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SCOTTISH NATIONAL BLOOD TRANSFUSION ASSOCIATION

Minutes of meeting of Regional Directors held at 11 am in St Andrew's House, Edinburgh on Tuesday 3 April 1973.

Present:- Dr I S Macdonald (Chairman)  
Dr C Cameron  
Dr I A Cook  
Dr R A Cumming  
Dr H B M Lewis  
Mr N A Milne  
Dr D P Thomas (DHSS part-time)  
Dr J Wallace  
Mr J G Watt (part-time)  
Mr R N Roberts )  
Miss M I Pollock) Secretariat

Minutes of meetings held on 9 January and 2 February 1973

1. 9 January: The minutes were accepted as a correct record subject to the following amendment page 3 - paragraph 23, first line delete "plasmapherised" substitute "plasmapheresed".

2 February: The minutes were accepted as a correct record.

Licensing of blood products

2. The Chairman welcomed Dr Thomas of the Medicines Division of DHSS who had agreed to speak to the meeting about the implications of the Medicines Act 1968 for the Blood Transfusion Service.
3. Dr Thomas said that the Medicines Act 1968 had arisen out of the Thalidomide disaster and was essentially a licensing procedure concerned with the safety, quality and efficacy of medicinal products. It was concerned with consumer protection. There were four types of licences (1) manufacturers licence (2) clinical trial certificate (3) product licence and (4) wholesale dealers licence. The Act affected the whole of the pharmaceutical industry and made provision for appeal procedure against a decision of the Medicines Commission.
4. Although it was sometimes difficult to define a medicinal product there was no doubt that blood must be treated as coming within the terms of the Act. The Therapeutics Substances Acts had applied only to material which was for sale but the Medicines Act covered sale and supply. Hospitals and transfusion centres under Regional Hospital Boards might have claimed Crown exemption but it had been decided that this should be waived and both treated in the same way as industry. The situation had been compounded by the importation of two Factor VIII products - Hemophil (USA) and Kryobulin (Austria). The Committee on the Safety of Medicines had examined both these products and recommended that licences should be granted; applications were pending for other commercial products which might therefore be on the market before long. Both the commercial products now licensed had come from factories which had been inspected by DHSS; samples and protocols had been sent to the National Institute of Biological Standards and Quality Control, Harpenden which was under MRC and Health Department control. No British blood product underwent similar inspection.

5. It had not yet been decided how licences for blood products should be provided. A major problem was in deciding who would hold the licences and it had been suggested that one way of overcoming it would be a central licence held by the Secretary of State and later the Common Services Agency. New fractions would require to get a clinical trials certificate in the first instance and then a products licence. Whatever was finally decided every effort would be made to keep the system as simple as possible and paper work to the minimum.
6. The initial approach by the Medicines Division to the BTS would be informal and on the basis of discussion and fact finding. The National Institute of Biological Standards and Quality Control would also be involved and the co-operation of all concerned would be required. It had to be acknowledged that the days for treating blood differently from other medical products was over.
7. In answer to a question about plastic bags Dr Thomas said that the bag was a device but a bag containing anti-coagulant was a medical product.
8. Dr Wallace said that although blood was not covered by the Therapeutic Substances Acts the BTS had tried to keep to the standards laid down in the Acts. Human blood was however a scarce product and he would not like to see lot of valuable material set aside for quality control. Dr Thomas had referred to a recent Report on Sterility; the Scottish RTC's were not aware of this Report and the point was made that there was sometimes a lack of communication and the BTS was not always kept in the picture. As far as infusion fluids were concerned the BTS was obliged to prepare certain fluids which were not readily available.
9. Mr Watt said that during the development of products the PFC had been using USA and similar legislation as a minimal guide but it would be happy to use the NIBS standards if they were as stringent as those already being used. It was easier to disguise the product than the process and it was important that there should be a build-up of rapport and knowledge of working before the licensing procedure became effective.
10. Dr Cumming said that he reinforced all that had been said by his colleagues. There were many implications and there would obviously be a heavy financial commitment because of such things as quality control and staff. It was important that administrative arrangements should not prejudice the availability of a product to a patient. As far as this latter point was concerned Dr Thomas said that in terms of the Act a doctor could write a prescription for any product provided the patient was named.
11. In answer to a question from Dr Cook about quality control Dr Thomas said that the tests would include the test already undertaken by BTS eg hepatitis, brucellosis, VD. It was hoped that the NIBS would be able to give advice on the best tests to apply although the licensing authority would set the standards not the NIBS. The Act would be seeking to set minimum standards but this would not preclude higher standards being applied in RTC's.
12. Dr Thomas stressed that there would be a need for dialogue between the Medicines Commission, NIBS, licensing authority and RTCs so that each could be aware of the others difficulties.

Anti-D Immaglobulin

13. The present stock held at the PFC was 1970 vials x 100ug, 1350 vials x 50ug, and 2 batches in process.

It had been agreed at the last meeting to postpone a decision on holding stocks of 200ug doses of Anti-D for use in treatment of recipients of incompatible transfusion until the outcome of further discussion by English RTDs was known. As no further information was available and as it was considered that the matter was one of some urgency it was agreed that the Department should write to Dr Maycock for his comments.

Anti Au/HAA Immunoglobulin

14. It was reported that the Department had written to SAMO's advising them of the availability of this material.
15. The PFC had 160 grams ready to put into ampoules and 2.8 litres of plasma in hand. At the last meeting of the Management Sub-Committee for the PFC it had been agreed that stocks should be made up in 0.5 gram ampoules and there was discussion about whether stocks should be cut to 250 milligram ampoules so that some regard could be made to stock conservation. It was felt however that in the light of the lack of authoritative advice on dosage stocks should be made up in 0.5 gram ampoules.

Likely usage of AHF

16. The minutes of the meeting of the Working Party held on 21 September 1972 had been approved at the CCC meeting on 15 March 1973 with the addition of the following rider:-

"Mr Watt had had no prior knowledge of the detail of the project mentioned in paragraph 13 and whilst approving the general principle of such a project, he had reservations regarding the establishment of a trial centre other than in the short term. The subject of cryoglobulin precipitate was not mentioned at the meeting in this context. Beyond general accord as mentioned he was not in a position to support this paragraph".

17. The Department had issued a letter to Regional Directors, SAMO's etc on 28 March about the treatment of haemophilia similar to a letter issued by DHSS although it was felt that Scotland was not so vulnerable to commercial inroads.
18. At a meeting at DHSS on 20 March it had been agreed that their Supplies Division would try to make central arrangements for the supply of the two commercial Factor VIII products. If these central arrangements were made SHHD would advise hospitals that the material was available from central purchase but that the BTS's own Factor VIII was also available.
19. The point was stressed that there was a need for clinical trials on the new fraction replacing Cohn Fraction I and that Haemophilia Centres should be given the opportunity of testing new material. It should be possible to hold trials in Scotland but the protocol would need to satisfy the Medicines Commission. The Department agreed to approach DHSS to find out what criteria would be required of a commercial firm and if possible to have a sight of the protocol used. It was agreed that Professor Douglas and Mr Watt should be asked to co-operate in the production of a protocol for circulation to Regional Directors.

Tetanus immunoglobulin

20. The PFC had 442 prophylactic doses in stock at present and a number of treatment doses. Mr Watt was concerned about the current practice of issuing anti tetanus immunoglobulin through hospital pharmacies as laid down in SHH 75/197



The Department said that the original thinking had been that since ovine anti-tetanus serum and human anti-tetanus immunoglobulin were used for the same purpose they should be issued through the same channel ie hospital pharmacies. It appeared however that some material had not been used and was now time expired although it was thought that this would not amount to much. It was considered that the human material should be held by the RTCs and it was agreed that when the revised SHM was issued this amendment would be made.

#### Supply of EDTA plasma

21. Consideration of this item had been deferred pending clearance of the CCC Working Party minute on Factor VIII and IX products. There was an urgent need for clinical trials of BTS material as more commercial material was coming onto the market. There was clearly a need for the Working Party to keep a continuing watchful eye on commercial developments and it was agreed that the Department should consider what follow-up was necessary.

#### Hospital transfusion arrangements

22. The Department said that it had been decided to defer issuing a revised SHM meantime pending the issue shortly of a circular in the Health Service Reorganisation series about the Blood Transfusion Service within the Common Services Agency. "Notes on Transfusion" was with the printer but the date of publication was not known yet. It was proposed to distribute copies with a short covering SHM.

#### Preparation of intravenous fluids

23. The Department had discussed the preparation of infusion fluids with their Chief Pharmacist. The policy had been to concentrate the bulk production of fluids into four laboratories - Central Infusion Laboratory, Knightswood; Pharmacy Department, Edinburgh Royal Infirmary; Pharmacy Department, Bridge of Earn Hospital, and the Pharmacy Department, Aberdeen Royal Infirmary. The manufacture of special fluids was confined to approximately fifteen area pharmacies.
24. Although relatively small amounts of fluids were prepared by BTS it was felt that some facilities to prepare fluids in RTCs was necessary and it was agreed that each Regional Director and the Scientific Director should be asked for details of their requirements.

#### Emergency arrangements

25. It was reported that no further information had been received from DHSS about this matter.

#### Plasma identification

26. Dr Wallace and Mr Watt had prepared a scheme which they hoped would be acceptable to each Region. In doing this they had looked ahead to computerisation of records in all Regions. It was agreed that a paper outlining the scheme should be prepared and circulated for comments.

#### Meetings of senior chief technicians

27. It was reported that the Executive Committee had given approval for meetings of all senior chief technicians in BTS to be held twice a year. The Secretary of the SMRTA was to be advised where and when the meetings were being held and reports of the proceedings were to be submitted.

#### PFC: Internal Symposium

28. It was reported that the staff of the PFC proposed to hold a two-day seminar in June. The purpose of the seminar was to familiarise technical staff with the development work being carried out within the Centre and it would be open to personnel below the senior grade. Each Region had been invited to send representatives. Whilst it was agreed that the idea behind the project was to be encouraged, it was thought that if all Regions were to be involved a formal approach should have been made to the SNBTA in the first instance; some oversight by senior staff was also required. It was agreed however that each Region should have authority to send 2 technicians to the seminar; Dr Wallace supported the project but wished to discuss the matter further with his Senior Chief Technician.

#### Joint staff discussions

29. Dr Cumming and Dr Wallace had been discussing the possibility of holding joint staff discussion meetings involving medical and scientific staff viz on the medical side consultants, senior registrars and medical assistants and all senior scientific staff. It was thought that in all approximately 20 persons would be involved probably at weekends. Again it was thought this project should be encouraged; an exchange of ideas and the circulation of information about new developments in other Regions would be useful. It was agreed that the suggestion should be put forward to the Executive Committee for their comments with details of the number and grades of staff involved.

#### Anti-vaccinia immunoglobulin

30. Dr Sharp and Dr Fletcher had carried out a survey on the Experience of Anti-Vaccinia Immunoglobulin in the UK which had been published in the Lancet recently. As a result of the survey a new report form had been designed which it was proposed should be returned direct to Colindale. The Regional Directors felt however that the forms should be routed through them so that they could know the effect and then to the PFC before they were returned to Colindale. The Department agreed to advise Dr Sharp accordingly.

#### Date of next meeting

31. The next meeting was arranged for 12 June 1973 at 11 am in the Blood Transfusion Centre, Archibald Place, Edinburgh.

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#### Full-time administrative structure

32. The Department said that the draft advertisement and job description for the Administrative Officer post had been passed to the NHS Staff Commission for approval; this was necessary for all posts carrying a salary of £3,800 upwards. A reply was awaited.

#### Hepatitis reference arrangements

33. A meeting had been arranged between Dr Cumming, Mr Watt and Professor B Marmion to discuss (a) regional and (b) PFC hepatitis reference arrangements. At present the regional requirements in the South-East were satisfactory.

34. The West Region were continuing to be their own reference centre in the first place and when required seeking advice from Dr Timbury, Western Infirmary, Glasgow.

Provision of plasma or serum to be used as bio-chemical control preparation

35. The meeting between English Regional Directors and bio-chemists had still not taken place.

Training of Medical graduates in blood transfusion

36. It was reported that the Scottish Council for Postgraduate Medical Education had set up a Working Party on the Recruitment and Training of Specialists in Blood Transfusion and that Dr Wallace and Dr Cumming had been invited to serve on it. The Working Party had held one meeting so far and a sympathetic hearing had been given to the Regional Directors' Memorandum.
37. The Joint Committee on Higher Medical Training of the Royal College of Physicians had passed the Memorandum to their Specialist Advisory Committee of Haematology for consideration.

Consultant Establishment

38. It was reported that the Working Group on Consultant Establishments set up by DHSS had held their first meeting on 22 March and that Dr Lewis had attended in Dr Wallace's place. There had been some difference of opinion about the ideal number of consultants in an RTC: variety of work and work-load was obviously a contributing factor. It was thought that the availability of outside experts who could be called on was also important and should be taken into account. Regional Directors were asked to let Dr Wallace have any comments on consultant establishment for the next meeting of the Working Group.

Tissue donors

39. There had been considerable discussion at the recent meeting of English RTDs about the problem arising from the request from the Westminster Hospital for a marrow donation. Two views had been expressed. The majority view was that however reluctantly, the Blood Transfusion Service would have to consider having a special panel of tissue typed donors. This would be useful for the transfusion of transplant cases and in connection with the production of platelets. The minority view held that the Blood Transfusion Service should not become involved; this view was subsequently withdrawn. There were however reservations on ethical grounds about how far members of the public should be invited to put themselves into a position in which one or two individuals might find themselves responsible for the life of a patient because they happened to be the only individuals of suitable type. It was felt that there was a need for a Working Party to include Regional Directors, immunologists and surgeons to advise the Health Departments; DHSS were now giving this consideration.
40. The point was made that if the BTS was to accept responsibility it would be essential to have safe-guards eg compensation for accidents, death etc and that the views of the CCC and the Executive Committee should be sought.

Any other business

Joint Working Party on Blood Products Production

41. In 1964 there had been agreement between the two Health Departments that there should be two centres for the production of blood products. It had been agreed that the Liberton centre should, as well as producing material for Scotland, also produce for the Northern Regions of England - approximately 10 million people. Dr Maycock and Dr Cumming had held frequent informal meetings since then but it was now felt that there was an increasing need for co-ordination and it had been agreed by the two Health Departments to set up a joint Working Party on Blood Products Production to advise on the production and distribution of products etc. Apart from Departmental representatives the National Medical Director and the Scientific Director of the FFC would be members of the Working Party. If its first meetings were held before the NMD was in post it was proposed that two Regional Directors could substitute.
42. The point was made that there was a need for fairly urgent action to safeguard the voluntary status of the BTS; England was already requiring to use imported commercial material.

18 April 1973