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HAEMOPHILIACS AND AIDS

INTRODUCTION

1. The burden of haemophilia has been greatly eased by the development of treatment with coagulation factors. The use of these factors has enabled haemophilics to enjoy a normal life.

The AIDS problem therefore came as a bitter blow to haemophiliacs and the medical staff who care for them.

EMERGENCE OF PROBLEM

In 1983 evidence emerged that in the United States of America haemophiliacs were contracting AIDS. Although the mechanism of infection was not known, it was presumed that it had been transmitted through use of blood products such as Factor VIII. Once the virus HTLV III had been idenfitied as the causative agent (first reported in April 1984) and it had been characterised, experimental evidence suggested that heat-treatment processes could inactivate the virus and could be employed to reduce the risk of transmission. Even before product licences under the Medicines Act were granted earlier this year, clinicians were free to prescribe imported commercial heat-treated products such as Factor VIII on a named patient basis. All Factor VIII now released for use in the United Kingdom is heat treated.

CURRENT POSITION

To date there have been 11 cases of clinical AIDS which have been diagnosed among haemophiliacs, and there have been 8 deaths. An unpublished paper by the Haemophiliac Centre Directors - AIDS group suggests that:

2,025 Haemophilia A patients have been tested and 896 found positive (44%)
324 Haemophilia B patients have been tested and 20 found positive (6%)

Together with sufferers from other coagulation disorders the total found HTLV III antibody positive is 35%.

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CURRENT POSITION ON SELF SUFFICIENCY

The estimated total consumption of Factor VIII of all types in England and Wales in recent years has been as follows:

Calendar Year	Millions of Units		
	Total Used[1]	BPL Production[2]	Proportion[3] (per cent)
1981	57.6	20.8	36.1
1982	65.3	22.0	33.6
1983	62.3	30.8	49.4
1984	69.6	27.9	40.0

Most of this Factor VIII was in the form of Factor VIII concentrate, but the total includes some units used in the form of cryoprecipitate and plasma produced by Regional Transfusion Centres.

SELF SUFFICIENCY

In order to enable England and Wales to become capable of self sufficiency in blood products, Ministers agreed to the redevelopment of the Blood Products Laboratory at Elstree and authorised considerable investment in this new factory, which will exceed £40m.

Construction started in May 1983 and is due to be completed later this year. It was necessary to incorporate heat treatment facilities for Factor VIII into the design at a late stage when the problem of AIDS and the effectiveness of heat treatment was established.

It is not possible for a complex pharmaceutical plant to reach full production immediately but it is expected that after the necessary period of commissioning, substantial production will be reached by mid 1987. Full self sufficiency will follow.

The Government has recognised the importance of this project and has fully provided the resources needed to complete the project as soon as possible.

GENERAL SAFETY OF FACTOR VIII

There is no evidence that heat treated Factor VIII used in this country will transmit HTLV III infection.

SAFETY OF BPL FACTOR VIII

All plasma used by BPL comes from the volunteer donors of the National Blood Transfusion Service. Since October 1985 all such donors have been screened. Only 1 donation in 45,000 has had to be rejected. This indicates the high level of safety of this plasma. The BPL product Factor VIII is also heat treated by a sophisticated technique which involves heating the material for 72 hours at 80 degrees centigrade. The BPL product is considered to be the safest available.

COMMERCIAL PRODUCTS

All commercial Factor VIII is licensed under the Medicines Act. All current production is made from plasma from screened donors and is heat treated to an accepted standard.

COMPENSATION FOR HAEMOPHILIACS WHO HAVE BECOME INFECTED

The Government have the deepest sympathy for the plight of haemophiliacs. However there has never been a general state scheme to compensate those who suffer the unavoidable adverse effects which can unhappily arise from many medical procedures. Compensation is awarded by the Courts in cases where negligence has been proved. It would of course be improper to prejudge any case which a haemophiliac might bring. However, no suggestion has been made that the doctors treating haemophiliacs have acted negligently. Before the availability of heat treated Factor VIII, the dangers of unheated Factor VIII had to be weighed against the effects on the lives of haemophiliacs of ceasing to have treatment. Doctors treating haemophiliacs were, we believe, careful in explaining these risks to their patients. The whole range of health services, social security and social services provision is available to help victims of AIDS, including haemophiliacs.

The vaccine damage scheme has been mentioned as a possible parallel. This is not intended as compensation. The aim is provision of financial support and is additional to the provision available to all disabled people whatever the cause of their disablement.

The Vaccine Damage Payments Act 1979 provides for a payment of £10,000(£20,000 for new claims made on or after 16 August 1985) where the Secretary of State is satisfied, on the balance of probabilities, that severe disablement resulted from vaccination. Severe disablement - either physical and/or mental is assessed as 80 per cent or over as defined under the industrial injuries scheme. At least 80% of disability must be the result of vaccination.

This statutory scheme deals with problems which are quite different from those of haemophiliacs