

MINUTES OF A MEETING OF THE MEDICINES INSPECTORATE AD-HOC PROJECT STEERING GROUP
HELD AT 10.00 AM ON THURSDAY 16 SEPTEMBER 1982 AT TRINITY PARK HOUSE, EDINBURGH

PRESENT: Mr R Wallace (Convener)
Mr R Y Anderson
Dr A E Bell
Dr J D Cash
Mrs M E Campbell
Mr M J Ord
Dr R J Perry
Mr J O Wastle
Mr J G Watt

Apologies for absence were received from Miss M Corrie, Mr J Maltman and Mr C H Wooller

16. MINUTES OF PREVIOUS MEETING

The minutes of the meeting held on 21 July 1982 were submitted and approved as a correct record subject to the following amendments:-

- (i) Page 1 paragraph 12(i) line 3 - insert "attended by" before "Mr Sivell";
- (ii) Page 1 paragraph 12(i) line 5 - amend "PSG(82)1" to read "PSG(82)2";
- (iii) Page 1 paragraph 12(i) - an appropriate insertion to be drafted by Mr Wastle regarding the agreement not to consider using a limited company as a comparator;
- (iv) Page 2 paragraph 12(i)(c) - insert "was reasonably" before "satisfied";
- (v) Page 2 paragraph 12(i)(d) - insert "representatives of" before "the Department";
- (vi) Page 4 paragraph 13 - delete from "during the present" to "installation".

Arising from discussion of the minutes, the following points were noted:-

- (a) The views expressed by Departmental officers serving on the Group could only be regarded as those of the Department if specifically expressed as such.
- (b) It would be preferable for communications with Mr Hibbert, the independent adviser on staffing structures, to be carried out through the Secretary of the Agency. The Convener advised that arrangements could be made to deal with this point.
- (c) Although the advantages of direct communication between the Blood Transfusion Service and Medicine Inspectors were clear, Dr Bell was concerned that the proper channel of communication with the Medicines Inspectorate, i.e. through the Scottish Home and Health Department, should be maintained. Where informal procedures had been adopted, the position of the Department must be reserved.

17. MATTERS ARISING

(a) Minute 12(1) - Staffing Proposals

In relation to the staffing proposals which had been considered at the last meeting, Dr Cash stressed the enormous advantage to the BTS in the relationships which had developed with the Medicines Inspector. He was anxious to avoid any unnecessary delay in dealing with the proposals pending an official pronouncement by the Department. It was essential that the Medicines Inspectorate were kept advised if this were to be the case.

The Convener asked whether a policy decision was any nearer regarding the future level of demand to be placed on the Protein Fractionation Centre. Dr Bell and Mr Wastle explained that Ministers were on the point of considering the options, and in the meantime, the Group should continue to proceed on the premise that the Protein Fractionation Centre would require to meet the demand for blood products of Scotland and Northern Ireland, i.e. the 80 tonne option which had been identified at an earlier meeting. Although in Mr Watt's view this option might not be the most economic, it was not the Group's role to assess the economic viability of the proposals, which would be done at a later stage. Mr Wastle reminded the Group that the Department were awaiting a response which would then be transmitted to the Medicines Inspectorate for assessment. No advice would be given by the Department on the acceptability or otherwise of the proposals until they had been submitted formally.

Mr Watt explained that the staffing structure document had been drawn up to provide a structure likely to satisfy the Medicines Inspector, and meet the production needs of the Centre, by people working within their knowledge and their understanding of the pay and conditions of service of the staff at the Centre. The document was an attempt to reflect the various production options on the assumption that pay and conditions continued to be those that are understood at the moment. It would require review in detail if these conditions changed. The document represented the "worst" case and indicated the staff required to operate the Centre at maximum efficiency. The 80 tonne option could be obtained through single shift working by most, but not all, staff at the Centre and in that case, up to half the numbers of staff shown on the chart would not be necessary although this would depend very much on the conditions of service which would apply. Referring to his paper containing revenue cost information, copies of which had been tabled, Mr Watt said that within the 80 tonne option, there was a range of levels of activity, at the lower end of which the Centre could continue to produce the present range of products, while at the higher end, it would produce the products more efficiently/effectively (for example, improved recovery of factor IX). Clarifying what he meant by the implications of conditions of service, Mr Watt advised that, particularly at the production level, wages were currently so low that they mitigated against the employment of a high calibre of staff, and higher wages could improve productivity.

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After some discussion it was agreed that the report should be prepared on the basis of the 80 tonne option, with appropriate qualifications being entered as to the level of service which could be provided within that option and with the assumptions made being stated clearly. It was agreed that Headquarters, in association with Mr Watt should prepare a revised document on staffing proposals on this basis.

(b) Minute 12(iii) - Upgrading, Extension and Integration of Production Facilities

It was agreed that these proposals should be revised on the same basis as for the staffing proposals above.

(c) Minute 15 - Distribution of Minutes

Mr Anderson reported that the Blood Transfusion Service Sub-Committee had approved the distribution of minutes of the Project Steering Group to the Transfusion Directors for their information.

18. The meeting was adjourned for lunch at this point.

19. FURTHER EQUIPMENT IMPLICATIONS

Dr Cash expressed concern at the need to commence Phase II of the upgrading of production facilities at the PFC, in the main the provision of a tunnel washer. The Convener advised that it was clear that this group had no authority to authorise expenditure and it was agreed that this issue should be highlighted in the submission to be drafted.

20. REGIONAL TRANSFUSION CENTRES - DRAFT MEDICINES INSPECTORATE REPORTS AND COMMENTS

There were submitted copies of draft reports of the Medicines Inspectorate, together with responses thereon by the various Transfusion Centres. Dr Cash explained that the responses merely corrected factual inaccuracies in the draft reports.

Mr Wastle advised that the Department understood that the final version of the reports would differ little from the drafts, and Mr Walker, Scottish Home and Health Department would be writing in the near future to the Secretary of the Agency to confirm this and to offer to meet to discuss the reports, and particularly the financial implications, both capital and revenue.

The Group expressed concern that there was a danger that availability of funds could determine the strategy in meeting the Medicines Inspectorate requirements, and it was agreed that the submission to be prepared should include a paper on how the funds available could desirably be spent within the restrictions which had been imposed by the Department. It was important to ensure that the requirements of the PFC, which were seen as having highest priority, should be taken into account in any decision on spending strategy and Mr Wastle agreed to propose to Mr Walker that the agenda for the meeting between Mr Walker and the Secretary and the Treasurer of the Agency should be broadened to include consideration of PFC priorities, in addition to the implications for the Regional Transfusion Centres in terms of spending.

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It was agreed that, in the light of the outcome of the meeting referred to above, the draft submission should be prepared and considered at a further meeting of the Project Steering Group on a date to be arranged. Thereafter the Project Steering Group would report to a special meeting of the Blood Transfusion Service Sub-Committee, which would consider and approve the submission to the Department.

21. DEPARTMENTAL REPRESENTATION

The Group agreed to defer for the meantime consideration of the question raised by Mr Wastle of the representation on the group of the Scottish Home and Health Department.