A H G FACTOR VIII

INTRODUCTION

1. At a Minister's meeting held on 22 January 1976 to discuss an application for a product licence for a Factor VIII concentrate, the Minister emphasised

(a) that there should be the maximum co-operation between all concerned in Scotland and England with the production at Elstree and Liberton of AHG;

(b) that the qualities and presentation of NBTS products must be such that they are equally as acceptable to clinicians as are the (imported) commercial products - particularly Hemofil as being the product most firmly established. In this connection there was a discussion on points such as relative volumes and solubility which required to be examined.

The Minister expressed a wish to have a report within a few weeks.

2. This memorandum examined the machinery which already exists for ensuring co-operation in production matters between England and Scotland and for reviewing the needs of clinicians and ensuring that NHS supplies meet these requirements.

3. The need to co-ordinate the production and development activities of the Blood Products Laboratory at Elstree and the Protein Fractionation Centre at Liberton was first recognised in 1973. Two bodies were envisaged at that time, an informal body at Departmental level to meet periodically to monitor performance, review progress and initiate any action needed in DHSS and SHHD, and a formal professionally orientated body which would meet regularly to oversee the work of the laboratories and ensure the implementation of policy. The composition of the formal body whose title, it was suggested, might be the "Joint Working Party on Blood Products Production" (later changed to "Joint Steering Committee on Blood Products Production") was as follows -

Consultant Adviser on Blood Transfusion to DHSS
Scottish National Medical Director
Representatives of both laboratories
Regional Directors as necessary (2 from England; 2 from Scotland)
Administrative and professional representatives of the two Departments

The terms of reference were as follows:-

"To advise and make recommendations on:

(a) the allocation of fractionation between BPL, Elstree and PFC, Liberton

(b) the provision of plasma and the distribution of products between the two countries

(c) the co-ordination of research and development.

(d) the standardisation of the fractions prepared and of equipment and apparatus

(e) the effect of medical developments on the activities of the laboratories.

(f) the financial implications of the work undertaken

(g) matters concerning applications of the Medicines Act.

(h) any other relevant matters."

The Joint Standing Committee held its first and apparently only meeting on 20 June 1973 when a significant divergence of view developed between the Blood Transfusion Services in Scotland and in England and Wales on the levels of production of blood products. Subsequent efforts to resolve the differences took place between the two Departments.

4. In March 1973 an expert group was convened to advise the Department on likely trends in haemophilia treatment and related matters. The group was chaired initially by one of the Department's Deputy Chief Medical Officers and was representative of the available expertise in this field. Its terms of reference were:

> "To advise the Department on trends in methods of treatment for haemophilia and allied conditions; to consider possible future requirements for the treatment of the condition and the consequences for the supply of therapeutic agents."

The Group eventually advised that 400,000 donations per annum would be required to treat UK sufferers from haemophilia of all degrees of severity, and more if strenuous efforts were made to clear surgical waiting lists and if home or eventually prophylactic treatment became accepted ways of treatment of the problems of haemophiliacs.

5. One specific aspect (and possibly others) of the problem of ensuring that supplies of Factor VIII are always available for individual patients, is about to be considered by an ad hoc group representative of Regional Transfusion Centres Directors and Directors of Haemophilia Centres who are shortly to meet to consider the arrangements to be adopted for the distribution of Factor VIII as supplies become more freely available. (proposal changed with the possible reactivation of the Expert Group on Treatment)

The respective roles of these bodies

6. It would be unwise to consider a possible future role for the Joint Steering Committee on Blood Products Production without taking account of the difficulties which arose at the one previous meeting which made further progress in this particular forum seem unlikely. Nevertheless, from its terms of reference and its constitution it might be expected to be the single body best able to examine the problems which Ministers now wish to examine, being equally well equipped to look at both requirements and the means of meeting them. The Expert Group could not directly advise on production and co-ordination of productive effort unless its remit were widened. Similarly, the study which the ad hoc RTD/HCDs group are about to embark upon is one part only of the study of arrangements for providing what is required which the terms of reference of the Joint Steering Committee were amply wide enough to cover.

See 5 above

Whilst theoretical considerations might therefore point to the Joint Steering Committee as the body to reconvene, the experience of those who served on this body might rule it out as impracticable. Even so it might be difficult to convince Ministers that differences which caused problems on a Committee some three years ago were such as to justify abandoning the Committee if otherwise it is the most suitable body for the purpose, especially as Ministers have expressed their concern to see co-operation between England and Scotland.

Furthermore, by remitting the problems to one single body it might avoid the kind of difficulty which would arise if various aspects of the matter under review were to be looked at by different bodies and they were to make recommendations which were not entirely compatible.

Conclusion

7. Subject to the strength of feelings of those who served on the Joint Steering Committee, which it is not possible to gauge from the papers, the

right course of action seems to be to consider with SHHD the possibility of reactivating the Joint Steering Committee and leaving this one body to consider all the matters which, in the view of Ministers, require attention.

GRO-C

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