



- (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) 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.
- (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.
- (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.

- (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.
- (9) Both immunoglobulins and albumins were considered. At present there is no evidence of risk from these products, and no action was thought to be justified. However, the position should be kept under close observation.
- (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.
- (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 and have started research work.

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