IRISH HAEMOPHILIA SOCIETY

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TRIBUNAL OF INQUIRY

(Into the Infection with HIV and Hepatitis C of Persons with Haemophilia and Related Matters)

PROCEEDINGS: Monday 21st May 2001 - Day 132

Martin Hayden S.C. for the Irish Haemophilia Society continued his examination of Mr. Michael Lyons of the Department of Health.

New documentation was presented by the State consisting of a document entitled "Clotting Factor Concentrates: The Present Position". Mr. Durcan for the Tribunal noted that this document may be the 1989 briefing document supplied by the BTSB to the Department of Health, which is mentioned in the minute of the BTSB board meeting of February 15th 1989. However, Mr. Durcan stressed that this document had not been identified as such by the BTSB, and stressed that its provenance in this respect was uncertain.

In continuing his cross-examination of Mr. Lyons, Mr. Hayden asked where Mr. Lyons had obtained his information upon which the 1989 briefing documents for the Minister were prepared. Mr. Lyons informed the Tribunal that he had received information from Mr. Collins in the Department and from two officials of the BTSB, namely Mr. Hanratty and Mr. Kelly. Mr. Lyons said he was confident the information he had received was accurate. He said he used his judgement at the time and was happy the information supplied was accurate.

Mr. Lyons said that information from the BTSB was possibly obtained by Mr. Collins for the Department. Mr. Lyons described the method by which such documents were compiled within the Department. There is no mention of the factor IX situation in the 1989 memo. Mr. Lyons said that if there was no mention of factor IX, it was because such information had not been furnished. If such information had been furnished it would have been included.

With respect to his sources within the Department, Mr. Hayden asked Mr. Lyons had he contacted Mr. McCartney as to the situation at the BTSB, given that Mr. McCartney was a member of the board. And if Mr. McCartney had been asked, would he not have come back to Mr. Lyons and told him that the information contained in the memo was incomplete and inaccurate.

With respect to why the first person with haemophilia who was infected with AIDS was not included in the briefing document, Mr. Lyons said it was taken as read that this was the case. In preparing for the Parliamentary questions in April 1989, Mr. Lyons said he had one week's notice to prepare the briefing document. He relied heavily on the BTSB document and there was no mention of factor IX or cryo infections. Mr. Lyons said he was relying on the BTSB's reputation as an organisation, which was considered to be among the best in its field.

With respect to the issues of recompense and compensation, it was noted that the advice was that there was no grounds in negligence for accepting liability for the HIV infections. Mr. Hayden asked Mr. Lyons, how could this be said without enquiry. Mr. Lyons said that the Collin's document showed that some enquiry had taken place. In an April 1989 document it is noted that two persons with factor IX deficiency had developed AIDS. Mr. Collins said this information had come to light as there was a lot of interaction with the Society and the Department. Mr. Lyons said he could not recall with whom he had had discussions. He said the information that there were two factor IX HIV cases sounded no alarm bells,

as he was dealing with it at that time on a general basis. He said the document in question had been prepared specifically for the Dail debate.

With respect to the Irish Times cutting of 9th June 1986, Mr. Lyons said the abstract would have been sent to the relevant division within the Department. If this document had been accepted by the Department it would have been sent to him or to the relevant division. Mr. Lyons said it was inconceivable that it would not be in the Department file. Mr. Lyons said the only conclusion he could draw is that the document was handed to him during one of the negotiating sessions. He said the cutting was not unique to the Department. Mr. Lyons said that the assessment of the State's case in law was based on the 1989 document prepared for the Dail debate in April of that year.

Mr. Lyons was cross-examined by Mr. Michael McGrath for the BTSB. Mr. McGrath referred Mr. Lyons to the Health Education Bureau/I.H.S. booklet "Haemophilia: The Basic Facts". Mr. McGrath pointed to differences contained in two versions of the booklet. Mr. Lyons was unable to assist the BTSB as to the significance or otherwise of these differences.

Mr. Lyons was examined by Mr. Ian Brennan for the Department of Health. Mr. Brennan asked Mr. Lyons was it the case that he had no information on factor IX when putting together the April 1989 memo.

Mr. Lyons was also examined by Mr. Gerry Durcan for the Tribunal.

Ms. Clohessy for the Tribunal examined Dr. Rosemary Boothman of the Department of Health. Dr. Boothman is Deputy Chief Medical Officer with the Department and acts as an adviser in respect of applications for new technology and high technology equipment to the Department.

In 1987 Dr. Boothman was involved in assessing an application by the BTSB where the board sought to introduce ALT testing of plasma as a precaution against infection with non-A, non-B hepatitis. Dr. Boothman said the Department accepted that the BTSB knew medically what it was talking about, and there was no question raised on this aspect of the application. However, Dr. Boothman said that the submission from the BTSB gave rise to more questions than it answered.

Dr. Boothman said that the application by the BTSB gave rise to a lot of concerns, among which were the BTSB's estimate of the amount of money lost through loss of blood donations turned down on failing the ALT test; the BTSB's estimate was put together on the strength of a pilot study, and the lack of an estimate of costs following the first year of operation of ALT testing.

Ms. Clohessy put it to Dr. Boothman that her primary concerns seemed to be related to costs. Did she ever address the issue of whether, on a medical basis, the ALT test was something which the Department would consider funding? Dr. Boothman said that where a clear medical case was made out on grounds of safety the Department would accept it but, the number of doubts raised in the BTSB's application for ALT testing, and their reluctance to clear up such doubts, meant the matter never progressed.

Dr. Boothman was cross-examined by Mr. Jim McCullough for the Irish Haemophilia Society.

Mr. McCullough asked Dr. Boothman why the BTSB wanted to introduce ALT and hepatitis B core testing? Dr. Boothman said she had no idea, only the BTSB would know that. She said she continued to be baffled by the fact that if they genuinely wanted to introduce it, why they could not have come up with the costing that could have been evaluated. Dr. Boothman said that the Department never received comprehensive submissions from Mr. Keyes concerning the test. She did not consider the information put before the board by Mr. Keyes to constitute a comprehensive submission on costings such that the Department could be satisfied that the costings reflected the actual expenditure to be incurred in introducing a test.

Dr. Boothman agreed that she was sceptical about the application for funding from the BTSB to finance the test. She said this was because of their reluctance to come up with costings. Dr. Boothman's line was that the costings presented by the BTSB did not satisfy the Department's requirement that the price of the ALT testing be determined before any agreement was entered into to fund such testing. However, Dr. Boothman said the concept of ALT testing was not rejected by the Department at that stage, nor did the Department refuse to make funding available. She said in order to make an amount of money available, one had to know what that amount of money was. Dr. Boothman said that the Department never at any stage denied funding for the ALT test. She said it was just that the amount of money being requested was well in excess of what it should have been.

Mr. McCullough asked Dr. Boothman, was it the case that BTSB plasma was left exposed to non-A, non-B Hepatitis. Dr. Boothman said it was for the BTSB to comment on that. She said the Department of Health was asked about the introduction of the test. She said the BTSB did not need the permission of the Department to introduce any test. Was it not the case that no money means no test, she was asked. "I would not expect so," she replied. She said the Department of Health never at any stage denied funding for the test.

Dr. Boothman was cross-examined by Mr. Michael McGrath for the BTSB.

Mr. Dermot Mulligan of the Department of Health was examined by Ms. Grainne Clohessy for the Tribunal.

Mr. Mulligan was an Administrative Officer at the Department of Health between 1985 and 1990. He worked with the general hospital services division. At that time blood policy was dealt with by the general hospital services division.

Mr. Mulligan processed the BTSB's ALT test application in 1987. Mr. Mulligan said he referred the application to Dr. Boothman, asking her to bring her experience, qualifications and medical knowledge to bear in relation to the proposal. Mr. Mulligan said he asked Dr. Boothman for her observations. When these observations were made available to him they related mainly to cost. Mr. Mulligan said the ALT proposal from the BTSB was presented to him in three phases with three different types of proposal on each occasion. Mr. Mulligan confirmed with Ms. Clohessy that while he was in the position of administrative officer with the general hospital services division, no decision was taken to introduce the ALT test. He further said that while no decision was taken to introduce the test, there was no decision by the Department to reject the test. Mr. Mulligan said that the finance unit was never asked to provide funding for the proposal, nor was it ever asked to approve a price rise to allow the BTSB to do the work.

Mr. Mulligan was directed to a letter sent by Mr. Keyes to the Department of Health. The letter from Armour Pharmaceutical Co. was in connection with fractionation of BTSB plasma. Mr. Keyes informed the Department that the issues raised by Armour had serious implications for the self sufficiency programme adopted by the Government and implemented by the board. This letter appears to refer to the Armour contract indemnity requested by the pharmaceutical company from the BTSB. Mr. Mulligan was asked, did this letter have any implications for Mr. Keyes' requests concerning ALT testing and hepatitis B core testing. The Chairperson ruled that it was unfair to ask the question as to how the witness would feel if he had seen the letter requesting the indemnity by Armour.

Mr. Mulligan was then examined by Mr. McGrath for the BTSB.

The Tribunal then examined Dr. James Walsh of the Department of Health.

Mr. Durcan for the Tribunal examined Mr. Gerry O'Dwyer, formerly Secretary General of the Department of Health and Children.

Mr. O'Dwyer said he was Secretary General from 1990 to 1994. During the 1980s was an assistant secretary. He said that it was very difficult for the Department to respond to requests for additional staff, given the severe financial stringency which then attended the operations of the Department. Mr. O'Dwyer said that the Department was concerned about financial and personnel systems at the BTSB during the early 1980s and in and around the time of the move to Mespil Road. He said that the retention of Dr. O'Riordan's services after his retirement age was not a regular occurrence but was not unusual either. He said the Department had total confidence in Dr. O'Riordan. Any doubts it had were about the structure of the BTSB. Mr. O'Dwyer said the Department took steps to address the financial difficulties of the BTSB and the structural difficulties were addressed by way of the appointment of a chief executive officer and the appointment of Mr. Fox and Mr. McCartney to the board to strengthen it at a governance level.

Mr. Durcan asked Mr. O'Dwyer, would he accept that the deficiencies in the organisation's structure meant that it wasn't in a particularly good position to face the challenges it had to meet in the early 1980s. Mr. O'Dwyer said it would have been desirable if changes had been brought about in that period.

Mr O'Dwyer was cross-examined by Mr. Raymond Bradley for the Irish Haemophilia Society. Mr. O'Dwyer agreed with Mr. Bradley that he was aware that Dr. O'Riordan was discharging his duties of National Director such that he had to undertake financial, administrative and medical responsibilities. And was he was also aware of the serious financial difficulties which faced the BTSB with respect to its move to Mespil Road? Mr. O'Dwyer agreed that the situation at the BTSB could have been better.

Mr. Bradley referred Mr. O'Dwyer to the provision of counselling and social work services at St. James's Hospital. Mr. O'Dwyer indicated that these requests occurred at a time of very serious financial cut-backs, and the hospital needed to indicate in very strict terms the personnel it required. He said at the time the Department was unable to offer help to St. James's Hospital from the normal Exchequer resources, and funding for the social work services was eventually made available from the National Lottery. Mr. O'Dwyer said that St. James' Hospital, through internal redeployment, did its best. At the time, the maintenance of a hospital service was made difficult by the reduction in the number of beds. Mr. O'Dwyer said that the finance unit of the Department of Health would have had no role in the negotiation of the settlement between the Society and the Government in 1991.

Mr O'Dwyer was cross-examined by Mr. Aston for the NDAB and Mr. Brennan for the Department of Health on the issue of NDAB staffing. He was also asked by Mr. Durcan for the Tribunal, was it correct that Dr. Scott of the NDAB, around and about 1986, was of the view that it would take five years to clear the backlog of work in the NDAB. Mr. O'Dwyer said he accepted there was a backlog. He wasn't in a position to judge whether it would take the five years to clear or not.

Mr. Barry Desmond, former Minister for Health, was then examined by Mr. Gerry Durcan for the Tribunal.

Mr. Desmond was Minister for Health between December 1982 and February 1987. Mr. Desmond agreed with Mr. Durcan that the Minister had ultimate political responsibility for numerous functions of the Department. Mr. Durcan asked Mr. Desmond, would he dispute the proposition that the Minister for Health had ultimate political responsibility in regard to carrying out the functions of the Minister. Mr.

Desmond said the Minister had a political remit. He said responsibility is devolved. It is delegated to various corporate statutory bodies, but the Minister has a remit to report to the Dail. He has a remit to answer Parliamentary questions. He has a remit to interact with senior officers of the Department insofar as the budget and health estimates are concerned.

Mr. Durcan said it was against this background of political responsibility that he wished to ask questions of the Minister. Mr. Desmond said that information would be brought to his attention by the Departmental secretary. He would examine such files as were referred to him by the Secretary of the Department and would expect to be kept informed, both internally and externally. Mr. Desmond agreed that by August 1983 the Department of Health knew of the AIDS virus, and that it was transmissible by blood and blood products. He said that he had not seen the recommendations of the Council of Europe and the recommendations had not come across his desk when he was Minister.

Mr. Desmond said he was aware that the BTSB had a policy of self sufficiency, but was not at the time aware that persons with haemophilia were reliant upon imported products from the United States. He said he had no knowledge of imported products during 1983. Mr. Desmond said he knew in 1985 that the Department had recommended the use of heat treated products only. With respect to any action taken to implement the use of only heat treated products, Mr. Desmond said he worked on the basis that heat treatment was being pursued. Mr. Desmond said he was not aware in 1985 that up to one third of persons with haemophilia had been infected with HIV. Mr. Desmond agreed that a note from the Minister prepared in 1985 in anticipation of Parliamentary questions, contained incorrect information in that the BTSB was using products other than heat treated products in 1985, whereas the Dail had been informed that the BTSB was not using non-heat treated products during this time.

Mr. Desmond said he was under a misapprehension from 1985 onwards. He was appalled that this should have happened, and he relied on the information that had been given to him. Mr. Desmond said a mutual trust existed between the Minister and his advisers, and he considered it to be a very serious matter that he had been given incorrect information. Mr. Desmond said that had he been aware that incorrect information was given, he would have immediately have taken action.

In respect of answering Dail questions in November 1985, the information at Mr. Desmond's disposal was that of 256 haemophiliacs tested, 33 per cent had proved positive for HIV. Mr. Desmond said he then knew that a serious problem of HIV infection had arisen within the haemophilia community. He knew that this had been caused by infected blood products. Mr. Durcan asked him, did he take any step thereafter to address the crisis? Mr. Desmond said he regarded the matter as extremely serious, but did not regard it as incumbent upon him to develop further strategies. He said the strategy was there and it was contained in the strategy to control the spread of AIDS, which was addressed in the Department's policy document. Mr. Desmond said he had no role in enquiring as to what was being done for haemophiliacs who had become infected.

Mr. Durcan asked Mr. Desmond, had he ever been told that the BTSB was using non-heat treated products during 1985? Mr. Desmond said nobody had informed him of that situation. The first he heard of it was at the Tribunal. Mr. Desmond said he was appalled that this should have happened and that information of that nature should have been given to him. Mr. Desmond said that he was aware that a serious situation had developed for people with haemophilia, but he was under the impression that the situation was being controlled. Mr. Desmond said that he had absolute trust in the information that he received from the Department, and could only presume that the Department was receiving information which enabled it to give him a degree of assurance. He conveyed that widely and unhesitatingly throughout the period.

Mr. Desmond was cross-examined by Mr. Jim McCullough for the Irish Haemophilia Society.

Mr. Desmond was asked, would he accept that, as Minister, he had a direct responsibility for the delivery of treatment to people with haemophilia. Mr. Desmond said it was his responsibility to see that the BTSB was in the position to deliver such treatment. Mr. Desmond said that delivery of the service, the management of the service and the authority to deliver the service, rested with the board and management of the BTSB.

Mr. Desmond agreed that the BTSB would be expected to implement the policies of the Department such as those contained in the Council of Europe recommendations. Mr. Desmond said the BTSB had responsibility for implementing the council of Europe recommendations which were the policy of the Department of Health.

Mr. Desmond was asked, given that a five year backlog existed at the NDAB, how could he as Minister discharge his role as the ultimate licensing authority? Mr. Desmond said that the NDAB was staffed with between 20 and 30 employees during the period. The backlog of work at the NDAB was never brought directly to his attention.

Mr. Desmond said that the factor IX situation was not brought to his attention at any time. Mr. Desmond said that he was never made aware that persons with factor IX deficiency had contracted HIV from products made in Ireland. Mr. Desmond said that if the situation had been brought to his attention he would certainly have done something about it, such as seeking a briefing from his officials.

Mr. Desmond was cross-examined by Counsel for Prof. Temperley, St. James's Hospital, the NDAB and the BTSB.

PROCEEDINGS: Thursday 24th May 2001 - Day 135

Mr. Gerry Durcan for the Tribunal examined Dr. Rory O'Hanlon, former Minister for Health. Dr. O'Hanlon was Minister for Health from March 1987 through to November 1991 in two different Governments. Dr. O'Hanlon described the serious financial situation which prevailed when the Government took office in 1987.

Dr. O'Hanlon said that the document "AIDS, Haemophilia and the Government" submitted by the Irish Haemophilia Society in 1988, would have been discussed with him by the secretary of the Department at the time. Dr. O'Halon said he could not remember specifically being referred to the document prepared by Mr. Collins, whereby it is estimated that a fund of £1 million would be needed to meet the demands contained in the I.H.S. submissions.

Mr. Durcan referred Dr. O'Hanlon to the meeting with the Irish Haemophilia Society in February 1989 and the document prepared by his department to brief the Minister in advance of the meeting. At the meeting the Irish Haemophilia Society was offered the sum of £50,000 to go towards counselling. Dr. O'Hanlon said he took ultimate responsibility for the offer of the £50,000. He said the figure would have been arrived at by his officials and he was dependent on them for advice. Dr. O'Hanlon said his view at the time was that all AIDS cases should be dealt with by the development of a better health service, rather than to deal with specific groups. Mr. Durcan asked Dr. O'Hanlon, was it the case that the representatives of the Irish Haemophilia Society at the meeting were not happy? Dr. O'Hanlon said yes, that is correct. The Minister said it was also suggested that a group be established under Mr. Layden, the Junior Minister, to enquire into the situation of people with haemophilia who were infected with HIV. The establishment of the committee was to keep the door open on the substantive issue. In April 1989 Dr. O'Hanlon said he brought the matter to Government. Prior to the 1989 general election the Government decided that no more than £50,000 would be paid.

Mr. Durcan referred Dr. O'Hanlon to the document prepared by Mr. Lyons dated 20th April 1989. This document was based on previous documents prepared by Mr Collins and Mr. Lyons and contains a summary of the situation that prevailed concerning people with haemophilia and HIV infection. The document states that heat treated products only were used from 1985. As soon as it was shown that heat treatment kills the virus, non-heat treated products were withdrawn. It also states that self sufficiency with Irish heat treated factor VIII was achieved in 1987. Dr. O'Hanlon agreed that he was under the impression from the document that Ireland had attempted to achieve self sufficiency as early as possible, and had in fact some success in that regard. He was also left with the impression that the BTSB also advocated the use of home-produced cryoprecipitate, both during and before the AIDS problem. He was also of the impression that Ireland did not have a case of blood-donation related HIV or AIDS.

Mr. Durcan referred Dr. O'Hanlon to his speech on the Labour Party motion on haemophilia, AIDS/HIV of the 25th and 26th April 1989. At the time the speech was made, Dr. O'Hanlon said he was not aware that seven people had been infected as a result of the use of factor IX produced by the BTSB which had been made from Irish blood donations. Dr. O'Hanlon said he was of this view up until very recently. Dr. O'Hanlon said that if the information concerning factor IX/HIV infections was known it would have been put before the Dail at the time. Dr. O'Hanlon said it was extremely important that a Minister put accurate information before the Parliament. Dr. O'Hanlon agreed that the consequence of the Minister's view was that the Government was acting on inaccurate information.

Dr. O'Hanlon agreed that the Government was in a delicate political situation. He said this was accompanied by the humanitarian aspect of the matter, but he was left in a situation where, through misinformation from the Department, the Government was acting information that simply was not

correct. Dr. O'Hanlon said: "Not alone did I give wrong information to the Dail, because that was the information that was in front of me, but I brought the same information to Government". Dr. O'Hanlon agreed that the decisions were made on the basis of wrong information. Dr. O'Hanlon agreed that the Government went to the country on this inaccurate and flawed information.

With respect to heat treated products only being used by the BTSB in 1985, Dr. O'Hanlon said last week was the first time he was aware that he had misled the Dail in this regard. Dr. O'Hanlon said he accepted that the way the whole issue of recompense was dealt with was incorrect. It was flawed in the sense that the Minister did not have all the information. In turn, the Government did not have all the information, and in turn the Dail didn't have all the information.

Mr. Durcan asked Dr. O'Hanlon, as a member of the Government and Minister in charge, that given the type of information which we now know about, such as the infections from factor IX, heat treatment not being in place in 1985, self sufficiency not being pursued as quickly as possible, did he believe that it was likely that the Minister and the Government would have taken a different view? Dr. O'Hanlon said he had no doubt he would have brought different proposals to Government. Dr. O'Hanlon said his policy at the time was to deal with the needs of all HIV and AIDS sufferers. He did not see the great justification for dealing with haemophilia independently, but if he had the information which is available to the Tribunal today, he would certainly have seen it as a reason why he should have brought different proposals to Government.

Mr. Durcan asked Dr. O'Hanlon, was it clear, therefore, that the Tribunal had established that what happened in1989 was inadequate and unsatisfactory from the point of view of persons with haemophilia? Dr. O'Hanlon said that in light of what the Tribunal knows today, he had no doubt he would have taken a different view. Dr. O'Hanlon said he could not say what would have happened, he could only say it would have been different.

Mr. Durcan then referred Dr. O'Hanlon to the settlement of litigation in 1991. Mr. Durcan asked Dr. O'Hanlon, had the inaccurate information of 1989 been put to right at the time the settlement came into view? Dr. O'Hanlon said the Government was still working off the same information and obviously had the view that everything was correct at the Blood Bank at the time.

By virtue of the Minister for Health having waived privilege over the Department of Health's documents certain documents containing legal advice were now available to the Tribunal. In one such document the Minister was advised that there may be a risk of liability on the State with respect to the various actions taken by people with haemophilia who had been infected with HIV. This potential liability was not exclusive to the Minister for Health, but would extend to other State agencies; the BTSB, the NDAB, St. James's Hospital, the Southern Health Board, two medical consultants involved and the pharmaceutical company. Dr. O'Hanlon said the Department would have taken heed of the legal advice at the time.

Further legal advice based on information available at the time indicates that the State had a strong case in law to defend the legal proceedings. However, with 70 cases pending it was not possible to give an assurance in all the cases.

Mr. Durcan asked Dr. O'Hanlon, would he now accept the position that in 1991 the Government acted on incorrect and inaccurate information? Dr. O'Hanlon said he accepted that persons with haemophilia whose situation was being considered at the time, were entitled to have their position considered on the basis of all the relevant facts.

Dr. O'Hanlon said that eventually a sum of £8 million was agreed to settle the litigation. He agreed that it was made clear to the Haemophilia Society that they either took the £8 million or they took their chances

in Court. Mr. O'Hanlon said that this aspect of the matter was discussed between himself and the Minister for Finance, Mr. Reynolds, and that the bottom line was either the £8 million be accepted on the lines decided by the Government, or the Society would have to reflect on whether they are willing to go to Court to seek compensation.

Dr. O'Hanlon was examined by Mr. Martin Hayden for the Irish Haemophilia Society, Ms. Murphy for St. James's Hospital and Mr. McGrath for the BTSB, and re-examined by Mr. Durcan.

Mr. Thomas McGuinn, Chief Pharmacist with the Department of Health since 1977, gave evidence. He was examined by Mr. Durcan, Counsel for the Tribunal. Mr. McGuinn described the role of the Department of Health in controlling and licensing drugs within the state. He also described the legislative framework which was used by the Department to control drugs within the State. He said that the role of the Department in the licensing and control of drugs was entirely administrative. Where the Department required technical, medical or pharmaceutical expertise, the Department would rely on external advice. Mr. McGuinn described two forms of legislative control on drugs within the State. The first was under the Therapeutic Substances Act 1932. The second was under regulations introduced pursuant to European Law.

Mr. McGuinn dealt with the regime under the Therapeutic Substances Act first. He said that blood products, including factor VIII and factor IX, came within the remit of the Therapeutic Substances Act. Under the Act, he said that import licences were granted on a product by product basis. The Minister for Health was the Licensing Authority under the Act. He said that up until 1955 the Therapeutic Substances Act provided an effective means of controlling goods within the State. Until 1955 criteria and standards for products were set up on a product by product basis under the Act. However, after 1955 standards for each product were no longer set up under the Act. The reason given was that, because of the ever increasing number of products, and the increasing scientific technology, it became too complicated to set up standards on a product by product basis. The Department of Health relied on the advice of Mr. Keenan, a Consultant Microbiologist from UCD. Mr. Keenan would receive information about a product and reply in writing advising the granting of a licence or, in the later years, he would often give oral confirmation on a batch basis over the phone. There was no specific standard or test set down for these products. The Microbiologist would use his own ingenuity or the British Pharmacopoeia, or whatever other standard he could find.

Under the Therapeutic Substances Act there were two forms of licence. One related to the manufacture of substances in the State, and the other related to the import. Between 1975 and 1990, while there were a number of licences granted under the Therapeutic Substances Act for factor VIII products, there were no such licences granted for factor IX products.

Mr. McGuinn said that he also suspected that there were factor VIII products on sale within the State, for which Therapeutic Substances Import Licences would have been required, but which did not have those licences. The BTSB factor IX never had a licence under the Therapeutic Substances Act. The responsibility for the policing of the Therapeutic Substances Act lay with the Minister for Health, Mr. McGuinn said. For long periods of time there was non-compliance with the provisions of the Therapeutic Substances Act, in terms of obtaining licences, and the products were on sale which required licences and nothing would appear to have been done about that. All in all, the Therapeutic Substances Act was an extremely ineffective mechanism of controlling drugs within the State.

Mr. McGuinn then went on to describe a second form of control that existed within the State for medicinal products. The European Community Proprietary Medicinal Products Regulations of 1974 was brought into force to implement the decisions of Counsel Directive 65/65 EEC. This Directive dealt with the control of medicinal products within Member States in the EEC. The 1974 regulations set up a requirement that all new proprietary medical products placed on the market after that date were to be the subject of what was called a product authorisation. However, Directive 65/65 did not apply to blood and blood products; these were specifically excluded by the Member States. However, in implementing the regulations, Ireland specifically included them. The reason this was done was in order to provide an effective means for controlling the sales and licensing of blood and blood products within the State.

Under the 1974 regulations for product authorisations, the Department of Health relied on the National Drugs Advisory Board for expertise in assessing licence applications. Under these regulations, the Minister was again the licensing party.

The original regulations introduced in 1974 were subsequently repealed and replaced by 1984 regulations. Under the 1984 regulations, proprietary products needed product authorisations immediately. Non-proprietary products did not require a product authorisation until 1989. BTSB factor VIII and factor IX were considered to be non-proprietary products.

Mr. McGuinn was referred by Mr. Durcan to a product authorisation application which was made by the BTSB in 1989. This product authorisation was for product which was to be produced by Armour Pharmaceuticals from Irish plasma. Under the product authorisation, BTSB would be licensed to market that product in Ireland. This product authorisation was never granted. Mr. McGuinn stated that, as is clear from a hand written note of his on the actual product authorisation document, he had concerns about the product authorisation application. His concerns were two-fold: a) that the product authorisation was not made by the Chief Executive Officer of BTSB, and b) that the BTSB may attract some liability in relation to the product if marketed under such a product authorisation.

Mr. McGuinn then said that in 1974 and 1975, when product authorisation regulations were introduced, there were also parallel regulations introduced which related to the distribution and the manufacture of medicinal products. The BTSB had a manufacturing licence under the manufacturing regulations. However, Mr. McGuinn said that it was still the case that the BTSB would also require a manufacturing licence under the Therapeutic Substances Act. Mr. McGuinn said, in relation to the heat treatment of products, that as far as he was aware the view of the BTSB in 1985 was that it was absolutely essential that both factor VIII and factor IX products should be heat treated. Mr. McGuinn said that in relation to products which did not have product authorisations between 1975 and 1990, and which required product authorisations, there was little done to enforce the regulations. Mr. McGuinn said that little was done to enforce the regulations because unfortunately, the Department of Health didn't know exactly what products were being used. Mr. McGuinn said that ultimately the responsibility for enforcing the regulations lay with the Minister for Health.

Mr. Giblin for the I.H.S. then examined Mr. McGuinn on a number of topics. Mr. Giblin asked Mr. McGuinn whether his concerns about the BTSB application for a product authorisation in relation to factor VIII, had anything to do with the indemnity that was demanded by Armour in relation to the marketing of its own factor VIII within the State. Mr. McGuinn denied that it had. Mr. McGuinn said that it would have been important for the BTSB to have a product authorisation, but it was up to the BTSB to apply for product authorisations. Mr. Giblin suggested to Mr. McGuinn that the appropriate action for the Department of Health to have taken would have been to introduce a comprehensive medicines act, as was done in the United Kingdom. Mr. McGuinn agreed that it was, but that this had not been done because of the volume of work it would involve. Mr. Giblin suggested that the appropriate thing would have been to adopt the Medicines Act from Britain and, as Mr. Giblin put it, a "paint the post boxes green" solution could have been applied.

Mr. Giblin then went on to ask Mr. McGuinn about prosecutions under the Therapeutic Substances Act. He pointed out that a breach of the Act may lead to the committing of a criminal offence. He asked how drug companies committing offences under the Act would know whether or not they would be prosecuted in the State. Mr. McGuinn said that there was no guarantee that pharmaceutical companies would not be prosecuted if they breached the Act. Mr. Giblin asked Mr. McGuinn if he was aware of any factor VIII or factor IX products which were being distributed in the State while applications for product authorisations were being processed. Mr. McGuinn said that there was definite information in relation to Octapharma factor VIII which was being distributed within the State before a product authorisation application was in.

Mr. McGuinn was asked by Mr. McGrath for the BTSB whether the regulations required that factor IX had a product authorisation if it was produced by the BTSB. Mr. McGuinn said that, because it was a non-proprietary product, a product authorisation was not required until 1989.

That concluded the business of the Tribunal for 25th May 2001, and proceedings were adjourned to Monday 28th May 2001.