

MINUTES OF A MEETING OF THE MEDICINES INSPECTORATE AD HOC PROJECT STEERING GROUP  
HELD AT 10.00 AM ON WEDNESDAY 21 JULY 1982 AT TRINITY PARK HOUSE, EDINBURGH

PRESENT: Mr R Wallace (Convener)  
Dr A E Bell  
Dr J D Cash  
Miss M Corrie  
Mr A G Jamieson (for Item 12(iii))  
Mr J Maltman (for Item 12(i) and (ii))  
Mr M J Ord  
Dr R J Perry  
Mr J O Wastle  
Mr J G Watt  
Mr C H Wooller

11. MINUTES OF PREVIOUS MEETING

The minutes of the meeting held on 26 May 1982 were submitted and approved as a correct record subject to the substitution of "decisions" for "discussions" in the third line on page 2.

12. MATTERS ARISING

(i) Minute 10(iii) - Staffing Proposals

Having briefly outlined the background to the development of a staffing structure for the Protein Fractionation Centre, Mr Maltman reported that at a meeting with Mr Watt and Mr Sivell of the Scottish Home and Health Department on 23 June detailed consideration had been given to the proposed staffing structure for the Centre as described in PSG(82)2 against the background of contacts with the Department, PSG(82)2 - 15 and an indication from the Medicines Inspector, in his letter of 22 April 1982, that the proposed job descriptions and management arrangements satisfied the Inspectorate's criticisms of the present arrangements. Particular consideration had been given to the top level posts and it had been agreed inter alia that:

- (i) if a post of Deputy Scientific Director was to be established it should have a significant role as well as the basic function of providing continuity at the Centre in the absence of the Director;
- (ii) the four section heads should be titled "Assistant Director";
- (iii) consideration of the administrative support requirements should be deferred for the time being.

In addition the details of some of the job descriptions eg. Assistant Directors had been clarified.

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At a further meeting on 19 July the proposed structure had been reviewed in the light of verbal comments received by Mr Watt from Mr S A Hibbert, the pharmaceutical consultant who had agreed to provide an independent professional assessment of the proposals for the Agency. The comments, which had subsequently been confirmed in a letter to Mr Watt dated 18 July, copies of which were tabled, related to the "deputy" positions which Mr Hibbert felt were never satisfactory and led to unnecessary duplication and the need to obtain information with regard to salary scales from companies other than Glaxo and ICI which, as far as the more senior rates of pay were concerned, were probably amongst the highest in the industry. In the light of these comments it had been agreed that further consideration should be given to the feasibility of dispensing with the post of Deputy Scientific Director and that Mr Maitman would seek to attach to the structure, as presently constituted, the salaries drawn from the information obtained from Glaxo thought to be comparable. It was then intended to submit a report to the Group.

After a full discussion of the significant matters arising from the report requiring resolution, i.e. identification of the appropriate salary levels, the need for a Deputy Scientific Director post in particular and other deputy posts in general and the need to identify the administrative support requirements and reflect these as necessary in the professional structure, and noting inter alia that:

- (a) the basic structure had the support of both the Medicines Inspectorate and the independent pharmaceutical consultant, the latter having considered PSC(82)1 - 6 inclusive;
- (b) notwithstanding Mr Hibbert's reservations and those of the Department, both Mr Watt and Dr Cash felt that a Deputy Scientific Director post should be established. Failing this, one of the Assistant Directors should be nominated as Deputy in the Director's absence;
- (c) having made appropriate enquiries, Mr Watt satisfied that Glaxo was close to the median in any comparative study of the salary levels of pharmaceutical companies;
- (d) while the Department thought a structure of this kind could be reasonable the revenue and other consequences would require serious consideration.

the Group agreed that:

- 1. the Officers considering the structure be recommended to delete the post of Deputy Scientific Director and consider the concept that one of the Assistant Director posts, possibly that of Assistant Director for Production, should be nominated to carry responsibility for deputising for the Scientific Director in his absence;

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2. Mr Watt, Mr Maltman and Miss Corrie seek to identify the administrative support requirements and taking into account the administrative and clerical grades and related salary levels which were available, make any necessary adjustments to the professional structure.
3. A further report be made to the next meeting of the Group.

(ii) Minute 10(v) - Documentation

Mr Maltman confirmed that negotiations were continuing within the Administrative and Clerical Whitley Council with regard to the introduction of "new technology" and that pending the outcome of these discussions Nalco would not conclude any local agreements. Representatives of the Nalco District Committee had also now declined to attend a meeting, under the Chairmanship of Mr Duncan, which it had been hoped would clarify the attitude of local Nalco officials to the introduction of word processors and other similar equipment, until the current pay dispute had been resolved.

The Group noted the position.

(iii) Minute 10(iv) - Upgrading, extension and integration of production facilities

Mr Jamieson presented his comparative feasibility study on the proposed alterations and extensions to the Protein Fractionation Centre, copies of which were tabled, drawing attention inter alia to:

1. the need for the scale of operation and operational policy to be clarified before a brief could be written;
2. the sequence of work proposed;
3. the reduced cost of the revised proposals for upgrading the existing facilities;
4. the ability of the 80 tonnes option to cope with up to 200 tonnes.

Arising from consideration of the study it was noted that in a letter to Mr Watt of 16 July 1982, the Medicines Inspectorate had indicated that the proposals would be accepted as a basis for meeting the deficiencies highlighted in the Protein Fractionation Centre report. Subject to clarification, however, the continued acceptability of the proposal was dependent on Phases 2 and 3 proceeding together so that the link up (Phase 4) was not delayed unnecessarily.

In the light of the foregoing it was agreed that the study be approved in principle and submitted to the Department and the Blood Transfusion Service Sub-Committee for consideration, subject to the addition of such further information in respect of estimated equipment costs and revenue consequences as could reasonably be obtained at this time.

13. Cold Storage Provision

Mr Watt presented reports by Dr Perry and Mr Lines of the Protein Fractionation Centre staff and Mr Thomson of the Edinburgh Office of the Building Division, copies of which had been circulated, following their visit to the Central Laboratories of the Netherlands Red Cross to examine the cold room provision which had succeeded in providing the type of clean environment believed to be necessary for plasma processing. Copies of a series of photographs prepared by Mr Thomson, which served to describe the quality of the environment achieved and also the difficulties which the Netherlands Laboratory had experienced, were also tabled.

Although there were design faults in the installation and these had led to a reduction in operating specification from  $-40^{\circ}$  to  $-30^{\circ}$  and finally to  $-23^{\circ}$ , it was felt that these faults could be avoided in the design of a new installation at the Protein Fractionation Centre which would, at the same time, meet the performance requirements of the original Dutch specification. In this connection it was noted that the Director of the Central Laboratories was proposing to rebuild the cold rooms using thicker insulation and incorporating a system of overhead evaporators, during the present Summer and therefore the performance of this modified design could be assessed before a final decision was made in regard to the Protein Fractionation Centre installation.

Arising out of the discussion of the reports it was also noted that, superficially at least, the DHSS Medicines Inspectorate demands a higher standard of building and environment than its Dutch counterpart and it was agreed that in these circumstances the Medicines Inspectorate should be asked to advise as to the acceptability of the modified Dutch solution to the problem of the cold storage provision.

## 14. DATE OF NEXT MEETING

It was agreed that a further meeting of the Group be held on Thursday 16 September 1982 at 10.00 am.

## 15. DISTRIBUTION OF MINUTES

It was agreed that a request made by Dr Cash for the minutes of the meetings of the Group to be made available to the Regional Directors be referred to the Blood Transfusion Service Sub-Committee for consideration.