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VISIT TO IMMUNO A.G., VIENNA, AUSTRIA,
JUNE 22ND 1973

Mr. Hart
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I accepted an invitation to visit the Immuno factories in Vienna on a purely informal basis. I was in Vienna attending the 4th International Congress on Thrombosis and Haemostasis, and I had expressed an interest to Immuno in seeing their factory. This was not an official inspection as Austria is a participating member of the EFTA Agreement, and we had been informed that while no objection would be raised over an informal visit, the Austrian Authorities would object to an official inspection by a D.H.S.S. officer. However, on the basis of a formal request from D.H.S.S. the Austrian Authorities have recently inspected the Immuno factory, and a full report has been promised in the near future. My visit to the factory was therefore quite informal and rather hurried. I did not feel, for example, that I could take any notes while at the factory. In the company of Dr. Katherine Dormandy, of the Royal Free Hospital, I was shown around the factory by Dr. Otto Schwarz, who is Managing Director in charge of Production.

The Immuno firm was founded about 20 years ago by 3 scientists from the University of Vienna, and has grown from the original 3 with laboratories at the University to a firm now employing about 600 people. They manufacture a wide variety of blood products, several of which they are licensed to sell in the United Kingdom. Of particular interest to me were their Factor VIII Concentrate, Factors II, IX and X Complex, and Plasma Protein Fraction, all of which are marketed in England by Serological Products Limited. Dr. Eibl, whom I had met on previous occasions in London, and Dr. Schwarz are two of the original founders of the company, and are still in complete scientific and technical control.

Dr. Schwarz took us first to a Plasmapheresis Centre at Marinelligasse. In addition to being a Plasmapheresis Station, it is also the main centre for fractionation of plasma. This building was in a rather run-down condition, although there were evident signs of reconstructive work going on. We were shown into a long and narrow room containing some 20 beds placed very close together. No patients were present and we were told that this was because the Austrian trade unions have ensured that work finishes very early on Friday afternoon. (We were there about 1.30 p.m.). We were told that this Plasmapheresis Station had a panel of approximately 1000 patients, who all came once a week. They were paid approximately £5 per session and the unit could bleed some 200 patients per day. The donors are mainly students and workers and Dr. Schwarz thought that about 60% of their panel were stable donors. Each donor, in addition to being screened for haemoglobin and haematocrit, is also screened on each visit for hepatitis B antigen, using a counter electrophoresis technique of Immuno. I was told that there was one nurse for every four donors and that there was always two physicians on duty during a donor session. They used a plastic bag of their own design, which was not a Fenwal type of closed bag such as is used in the U.S.A. The reason for this is that they do an ABO cross-matching at the bedside before the red cells are returned to the donor and therefore need to express a small quantity of blood from the bag. In addition to all the usual precautions that are taken, such as requiring the donor to identify his name on the bag of red cells that are being returned to him, a rapid cross-matching is carried out alongside the patient.

The blood is then passed through to an adjacent room where there is a bank of centrifuges. After centrifugation, the plasma is expressed into bottles, and because it is not a completely closed system, this operation is carried out in a laminar flow cabinet. The bottles of plasma are then taken to an adjacent building where fractionation is carried out. Overall, I thought the plasmapheresis centre was adequate, although the conditions there were likely to be very crowded when donors were being bled. This would tend to increase the chance of the wrong cells being returned to donors, and perhaps this makes the bedside cross-matching necessary. Although I did not see any of the donors, I was assured that they were not "down and outs". It is of interest that the Austrians pay their donors two and a half times the amount paid in the United States. I asked Dr. Schwarz how the Austrian Red Cross felt about his firm paying donors for plasma. He pointed out to me that their total donor population in both Austria and Germany was somewhere between 5,000 and 10,000 people. The Austrian Red Cross had something like 300,000 donors per year, so that the donors that contributed plasma for Immuno constituted a very small percentage of the total pool of blood donors. As Immuno had 95% of the market in Austria for blood products, it would appear that with 5% of the total blood donors contributing by plasmapheresis to a Plasma Protein Laboratory, the national needs for blood products can apparently be satisfied.

We then went to the fractionation room where we saw 6 large stainless steel refrigerated tanks where a Cohn-type fractionation was proceeding. I was told that their usual pool of plasma was about 1500 litres, and that 80% of their fractionation was the cold ethanol type. From these tanks where the alcohol and plasma were mixed and stirred, the fractions were piped to another room where there were about 8 high speed centrifuges situated in a large cold room. Somewhat to my surprise, we all tramped round this room, and I asked Dr. Schwarz whether or not he was worried about the possibility of an aerosol effect from the plasma fractions in the centrifuges, with the consequent hazard of hepatitis to the personnel. At other factories, I have only been allowed to see the room where centrifugation of plasma takes place by observing through a glass window, for fear of hepatitis. Dr. Schwarz shrugged his shoulders and said that they had four cases of hepatitis about 3 years ago and none since. He commented that they had had an outbreak, presumably from a virulent virus which had gained access to the factory, but the 4 cases were scattered all over the factory, and were not concentrated among personnel in any one area. He was disarmingly frank about their cases of hepatitis in contrast to laboratories I have visited elsewhere (e.g., Elstree and Cutter) where everybody virtually denied they had ever had a case! My impression of the Fractionation Centre was that the operation seemed quite adequate, although in terms of physical plant and equipment, the new Blood Productions Laboratory at Elstree is much more impressive.

We were then taken to the part of Immuno which is at Industriestrasse, where some fractionation is carried out, but it is mainly the factory for packaging, quality control, and research. These buildings were the original site of Immuno, and were an untidy complex of buildings. They still use ammonium Sulphate fractionation for preparing gamma-globulin, and this struck me as very old fashioned and inefficient, with long rows of Buchner funnels and conical flasks. The whole place had a crowded and messy air about it and the storage rooms were particularly untidy. A storage room completely filled with biological products ready for shipping had very little evidence of efficient organisation. The only part of the factory that I thought was up to modern standards was the Sterile Filling Area, which was opened within the

past year. This consisted of an outer corridor encircling an inner sterile area. There were 4 main rooms, two of which contained large laminar flow cabinets. No filling was going on while we were there so it was hard to judge the quality of the work. There were some women around, who were dressed in protective clothing, and I did notice that they were not wearing trousers. The sterile filling rooms seemed rather cluttered, and it was apparent that they rely heavily on the laminar flow cabinets to maintain asepsis. The rooms were again rather cluttered and I noted that the doors of the sterile filling rooms opened directly into the corridor. I was shown the changing rooms very briefly and as best I could judge they seemed satisfactory. Overall, one got the impression that Immuno were modernizing their factory piece-meal. Some of it was good - for example the Sterile Filling Area was at least modern and up-to-date - whereas some of the factory was really quite old-fashioned.

We were taken finally on a quick tour of the Packaging Area and the Quality Control and Research Departments. The Packaging Area was spacious and seemed very clean and I could see no obvious faults there. It was very striking to see how excellent the Quality Control and Research Development Laboratories were. These were all large, spacious, and modern laboratories with all the latest equipment. Unfortunately, no work was going on, so that one could not get more than a brief impression of the area. I came away feeling that Immuno is in the forefront in so far as scientific knowledge, research and development is concerned. This, after all, is what one might expect from a firm that is basically run by scientists. In keeping with this, the research and quality control laboratories were superb and obviously lacked for nothing in the way of equipment. On the other hand, their managerial organisation is probably not so strong, parts of the factory are quite old fashioned, and there was an unevenness about the whole operation which was noticeable. However, I have no doubt that Dr. Eibl and Dr. Schwarz are highly competent scientists who know a great deal about plasma fractionation and at this level Immuno is a very well run factory. I suspect however, that their infra-structure is less strong, although there were indications that they were improving matters in this area.

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D. P. Thomas

3 July 73