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COMMERCIAL IN CONFIDENCE

COMMITTEE ON SAFETY OF MEDICINES

SUB-COMMITTEE ON BIOLOGICAL PRODUCTS

Minutes of the meeting held on 13 July 1983

PRESENT

[redacted] (Chairman)

[redacted] (attended morning only)

[redacted] (attended morning only)

[redacted] (attended morning only)

[redacted] (Medical Assessor)

[redacted] (Pharmaceutical Assessor)

[redacted] (Secretary)

[redacted])
)
)attended morning only
)
)

ALSO PRESENT

[redacted])
)
)
) NIBSC
)
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[redacted] (attended morning only)

[redacted] (attended morning only)

[redacted] (attended morning only)

[redacted])
)
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)attended morning only
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1. Confidentiality and Announcements

The Chairman welcomed [redacted] and the DHSS officials, who were attending the meeting for item 5 on the agenda only. He said that this item would be considered first. The Chairman reminded members, and guests, that the material they received was confidential and should not be disclosed outside the meeting.

2. Apologies for Absence

An apology for absence was received from [redacted].

3. Minutes of the Meeting held on 11 May 1983

These were agreed and signed by the Chairman as a correct record of the proceedings.

4. Matters arising from the minutes

The Sub-Committee noted the CSM's advice on applications previously seen by the Sub-Committee.

5. Acquired Immune Deficiency Syndrome

The Sub-Committees' consideration of the question of AIDS and licensed blood products was augmented by the following expert advisers:

[redacted] Professor of Haematology Welsh National School of Medicines, Cardiff and Chairman of the Haemophilia Centre Directors Committee;

[redacted], Consultant Virologist, PHLS;

[redacted], Director of the Communicable Disease Surveillance Centre PHLS;

[redacted], Director, Regional Blood Transfusion Laboratory, Manchester, DHSS Adviser in Blood Transfusion;

[redacted], Consultant Virologist, PHLS.

Consideration was given to the current information available on incidence and epidemiology, aetiology and related factors. Strategies for limiting or eliminating risks from blood products were examined, together with possible practical measures.

The following conclusions were reached:

5.1 The cause of AIDS is unknown, but an infectious aetiology seems likely. A previously unrecognised or new agent may be responsible, but repeated exposure to, or reactivation of, known agents, (eg CMV, EBV) may be involved. Heightened susceptibility may be an important factor, e.g. immunological deficiencies induced by unusual sexual practices or exposure to blood products. Based on the clinical evidence, transmissibility of the supposed agent(s) appears to be low, requiring intimate contact or introduction into the tissues.

5.2 Patients who repeatedly receive blood clotting-factor concentrates appear to be at risk, but the evidence so far available suggests that this risk is small. The risk appears to be greatest in the case of products derived from the blood of homosexuals and IV drug abusers resident in areas of high incidence (eg, New York and California), and in those who repeatedly receive concentrates in high dosage. Balanced against the risks of AIDS (and of other infections transmitted by blood products) are the benefits of their use; in the case of haemophilia they are life-saving.

5.3 The possibility was considered of withdrawing clotting factor concentrates from the market and replacing them with cryo-precipitate. It was concluded that this is not feasible in the UK on grounds of supply.

5.4 The possibility was considered of withdrawing US preparations from the UK. It was concluded that this is not at present feasible on grounds of supply. Moreover, the perceived level of risk does not at present justify serious consideration of such a solution. Efforts are however being made to secure UK independence of foreign suppliers of clotting factor concentrates. This should

reduce markedly, although not eliminate, the risks to recipients of these products, and the Sub-Committee strongly supports this aim. The Sub-Committee was also informed that the UK Haemophilia Centre Directors have adopted a policy for use of US Factor VIII in order to minimise risks as far as possible.

5.5 It is advisable that all clotting-factor concentrates derived from US plasma sources and intended for use in the UK be prepared only from material manufactured from plasma collected after new regulations were introduced by the FDA on March 23rd 1983. These regulations were introduced specifically to minimise the likelihood of collecting blood from affected donors. This step is recommended notwithstanding the possibility that its practical value may be relatively small. It cannot, however, be taken until supplies of post-March 23rd material can be assured. It is recommended that close contact is maintained between the Licensing Authority and Supplies Division with the aim of introducing this step immediately it becomes feasible.

5.6 The introduction of products treated in ways likely to inactivate viruses is a promising future development. At present no such products are available in the UK but it is known that manufacturers are working upon their development. When licence applications are received it is important to examine not only possible improvement in the safety margin but also the clinical effectiveness of material treated by heat or by other means. Thus, for example, treated material could possibly induce reactions in recipients which could render them more susceptible to infectious agents.

5.7 The Sub-Committee learnt that manufacturers were producing advertising material for use in the UK which appeared to make unjustified claims concerning the safety of heat-treated Factor VIII. It is advised that this should be stopped. It is feared that unlicensed material could be used on a named-patient basis, despite the fact that its safety and effectiveness had not been established or considered by the Licensing Authority.

5.8 Hepatitis B vaccine was considered. At present there is no evidence of any risk from the material licensed in the UK, and it was concluded that the licence should remain unchanged, i.e. for use in high-risk groups only. Such groups have a clear risk of hepatitis B, which is a serious and potentially fatal disease. The position should, however, be kept under close observation. It is recommended that the manufacturer be asked to provide ongoing data relating to the safety of the product in respect of AIDS. It is understood that ARVI have recommended that the PHLS undertake surveillance of recipients of Hepatitis B vaccine, and such a study has been planned by the PHLS; the Sub-Committee supports this recommendation. The currently licensed vaccine, manufactured by MSD, has been subjected to three separate inactivation processes, and it is recommended that any new vaccines derived from human blood should be licensed only if subjected to similar stringent treatment.

5.9 Both immunoglobulins and albumins were considered. At present there is no evidence of risk from these products, and no action was though to be justified; however, the position should be kept under close observation.

5.10 Many groups, inside DHSS and outside, are professionally involved in the AIDS question. The Sub-Committee recommends that the DHSS makes sure that adequate arrangements are maintained to ensure coordination of activities between these groups. The PHLS, through its Communicable Disease Surveillance Centre is

co-ordinating clinical observations on the condition and the Sub-Committee believes it essential that this co-ordination continue and that all relevant departments of the DHSS continue to keep in close touch with its findings.

5.11 There is need for research work on AIDS in the UK, especially in relation to the possible new introduction of this disease into the virgin soil of the United Kingdom. The Sub-Committee was glad to learn that a number of groups, including the Medical Research Council, are planning or have started research work.

6. Consideration of Applications

6.1 [redacted]

6.2 [redacted]

6.3 [redacted]

6.4 [redacted]

The Sub-Committees recommendations on these applications for product licences are attached at appendices A-D.

7. Written Representations

[redacted]

7.2 PL/0125/0021-22 Immuno Ltd, Feiba Immuno-Factor VIII Inhibitor By Passing Fraction Human.

The Sub-Committee recommendations on these written representations are attached at appendices E-F.

8. Proposed dates for meeting 1984

The Chairman drew the Members attention to the dates of next years meetings. These adates are:

January	4th
March	7th
May	2nd
July	4th
September	5th
November	7th

9. Items for information

[redacted]

10. Any other business - None.

11. Date and time of next meeting

Wednesday 14 September 1983 at 10.30 am.

14.9.83.