

MINUTES OF A MEETING OF THE MEDICINES INSPECTORATE AD HOC PROJECT STEERING GROUP  
HELD AT 10.00 AM ON WEDNESDAY 5 MAY 1982 AT TRINITY PARK HOUSE, EDINBURGH

PRESENT:                   Mr R Wallace (Convener)  
                          Dr A E Bell  
                          Dr J D Cash  
                          Miss M Corrie  
                          Mr M J Ord  
                          Mr J G Watt  
                          Mr C H Wooller

1.     Terms of Reference

It was noted that the terms of reference of the Group, as defined in Minute 1644(iii) of the meeting of the Blood Transfusion Service Sub-Committee held on 24 February 1982, were as follows:

- (a)     To give detailed consideration to Appendix II of the paper submitted to the Blood Transfusion Service Sub-Committee at its meeting on 24 February 1982 and to advise the Sub-Committee on the detailed brief for the proposed works at the Protein Fractionation Centre and to identify the notional capital and revenue implications of the programme.
- (b)     To co-ordinate matters relating to the Medicines Inspectorate as they arose from the Regional Transfusion Centres.

Arising from consideration of the terms of reference it was agreed that the Blood Transfusion Service Sub-Committee be requested to consider extending the remit of the Group to include the associated staffing proposals, which were at the present time the subject of ongoing separate discussions between the Department, appropriate representatives of the Blood Transfusion Service and the Personnel Officer.

It was further agreed that the Blood Transfusion Service Sub-Committee be asked to clarify the extent of the Convener's authority to act without reference to the Sub-Committee.

2.     Membership

Noting its power to co-opt additional members the Group agreed that Mr B Sharry, Senior Executive Officer, Scottish Home and Health Department and Dr R J Perry, Principal Biochemist, Protein Fractionation Centre be invited to become members of the Group and that Mr A G Jamieson, Divisional Architect, Building Division be invited to attend future meetings as appropriate.

The Group also noted that an industrial pharmaceutical consultant who had assisted the DHSS with the development of the Blood Products Laboratory at Elstree had indicated a willingness to act in an advisory capacity to the Agency and it was agreed that such advice as proved to be necessary should be sought on an ad hoc basis.

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With regard to the relationship between the Group and the Medicines Inspectorate there was general agreement that when submitting proposals to the Blood Transfusion Service Sub-Committee for consideration the Group would require to be assured formally that the proposals were acceptable to the Inspectorate and this formal response would be best obtained through Mr Wooller. However, the formulation of proposals would be greatly assisted by continuation of the existing dialogue between Mr Watt and his colleagues and the Inspectorate at a professional level.

### 3. Finance

Mr Ord presented a paper submitted by the Treasurer which indicated inter alia as follows:

- (i) A paper would be submitted to the next meeting of the Blood Transfusion Service Sub-Committee to enable the Sub-Committee to continue their consideration of the revenue development proposals for 1982/83 submitted to the Sub-Committee on 24 February.
- (ii) The financial allocation included an increase in development funds, beyond those for the Microbiology Laboratory which were included in the Agency's estimates, as indicated in the Department's letter of 26 February in view of the financial implications arising from the Medicines Inspectorate's Report.
- (iii) The breakdown of the development funds as shown in the Department's letter was
 

(a)	Microbiology Laboratory	£340,000 - <i>Recurring</i> → <i>M.I.</i>
(b)	Revenue consequences of the move of the Edinburgh & South East Scotland Centre to new premises	£160,000
(c)	Medicines Inspectorate consequences at the Protein Fractionation Centre	£212,000 - <i>Recurring</i>
- (iv) The Department had indicated that
  - (a) Inclusion of the Edinburgh Centre had been made on the basis that the move to the new premises would forestall many of the Inspectorate's criticisms of the present premises; and
  - (b) resources were being made available on the understanding that they would be used exclusively to meet the financial consequences of the Inspectorate's Report.
- (v) Since the item at paragraph (iii)(c) above had not featured in the Agency's estimates at the time of the receipt of the Department's letter, neither its composition nor its basis (recurring or non-recurring) was known. Nor, given the way the funds had been introduced, could any firm indication be given on how the Department intended from a financial point of view, to deal with the Medicines Inspectorate's requirements in subsequent financial years.

Arising out of discussion of the paper Mr Ord reported that it was understood that

- (a) the amount of £340,000 (item (iii)(a) above) had been made available for general revenue developments within the Blood Transfusion Service with the commissioning of the Microbiology Laboratory being the first claim on these resources. Any underspending of this allocation, therefore, in 1982/83 could be used for general revenue developments within the Service.
- (b) The amount of £160,000 (item (iii)(b) above) had been made available on the basis of estimates prepared by the Blood Transfusion Service. Any underspendings, however, would be required to be used for Medicines Inspectorate purposes within the Service on either a non-recurring or recurring basis provided in the latter instance that the full amount was not required in a full year.
- (c) The amount of £212,000 (item (iii)(c) above), which it was advised was input on the initiative of the Department to enable the Blood Transfusion Service to meet the initial requirements of the Medicines Inspectorate in 1982/83, would require to be used therefore for Medicines Inspectorate purposes only, on a non-recurring basis with funding for subsequent years having to be considered annually in the course of the estimates.

The Group noted the position.

#### 4. Background Papers

The undernoted papers, which were tabled by Mr Watt, were received:

- PSG(82)1      Introductory remarks on Med Insp criticisms of PFC
- PSG(82)2      Proposed staffing structure for whole of PFC
- PSG(82)3      Qualifications and Experience for the Senior Posts
- PSG(82)4      A Note on the Salaries paid to Senior Staff by a Pharmaceutical manufacturer in the UK
- PSG(82)5      A Note of Salaries/Wages paid to non-senior staff by a Pharmaceutical manufacturer in the UK
- PSG(82)6      A preliminary assessment of process options at PFC
- PSG(82)7      New Staffing Lists
- PSG(82)8      Special Note on New Staffing Requirements for QA Section
- PSG(82)9      A Proposal for commissioning the Microbiology Extension (Phase I) with respect to staffing

- PSG(82)10 Financial consequences of PSG(82)9
- PSG(82)11 Job Descriptions related to PSG(82)9
- PSG(82)12 Proposal for building modifications and purchase of equipment for upgrading existing building (Phase II)
- ℓ PSG(82)13 Schedule of accommodation for Phase II
- PSG(82)14 Environmental cleanliness in enclosed spaces (BSI) Parts 1, 2 and 3
- PSG(82)15 Current problems associated with documentation with proposal for resolution

5. Protein Fractionation Centre - detailed consideration of Appendix II

(a) Commissioning of Microbiology Laboratory

Mr Watt reported that the extension to the Animal House was likely to be made available in July with the remainder of the new building being handed over in February/March 1983. The necessary additional equipment was also being ordered. However, as noted in Appendix II, the staffing structure which had now been funded had been drawn up in 1974 and did not take account of the Medicines Inspectorate's current requirements. In these circumstances he and his colleagues were of the view that the Laboratory could not be commissioned until such time as decisions had been taken on the revised staffing proposals (Minute 1 above also refers).

In the light of this advice it was agreed that Mr Watt and Mr Maltman be requested to expedite consideration of the staffing proposals with a view to a report being submitted to the meeting of the Blood Transfusion Service Sub-Committee to be held on 26 May 1982. In the interim Dr Cash undertook to consider with Mr Watt and Miss Corrie the extent to which the Microbiology Laboratory could be commissioned on the basis of the existing staff structure.

(b) Upgrading, extension and integration of Production Facilities

Mr Watt presented a paper submitted by Dr Perry outlining the proposals which had been developed in consultation with the Building Division for upgrading the existing production facilities. Informal consultations with the Inspector had secured provisional acceptance of the proposals on the understanding that the upgrading programme and the scheme to extend the production facilities would proceed practically contemporaneously.

The Group also received and noted a letter dated 30 April 1982 from the Department which indicated inter alia that

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- (i) the Medicines Inspectorate would like to see
  - (a) an itemised list of the improvements and alterations proposed for the upgrading of the existing production facilities with, if possible, some tentative costings to give an indication of the scale of the exercise.
  - (b) a timetable indicating the items to be tackled before the proposed shutdown, those to be carried out during the shutdown and any which it was proposed to undertake after operations had restarted.
- (ii) some of the issues identified as lying within the scheme to extend the production facilities did not necessarily require to be tackled after completion of the works of upgrading. It was desirable, therefore, also to incorporate much of what was proposed in the scheme to extend the production facilities in the list and timetable referred to at (i)(a) and (b) above.
- (iii) the Medicines Inspectorate were very anxious to proceed quickly and that it would be helpful if an appropriate response from the Agency could be made by, and if possible before, the end of July.

After a full discussion, during the course of which it was noted that any extension to the existing production building would require the acquisition of part of the adjacent endowment land from the Lothian Health Board and that in due course it might be necessary to seek authority to proceed with the agreed works outwith the terms of the Scottish Health Building Code, the Group agreed to recommend to the Blood Transfusion Service Sub-Committee as follows:-

- (a) that the Building Division be requested to undertake a feasibility study of the proposals developed to date for upgrading and extending the production facilities as a basis for the drawing up of a detailed brief for a design team and a response to the Department by the end of July.
- (b) that the feasibility study should be undertaken on the assumption that the scale of operation required was that appropriate to Scotland and Northern Ireland.
- (c) that, in view of the Department's request for an appropriate response to its letter of 30 April by the end of July, priority be given in the feasibility study, if necessary, to the proposals for upgrading the existing production facilities.

- (d) that if practicable the feasibility study should indicate the consequences of any decision to extend the scale of operation required beyond that presently assumed.

It was further agreed that in the interim Mr Wooller advise the Department of the Group's intentions.

6. Documentation

Referring to PSG(82)14 Mr Watt drew attention to the urgent need for access to word processors and indicated that he had received information to the effect that Nalco had withdrawn from national negotiations about the introduction of such "new technology" and was seeking to conclude local agreements.

Mr Wooller undertook to seek to clarify the position.

7. Regional Centres

Dr Cash reported that it was the intention of the Inspectorate, having made two visits to each Centre, to make draft reports available to the Directors by 11 June 1982. Thereafter it was proposed that each report would be considered by a group comprising himself, Miss Corrie, the appropriate Regional Centre staff and Mr Wooller as a preliminary to consideration by the Group.

8. Future Meetings

It was agreed that meetings of the Group be held as follows:

Wednesday 26 May 1982 at 2.00 pm	Committee Room 1 Trinity Park House
Wednesday 23 June 1982 at 10.00 am	Committee Room 2 Trinity Park House
Wednesday 21 July 1982 at 10.00 am	Committee Room 2 Trinity Park House