DW/15

Appendix

Number:

PL/0116/0011

Company:

Travenol Laboratories Ltd

Product:

Hemofil

Therapeutic Class:

Blood Product

Active Constituent:

Factor VIII

SUB-COMMITTEE ON BIOLOGICAL PRODUCTS 14 SEPTEMBER 1983

RECOMMENDATION

On the evidence before them the Sub-Committee on grounds of safety, quality and efficacy was unable to recommend that the Product Licence should be varied as indicated.

The Sub-Committee considered that

1. justification should be provided for the inclusion and choice of the heat treatment step.

2. the heat-treated product was inadequately characterised.

3. inadequate evidence of safety and efficacy was provided.

4. in the event of the grant of a variation to the licence, labels and data sheets should be modified to the satisfaction of the Secretariat.

REMARKS

1. Promotional letters making unjustified claims on improved safety margins in respect of infection and AIDS were seen by the Sub-Committee and strongly deprecated.

2. Evidence of the long-term safety in haemophiliac patients of treated products such as this is regarded as an important prerequisite of licensing.