

MEETING AT BPL  
Wednesday, 15th December 1982

Present:



24

Agenda

The implications for the Haemophilia and Blood Transfusion Services of Commercial Introduction of "Hepatitis-Safe" Factor VIII and IX.

Commercial Consideration

Factor VIII concentrates occupy 13% of the gross operating turnover of blood products. Factor VIII therefore lies fourth to albumins specific immunoglobulins and normal immunoglobulin which collectively occupy 86% of the market. Factor IX, with all other products, occupies less than 1% of the market.

Price instability in the world market on blood products has introduced many bizarre effects, particularly in Europe. The price battle for Factor VIII intermediate concentrate in the UK is an example. Intense competition and unacceptably low prices is alleged to have resulted in the withdrawal of Byland Hepophil II from the UK market and the threatened possibility of a second major company withdrawal in 1983. USA → Europe 4% *John*

*by* The withdrawal of standard intermediate concentrate allows certain logical predictions:

- (1) Residual monopoly of standard concentrates allows lack of competition to move the price upwards.
- (2) A clear-field entry for commercial "Hepatitis-Safe" Factor VIII, which by nature of its "special-product" status (unproven) can command a price structure more in keeping with market expectations.
- (3) Through loss of yield in production of "Hepatitis-Safe" products, "special status" is augmented by scarcity value since there must be a shrinkage in world availability of the new concentrates.

BOX 21  
JKP/1  
75



115/25

25

3. Efficacy and Safety of HSVIII and HSIX

The above statement defines the need for centralised, fully controlled prospective trials of "HS" materials, best operated through a properly executed National Clinical Trial lodged with the Regulatory Authority.

End results will carry a level of significance of value to user and producer. Information beneficial to the UK will be optimised.

Manufacturers entering the trial should undertake to make positive contributions of data and financial support in return for a properly conducted trial in a well-documented community of haemophiliacs.

[It is realised that overseas producers do not have access to trial facilities of equivalent quality and veracity elsewhere.]

Proposals

- (a) That random exploitation of the haemophilia service by commercial organisations for the study of "hepatitis-safe" products should be discouraged.
- (b) That the Haemophilia Services should create a formal basis for controlled clinical trial of alleged "hepatitis-safe" products in line with the requirements of Medicines Act.
- (c) That the Haemophilia Services, PELS and NBTS should combine resources in a manner likely to advance economic treatment of NHS haemophiliacs with safe products.

██████████  
██████████ BPL.

15th December 1982.