NATIONAL BIOLOGICAL STANDARDS BOARD

NOTES of an informal meeting held on 16 September 1986 at the National Institute for Biological Standards and Control, Hampstead, London NW3.

PRESENT:

Dr G C Schild	NIBSC	Mr K J Ayling	DHSS
Mr M C Lort	NIBSC	Mr R G B Cox	DHSS
Mrs R Michael	NIBSC	Dr R Moore	DHSS
		Dr J Purves	DHSS
		Dr A Smithies	DHSS

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1 BACKGROUND

1.1 The meeting had been called in the light of concern over the risk of transmission of viral infection through blood and blood products, in particular AIDS and non-A non-B (NANB) hepatitis. The Board had been asked by the DHSS Health Services Division to undertake the examination of unlicensed blood products manufactured by the Blood Products Laboratory (BPL) at Elstree with the object of indicating their acceptability for clinical use. Dr Cuthbertson of the Protein Fractionation Centre (PFC) in Edinburgh had requested NIBSC to test samples of each batch of blood products prepared there.

1.2 The risk factor had been previously raised at the CSM Biologicals sub-committee. NIBSC had recommended that, as far as possible, all products derived from human plasma should be made exclusively from donations screened for antibody to HIV. The CSM had endorsed the proposal and agreed that licensed manufacturers should be instructed to this effect, with target dates for introduction of the arrangement, ie intravenous immunoglobulin and blood clotting factors by July 1986 and intramuscular immunoglobulins by December 1986.

1.3 The Board and its Scientific Policy Advisory Committee had, for some years, expressed concern at the manufacture of unlicensed blood products. While this concern was mainly in relation to the BPL, it also applied to the PFC.

1.4 Dr Harris (DCMO at the DHSS) had directed BPL to submit samples and protocols of all batches of blood products manufactured at Elstree for examination by NIBSC with immediate effect. This arrangement was to continue until such time as the laboratory obtained licences for the products concerned under the Medicines Act, or a comparable administrative alternative agreed with the Licensing Authority. It was not likely that this would be achieved in less than one year.

1.5 The SPAC at its meeting the previous week had welcomed and supported the direction in principle but emphasised that additional resources should be made available to fund the work, which ought to be on the basis of an agreed, appropriately staffed scientific programme.

1.6 A major problem was the absence of adequate information on source plasma and the full specifications which would normally be available, as part of a product licence, to the examining scientist at NIBSC. Without such information, a 'release' in the terms applicable to licensed products on batch release orders could not be issued.

1.7 In February 1986, the DHSS had discovered that Armour, who had advised that, from October 1985 they were using only plasma from donors screened for antibody to HIV in their heat-treated Factor VIII concentrate, were not in fact doing so.

2 PRODUCTS TO BE EXAMINED

The products involved and estimated numbers of batches to be tested by NIBSC were as follows:

2.1 BPL Elstree

Immunoglobulins

Approximately 50 batches per annum.

Albumins

Approximately 150 batches per annum.

Factor VIII

Approximately 250 batches per annum.

2.2 SPFC Edinburgh

Dr Cuthbertson had asked if NIBSC could undertake examination of the following:

Immunoglobulins

30 batches per annum.

Albumins

100 batches per annum.

2.3 NIBSC released an average of just over 200 batches of licensed blood products per annum. The additional number to be examined under the proposed scheme would be of the order of 450 from the BPL and 230 from the PFC, ie some 700 batches per annum including a small number of Factor VII and Factor IX. Consideration was being given to the possibility of increasing batch sizes, which would partially reduce the anticipated extra workload at NIBSC. Dr Schild stated that tests on plasma pools would be of value, but that this would appreciably add to the volume of work envisaged.

3 RESOURCES REQUIRED

3.1 NIBSC was anxious to provide every assistance, but Dr Schild emphasised that, under present arrangements, the work could not be sustained from within the Board's existing resources. It was not in accordance with Board policy to charge manufacturers for testing or examining their products, or to discriminate between manufacturers by allocating priorities for examination once the work had been undertaken.

3.2 NIBSC departments involved would be Blood Products amd Immunobiology in collaboration with Viral Products.

3.3 Dr Schild envisaged that a post doctoral scientist, supported by one technician, would be required in both the Blood Products and Immunobiology Divisions, plus the necessary consumables in all three departments. Budget requirements had still to be evaluated but they were unlikely to be less than £70,000 per annum. It would take about three months to recruit the staff and set up an appropriate work programme, including record keeping and 'release' procedures, which would involve at least a 50% increase in administrative work.

3.4 However, it should be recognised that the project could only be undertaken on the understanding that the blood products laboratories were actively working towards attainment of fully licensed status or an agreed administrative arrangement with the licensing authority, which would enable the Board to examine their products under the same terms as those of licensed manufacturers.

4 CONCLUSIONS

4.1 The Institute agreed to undertake examination of the unlicensed blood products identified above on the understanding that the objective of the blood products laboratories to obtain appropriate product licences, or agree acceptable alternative arrangements with the licensing authority, was being actively pursued.

4.2 The project would require to be executed on the basis of an agreed scientific programme, appropriately staffed (as outlined at paragraph 3.3) and funded, and co-ordinated by Dr D P Thomas, Head of the Blood Products Division.

4.3 Examination of samples (to include in-process samples as required) and protocols would be at the discretion of the NIBSC scientists concerned, but would include screening for antibody to HIV.

4.4 An agreed form of certificate indicating acceptability of batches for supply for clinical purposes, taking account of the limited information on product specifications provided, would be issued to the BPL on Dr Thomas's instructions, prior to receipt of which the relevant batches would not be released for use. Reports on batches considered unsuitable for release would be made by NIBSC to DHSS Medicines Division.

4.5 It was anticipated that the project would be started on 1 October 1986.

5 ACTION TO BE TAKEN

5.1 Liaison maintained between NIBSC, DHSS Medicines Division, the Inspectorate, Hospitals Supply Division and the Blood Products Laboratories (Dr Snape at BPL and Dr Cuthbertson at SPFC).

5.2 A copy of NIBSC's release certificate to be sent to Dr Smithies.

5.3 Dr Moore to contact Mr Lort in the course of the following week to advise on outcome of enquiries regarding funding of the work. This was particularly important since batches had already been submitted under the new arrangement.

5.4 NIBSC to prepare a detailed estimate of resource requirements having regard to the increased work-load and scientific programme.

5.5 Appropriate administrative procedures to be prepared.