Initial Comments of the Meeting Between Immuno and DHSS - August 12th, 1987

Present:	IMMUNO	DHSS
	Mr. Berry	Mrs. Sylvester - Principal Pharmacist
	Mr. Coombes	Mr. Sloggem - Pharmacist
	Dr. Igel	
	Dr. Elsinger	

This was an extremely informative and beneficial meeting to all concerned and I hope Drs. Igel and Elsinger went away with a true picture of the licencing situation cocnerning Kryobulin and a general feeling of problems in the U.K.

The general comments of the Pharmacists were that the variation was difficult to follow and not methodically constructed so as to take the assessor through it in a logical sequence showing the changes that had taken place. More attention to detail should be given to the changes and the way in which they are presented. The variation did not show in detail every change that had occurred in the change from dry heat to vapour heat and why these changes had been carried out. For example it was not made clear at an early stage in the application that there had been a major change in production to a highly purified product. This he found out when he was well into the assessment and at that stage I am sure felt that we were giving as little information as possible with a view to hiding the change. Mr. Berry and I felt that the comments made by the Pharmacists were in most cases valid and I think Dr. Igel agreed. Mr. Sloggem who dealt with this assessment specialises in viral inactivated products and is likely to deal with most of our products. It is obvious that the data submitted may be good enough for other European countries but not for U.K. A decision needs to be made whether the situation can be dramatically changed otherwise these problems will continue and we will never achieve the necessary registration. Looking at future sales situations in U.K. for certain of these products we also need to decide apart from the U.K. commercial situation whether there is also an advantage to Vienna in obtaining these licenses to help them in other countries. The current waiting time before they even start tolook at abridged applications is 15 months and therefore we should not expect registration of Kryobulin Vapour Heated for at least two years, unless this period is reduced. With central registration starting soon in Brussels for Biotechnology products and Blood Products will probably follow in the future, it must be to our advantage to improve our applications otherwise we will find that each of the member states will be sending their reports back to Brussels and if they agree with the comments say from U.K. they could stop registration in other EEC countries which perhaps in the past would have been successful.

Some of the points raised by Mr. Sloggem were those which Immuno Ltd had raised with Vienna in the early stages of the application e.g. the statement on Hepatitis and HIV which following our discussions with Vienna though eventually modified were still not acceptable to the DHSS.

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In conclusion therefore I feel that a considerable amount of work needs to be carried out in Vienna to satisfy the authorities and it needs to be presented in a much improved logical format as opposed to a selection of documents each compiled by a different department in Vienna. I feel that before the meeting Mr. Sloggem was not very impressed with Immuno because he felt that we were not supplying enough detail in order to hide changes in the variation. This made him look even more carefully at the variation. Following the meeting I feel he now realises that this was not intentional and I feel he now has a better impression of our company in Vienna.

We will shortly be submitting our appeal for Tisseel and we must hope that Mr. Sloggem will not assess that data otherwise I am sure we will not obtain a licence. The current data for Tisseel is we feel the best available but there are reservations on a number of major issues.

A report on the Minutes from the Biological Subcommittee Meeting dealing with Kryobulin are attached. A report giving some additional detail will be prepared within the next few days, together with telephone comments from Mr. Sloggem.

PJC/jar
14 August, 1987