in this product than in Hemofil. And that, of course, must be seen in the context of this product, and as we know, the donor pool size was said to be 1,000.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: In his conclusion he says this:

"I am in favour of granting a licence if Serological Products Ltd can supply the data regarding stability, the information mentioned above about the method of preparation, and more detailed information about its clinical use. Its sale should be restricted to haemophilia centres and hospitals and, initially, to a number of selected haemophilia centres so that the clinical efficacy of Kryobulin can be critically appraised."

That is the view expressed by Dr Maycock, and it's expressed from 4 January 1973. It's not dissimilar to the view of Dr Thomas.

Despite those views and the proposal that further information be obtained before a final decision, the Subcommittee on Biologicals at their January 1973 meeting recommended the grant of a product licence subject to three provisions, one being that the supply of the product be restricted to hospitals and haemophilia centres. The Subcommittee on Toxicity [and] Clinical Trials supported the granting of the licence and the CSM main committee advised that the licence be granted in February 1973, subject to the provisions recommended by the CSM(B).

The document is DHSC0003952_048, page 13. It's not clear from the papers that we have reviewed why Dr Thomas' recommendation that the licence be deferred pending further information was not followed.

I would also add a further reference, sir: the minutes of the CSM(B) meeting themselves are at DHSC0105593_002.

I note from those minutes that it was intended to ask the Austrian authorities to carry out an inspection of Immuno's premises on behalf of the Licensing Authority and you will recall, sir, that

there is a provision for an undertaking to that effect in the 1968 Act.

The same meeting approved the licence application for Hemofil, which we will refer to tomorrow.

The DHSS --

SIR BRIAN LANGSTAFF: So you've told me thus far that the advice to the Licensing Authority was, in February '73, that a licence be granted, and you've told me that was at the same time as the licence for Hemofil, which plainly was in the minds of Dr Maycock. When was it actually granted?

MR HILL: Well, the -- Serological Products Ltd were informed on 22 March 1973 that the licence was going to be granted, and they were given a product licence number --

SIR BRIAN LANGSTAFF: So the date for my purposes will be 22 March '73, would it?

MR HILL: That is the date from which that letter was allowed to stand as a full product licence, until the full product licence itself, which was issued on 21 June 1973. But de facto it is licensed from 22 March 1973.

SIR BRIAN LANGSTAFF: So under the Act, between March and June, the product could be distributed, could it?

MR HILL: That is my understanding, yes, sir. The letter of intent is said to act as a full product licence.

SIR BRIAN LANGSTAFF: So the effective date is 22 March '73.

MR HILL: Yes, sir. References for the transcript for that are SHPL0000071_170, SHPL0000071_172, and MHRA0033322_061.

I would also note, sir, that the licence -- and this is clear from the last of those references I gave -- was that Kryobulin could be supplied through hospitals and haemophilia treatment centres, but it wasn't restricted to a small number of haemophilia treatment centres, as Dr Maycock had suggested.

On 2 July 1973, Norman Berry wrote to the DHSS to inform that Kryobulin was now on the UK market. That is MHRA0033322_014.

Soumik, can we have onscreen, please, DHSC0003741_025.

We jump forward a little, sir, to October 1973. This is a letter from the Department of Health and the Welsh Office jointly, to "Secretaries of: - Regional Hospital Boards, [the] Welsh Hospital Board [and] Boards of Governors [and the] Hospital Management Committee". It is entitled "HUMAN CONCENTRATED FACTOR VIII FREEZE DRIED". It comes from the -- or

it's sent on behalf of the director of the hospital supply branch, who was GE John at that time.

The letter says:

"Dear Sir

"HUMAN CONCENTRATE FACTOR VIII FREEZE DRIED .

"Central contracts for a period of one year commencing on 1 November 1973 have been placed with Serological Products Ltd and Travenol Laboratories Ltd for the supply of packs of Human Concentrated Factor VIII Freeze Dried to Haemophilia Centres in the United Kingdom."

And then full details are given in an attachment. The letter also says:

"It is stressed that the contracts provide FOR SUPPLY ONLY TO HAEMOPHILIA CENTRES ..."

And that is emphasised in capitals and underlined.

We will come back to this central contract later in the evidence, when dealing with the civil servants and the Government decision-making at the time. But it is a contract which has been placed with the two companies mentioned. We know from other documents that the products are Kryobulin and Hemofil. We also know from other correspondence that the supply was for -- or was proposed to be for 5 million

international units of each.

If I give the references for that information, it's DHSC0003741_024, and DHSC0100005_044.

So that is a contract by the Department of Health and the Welsh Office to import 5 million international units, we suspect, of Kryobulin and of Hemofil.

That is an annual contract.

If we could turn now, please, Soumik, to DHSC0003719_118.

Again, we come forward a little in time to 21 December 1976, and a memorandum which is sent from GA Drew of the supply department of the Department of Health and Social Security, to Dr Waiter, entitled "Factor VIII":

"Further to my minutes dated 3 November 1976, sales figures for October, together with total figures for the contract year, are set out below."

I pause there, sir. So we have a monthly sales figure in the left-hand column, a total sales figure for the year in the right-hand column, and it's expressed to be the 12 months to 31 October 1976. Then added in hand on the far side is a column entitled "Value".

We can see there the amounts of the different

products being sold at that time. The first entry is for Armour, which is for Factor VIII, in October: 271,902; international units for the year: 897,308 units. The value is stated to be £71,785. It's not clear whether that is a value for the month or for the year.

The next --

SIR BRIAN LANGSTAFF: Well, I think it is, actually, because if you look at the bottom, you see "October Sales", "Abbott", "Nil", the value was nil --

MR HILL: Oh, yes, you're quite right, sir. Yes, it is the annual figure.

SIR BRIAN LANGSTAFF: It would have to be, I think. And you could work out from that, I suppose, the cost per unit.

MR HILL: Yes. There are some documents that we have which do refer to costs per unit, but it's very difficult to try to pin those down to a point in time and whether or not they eventually made their way into a contract.

The other point that I would raise about the cost per unit calculations is that we've seen from other material that sometimes there is a tapered pricing system, that if you buy a certain amount of the product then the cost per unit if you buy 50,000

international units is X, if you buy 100,000 units, it's Y. So it's not always possible --

SIR BRIAN LANGSTAFF: Well, you'd normally expect a reduction for bulk.

MR HILL: You would.

SIR BRIAN LANGSTAFF: But if you look at these figures, just very roughly, it would look as though Armour was a bit cheaper than Immuno.

MR HILL: Yes, and that is something which is reflected in the papers, as we go through.

Travenol, the second of the products listed -- this is Hemofil -- is 865,680 units for the month, 5,231,146 units for the year. That's an adjusted figure, as can be seen from the asterisk. The value is £627,738.

Immuno, Kryobulin, 238,123 units in the month, 4,098,815 for the year, value £491,041.

Abbott, as you've said, sir, no units for the month, for the year 383,624, at a value of £38,308.

So the cumulative total is just over 10.5 million units, at a cost of just over £1.2 million.

Taking the story of Kryobulin forward, Serological Products Ltd applied for a variation to the product licence on 10 October 1975, and it was

approved on 14 October 1975, and that changed the testing method for detecting the presence of hepatitis antigens from electrophoresis to a radioimmunoassay, RIA. So that is October 1975. The references are MHRA0033321_097, and MHRA0003321_099.

There was a further variation of the licence in April 1976, concerning increased solubility. That's MHRA0033321_076. And the same reference for a further variation in August 1976, which registered the change of the company name from Serological Products Ltd to Immuno Ltd.

You can see there, sir, the point that was picked up in the Cunliffe Evans report earlier, that there is a wide disparity about the types of application that are being made for variations of licences. Some are purely administrative, changing the name of a company, some are of scientific importance, such as the introduction of RIA testing.

If we could have on the screen, please, Soumik, MHRA0033321_085. This is a further application for a variation of the licence. You can see at the top left-hand corner the:

"Licence number: 0215/0003."

And you can also see that it's for Kryobulin. This is a standard form that you're required to use to

make such applications.

There, we can see the proposed change that is in the licence, and it is to change the source of the plasma from the present situation, which is that the plasma was obtained from plasmapheresis stations, five in Austria and two in Germany, and the proposed change is for licensed plasmapheresis stations in the United States of America, so the source of the plasma used to make the Kryobulin would be American plasma.

As will be seen in some of the documents that we go through, I think it is worth flagging now, this is not an application to cease to provide European plasma-based Kryobulin; it is an application to allow either European plasma-based Kryobulin or American-based plasma Kryobulin. The reason for the change is set out on the form. It says:

"It is possible to sell Factor VIII Concentrates produced from plasma of US origin at lower prices than European-based material. Because of the preference in the UK market for this lower priced material, we also wish to make it available. Packs of Kryobulin from alternative source material will be of a clearly distinguishable colour eg blue as compared with present red. We will continue to make available European as well as the proposed new concentrate

derived from American Plasma."

The date of the application is 11 November 1976.

You noted earlier, sir, the Armour product, which was produced from the American-based plasma, appeared to be available at a lower unit cost.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: We get further insight into this application from a document that was originally in German.

And, Soumik, if I could ask to have on the split screen, SHPL0000071_083, and also, on the other side of the screen, SHPL0001094.

The document on the left is the original in German, the document on the right is a translation the Inquiry has obtained. If everybody will excuse me, I'll work from the English version.

It is a memorandum of a meeting with Dr Schwarz. I referred to him earlier, the head of research and development -- forgive me -- sorry, the managing director of production, on 24 November 1976. The subject is "KRYOBULIN England". Also present are Dr Schwarz and Mrs Diernhofer and two others, Dr Elsinger and Mr Lendvay.

The memorandum begins by referring to a telephone conversation between Dr Schwarz and Mr Berry. I emphasise that there is no evidence that

Mr Berry was at this meeting. It's merely referring to a phone call from him. That is initially about the solvent content in Kryobulin. But the point of interest to the application to change to American plasma comes on the next page -- please, Soumik -- in a "Note for the Registration Department".

It says this:

"In the future two types of KRYOBULIN concentrate will be sold -- KRYOBULIN 1 and KRYOBULIN 2.

"KRYOBULIN 1 - made from European plasma (with a lower hepatitis risk - publication by ..."

And there is a publication cited, but we can't read what that publication is:

"KRYOBULIN 2 - made from US Licensed Source Plasma (proven to have a significantly higher hepatitis risk ..."

And the publication is again cited:

"KRYOBULIN 2 will be significantly cheaper than KRYOBULIN 1 because the British market will accept a higher risk of hepatitis for a lower-priced product. In the long-term, KRYOBULIN 1 will disappear from the British market."

It goes to on to say that the respective label information hasn't been definitely determined.

You can see the date of that is 5 November 1976 and the signature is made by Ms Diernhofer. That reflects the thinking within Immuno AG in --

SIR BRIAN LANGSTAFF: So Immuno considered, from their experience in the UK, that the UK would buy a less safe product for patients in the UK because it was cheaper?

MR HILL: That is my interpretation of that document, yes.

SIR BRIAN LANGSTAFF: Well, I don't, at the moment, see what other inference can be drawn.

MR HILL: Nor do I.

SIR BRIAN LANGSTAFF: Yes. And this was in 1976?

MR HILL: November 1976. This coming a couple of weeks after the application has been made to the UK Licensing Authority to make that change.

SIR BRIAN LANGSTAFF: Yes. And the UK Licensing Authority's -- well, we'll find out in due course what they may have known, but at this stage it was after the Granada World in Action programme in 1975.

Yes; thank you.

MR HILL: Turning then back to some of the documents about the licensing application. I won't ask to bring all of these up.

29 November 1976, Immuno Ltd wrote to the DHSS proposing to name the product Kryobulin 2, the America

product, and it provided samples of the proposed packaging. The reference is SHPL0000271_069. I'm not going to look at the packaging now, sir, but I will be coming back to it in due course.

On 26 January 1977, AP Fletcher, a senior medical officer at the DHSS, wrote to Immuno Ltd about the application. He requested additional information concerning the proposed plasma source, including details of which plasmapheresis stations Immuno intended to use. The reference is SHPL0000271_077.

Immuno replied on 1 February 1977, saying that plasma was, and I quote the word, "obtainable" from licensed plasmapheresis stations located across the United States, including Hawaii, but at that time the company was obtaining plasma from stations in New York, Baltimore, Birmingham, Philadelphia and Knoxville. The reference is SHPL0000271_073.

SIR BRIAN LANGSTAFF: They are all large urban centres.

MR HILL: Yes.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: I understand that the document was phrased so as not to limit Kryobulin to those centres in due course. It said that it was "obtainable" --

SIR BRIAN LANGSTAFF: So you are saying that that's where they were getting it from at the moment?

MR HILL: At that time, yes, correct.

Now it appears that the DHSS either didn't receive or didn't register the letter sent on 1 February 1977. As a result, no action appears to have been taken on the licence for about a year. The reference to that is SHPL0000271_059.

In a letter to the DHSS on 16 February 1978, so we are now more than a year down the line, resending the letter of the previous February, Mr Berry noted that Immuno wished to continue to use plasma from Austria and Germany, but sought -- I quote his words here "the ability to also use American plasma in the same way that our competitors do".

The reference to that is SHPL0000271_058.

We don't have, or have not found, more accurately, the discussion that took place within the CSM(B) or the CSM or the Medicines Division about the application. We continue to look, and if others can find it one would be very interested to see it.

What we do have is a letter dated 7 April 1978 from Mr Berry to Immuno, informing them, and I quote:

"We are now authorised to issue Factor VIII concentrate from American plasma."

The reference is SHPL0000271_057. That suggests that the variation application had been approved, and

he added that it was necessary to have a distinguishable pack. As I say, we will come on again to look at the packaging in due course. Subsequent licensing documents --

SIR BRIAN LANGSTAFF: Can you just remind me of what you told me earlier. The criteria for licensing included safety, efficacy and quality?

MR HILL: Yes.

SIR BRIAN LANGSTAFF: And so far as efficacy was concerned, you told me that the regime was one that didn't draw any particular distinction between one product and another on the grounds of efficacy, although on the grounds of safety you told me that you could take account that another product is safer and just as or more efficacious?

MR HILL: That's correct, sir.

SIR BRIAN LANGSTAFF: I see. So in deciding whether to amend the licence, the Licensing Authority would, on that basis, here have to consider whether another product was safer than the American-sourced product, and just as or more efficacious?

MR HILL: It certainly could consider that, sir.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: At that time, as of 1978 --

SIR BRIAN LANGSTAFF: Yes.

MR HILL: -- there were a number of licences that were in place for products using American-based plasma as well.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: We know, or we --

SIR BRIAN LANGSTAFF: This would, in effect, be licensing Immuno to produce a less safe product, assuming that it is as efficacious, on that assumption?

MR HILL: Certainly according to the internal Immuno AG documents, it was a product that they considered to have a significantly higher hepatitis risk.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: Those documents, of course, were internal. Those particular documents weren't seen by the Licensing Authority, but the Licensing Authority would have been aware of the distinction between European plasma and American plasma.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: The documents that we do have suggest that the variation was approved on 28 March 1978. That's SHPL0000376_005.

So after the period of a year's delay, when the information seems to have either been lost in the post or not processed at the DHSS end, there is a relatively short period between the letter being

resent on 16 February 1978 --

SIR BRIAN LANGSTAFF: Would it have been around about March '78 that the licenses were coming to the end of their five-year term and would have to be renewed, the ones for Hemofil and Kryobulin?

MR HILL: Yes, it would have been.

SIR BRIAN LANGSTAFF: And the review criteria would include exactly the same criteria?

MR HILL: I hesitate about exactly the same --

SIR BRIAN LANGSTAFF: That's why I'm asking.

MR HILL: I can go back to the Act over lunch and check.

SIR BRIAN LANGSTAFF: I'd be grateful if you would.

MR HILL: I will do so, sir.

Something that is not clear to us from the documents that we have looked at, is whether or not, in this period when the licence was being considered, whether or not Kryobulin from American plasma was available on a named-patient basis. We have one document, with the reference SHPL0000271_072, which is -- actually, Soumik, perhaps we can bring that up, it might be helpful: SHPL0000271_072. We can see that this is a letter which is sent on 25 November 1976 to HM Customs and Excise, so this is around the time of the original variation application. It's sent by Immuno Ltd. The name is crossed out but we know that

that is Mr Berry, the managing director:

"Dear Sirs,

"We are proposing to import Kryobulin Factor VIII Concentrate for the treatment of haemophilia A.

"This material is processed in Vienna in Austria from human plasma obtained in the USA.

"Please let us know our liability for Duty on this product.

"An early answer is requested as the material is urgently required for use in UK hospitals."

There is a reply, sir, which is to the effect that no duty was payable. So we know that they were asking about that in November 1976. But we also have another document -- could we have this onscreen as well, please, Soumik, HHFT0000925_002. This is a letter dated 20 April 1977, so a few months after the application to vary the licence, and a few months after that letter to customs about duty. It's sent by Dr David McGrath of NIBSC and it's to Dr Kirk at the Treloar Haemophilia Centre. He says:

"Dear Peter

"Many thanks for your letter. I completely agree with your proposals as I can see no group differences between the commercial Factor VIII

concentrates in their positivity for HBsAG. In fact at the moment everything including the cryoprecipitates comes out clearly negative by Austria II."

I don't seek to try to decipher that now.

"One point in your letter was not correct, in that all Kryobulin batches supplied to this country are at present prepared solely from Austrian or German donors."

As of April 1977, it was Dr McGrath's understanding at NIBSC that all of the Kryobulin was still from European plasma. He was, we can see, correcting Dr Kirk on that point, we don't know the reason why that correction was necessary, and it is a situation where we cannot say to you, sir, whether or not American Kryobulin was being imported into the UK on a named-patient basis. Those are snippets of evidence we have on that point.

Turning back then, to the wider story of Kryobulin and drawing on a point that you raised earlier, sir. There was a separate application to renew the licence on 23 December 1977, the reference is MHRA0033321_076 and the same stem, _077.

The renewed licence was issued on 27 October 1978, but with a stated renewal date of 22

March 1978. So two points from that, sir. First, it's that process that we were talking about in the 1968 Act coming into effect. If you have applied for a renewal before your licence expires then it can be, in effect, retrospectively run from the time of the expiration. The second point is that the renewal of the licence, which was approved on 27 October 1978 and backdated to 22 March 1978 is distinct from the decision which was taken on the variation of the licence, which was dated 28 March 1978. These are two, formerly two separate decisions, the extent to which those making them knew or were aware of the other variations is something that we don't know at this stage.

Could we have onscreen, please, Soumik, DHSC0046258_098. We can see here Immuno's price list from 1980, and if we could go, please, to page 6. Listed in the price list are "Kryobulin (red pack -- plasma source -- Europe)", the product licence is the same product licence we were discussing earlier, 0215/0003.

Then further down, "Kryobulin (blue pack -- plasma source -- America)", you can see the same product licence. So these are two variants of Kryobulin which are both available on the same licence

as of 1980.

The bottom of that page, please, Soumik, "Prices available on request", so I can't tell you the unit price here, unfortunately.

SIR BRIAN LANGSTAFF: So a price list says we're not telling you what the price is?

MR HILL: Yes, sir.

I'll turn now, sir, to more information about how much Kryobulin was being used at around this time, 1980.

If we could have, please, RFLT0000363. The next three documents I'm going to show you are all annual returns for the UK Haemophilia Centre Directors Organisation, which were from three different hospitals: Royal Free, one for Northern Ireland and one for the Royal Victorian Infirmary in Newcastle. It's just to give you a snapshot of how use varied across the country at this time.

We can see that this table is for haemophilia A patients. We understand it to include those who were treated for factor inhibitors as well. If we could expand, please, to show the whole document there, Soumik. I won't go through all of the different products, but we can see that Immuno, the total used at hospital in-patients at the Royal Free was 424,585

international units, and for home treatment, 594,814 international units. So approximately 1 million units in total, which made it the second most used commercial product, and indeed second most used product, full stop, after Factor VIII.

What this doesn't do is breakdown between red and blue Kryobulin.

The next one, please, Soumik, is HCDO00001394 -- let me try again HCDO0001394, thank you.

Now, in Northern Ireland, we can see here Immuno is used to the extent of 63,809 international units for in-patients, 597,761 international units for home treatment. That makes it the most used of the products in Northern Ireland. Interestingly, Hemofil, which is just above it in the table is used to a similar but slightly less amount, 520,887 units but all of that was used for in-patients, none of it was used for home treatment.

Finally, HCDO0001451. This is the Royal Victoria Infirmary in Newcastle. These figures are caveated with an asterisk which says "See attached note". We don't have that note, unfortunately, but the point I would take from this is that Immuno, there is no entry next to it, it doesn't appear to have been used at the Royal Victoria Infirmary in Newcastle,

which used, instead, Profilate Factor VIII and Koate in particular. All of those are from 1980.

If we could take that down now, please, Soumik. In 1981, the licence for Kryobulin was altered to allow points of sale to include retail pharmacists, the references are MHRA0033321, page 3, and SHPL000036_005.

There was an application to renew Kryobulin on 2 March 1983, which was approved on 8 September 1983. The references are MHRA0033321_110 and the same stem _026.

The final document I'd like to show you before lunch, sir, if I may, if we have time, is from the DHSS in 1983. It is DHSC0002229_055. This is a document that we will return to. The context of it is, as we can see from the introduction, is that, following a meeting on 3 June 1983:

"... HSIB [which is part of the DHSS] circulated the questions listed in Dr Walford's minute of 14 June ... to suppliers and possible suppliers of coagulation [factors]."

We will come back, sir, to that minute and the questions that were being asked of those manufacturers.

We will see, if you can expand, please,

Soumik -- thank you -- that the following firms are suppliers of blood products to the UK, Alpha, Armour, Travenol, Immuno and Miles Laboratories -- Cutter.

"Annual imports of [Factor VIII] by the above firms total about 42-50 million units.

"With the exception of Immuno the firms state they do not or have ceased to collect in 'Epidemic' areas. All state that their collection centres are FDA licensed."

We'll come back to the replies, as I say, sir, about that. That's something that we will deal with in particular in the November presentations about the response to the risk and particularly the risk of AIDS.

"The plasma in each case is pooled prior to processing. In the case of Immuno products, European plasma and USA plasma are pooled separately.

"The origin of all plasma is identifiable.

"Each has given assurances that future sales will comply with FDA guidelines."

Another point that we will come back to. A further company, Cutter, haven't replied.

If we could go to the next page, please, sir, this is the point I wish to draw out for present purposes. If we look at the entry for Immuno, this is

a table which is based upon the replies that have been given by the companies. We can see that they were asked for their annual UK sales. Kryobulin Red, which is the product made from German or Austrian plasma, is 0.9 million international units; Kryobulin Blue, the product made from American plasma, is 4.1 million units. So 82 per cent of Kryobulin, as of 1983, was the American plasma. I note the time, sir.

SIR BRIAN LANGSTAFF: Yes. Well, we'll take a break until 2.05. 2.05.

(1.08 pm)

(The luncheon adjournment)

(2.05 pm)

MR HILL: Sir, you asked before lunch whether the same criteria about safety, efficacy and quality applied to a consideration of a renewal of a licence under the 1968 Act --

SIR BRIAN LANGSTAFF: Yes.

MR HILL: -- as they did in consideration of the original licence. The short answer to the question is that, yes, they do. That can be found in Section 24, and particularly Section 24(4) of the 1968 Act, which says that when a renewal application is being considered, Section 19 of the Act applies.

Soumik, if we could have up, please,

RLIT0000691, page 11. This is Section 19 of the Act and so that you have the exact statutory language, sir, we can see Section 19(1) says that:

"Subject to the following provisions of this Part of the Act, in dealing with an application for a product licence, the licensing authority shall in particular take into consideration --

"(a) the safety of medicinal products of each description to which the application relates;

"(b) the efficacy of medicinal products of each such description for the purposes for which the products are proposed to be administered; and

"(c) the quality of medicinal products of each such description, according to the specification and the method or proposed method of manufacture of the products, and the provisions proposed for securing that the products as sold or supplied will be of that quality."

Soumik, if we could expand, please, and go on to (2). This is the point about when you can take efficacy of another product into account:

"In taking into consideration the efficacy for a particular purpose of medicinal products of a description to which such an application relates, the licensing authority shall leave out of account any

question whether medicinal products of another description would or might be equally or more efficacious for that purpose:

"Provided that nothing in this subsection shall be construed as requiring the licensing authority, in considering the safety of medicinal products of a particular description, in relation to a purpose for which they are proposed to be administered, to leave out of account any question whether medicinal products of another description, being equally or more efficacious of that purpose, would be or might be safer in relation to that purpose."

That is what I tried to summarise earlier, sir, in, I hope, slightly more user friendly language, about when you can or can't take the efficacy of another product into consideration.

SIR BRIAN LANGSTAFF: Yes. Yes, thank you.

MR HILL: As I say, sir, that applies both to renewal and to the original application.

SIR BRIAN LANGSTAFF: Yes. The criteria don't exclude cost being a consideration, but they don't mention it and they give primacy to those three points.

MR HILL: Yes, cost comes up somewhere else.

So it's Section 20 that deals with the point about costs, which is that:

"The licensing authority cannot refuse a licence on the grounds of price and cannot make a licence provisional on the product being sold at a particular price."

SIR BRIAN LANGSTAFF: So the Licensing Authority could make it a requirement of the licence, could they, that the licensed party informed those who were to receive the product that there was a -- sorry, that the information that would be given to the public, that there was a safer product manufactured by the same company at a different but higher price.

MR HILL: I can see no reason why that couldn't be made a condition of the licence.

SIR BRIAN LANGSTAFF: One --

MR HILL: They could, of course -- one of the ways of doing that would be to specify as a condition of the licence --

SIR BRIAN LANGSTAFF: Yes.

MR HILL: -- or as part of a negotiation which leads to the final licence, but in your product sheet you put a statement to that effect. We will go on to to see in some of the evidence that we look at this afternoon a specific requirement being made by the Licensing Authority about a particular statement, which should be placed either in a data sheet or on a label, so

that is an option that is open to them. What they can't do is fix the price.

SIR BRIAN LANGSTAFF: Yes. Thank you.

MR HILL: One further document, sir, before we move to heat-treated products. Could we have up onscreen, please, Soumik, HCDO0000403. I'm grateful for this having been brought to my attention. This is the "Minutes of the Eighth Meeting of the Haemophilia Reference Centre", held 6 April 1979, at St Thomas' Hospital. We can see those who are present, Professor Blackburn in the chair, and then names that will be familiar to you and those who are watching this.

If we could turn, please, to page 2, the bottom of page 2, item 5. The minutes record this:

"Concerning factor VIII concentrates (Kryobulin) supplied my Immuno Ltd.

"It was pointed out that the company was now selling Kryobulin factor VIII at two prices, the cheaper preparation being made from American plasma. The implication is that the cheaper product carries the higher risk of plasma viral hepatitis. This has worried some of the Directors. Professor Ingram has been in contact with Mr Berry of Immuno who had said that their action was aimed at making available to clinicians material which may carry less risk of

transmitting hepatitis."

There was then some general discussion about the price of Factor VIII and the fluctuation in prices.

SIR BRIAN LANGSTAFF: That expression of the reason for providing two priced products was that the -- it was to make available the safer product, though more expensive, as opposed to the inference from the German document translated, which was that it was exactly the other way around. It was Immuno seeking to give or put on the market something which was cheaper because, well, it was riskier, from American plasma, but their main object was not safety, it was cheapness.

MR HILL: Yes, sir, I would agree with that analysis. The other point --

SIR BRIAN LANGSTAFF: If that's right, and if Mr Berry had been properly informed and if it's properly reported what he said to Professor Ingram, it's almost deceptive. I don't know about the "almost".

MR HILL: There is no evidence for Mr Berry that we have that Mr Berry was informed of those Immuno AG documents. We simply don't know whether or not he was aware of that discussion.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: What we can say from --

SIR BRIAN LANGSTAFF: But he is making a claim for what

the purpose was.

MR HILL: According to this minute.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: Yes.

SIR BRIAN LANGSTAFF: Only if he's reported properly and accurately, that will be so.

MR HILL: The other point that I would make, sir, is that the application that was made to the Licensing Authority -- if we could have it onscreen, please, Soumik -- MHRA0033321_085. So this is the application to change to allow American plasma, and if we could go down to the reasons, please:

"It is possible to sell ..."

So this is the stated reason as part of the application to the Licensing Authority, why they are seeking this change:

"It is possible to sell Factor VIII Concentrates produced from plasma of US origin at lower prices than European based material. Because of the preference in the UK market for this lower priced material, we also wish to make it available. Packs of Kryobulin from alternative source material will be of a clearly distinguishable colour ... and we will continue to make available European as well as the proposed new concentrate derived from American plasma."

SIR BRIAN LANGSTAFF: Yes.

MR HILL: That is the stated reason, and if we could go -- the signature has been, for obvious reasons, redacted on this version. I have a version which seems to be signed by Norman Berry.

SIR BRIAN LANGSTAFF: By Mr Berry?

MR HILL: By Mr Berry.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: That's 11 November 1976.

SIR BRIAN LANGSTAFF: Thank you.

Well, I think it would be in the public interest to remove that GRO-C cover.

MR HILL: We will make arrangements for that to be so. Of course, if any Core Participant wishes to raise any objection --

SIR BRIAN LANGSTAFF: Of course. I'll listen to any objection there is to that course.

MR HILL: I turn now, sir, to the issue of heat treatment.

Soumik, can we have onscreen, please, SHPL0000068_070.

We can see this is a note of a discussion from 24 November 1984, so we've come forward a few years in time. Present are Dr Eibl, Dr Schwarz, Mr Berry and others, including Mrs Diernhofer. This is a meeting in which the heat treatment of Kryobulin was

discussed. If we could turn, please, to the second page -- sorry, the fourth page. Under the heading "Virus inactivated coagulation products", this states:

"Dr Schwarz tried to give a survey of the various heat and steam inactivation procedures."

This is what I alluded to earlier, sir, the different types of treatment which were available as of November 1984. We can look at them here:

"TIM 2 ..."

This is the dry heated treatment:

"... 10 hours, 60°C, dry state.

"TIM 3 -- 10 hours, 60°C, dry state ..."

I pause there to note that although those details at the same, there are other ways in which the two methods differ:

"TIM 4 -- 10 hours, 80°C, dry state.

"Neo TIM 2 -- 1 hour, 60°C, 200 mbar."

That is a reference to it being steam or vapour heated under pressure, and the 200 millibars is for pressure.

"Neo TIM 3 -- 5 to 10 hours, 60°C ..."

Again under pressure.

And:

"Neo TIM 4 -- 1 hour, 80°C ... 250 mbar + 10 hours, 60°C ... [at] 200 mbar."

So those are the different ways in which Immuno were seeking viral inactivation in their products. Different times, different methods of heating, different temperatures. And in one instance a different pressure as well. This applies to Kryobulin but it also applies to the other products that we will consider in due course.

What the meeting then goes on to say is this:

"As to methods TIM 2 and TIM 3, as well as TIM 4 [these are the dry heated treatments] we may run into difficulties with respect to patent protection. There exists a Hyland patent for this kind of inactivation. For methods Neo TIM 2, 3 and 4, we have already applied for patents.

"As Mr Berry explained it will be essential to amend our product licence applications to introduce inactivated products if we do not want to lose the British market. Lane [that's a reference to Dr Lane of BPL] promised that products that have not been virus-inactivated will not be used after April 1985. Bloom [that's Professor Bloom] also stated that he will no longer use any products that have not been inactivated after his stock has run out.

"It was decided that, for the time being, data for Kryobulin TIM 2 should be submitted to the

authorities in order to maintain our market position and to achieve a slight price increase."

The document then goes on to discuss ways of heating FEIBA and Prothromplex.

If we could turn then SHPL0000067_028. It's a letter dated 26 November 1984, so two days after that meeting where the discussion was taking place about the viral inactivation techniques. It is a letter from the DHSS, and particularly from Dr Mary Duncan of the DHSS, to Mr Nicholson, that's Robert Nicholson of Immuno Ltd, the British company. What it says this is this:

"Dear Mr Nicholson.

"HEAT-TREATED FACTOR VIII.

"Following our recent telephone conversation may I confirm that the licensing authority wishes to encourage all companies involved in the production of Factor VIII to use a dry heat treatment process in the course of manufacture.

"We are inviting each company to consider this proposal and, hopefully, to make early (abridged) application for a new product licence.

"I look forward to hearing from you in the near future."

This, sir, is in the context of the

understanding that had developed during the autumn of 1984 that HTLV-III could be inactivated by heat treatment. So we can see there are discussions taking place within Immuno AG and between Immuno AG and Immuno Ltd, and also encouragement from the Licensing Authority, the Department of Health, to put forward applications for dry-heated-treated licences. The following month, December 1984, Immuno applied to change the Kryobulin product licence to introduce a heat-treatment step. That was said to be done "to reduce the risk of transmission of viral diseases". They proposed renaming the product Kryobulin TIM 2.

In a letter dated 18 January 1985, the Licensing Authority required Immuno to confirm in writing that the data sheet for the Kryobulin TIM 2 would include a statement that the product had been heated for 10 hours at 60 degrees.

I pause there, sir, to say that this is an example of the types of requirement that the Licensing Authority can make in terms of how a product is presented to those who are using it.

That was agreed by Mr Berry on 23 January, a variation application was approved on 7 February 1985. So we can see, November, encouragement to make the licence applications for

dry-heated products, licence application goes in in December 1984, and it is approved on 7 February 1985.

So that they're on the transcript, the references are MHRA0033320_066, SHPL0000271_021, SHPL0000271_020, and SHPL0000271_011.

An insight into the way that the process was working at this time is provided by a document that was sent on 8 January 1985, and could we have, please, Soumik, MHRA0019502.

This is a letter which is sent from Dr Duncan Thomas of the National Institute for Biological Standards and Control, the head of the Blood Products Division, and we've heard his name a couple of times today. It's sent to Dr Duncan of the Medicines Division, the same woman who had sent the letter that we have just looked in November, encouraging applications for heat treatment. This is what Dr Thomas says:

"Dear Mary,

"Heat-Treated Factor VIII

"Thank you for your letters of December 18th and 27th, 1984. I have now had a chance to look at three sets of data relating to this product, provided respectively by Miles, Travenol and Immuno. While all three companies are currently heat-treating their

Factor VIII, and appear to be producing a satisfactory product, there are marked discrepancies between them in relation to the temperature and length of time for which the product is heated. The other obvious discrepancy is in the extent to which the companies have used marker viruses to assess the efficacy of their heat treatment. For example, Miles Laboratories have used five marker viruses and heated for 72 hours at 68°C. In contrast, Immuno used only one marker virus and heated their product for only 10 hours at 60°C. Travenol studied four marker viruses and heat-treated their product for 72 hours at 60°C. Just to add to the confusion, I learned yesterday that all Scottish-produced Factor VIII is now currently being heated for two hours at 68°C! I must confess that I find this all rather worrying, particularly as the Licensing Authority has decided to deal with the matter 'in house' and not refer to the Committee for advice.

"On the basis of the data provided, I am [most] impressed with that supplied by Miles Laboratories (Koate, Cutter)."

SIR BRIAN LANGSTAFF: "Most" or is it "more"?

MR HILL: I'm sorry, "more":

"Not only did they use several marker viruses,

they also actually studied effect of heat-treatment on two of the three AIDS-related viruses (LAV and ARV). If they find it necessary to heat to 68°C for 72 hours, one wonders why Immuno believe that they can get away with only heating to 60°C for 10 hours. While it seems reasonable to conclude that all of the regimens of heat treatment reduce infectivity, particularly in relation to AIDS, one is very struck by the variation in quality of the data provided. In particular, I am worried about the paucity of data provided by Immuno in relation to the efficacy of their heat treatment. As you know, we have looked at most of the heat-treated Factor VIII in the laboratory, and find no significant difference from the untreated material in relation to solublity, assay characteristics, evidence for neo-antigens, etc.

"I hope these few comments are of some help to you in your deliberations!

"With all good wishes,

"Yours sincerely,

"Duncan ... Thomas."

We take from that, sir, aside from Dr Thomas' comments on the various products, that the licence applications were being considered, as he put it, in-house, by the Medicines Division of the Department

of Health and Social Services, not being sent out to the Committee on the Safety of Medicines. We will, no doubt, hear further evidence on that, the context, of course, is the pressing need to do something in response to the risk of AIDS.

Mr Thomas' concerns about the quality of the data being provided by Immuno seemed to have been shared with at least some of those in the company.

Soumik can we have onscreen, please, SHPL0000048_026. This is dated 5 March 1985, and it is a letter that is being sent from Mr Berry as chairman, and Mr Coombes as managing director of Immuno Ltd to Dr Eibl and Dr Schwarz in Immuno AG. In respect of Kryobulin, the letter says this:

"Subject to minor alterations in title and direction circular, we have been awarded a Product Licence Modification. We have, however, been informed both unofficially and officially that the information submitted by us for this modification was most inadequate and but for the panic situation which existed to get everyone on heat-treated material as quickly as possible, we would have been turned down. They expected far better proof of inactivation with evidence obtained against 6, 7 or 8 different viruses. They wanted greater evidence shown by clinical

evaluation that the product remained equally effective and with no increase in side effects."

A little later on the same document, towards the bottom of that page, Mr Berry and Mr Coombes go on:

"You will recall that on receipt of both of these amendments [this is referring to Kryobulin and Prothromplex], we phoned and complained about the paucity of information, but you insisted that you were providing all that is needed. It is obvious that the American companies were lavish in supply of detail and our submission had compared most unfavourably. The nadir of our submission was the Gammabulin Product Licence Application."

That was an immunoglobulin.

"Since then our reputation for poor submissions has improved and in fact Endobulin has received a measure of commendation. The Kryobulin and especially the Prothromplex amendments have had a further adverse affect on our reputation."

This is a comment which is echoed in later correspondence about concerns expressed by those in Immuno Ltd about the amount of data, the amount of information, that was being provided to support applications by Immuno AG.

We go a little further down the page, we see,

under the heading of "Pricing", on Factor VIII they write:

"We have been endeavouring to get 14p per unit, but Armour, Cutter and Alpha are selling at 12p. This morning we have learned that Hyland have re-entered the fray at 10.5p.

"We understand that you do not wish to reduce the price to us in order to protect your German business. If, however, these competitors decide to attack you in Germany with lower prices there, then will be no business there, nor any in Great Britain.

"We are also losing established customers to Alpha who maintain that their wet heated method removes the risk of non A, non B hepatitis as well as AIDS. This has the support of the Royal Free Hospital and St Thomas', both of whom have used the material for 6 months on virgin patients without transmitting NANB."

The paragraph below that says:

"When the Ministry first contacted us concerning the issue of heated material, they made it clear they were looking for dry heated products. They now say that this was merely to avoid severe losses if they had specified wet heated. It is our view, however, that they are embarrassed by the new claims for wet

treated material and are trying to avoid a position where they backed the wrong horse. Alpha are, however, selling this material at 14p and are hoping to increase their price to somewhere 15p and 20p."

So that, sir, is a reflection of what was being communicated between Immuno Ltd and Immuno AG at that time.

In a letter to doctors on 11 March 1985, Mr Nicholson notified them that Immuno could supply heat-treated Kryobulin, which would henceforth be known as Kryobulin Heat-treated. So not TIM 2, the name that was given was Kryobulin Heat-treated. The reference is PRSE0002530.

Moving forward to October 1985, there was discussion within Immuno about proposing changing the viral inactivation method from dry heat treatment to what was then described as steam heat treatment. A fax from Immuno AG to Immuno Ltd stated that this was both because test results showed superior HTLV-III inactivation through the use of steam treatment, and, and I quote, "for reasons of patent law".

The reference is SHPL0000050_013. You will recall, sir, from some of the documents that we looked at earlier that there was a concern that there wouldn't be patent protection for dry heated treatment

but there would be potentially for steam for wet heated treatment.

For Kryobulin it was necessary to get a variation in the existing licence in order to provide a steam treated Factor VIII product, because the licence specified the dry heat method. The reference for that is SHPL0000050_011.

It may help at this point, sir, to go to a document which shows which products were available when in the UK, and on which basis.

Soumik, could we have SHPL0000066_001.

SIR BRIAN LANGSTAFF: I'm sorry just to ask you to pause for a moment, because I'm just thinking about what you've just told me about SHPL0000050_011, which was that it indicated that the Immuno would have to show that the wet heated Kryobulin was superior to the dry heated.

MR HILL: Yes, sir, so it's -- in order to get the variation of the licence there was an expectation that you would have to explain why at it that you're now burying this licence which you obtained just some eight to ten months earlier. That would require them to show that the steam treated method was superior or -- certainly the phrase "superior" was used in the document, but --

SIR BRIAN LANGSTAFF: I'm just, in my mind, puzzled by the comparison between this application having to show that the varied product was superior, and the variation earlier on -- which we were discussing just before lunch and immediately after -- as to the variation of source material for the product, where no such requirement seems to have been mentioned.

MR HILL: No, sir.

SIR BRIAN LANGSTAFF: From what you've shown me from the Act, it's not a requirement as such to show that a product or licensing is superior to a previous product.

MR HILL: No, sir, I think this was an expectation within Immuno Ltd about what they were going to need to demonstrate based on their knowledge of how the process worked. It wasn't a mandatory requirement.

SIR BRIAN LANGSTAFF: So it's a form of practical reflection on what they saw or thought was happening, which may or may not be right?

MR HILL: Yes.

SIR BRIAN LANGSTAFF: Yes, I see. Thank you.

MR HILL: The document that we have onscreen now, we can see is sent from Immuno AG to Immuno Ltd, sent to Mr Coombes. It's dated 20 December 1989. It attaches a list of all copies of Kryobulin and Prothromplex

texts. We'll come back this document because it helps us to understand how the warnings developed in the data sheets.

But at the end of the file -- at page 80, please, Soumik -- we have a fax which was sent the other way, from Mr Coombes to Immuno AG. It again refers to pack inserts and it comes from November 1989. And it is, seemingly, a list of the products that were available on the UK market, when they were available, and the status of those products.

We can see the Kryobulin, the non-treated product, which was licensed, was available until December 1984. The dry heated Kryobulin was supplied on an unlicensed basis between December 1984 to March 1985. That ties in with the dates that we've just been discussing.

Then Kryobulin dry heated licensed, supplied from March 1985 to December 1986. Then Kryobulin TIM 3 (steam), so this is a steam treated product, unlicensed, supplied from October 1986 "to date". The date of that is November 1989.

Without wishing to give away the next step in the story, that shows that while Immuno retained a licence for dry heated products in the UK, they did not, in the 1980s, have a licence for steam treated

products, despite the applications that we're going to come on to discuss.

But this document appears to show that that was nonetheless supplied, presumably on a named patient basis, possibly on a clinical trial basis.

The first application to switch to steam treatment was made on 5 March 1986. The reference is MHRA0033320_040.

The pharmaceutical assessor raised several points on receipt of the application, raised them with Immuno, and these included a request for further information on the moisture content in the steam treatment process, and it was noted that the assessor was not convinced that steam treatment offers any advantage over dry heat in terms of viral inactivation. The reference is SHPL0000065_028.

The Committee on Safety of Medicines Subcommittee on Biological Materials assessed the application in July 1986. They considered that they were unable to recommend the variation on the grounds of quality and safety, and requested further information about the process and justification of the steam treatment. They also noted, and I quote here:

"The term 'steam treatment' is a misnomer and is unacceptable."

The reference is MHRA0033320_044.

The application was rejected on 11 July 1986, SHPL0000271_008.

We will come back to the terminology, steam treatment or vapour treatment, when we come to look at the packaging.

Immuno prepared a variation application to change to what was now termed a "vapour heated product", after getting that rejection. The reference is SHPL0000141_220.

In a memo which is at that reference it was stated that:

"It [was] essential that we obtain the Kryobulin licence amendment as soon as possible as we are now no longer able to apply for Factor VIII contracts due to the fact that we do not have a licensed product."

The variation application -- the next variation application was sent in a letter on 23 December 1986. The term used was "vapour heated product". It was a method 3 product, so a steam TIM 3 product. It was differentiated from the March 1986 variation, which had been unsuccessful, and Mr Berry said in his submissions to the Department that the proposed changes would introduce into the UK, in his words, "the most rigorously treated Factor VIII concentrate

currently available from Immuno". He stressed that the product for which the licence was sought was totally different, in terms of heat treatment and viral inactivation profiles, from that which had been rejected in March 1986.

He stated that the concentration of HTLV-III was reduced by six log steps after vapour heating for three hours, but to ensure an even greater level of safety, in his words, it was heated for a further seven hours.

The reference is MHRA0033319_017.

The sum total of that is that the product was heated for 10 hours at 60 degrees Celsius in the presence of moisture.

The variation application included information that the donors were tested for antibodies for HTLV-III using FDA approved tests.

It was stated, and I quote here -- actually,, Soumik, can we have this on the screen, please, MHRA0033320_006.

That, sir, is now -- I'm sure people will now begin to recognise this as a variation application form. You can see that it's to vapour heated Factor VIII, method 3.

If we could go, please, Soumik, to page 3 of

that. This is what it said about the -- underneath the headings "Precautions and warnings":

"The careful selection of donors and plasma and the vapour heated treatment process which has been shown capable of reducing artificially introduced HTLV-III by 6 log steps, suggests that in the light of present knowledge the transmission of HTLV-III can be excluded.

"The above measures will certainly reduce the risk of transmission of viral hepatitis. This is being demonstrated by the fact that upwards of 20 naive patients have been followed up by ALT tests for 4 months and have not acquired NANB infection but transmission cannot be entirely ruled out."

So that is what was said or proposed to be said in the warnings were an application to be granted.

The application was considered by the CSM Subcommittee on Biologicals in July 1987.

Soumik, could we have up, please, MHRA0033319_044.

You can see that the Subcommittee recommendation was that:

"On the evidence before [them], the Subcommittee on grounds relating to quality and safety were unable to recommend the grant of the variation of the Product

Licence for this preparation."

I won't go through all of the points which are raised as to why they came to that conclusion, but I would highlight point 12 -- which is on the following page, Soumik.

"There was concern regarding the transmission of Hepatitis B by this product."

There was also a remark to the company from the Subcommittee:

"In view of the number and importance of variations contained in this application a fuller and clearer list of where changes in application and quality control standards and procedures should have been given."

Again, the complaint about Immuno not providing sufficient information to back up the applications.

Mr Coombes from Immuno Ltd wrote to Immuno AG on 20 July 1987 to relay the fact that the variation was going to be rejected, and to give details of conversations he had had as to why it was going to be rejected. One of the things that he said in that letter is that the Subcommittee were currently looking at products heated at 80 degrees for 72 hours, and therefore products heated for 10 hours at 60 degrees were looked upon with great suspicion. He adds:

"They know that dry heated products at 60 degrees for 30 hours have caused seroconversion in the United Kingdom."

Which I take to be a reference to Factor VIII. We'll come on to that in due course. The reference is at SHPL0000141_151, and SHPL0000141_158.

There was a meeting between representatives of Immuno Ltd and Immuno AG, and members of the Licensing Authority, to discuss the variation application, not just Kryobulin but also Prothromplex and FEIBA. That took place on 12 August 1987.

Immuno undertook to withdraw the applications and agreed to submit an abridged product licence application for Kryobulin, including expert reports. The reference is MHRA0033319_040, and SHPL0000141_136. The formal rejection of the application came on 16 September 1987, the reference is MHRA0033321_021.

I'm not going to go through those documents, sir, but the references are there, and if people are interested in how the licensing process worked and the way in which discussions took place between representatives of the company and representatives of the Licensing Authority, those documents provide some insight into that.

A further application to -- sorry, not

a further -- an application to renew the existing dry heat-treated licence was made on 3 March 1988. Now, the submission that accompanied the application pointed out that the dry-heated product was no longer sold in the United Kingdom, and Immuno were currently preparing data for an abridged licence application for a vapour-heated product which they hoped to sell instead. The references are MHRA0033319_001, and the same stem, _ 002.

The point here, sir, is that they have the licence for a dry-heated product, even though they're not selling that product in the UK they want to maintain the licence so that they can then apply to vary it to produce the steam-treated product, rather than starting from scratch and putting in a new licence application. It should be noted that the Licensing Authority were made fully aware of the fact that this is the approach that they were seeking to take.

Soumik, if we could have onscreen, please, SHPL0000141_097. The situation as of 7 July 1988, as we understand it from the documents that we have looked at, is that Immuno Ltd were still providing UK clinicians with a Kryobulin product, it was a steam-treated product, the only that was available

in the UK at that time, but it was unlicensed steam treated product, so presumably it was being provided on a named-patient basis, possibly on a clinical trial basis. What is said in this letter to Dr Schwarz is as follows:

"We have been informed this week that the Regional Haemophilia Directors in the UK have sent a circular letter to all Haemophilia Centres informing that the only Factor VIII products to be used in the UK are as follows, in order of priority:

"1. Factor VIIIY [from] BPL

"2. Haemate P [from] Behring

"3. Profilate [from] Alpha

"A customer of ours who has constantly been in touch with us to establish when we are going to obtain a Licence, has contacted one of the Regional Haemophilia Directors in response to this letter and has been informed that if she uses unlicensed products then she will not have any backing from the Haemophilia Directors and must take sole responsibility for its use. She is, therefore, now having to decide whether to change to another product. We will have to be very careful that this situation does not sent to Feiba as this currently provides a very important part of our turnover."

FEIBA being a different product.

So we could see there that steam-treated Kryobulin was still being provided, but there were concerns amongst Immuno Ltd that its market share was diminishing rapidly.

There are further letters -- I won't go through them all, I will give the references in a second -- the general tenor of which is Immuno Ltd contacting Immuno AG, urging the need to sort out licence applications and to get a licence in order to protect market share for Kryobulin within the UK.

The references are SHPL0000141_086, the letter dated 27 September 1988; SHPL0000010_005; and SHPL0000106_165. That final reference contains a note from Mr Coombes to Immuno AG saying that their current licences could be cancelled, these are his words:

"... if the DHSS realise that Kryobulin and FEIBA are dry heated and Prothromplex is non-heat-treated."

So he's concerned about the cancellation of those licences. It should be added that the dry-heated Kryobulin was not being sold even though the licence still existed.

There was -- an abridged product licence for Kryobulin was made on 24 May 1990, so sometime after

those initial letters. The reference is SHPL0000068_001. This was, again, referred to as a "method 3 product".

So that application was made on 24 May 1990. The next correspondence that we have, which is relevant to the licensing, comes from 30 April 1991, so nearly a year later, and it is from the Medicines Control Agency, who, as we know have taken on the work of the Medicines Division. That renewed the existing Kryobulin heat-treated licence. So we understand that to be a renewal of the dry heat-treated product. That is SHPL0000067_001.

The application to vary that licence to a vapour-heated product was considered by the Committee on Safety of Medicines on 27 June 1991, and on 8 July 1991 they informed Immuno that they were unable to advise the grant of a product licence on grounds relating to safety and quality. The reference is MHRA0034575_058. Several reasons were cited, including concern over the transmission of hepatitis B and non-A, non-B hepatitis and also, in quotes, "the risk/benefit ratio was unacceptable".

Mr Coombes subsequently wrote to Immuno AG on 31 July 1991, the reference is SHPL0000106_094. What he said in the letter was, and I quote: **

"I suspect that six log steps is no longer acceptable to the Licensing Authorities, and we will not be able to show a significant improvement from dry heat."

He noted in the letter that: **

"By contrast, another product, Monoclate was claiming a reduction of HTLV spiked virus over 15 log steps."

So the concern is expressed by Mr Coombes in this letter, in effect, that the viral inactivation method that Immuno were seeking to have licensed, compared unfavourably with those that, by that time, were on the market and being considered by the Licensing Authority. He thought that they were going to have great difficulty in getting a licence.

There were further meetings with the Medicines Control Agency, SHPL0000106_080, in which there was a discussion about why the Medicines Control Agency were reluctant to grant the licence. I won't go through it, people are invited to consider and read it again as it shows an insight into how this works. But, to sum it up shortly, it's fair to say that the MCA were not persuaded that vapour heating was effective. They said that there was a spectrum between, on the one hand, dry-heated products at the

lesser end of effectiveness, and what was referred to as pasturisation, so that's heating in a solution, at the other end, which was safer, and the MCA considered that steam treatment was -- vapour treatment was somewhere in the middle and they couldn't quite place where on the scale it was. That was one of the reasons why they were not allowing the application.

As we move into 1992, I won't go through all of the correspondence, there was a decision taken that the Kryobulin heat-treated licence should be given up, and an acceptance that there was no way that they could be used in the future by Immuno Ltd, and an acceptance, it seems, that the steam-treated product -- sorry, the vapour-treated product was not going to get through the Licensing Authority. The references are SHPL0000148_001; SHPL0000067_006; and SHPL0000067_005.

The licences for Kryobulin heat-treated and indeed for Prothromplex were cancelled by the MCA on 14 April 1992.

That, sir, is the story of Kryobulin. It's been slow going but hopefully, having seen some of these documents, there will be no need to go back to them and there will be a greater understanding of how the process works and we'll pick up some pace, I hope,

going forward. I am about to turn to Prothromplex. I'm conscious of the time, I don't know if you wish me to continue or to take a break at this stage.

SIR BRIAN LANGSTAFF: Well, if it's a convenient moment to take a break, yes, we'll take a break until 3.20.

MR HILL: Thank you, sir.

SIR BRIAN LANGSTAFF: Make it 3.25, to allow people time. 25 past.

(3.01 pm)

(A short break)

(3.25 pm)

MR HILL: Sir, we turn now to Prothromplex, which was the Factor IX product. Serological Products Ltd applied from a product licence for Prothromplex on 20 December 1972, SHPL0000197_078. It was stated that it was manufactured in Austria and would be imported into the United Kingdom. The warning was given in similar to terms that we've seen before, and I quote:

"Despite the precautions taken in the selection of donors the risk of transmission of homologous serum hepatitis cannot be entirely excluded."

That is SHPL0000197_092. At the same time there was an application for a clinical trial certificate for Prothromplex for a particular -- for its use in a particular purpose. That's SHPL0000665_019. So two

applications: product licence and clinical trial certificate.

The application was successful and a licence was issued in August 1973. One document that falls between the two periods, which is of interest, is at SHPL0000665_142, if we have that onscreen, please, Soumik. This is a letter or a fax sent from Mr Berry to Dr Eibl on 17 March 1973 and in relation to Bebulin, which I understand to be an immunoglobulin, and Prothromplex. It says:

"The committee of Safety of Medicines ask that we

"Test the final products for absence of HAA ..."

Which is Hepatitis Associated Antigens, so as well as testing for donors you test for final product as well.

If we look at point 7:

"The Committee sees the justification of some risk of hepatitis in treating a haemophiliac who would otherwise die from Haemorrhage."

So we can see the risk/benefit analysis as reported by Mr Berry as having been considered.

The licence, as I say, was issued on 14 August 1973, SHPL0000197_078, and the clinical trial certificate was also issued on the same date,

SHPL0000665_019. The formal licence was issued on 10 December 1973, SHPL0000197_004. So the same process again, but a letter of intent to issue a licence stands as the licence.

It is sometimes said or thought, sir, that the United Kingdom was practically self-sufficient in Factor IX, but we can see from Prothromplex that the product was used in the United Kingdom for the treatment of patients who required Factor IX.

If we look at BAYP0000022_069. This is a document, we don't know the hospital from which this comes but, for reasons I'll explain, we suspect it comes from a Scottish hospital. It comes from a department of haematology and blood transfusion and it the gives totals of products used in 1975. We can see the Factor VIII there lists cryoprecipitate, Hemofil, Kryobulin and Edinburgh concentrate (PFC), which is why we suspect this probably, given that it's in 1975, is a Scottish hospital. If we go down, we can see Factor IX -- sorry, just go up a little there, Soumik, thank you.

So the Factor IX totals, by the far most used product is Edinburgh Defix, provided by the Protein Fractionation Centre, 403,600 units. Prothromplex, stated as being from Immuno in Vienna, is 30,000

international units. So we can see that the product is being used.

Indeed, if we look at OXUH0000212_002 -- sorry, OXUH0000212_002. Thanks. These are the annual returns of 1978, as collected by the UK Haemophilia Centres, and collected, in particular, by the Oxford centre. If we look at page 3, please, Soumik. We can see that Prothromplex is listed as one of the materials used for haemophilia A patients with Factor VIII antibodies. So for antibody patients 12,000 units of Prothromplex have been used.

If we could go to page 5, please, Soumik. While we are on this document and because we will be coming it to later, we can see at the same time for FEIBA, this is for Factor VIII antibody patients, 1.928 million units of FEIBA used at this time, and we'll come back to that in due course.

The Prothromplex product licence was renewed on 17 August 1978, SHPL0000377, and in September 1981 we have a letter from Mr Berry which states that Immuno AG "only have permission to use European plasma for Prothromplex". That is SHPL0000271_040. So only European plasma at that time, 1981.

If we could have onscreen, please, DHSC0002229_055, this is the same document that we

looked at earlier, sir, this is the DHSS document collating the information that was providing in response to Dr Walford's questionnaire of the manufacturers. If we go to page 2, please, Soumik. This is dated 28 June 1983. If we look at the heading for Immuno, we can see annual sales for Prothromplex of 0.8 million international units, and it is stated to be for Factor IX, although this is a table which doesn't go into a great detail, it may also have been being used for Factor VIII inhibitor patients. Interestingly, in this table, it is stated that Prothromplex is made from European or US plasma.

Now, we don't know the basis for why that is said. It's something that we will continue to investigate. But you will have seen from the previous reference, September 1981, the understanding was that there was permission only to use European plasma. It could be a mistake on the table, we don't know. But that is something that we will continue to examine.

Again, I note FEIBA there, 1.5 million international units provided in 1983 on an annual basis.

By November 1984, Immuno were preparing to submit a variation for Prothromplex licence, which was for a dry heated product, heated at 10 hours at

80 degrees. So this was what was known as the TIM 4, the method 4 dry heated product.

The reference is SHPL0000168_020, SHPL0000168_022, and SHPL0000068_070.

It's not entirely clear when the variation was submitted. It was being prepared in November '84, we don't quite know when it was submitted, but we do have a note from 5 March 1985 to say that the application had been rejected. The reference is SHPL0000048_026.

We looked earlier, sir, at some of the documentation about the urgency with which heat-treated products were being approved at that time, in terms of Factor VIII. But despite the application taking place in exactly the same period, the Prothromplex application was refused, and one of the reasons given was the need for, and I quote "clinical proof that heat treating does not cause thrombogenicity". So this is a recurrent concern with heat-treated Factor IX products that, by treating those products in order to try to inactivate HIV, you may be increasing the risk of causing blood clots as a result of the nature of the protein changing in the heat treatment process.

So that is one of the reasons why this application was unsuccessful.

Even though that application was unsuccessful, there is evidence that Prothromplex TIM 4, the dry heated TIM 4 product, was nonetheless available in the United Kingdom, presumably on a named patient basis. Could we have this onscreen, please, Soumik -- SHPL0000067_054.

We have a fax from Mr Nicholson of Immuno Ltd to Immuno AG, 21 December 1984, particularly to Mrs Diernhofer of the licensing department. It says:

"Thank you for your combined efforts in getting new heat-treated packaging done for Kryobulin, FEIBA and Prothromplex. Our initial stocks have not arrived."

Then it says:

"We were slightly concerned that the PL and PA nos. [so that's product licence and product application numbers] appeared on the Kryobulin TIM 2 and [product licence] no. on the Prothromplex TIM 4 as both these are still unlicensed products.

"We will probably have to send a letter with each consignment so that customers do not believe the products are already licensed."

Evidence, sir, that the unlicensed product is still being provided within the UK at that time and that there has been a mix-up in the labelling of that

product.
A further document may assist, sir.
PRSE0002530.
SIR BRIAN LANGSTAFF: Just pausing there for a moment. If the named patient basis was the only basis for supply, then it seems rather odd that there is a consignment, references to a consignment, and that customers don't believe the products are already licensed, because by definition if it's for a named patient, that's what will have been applied for by the clinician and they know perfectly well that it's not licensed, which is why they're asking for a named patient basis supply.
MR HILL: That's correct, sir, there is a possibility that the concern would be that the customer knew that a licence had been applied for, and that if they received a box which has the licence number on it, they would understandably assume that the licence had been granted. So it may be that that was Mr Nicholson's concern and that was why he was intending to send the letter.
SIR BRIAN LANGSTAFF: Yes. So the product they wanted, they were getting, but this is a bit of information which just needed to be right?
MR HILL: Yes.
SIR BRIAN LANGSTAFF: I see.

MR HILL: Yes.
If we could have a further document up, PRSE0002530, tab 102.
Now, this a document which is dated 11 March 1985. The opening paragraph informs doctors, and it's a "Dear doctor" letter, that the product licence for heat-treated Kryobulin had been granted, and then ... sorry, if we could go back to the full -- thank you, Soumik.
It then goes on to discuss some other aspect of the Kryobulin element.
Then it goes on to say:
"As you may know, we have held a Product Licence for our Factor IX concentrate, Prothromplex, for over 11 years, but at the present time our standard product is no longer available within the UK. We are in the process of seeking an amendment to our Licence to supply heat-treated Prothromplex TIM 4., but until this has been approved, we can only supply this on a doctor/named patient basis."
Then it goes back to Kryobulin.
I draw this to your attention, sir, for your consideration about the prohibition, as we have discussed, on advertising and making representations about a product. We make no submission on that now,

but it is a matter that you may wish to consider. But what this does show is that the non-heat-treated Prothromplex was no longer available in the UK, that Prothromplex TIM 4 could be supplied on a doctor/named patient basis, even though it was not licensed.
A little context for that letter comes from a fax sent from Immuno Ltd to Immuno AG the following day. That letter was dated 11 March 1985; this fax is 12 March 1985.
Soumik, it's SHPL0000048_029. If we go down to the second paragraph, the first paragraph concerns a different form of heat treatment which I won't trouble everybody with now.
It says:
"As we predicted hospitals are now changing over to heat-treated Factor IX as there is no health service product available. There is a market for at least 12 million units and our competitors are already taking this business with their competitive prices. I appreciate your problems with prices in other countries but we cannot understand why this does not seem to bother all of the other blood product companies, Alpha, Travenol, Cutter, Armour who also sell in Europe.
"We could do well the Prothromplex TIM 2 if we

can move quickly and the price looks very interesting."
That is a reference to the other form of heat-treated product which, as far as I understand, was not made available in the UK. But the previous paragraph is the context to which I wished to draw your attention.
On 4 April 1985, the previous correspondence coming from the previous month, Immuno AG informed Immuno Ltd that they shouldn't take any further action on licence variations for Prothromplex, because there was an expectation that they would soon receive some additional data about viral inactivation against HTLV-III. That's SHPL0000048_025.
So, as of April 1985: no licence and stop seeking to make any variations to the licence until we have this new data.
SHPL0000048_024, please, Soumik.
11 April 1985. Mr Berry faxing Immuno AG saying:
"We need further evidence that anti-viral treatment photograph Prothromplex and FEIBA does not cause thrombogenicity. We are selling substantial quantities of both products and if you will advise us on what tests will clarify the situation, we can

arrange to have these done."

So substantial products of Prothromplex being sold presumably on a named patient basis, at a time when there had been an instruction not to take any further action on the licence.

Soumik, if we could have on screen, please, SHPL0000066_01. It's page 80. This is the same document that we saw earlier, which provides an overview of when products were available in the UK, and the nature of those products, and we can see for Prothromplex that there was a licensed non-heat-treated version available until December 1984. That's when the non-heat-treated ceased to be available. Then Prothromplex, TIM 4, dry heated, unlicensed, from December 1984 to November 1985. So at the time that we are talking about here in these letters it seems to be the dry-heated TIM 4 which is being provided on an unlicensed basis.

Prothromplex Steam 2, January 1986 to September 1986, on an unlicensed basis -- forgive me, I'd said earlier that I didn't think that that was provided, but it was -- and Prothromplex TIM 4, steam treated, January 1987 to the date of the letter, which is November 1989, and although it is not stated in the

letter, as we will from the documents, that product, too, was unlicensed.

So the last licensed variant of Prothromplex in the UK was sold in December 1984.

If we could just leave that up for a moment. The Prothromplex product licence was renewed on 13 September 1985, SHPL0000377, again that was given retrospective effect, so this is for the non-heat-treated product that the licence remains so that they can apply for variations to it.

The TIM 4, steam treated, which was introduced in January 1987, that was heated at one hour -- for one hour at 80 degrees and for 10 hours at 60 degrees, and it was increasingly to that product that Immuno sought to change the licence.

If we could -- yes, we can take that down now, please, Soumik, thank you.

There was another variation application submitted on 23 December 1986, MHRA0033300_033, but that was withdrawn on 8 September 1987, SHPL0000106_220.

The non-heat-treated licence was renewed on 21 February 1989, SHPL0000377. Even though the product wasn't being sold, it is still there to allow for the variation applications to be made.

Mr Nicholson commented that he was rather surprised that that licence was renewed. The reference to that is SHPL0000175_009.

There was a further application to vary the Prothromplex licence in September 1990, SHPL0000311_039, and this was the steam-treated TIM 4 variant. The CSM, Committee on Safety of Medicines, considered that application, and concluded that they were unable to advise the grant of the variation on grounds of safety and quality. They provided several reasons, including the view that:

"In view of a potential for hepatitis transmission by the product, the risk/benefit ratio was inappropriate."

The reference is MHRA0034575_060.

SIR BRIAN LANGSTAFF: Is there any documentation, which we have from the Licensing Authority itself, about the renewal of licences for non-heat-treated product in the mid-'80s and again in '89, '84 and '89 -- '85 and '89.

MR HILL: We can check to try to find further detail.

SIR BRIAN LANGSTAFF: But, on the face of it, it looks a little -- it looks as though it might require further investigation because it could well be that these are products which, not being heat-treated, may

not have viruses in them inactivated.

MR HILL: Yes, sir, I think we will investigate it further. A possible answer is that the advantage to a company of maintaining that licence, even if they're not selling the product, is that the licence is then there and they can apply to vary it.

SIR BRIAN LANGSTAFF: This isn't a question really about the advantage to the company.

MR HILL: Yes.

SIR BRIAN LANGSTAFF: It's a question about the reason for the Licensing Authority giving a licence. Why would you give a licence to a company for unheat-treated product if, at the time, the only products which were supposed to be distributed, at least for Factor VIII and probably for Factor IX, were those which had been heat-treated.

MR HILL: I don't want to pre-empt the evidence that may be given later --

SIR BRIAN LANGSTAFF: But, I mean, that's the subject of inactivation, there may well be some reason for it and I'm just wondering if you knew it at this point.

MR HILL: I don't have any firm evidence. What may have been in their minds, and we can see it from the Cunliffe report, is that it's easier for the Licensing Authority to consider an abridged product licence when

the licence is already there, and then you look at the steam-treating method or the dry-heat-treating method and see if it is sufficient to allow the licence to be granted.

It might be that it is more efficient, quicker, to do that than to get rid of the licence and start again from scratch. The licences can be dependent upon an undertaking that a product is not actually being sold at that time, so there may be an understanding that that is why. But that is something that we have to look into, sir.

There is no evidence that I have seen that any of these untreated products were actually being imported and used in the UK at that time.

SIR BRIAN LANGSTAFF: No, well, I follow that. It's just rather curious --

MR HILL: Yes.

SIR BRIAN LANGSTAFF: -- and I suppose it fits in with the licensing regime because the Licensing Authority can take into account matters other than the three principal ones. I'll wait to hear in due course.

MR HILL: Yes, there is certainly -- as we've seen, there are one or two eyebrows raised in the correspondence from people within Immuno Ltd, saying that they were surprised that the licence renewal had been approved.

I won't go through all of the correspondence, sir. There is a similar pattern for Prothromplex as there was for Kryobulin, an increasing acceptance from Immuno Ltd that there wasn't going to be an acceptance of their steam treated methods by the Licensing Authority. And by the early 90s there is an acceptance that they're going to give up these licences. And as we've heard, and I've cited the references before, the licences for both Prothromplex and Kryobulin were cancelled on 14 April 1992.

One point which is perhaps worth making at this stage is that although a licence wasn't granted for the TIM 4 steam vapour heated product, there is some evidence that it subsequently came to be considered by some, at least, as one of the more effective heat-treating methods at that time. We have an email from Dr Peter Foster, who has given evidence both to Lindsay and to Penrose. He was sometime Head of Research and Development at the PFC in Edinburgh.

If we could have on screen, please, Soumik, MACK0002301_022.

In this email Dr Foster is responding to a question that has been asked of him, seemingly about which products were considered to be safer as time went on. What Dr Foster is this, and this is dated

11 January 2000:

"Perhaps we need to begin by defining which products we now regard as being hepatitis C safe. According to recognised international experts (Mannucci and Horowitz), these would have been:

"a. Solvent/detergent treated.

"b. 80 [degrees Centigrade] dry heated.

"c. Pasteurised [at] 60 [degrees Centigrade for] 10h.

"d. Vapour heated (Immuno) - final version (TIM 4)."

And he cites Horowitz and Mannucci. The two articles are PRSE302445. That's the Horowitz article cited there. And the Mannucci article is DHSC0038508_045.

Dr Foster goes on to say:

"[Solvent detergent] products did not have marketing approval in the UK prior to 1989 at the earliest.

"Pasteurised Factor VIII from Germany was not generally available because of the very low yield/small quantities exported (I have a copy of Behringwerke's export figures for this period which prove the point).

"The earlier Immuno vapour heated (TIM 2/TIM 3)

products did transmit hepatitis -- precisely when the TIM 4 version became available in the UK is unclear (possibly around 1986-87).

"Therefore, apart from 8Y [that was a product produced by BPL], the only 'hepatitis-C safe' Factor VIII likely to have been available in [England and Wales] prior to 1989 would have been Immuno's TIM 4 product -- it is difficult to imagine that this would have accounted for all the imported Factor VIII used at this time."

Now, I pause there, sir, to make a couple of observations on this, and these are made in no way critically of Dr Foster. But the TIM 4 product that was in the UK, so far as we can tell from the papers, was the Factor IX product, Prothromplex, not the Factor VIII product, Kryobulin. The date from which it is available, and we've seen it from the documents we've looked at, was some time around January 1987, which ties in there with what Dr Foster was saying.

The further point that I make about this is that the fact that, in 2000, one can look back and say that this was a hepatitis-safe product does not mean that the Licensing Authority somehow got it wrong at the time; they were working with different data and were responding to the application that they had in front

of them.

I will just cite a couple of other articles just by reference to their URNs. IPSN40156_093, which is an article from Professor Mannucci and others from a British Journal of Haematology in 1988, volume 68, pages 47 to 430. That includes a study of the TIM 3 product, which found that four of the 28 previously untreated patients in Italy who were given that product developed hepatitis B.

We've seen the documents, references to the Licensing Authority being concerned about the transmission of hepatitis B, and that may be where those concerns came from. However, the findings of that study were challenged by Immuno, two references SHPL40174_002 and SHPL0000106_099. The scientists including scientists from Immuno questioned the way in which the Mannucci trial had been conducted, and about the findings of hepatitis B that were associated with the TIM 3 product. As of April 1991, Immuno's position was that the Italian study, Mannucci study couldn't be said to be "appropriate to document the virus safety of Kryobulin". So they were contesting that study and I've already given a reference to a subsequent study by Professor Mannucci which primarily concerned the TIM 4 product, but also refers

back to his earlier work.

That, sir, is all I say about Prothromplex.

I turn now to FEIBA, which is the Factor VIII Inhibitor Bypassing Fraction, which is what FEIBA stood for. The reason I couldn't remember what the "A" stood for was because the "A" doesn't seem to stand for anything. But it's Factor VIII inhibitor Bypassing Fraction, so a product that was primarily intended to assist those who needed Factor VIII that had developed inhibitors.

SIR BRIAN LANGSTAFF: I think it may stand for "agent".

MR HILL: It may, yes, sir.

We know from a letter dated 12 August 1975 that there was notification to doctors of a new product called Fraction R, and that's an early name for FEIBA. That's at CBLA0008057. That's the first reference that we have been able to find to FEIBA in the UK market, so that's 1975.

A 1976 report on the clinical application of FEIBA detailed how it had been administered to 52 patients in 17 European haemophilia centres, including the Manchester Royal Infirmary, that's SHPL0000086_031. So we can see from that that by 1976 it was certainly being used in trials in the UK.

Immuno applied for a product licence for FEIBA

on 30 March 1977, SHPL0000086_011. That application was considered by the Committee on Safety of Medicines, and a provisional decision was communicated on 9 August 1977, in which the CSM indicated that they may be unable to recommend the product be granted a licence, because the application was:

"... inadequate to judge the product on safety, quality and efficacy."

That's SHPL0000085_114. So it is not saying that it wasn't safe, efficacious and of acceptable quality, but that they had inadequate material to judge whether it was -- met those criteria.

Immuno met with representatives of the Licensing Authority in September 1977, and they were told at that time, or it was hinted at that time, that they would succeed with an application for a clinical trial certificate, but they would need to provide more information if they wanted a full product licence.

That reference is SHPL0000085_111. So the Licensing Authority also saying that they wanted convincing trial reports concerning efficacy -- they need more information if they're going to give a licence.

Even though FEIBA remained unlicensed, it did -- it was used widely within the UK. If we could have,

please, Soumik, OXUH0000212_002, the annual returns for 1978, which we've seen before. If we could go on, please, to page 3. There we can see 1.928 million units of FEIBA in 1978, an unlicensed product. SHPL0000085_095, please, Soumik.

This is a fax dated 18 June 1980, sent from Mr Berry of Immuno Ltd to Immuno AG, and it says this:

"in view of the long discussion i have had with our medical advisor, and due to the fact that professor bloom has written to us as follows ..."

It says:

"... i am completely revising my treatment schedules for our patients with inhibitors and in the immediate future our first line of attack for high responders will be with feiba. at least this is the only material that has given us significant controlled clinical trial."

What Mr Berry says in light of that is, and I quote:

"i intend applying for a product licence for feiba."

So he's going to apply for that licence, the date is June 1980. The application wasn't made until September 1981, the reference for that is SHPL0000091_005.

A further reference is at SHPL0000209, which is to -- part 4 of the application which summarises clinical data and includes a note that:

"In nine cases the transmission of hepatitis, as a result of the FEIBA treatment, could not be excluded."

The Committee on Safety of Medicines considered the application in February 1982. The assessment prepared by the Subcommittee on Biologicals noted that the product had been available on a named patient basis for six years, and said this:

"Nearly 1 million units were used in the NHS in the last complete year for which records are available and the total use over the last six years is 14.5 million units."

That's DHSC0105547_002.

The same assessment which was prepared for the Subcommittee on Biologicals gave the view that there was evidence of efficacy of FEIBA, but while it was quite extensive it was largely anecdotal and uncontrolled, meaning no controlled experiment was run alongside the trial that was being done.

"The CSM main committee advised that they were unable to recommend that a product licence be granted on grounds related to quality and efficacy. In

particular they noted that adequate evidence of efficacy in relation to several claims should be provided in addition to complete data of the manufacturing process and on product labelling."

That is DHSC0105547_002.

Immuno were informed of the CSM's decision by letter of 19 March 1982, SHPL0000093_018.

On 26 October 1982, Immuno wrote to the CSM providing additional information, and that included the fact that the United States had issued a product licence for FEIBA, and that had been done on 24 September 1982, and we can see from the other documents I've cited that the product by this time was also licensed in Brazil, Denmark, West Germany, Switzerland and Austria.

The same letter, of 26 October 1982, said that Immuno weren't going to advise the use of FEIBA for patients with Factor IX and IX A inhibitors anymore, just Factor VIII. That's SHPL0000104_037.

Further written representations were made to the DHSS on 1 June 1983, SHPL0000093_009, and that included a copy of a data sheet that warned that:

"Despite precautions taken in the selection of donors and the testing of donations, it is impossible to exclude transmission of viral hepatitis."

The further submissions were considered by the Committee on Safety of Medicines on 21 July 1983, and their conclusion was that it was still unable to advise that a licence be granted on the grounds of efficacy and quality. That was communicated to Immuno on 5 September 1983. SHPL0000104_026.

If we could have on screen, please, Soumik, SHPL0000085_037.

This is a letter from Mr Berry to Immuno AG, informing them of the rejection of the licence. The first two paragraphs of that letter it says:

"We have now been informed that the Committee of Safety of Medicines are unable, on the grounds of efficacy and quality, to recommend the Licensing Authority to issue a Product Licence for FEIBA.

"You will notice that they have not included, 'on grounds of safety', so we will not be prevented from continuing to sell on a doctor/named patient basis."

That is dated 27 September 1983. I pause there to note, sir, that other licences, notably for Prothromplex, were rejected on the grounds of safety and, from the documents we have seen, I've seen no suggestion that they ceased to be sold on a named patient basis because of that.

SIR BRIAN LANGSTAFF: Is there anything in the Act which would lead to that conclusion?

MR HILL: Not as far as I'm aware.

SIR BRIAN LANGSTAFF: So the only barrier might be, assuming there is no other statute that might preclude the sale, might be the duty of a doctor to take reasonable care for his patient -- the law of negligence, in effect -- and if something is not known -- or ought to be known as not reasonably safe, not using it.

MR HILL: Yes. But the other option that was available to the Licensing Authority, as we saw from the way that the named patient secondary legislation developed, was that by 1984, or 1985, that there was a process by which the Licensing Authority had a period, I forget now if it was 28 or 35 days, but they had a period in which they could say that they were not prepared to allow --

SIR BRIAN LANGSTAFF: Yes.

MR HILL: -- the --

SIR BRIAN LANGSTAFF: But this pre-dates that, doesn't it?

MR HILL: This is September 1983. Yes, it does. But that would have been governed by the previous order, which meant that they at least -- the Licensing Authority had to be notified, and they could have taken action

thereafter when they were notified.
SIR BRIAN LANGSTAFF: Under what head?
MR HILL: I --
SIR BRIAN LANGSTAFF: You can come back to me on that.
MR HILL: I will come back to you on that, but I -- I think it may have involved the use of stop orders, but we will come back on that.

On 29 October 1984, so stepping forward a year, Mr Berry informed the Medicines Commission that he intended to make representations and have a hearing about the FEIBA application, SHPL0000104_017. So this is the appeals process that the Act allowed for.

As part of the -- sorry, I've written down 29 October 1984, I suspect that actually should be 29 October 1983.

Soumik, can we have SHPL0000104_017, please?

Sir, this is the -- the letter is from 29 October 1984. This refers to the point at which Immuno had, as it were, got their ducks in a row in order to make the application to the Medicines Commission, because earlier correspondence, from earlier on in the year, shows that among the work that they did is they enlisted Dr Preston to act as a party to present the case to the Medicines Commission, and they also involved a number of Haemophilia Centre

Directors in a trial for FEIBA, which seems to have been a retrospective trial to show how the product had operated. All of this was presented as evidence to the Medicines Commission in order to try to get the licence. The references are SHPL0000101_045, _046, _024, and SHPL0000078_030.

Sir, while efforts are being made for the non-heat-treated FEIBA application, there was also, going along in parallel, efforts to introduce a heat-treated version of the product in 1984, and it was the method for heat treatment, dry heat treatment, 10 hours at 80 degrees, that was settled upon. That's SHPL000068_074. So those two processes going along in parallel.

By April 1985, Immuno Ltd were selling, and I quote: "... substantial [quantities]" of heat-treated FEIBA, and they wanted "further evidence that anti-viral treatment does not cause thrombogenicity."

That is the document we looked at earlier in respect of Prothromplex. The reference is SHPL0000048_024.

So substantial quantities of the heat-treated product being sold.

The hearing before the Medicines Commission took

place on 21 June 1985. By then, FEIBA had been available on a named patient basis for nine years. There is a pharmaceutical examiner's report at SHPL0000078_010, and a medical assessment, which I'll ask for Soumik to put on the screen, please, it's SHPL0000078_011. This, if we could go down to, please, paragraph 7.1. I don't have the page number, so scroll through. One up, please.

So this was prepared by a Dr P Adams, and among the things that is said about heat-treated -- the heat treatment is the efficacy of the heat treatment is only demonstrated in relation to the virus ATC C VR 68 at 60 degrees Centigrade for 10 hours it would be normal practice to demonstrate the heat treatment method effective against a wider ... (reading to the words) ... company does not claim total viral sterility but says "despite the measures taken to reduce the risk the transmission of viral hepatitis or other viral infections cannot be ruled out"."

I we could go to the next page, please:

"Despite this caution it is currently thought if the method of heat treatment is performed as stated in this document there is little risk of the AIDS implicated virus being transmitted through the administration of the product."

In the same report, Dr Adams notes that there is a lack of control data in respect of efficacy, but says that there seems to be a general professional confidence in the product.

On 22 August 1985, DHSS informed Immuno that the commission agreed to advise the Licensing Authority that a product licence be granted. That is SHPL0000104_010. That licence was granted on 17 October 1985, SHPL0000109_049.

It's clear from the papers that that licence is for the dry-heated FEIBA. During the time that the licensing process has unfulled, as we know, Immuno have moved towards steam or vapour-treated products and so, as with the other products, there then follows a process of seeking an amendment to the licence to change it too steam-treated product. We can see that at SHPL0000050_011.

There was discussion at around this time, October 1985, about whether or not to apply straightaway for an amendment or whether to wait for a period of time, given that the product has only just been licensed for dry-heated heat treatment and the latter view was one that was expressed by Immuno Ltd. That's SHPL0000067_030.

By July 1986, it appears that Immuno Ltd had

either applied for a variation to allow for vapour or steam treatment, or had intimated to the Licensing Authority that they were going to do so. The reference is SHPL0000102_142. It was in respect of that if that the Committee on Safety of Medicines sent a letter expressing concerns about the product, and included the fact that they considered steam treatment to be, as they put it, a misnomer and unacceptable. Again, we'll come back to that.

Immuno wrote to doctors on 21 July 1986 informing that, henceforth, they would only be supplying FEIBA steam-treated, as Immuno AG were no longer able to produce the dry-heated product for the UK. If we could have that up, please, Soumik, SBTS0000330_115.

I'll remind you again, sir, of the prohibitions on advertising and making representations about an licensed product. 21 July 1986:

"Dear Doctor

"We wrote to you in January this year informing you that FEIBA heat treated was licensed for sale in the United Kingdom. This product is heat-treated by a dry heat method for 10 hours at 80 degrees [Celsius].

"Our company in Austria has now developed

product specific steam treatments and their policy is to change over to steam treatment in all countries. They are no longer able to produce the dry heated product for the UK as all other countries have already changed over to steam treatment, including the USA where the product is known as Feiba vapour heated and was licensed in March 1986. The product specific steam treatment for Feiba is 10 hours at 60 degrees [Celsius] at an excess pressure of 190 [millibars] and a further treatment for 1 hour at 80 degrees [Celsius] at an excess pressure of 375 [millibars].

"From today's date we shall only be supplying Feiba steam treated. This can only be issued on a doctor/patient basis until we have amended our current Product Licence. The price for Feiba steam treated will be maintained at 30 [pence] per unit.

"We have applied for a variation to our Product Licence and we will inform you as soon as this hasbeen approved."

That was sent by Peter Coombes, at that time the managing director.

The application for an amended licence for FEIBA vapour heated was submitted at the end of November 1986. That's SHPL0000094_004.

On 12 August 1987, Immuno met with members of

the Licensing Authority and they discussed the Kryobulin Prothromplex and FEIBA licence applications. We've looked at the documents about that meeting. I won't take you back to them. The reference is MHRA0033319_040. Immuno withdrew the FEIBA and Prothromplex variation applications on 8 September 1987, that's SHPL0000106_220.

So far as we can tell, Immuno submitted no further documents to the DHSS in relation to FEIBA vapour heated during 1988 and 1989. There were letters at this time going between Immuno Ltd and Immuno AG expressing concern about the licensing situation, and we referred to those earlier. Immuno Ltd saying, "We need to sort out licences in the UK if we're going to be able to continue selling our products here".

In July 1990, Immuno submitted two applications. One was to -- or two sets of applications. One was to vary the FEIBA product licence to change it to vapour heating and the other was to renew the existing dry-heated FEIBA product licence, even though that product was not being sold in the United Kingdom at that time. The references are SHPL0000106_098 and SHPL0000311_055.

A further reference, SHPL0000102_119. In the

application it was said that:

"It cannot be precluded with certainty that both known or unknown viruses which may occur in plasma are transmitted through factor concentrates."

But it also added that:

"Clinical safety studies have shown no cases of hepatitis B, NANB or HIV transmission in the product."

The CSM considered Immuno's variation application in June 1991 and concluded, again, that they were unable to advise the grant of the variation, this time on grounds of safety and quality. The reference is MHRA0034575_059.

They provided several reasons, including that the rationale for the second vapour-heating step, which is one hour at 80 degrees, hadn't been provided. That comparative viral inactivation data had not been presented for the dry-heat process and that each plasma donation had not been tested for HIV 2 antibodies. Immuno were informed of the decision on 19 July 1991, SHPL0000268_045.

Further correspondence took place between Immuno AG and Immuno Ltd, SHPL0000106_094, and there was a meeting on 8 October 1991 between Immuno, the Medicines Control Agency, SHPL0000106_080. It is fair to say that Immuno and Immuno -- Immuno AG and Immuno

Ltd were both more optimistic about the prospects of getting a revised licence for FEIBA and continued to seek to do so at a time when they had pretty much given up on Kryobulin and Prothromplex.

That is shown by the setting up of the task force to try to obtain the licence in December 1991. That's SHPL0000106_073.

The new application was submitted on 26 March 1992, SHPL0000266_041, and also in 1992 there was an application to renew the licence under an EU legislation as well, MHRA0029398. The Subcommittee on Biologicals assessed Immuno's March 1992 submissions in April 1993 and recommended that the variation application be approved. The reference is MHRA0027402.

The Subcommittee remarks included that:

"From the evidence presented it cannot be presumed that the lyophilisation process will consistently contribute to the removal of contaminating viruses."

That's a technical point which may be of relevance later, sir.

The Medicines Control Agency informed Immuno on 4 May 1993 that the application had been approved, that's SHPL0000266_039, and the variation to the

Licence that they're now meant to be steam treated was granted on 10 June 1993. SHPL0000109_001.

From our analysis of that chronology, it follows that between the introduction of FEIBA in the mid-1970s to the UK market and the granting of the variation licence in June 1993, the only time at which variants of FEIBA were provided for use in the UK under a contemporary licence was a 10-month period between October 1985, the date of the first licence and July 1986, the point at which dry heated FEIBA ceased to be provided. For the rest of this period, approximately 18 years, FEIBA variants were supplied on a named patient basis.

We do note, however, that the licences were granted in 1985 and 1993 for products which had been previously supplied on a named patient basis.

That, sir, concludes what I have to say about FEIBA, and about the licensing process in respect of the Immuno products.

I appreciate it has been something of a slog today. The next step in the presentation will be to talk about the way in which risk was communicated in the labels in the leaflets of the various products including the way that the distinction between European Kryobulin and American Kryobulin, if it can

Be put in those terms, was expressed.

I'm conscious of the time, sir, and I'm in your hands.

SIR BRIAN LANGSTAFF: Very well. Thank you very much. 10 o'clock tomorrow. 10 o'clock.

(4.33 pm)

(The hearing was adjourned until 10 am on Friday, 24 September 2021)

I N D E X

Presentation by Counsel to the Inquiry on the Pharmaceutical Companies 1

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