ATTENDANCE AT THE MEETING

The Haemophilia Society

The Haemophilia Society will be represented by :

Prebendary Alan Tanner - Chairman *

Graham Barker - Director of Services and Development

(and others yet to be notified ?)

* Prebendary Tanner is also Chairman of the Macfarlane Trusts, the Macfarlane Special Payments Trusts and the Eileen Trusts which make special payments/hardship payments to those infected with HIV through blood or blood products, so he has a good detailed knowledge of these arrangements.

Officials

Officials attending the pre-meeting at 4pm on 26 March, and for the meeting itself if PS(H) wishes, will be :

Mr Pudlo CA OPU2 (responsible for blood safety and any related compensation)
Dr Rejman CA OPU2 " " "
Ms Phillips HCD SCS (responsible for hepatitis) (or Mr Kent)

Dr Toy -responsible for research - is not avaliable for either meeting.

HANDLING AND LINE TO TAKE - GENERAL

1. The Department has good relations with the Society and there is regular contact between officials and the Director of Services.

2. The Society has a good reputation and PS(H) may wish to take the opportunity to congratulate it on the way it has represented the interests of its members - for example in the development of treatment guidelines and most recently the research report. Although the report is largely anecdotal and unscientific it does provide valuable insight into the experience of patients coinfected with Haemophilia and Hepatitis C.

3. The Society is likely to see the meeting as an opportunity to renew contacts with Ministers but also to promote its campaign on behalf of Hepatitis infected members.

4. The following briefing provides a number of positive developments towards meeting the majority of the campaign ends - notably in relation to treatment and research. The Society have publicly acknowledged such developments but have expressed frustration at the speed of progress. They can be reminded that Hepatitis C is still a relatively poorly understood condition, this is inevitably a limiting factor but that action is being taken to improve understanding.

5. PS(H) is aware that the Society will focus on the issue of compensation. From informal contacts, it is known that the Society have had difficulty in identifying a scheme that would be both affordable and satisfy all their members (who tend to model their hopes on the HIV scheme). They also recognize that any scheme is likely to have consequences for non-haemophiliacs but they can reasonably argue that this is not their problem.

6. The Society are not aware that PS(H) is currently looking at options prepared by officials. They have interpreted what they see as a softening of Ministers' position as placing a responsibility on them to come up with definite proposals however it is unlikely, for the reasons in 5 above that they will be in a position to present anything beyond the rather vague terms contained in the letter to SofS.

7. In the circumstances PS(H) will wish to listen and offer to consider carefully any proposals.

GENERAL BACKGROUND

1. A Haemophilia Society campaign, launched in March 1995, called for a number of actions to address the problems of haemophilia patients who have contracted hepatitis C from contaminated blood products, including financial assistance similar to Government help for HIV infected haemophilia patients.

2. DH Section 64 funding for the Society's Hepatitis "ABC project" enabled the society to employ a research worker to look at the needs of haemophiliacs infected with Hepatitis, although DH was not directly consulted about the detail of the approach taken. An interim report published on 4 December 1995 described the experiences of a number of members with HepC. Ministers written response at the time said that they wanted to give the report the attention it merited and they were reading it carefully, although their first impression was that although it appeared to relate to a relatively small sample of commentators it graphically described the range of problems experienced by people co-infected with haemophilia and Hepatitis C "in a way that cannot help but arouse great sympathy." The letter went on to reaffirm the government's opposition to paying compensation., in the absence of fault, and view that resources could best be used to improve treatment, research etc. It suggested a meeting in the New Year.

3. The Society sent the final report to Ministers on 20 February (see appended sheet for summary). The associated press release says that the report examines in detail the services which people with haemophilia need from both haemophilia centres and the Haemophilia Society. Treatment, counselling, information and self-help groups are mentioned. The press release recognises what the Government has done in dealing with problems about treatment with alpha interferon and in funding research. It calls for further Government action in terms of :

- Financial help for those infected with Hepatitis C through NHS treatment, especially those who are already ill and dependants of those who have already died
- Funding for, and clear guidance on, treatment, counselling and management of Hepatitis C
- Further research, particularly on combination therapies
- a public education programme about Hepatitis C
- funding for the Haemophilia Society in delivering information, advice and support
- funding to ensure that plasma-based products are replaced by recombinant products.

It also calls for a meeting with DH Ministers. The Society' letter to SoS covering the report took a similar line.

4. The majority of haemophilia patients treated prior to 1985, when measures were introduced to destroy viruses in Factor VIII products, will have been infected with hepatitis C through NHS treatment. The precise number of patients infected in this way is unknown. Best estimates suggest about 3000 haemophiliacs not covered by the HIV payment scheme have been infected. In addition it is expected that some 3000 live patients will be identified as a result of the lookback exercise of patients who had blood transfusions.

5. 50% of sufferers may progress to chronic hepatitis with varying degrees of good and ill health. Perhaps 20% of infected patients will develop cirrhosis, a progressive destruction of the liver, that may take 20 to 30 years. The majority of those years will be trouble free in terms of ill health and only a small percentage will actually die of liver disease.

6. In the 1980s, the Government accepted that the patients who, tragically, contracted HIV through NHS treatment were a very special case and unusually made provision for them. Those affected were all expected to die very shortly and were subjected to significant social problems, including ostracism.

7. Ministers have said in debates in Parliament that they have great sympathy with those who have contracted Hepatitis Cs through blood or blood products, but that as no fault nor negligence on the part of the NHS has been proved, they have no plans to make special payments. They have also said that they are willing to consider suggestions for a limited scheme to help those affected, but have given no undertaking to accept any such proposals.

8. Steps already taken by the Department to improve understanding and treatment of the disease include :

(i) Support for an initiative by the Haemophilia Society to undertake a study into the best way to support its members who are infected with the virus, with a grant of over £90,000 this financial year and £117,000 in 1996-97 (on top of core funding of £35,000 this year and £38,000 in 1996-97).

(ii) With other Health Departments - a UK wide look back exercise to trace, counsel, and where necessary treat those who may be at risk of hepatitis C through blood transfusion. The start of the exercise was announced on 4 April 1995.

(iii) Support for the British Liver Trust with assistance through the Sec 64 grant scheme. This includes a grant specifically to deal with the additional workload of advising patients infected with the virus.

(iv) The Standing Group on Health Technology have identified the evaluation of the use of alpha interferon in the treatment of hepatitis C as a top priority for the NHS. This is being actively taken forward by the Medical Research Council.

(v) Work is being taken forward on establishing a national registry of transfusion acquired Hepatitis C infection of a known date of acquisition.

(vi) Research proposals are being sought on establishing the prevalence, transmission routes and natural history of Hepatitis C infection.

(viii) A ministerial commitment to investigate allegations of problems of access to alpha interferon. A few cases were identified by the Society, all of which have been resolved.

NOT TO BE DISCLOSED

9. At the request of PS(H), officials put forward a submission on 9 February which discussed and gave estimated costs for various options for financial help to those affected, including schemes limited to those becoming seriously ill.

THE HAEMOPHILIA SOCIETY'S RESEARCH REPORT : "HAEMOPHILIA AND HEPATITIS RESEARCH PROJECT REPORT"

(The main body of the material, in normal type,summarises the content of the report. Any brief DH comments in response to these points, and not discussed fully in the more detailed briefing which follows, are in italics]

Fact and comment

1. The report includes the material from the interim report received last autumn which describes the experiences of some of those who have been infected with Hepatitis C, under the headings health problems, social and financial problems, family life and relationships, employment and education. It makes recommendations for Government financial help which seem to be the basis for the recommendations made in the final report. While this graphically illustrates the problems experienced, with quotations, it apparently only relates to 18 individuals and does not necessarily reflect the common experience of sufferers.

2. The body of the final report is based on some 105 questionnaires completed by haemophiliacs infected with HepC, plus information from others spoken to by phone, and a small number who attended special meetings. It also draws on response to questionnaires or information gleaned on visits to a number of Haemophilia Centres. Like the interim report, it is largely anecdotal, with figures being provided in only a very few cases.

3. 1,900 infected haemophiliacs are said to have been identified (via Haemophilia Centres). But the report suggests that the true figure is a lot higher, broadly in line with our own estimates of some 3000 people infected in this way.

4. Much of the rest of the report is a summary of people's experiences of the treatment, counselling, advice and information they have received, and suggestions for improvements. There is little of any surprise here, but points which may be worth noting are :

* testing was sometimes done without informed consent, and information was not always passed to patients' GPs (page 7)
DH comment - many GPs have not been told either that their patients are HIV positive. whether such information should be passed to the GP should be discussed with the patient.

*some centres still had tests left to do, and some patients wanted centres to be more active in encouraging people to be tested (page 8)

* people often wanted not just information but an opportunity to discuss the implications for them. Families and bereaved people also looked for support. Social worker involvement was thought helpful (pages 8,9)

* patients sometimes wanted information about symptoms they might expect which doctors considered it unhelpful to give (page 11)
DH comment : agree that it may not be helpful to tell patients of those symptoms not specific to Hepatitis C; but should warn at appropriate stage of specific symptoms that might require urgent action.

* information about a wide range of related topics and for people in a variety of circumstances was considered important (pages 11-13).
DH comment -

* there was some disagreement among medical staff about whether to warn of dangers of sexual transmission of HepC, but patients generally wanted to be told the facts so as to make their own decisions about behaviour (pages 13, 14)
DH comment - the risk is believed to be small, but precise information is not available.

* differing advice was also being given about whether patients should drink, and advice was lacking on the effects of taking drugs (pages 14,15).

* there was concern that the true facts about Hepatitis be disseminated to break down stigma experienced from both the public and health professionals, eg dentists, midwives (pages 15,16). *DH comment - little evidence of incorrect attitude by health professionals included in report and officials are not aware of this being widespread. Treating infected dental patients last, as mentioned in the report, is good practice. The case of refusal of treatment might need to be taken up with the appropriate authority if the facts supported the allegations in the report.*

* some respondents wanted DH clarification of responsibilities of Haemophilia centres, and pressure to implement centre directors guidelines on management and treatment of HepC. Some suggested centres should have liver specialists attached , or at least a better system of referrals to them (pages 17,18).

5. Pages 19 and 20 include tables showing which of the haemophilia centres sampled operated in which way, in relation to :

- where people saw liver specialists
- Polymerase chain reaction and genotype testing
- policy on biopsy

These show variations in practice between some centres in these respects

DH comment : this could be accounted for by the different needs of the patients they treated, and there are differences of views between individual clinicians.

6. Paragraph 4.10 gives the numbers of patients covered who were being treated with interferon and reports that 2/3rds of patients had not been offered treatment with interferon. Reasons for not offering such treatment given by centres were said to include funding difficulties, as well concerns about long-term and side-effects.

DH comment : It is for the doctors treating each individual patient to decide what treatment they need. Treatment with alpha interferon will not be desirable in every case. The few cases referred to us as causing problems have been satisfactorily resolved. (See Section 2 of briefing (treatment etc) for more details.)

Recommendations

7. The report concludes with various sets of recommendations (pages 22-28) :

(a) to the Haemophilia Society :

- the first section of these are for lobbying activities (5.1). These form the basis of recommendations for Government in their press release and letter to Ministers. Noteworthy points included only in the report are the suggestion (5.1.2) that the Society monitor requests for assistance as a means of assessing the extent of unmet need, and (5.15) the Society lobby for the removal of VAT on recombinant products.
- the remaining sections outline way in which the Society could further support and advise members, improve liaison with other agencies and develop/monitor its services. (Increased Section 64 funding might be requested as a result).

(b) For Haemophilia Treatment Centres (6) : the list of recommendations largely picks up on areas mentioned by patients as offering scope for improvement in relation to work on Hepatitis C testing, counselling and treatment. However 6.10 recommends research into complementary medicines/therapies

DH comment - this research proposal seems more a matter for DH, than for haemophilia treatment centres. We are not sure there is any evidence that complementary medicine is of use in relation to Hepatitis C (see Section 2 of briefing for material on research on complementary medicine generally).

(c) a separate section (7) aimed at Haemophilia Centre Directors talks about data collection, promotion of good practice, national wide monitoring of treatment and care. It also encourages centre directors to lobby for funding for better services (7.4) and suggests clinical research on interferon and on "combination therapy" with Ribavarin. Others proposals are for a working party to look at the particular needs of children, encouraging uniform PCR testing, and publication of the results of the haemophilia centre peer review. (Again a number of these points seem more appropriate to DH/MRC.)
DH comment : as Ribivarin is not licensed, research must be within the context of proper clinical trials.

1. POLICY ON COMPENSATION

Society's recommendation

1.1 Financial help for those infected with Hepatitis C through NHS treatment, especially those who are already ill and dependants of those who have already died. The letter to SoS advocates across the board payments to all those infected and additional payments to those who become ill, with financial help for the dependants of those who have already died. It suggests that this will recognise that infection was through the NHS, and help meet additional costs and loss of earnings.

Line to take

1.2 Great sympathy for those infected with hepatitis C as a result of NHS treatment, but these patients received the best treatment available in the light of medical knowledge at the time. No fault or negligence on the part of the NHS has been proved, and we have no plans to make special payments. The Government remains opposed to no-fault schemes.

1.3 Our view remains that the best way the government can help is to encourage research (section 3 below), and best treatment (section 2 below) for those infected, as well as supporting voluntary groups working with those infected (section 5 below).

[1.4. However, if the Society has specific proposals to put forward, as said in the House we would be prepared to look at these.]

Background

1.6 This is the only area in which Ministers cannot claim to have taken action to meet the Society's campaign aims. The Society are well aware of the Government's position on the issue of compensation generally. They accept that no negligence was involved in infecting their members but are likely to argue that there is no real difference between the HIV cases who received compensation and the HCV cases who did not and that natural justice demands equal treatment. [SofS, in evidence to the Health Committee, whilst rejecting the argument for compensation accepted that the HIV position was illogical - the Society have so far not used this].

1.7 The Society have been encouraged by what they perceive to be a softening in Ministers' position, to consider in more detail the sort of compensation they are seeking. They are believed to have encountered difficulty in balancing the aspirations of members with the need for economic realism and the current demands remain vaguely worded with no specific sums mentioned. The John Marshall proposal to confine compensation to cases of cirrhosis is thought unlikely to be acceptable to the Society as it would split the membership.

1.8 At PS(H)'s request, officials have submitted a range of costed options. The Society are not aware of this. That submission emphasises that, although the Society's interest is limited to its own group, in practice it would be difficult to confine any settlement to haemophiliacs.

2. TREATMENT, COUNSELLING AND MANAGEMENT OF HEPATITIS C

Society's recommendation

Funding for, and clear guidance on, treatment, counselling and management of Hepatitis C

Lines to take

1. It is Government policy to allocate NHS funds to purchasers of health care and to leave it to them to decide what services they wish to purchase to meet local needs (including treatment, counselling and management of disease) \within the framework of national policies and priorities. They, in consultation with local providers are in a far better position to know about local needs than Ministers or central government officials.
However, the Department of Health will remain in touch with the Haemophilia Society and the British Liver Trust , and will continue to take feedback from patients and their families, professionals in the field and connected organisations on these important subjects.

Treatment with alpha interferon

2. It is for the doctors treating each individual patient to decide what treatment they need. I understand that treatment with alpha interferon will not be desirable in every case. As promised in the July adjournment debate we have looked into allegations that then problems with the provision of alpha interferon treatment. So far evidence of any problems has been very limited, and the few cases referred to us have been satisfactorily resolved.

Background

1. Hepatitis is inflammation of the liver with accompanying damage or death of liver cells. There are several forms of hepatitis virus. Hepatitis C virus (CV) was not identified until 1989. Routine testing of blood donors commenced in 1991. In most cases infection with CV is asymptomatic for many years, but if hepatitis ensues it can lead eventually to cirrhosis of the liver and liver failure or, in some cases, to cancer of the liver.

2. Groups at risk of Hepatitis C virus (CV) include intravenous drug users people who receive blood transfusions where testing arrangements are inadequate, and people who receive products made from blood which have not been subject to proper viral inactivation processes. The latter group, of course, includes haemophiliacs. People who may have become infected with CV should be counselled before being tested (as with testing for AIDS). If positive they should be referred to a hepatologist for assessment. A biopsy of the liver will be helpful to establish whether hepatitis has developed.

3. Hepatitis caused by CV can be treated with the drug Alpha Interferon but the treatment has side effects and has to be given over a long period. It is not suitable for all patients with proven hepatitis, and calls for all patients infected with CV but who have not developed hepatitis cannot be justified.

4. Although Alpha Interferon is not a universal panacea for CV patients, it has been shown to have real benefits for a proportion of sufferers. It is important, therefore, that those people who could benefit receive it.

5. There have been allegations that patients whose consultants wish to prescribe Alpha Interferon drug) are refused treatment due to a lack of resources. While some of the voluntary organisations involved have referred to a lack of availability of this treatment, this remains anecdotal, as far as we know. Officials are in contact with the Haemophilia Society seeking to identify the nature and extent of any problems there may be relating to provision of alpha interferon. So far evidence of any problems has been very limited, and the few cases referred to us have been satisfactorily resolved.

6. There have also been calls on the Government to allocate central funds specifically for dealing with Hepatitis C. It is Government policy to allocate NHS funds to purchasers and to leave it to them to decide what services they wish to purchase. These decisions are based on an assessment of need that take account of local circumstances and characteristics, within the framework of national policies and priorities. The Department does not allocate resources to support specific treatments for particular groups.

7. These principles apply to the funding of treatment for Hepatitis C, as well as appropriate counselling and testing. Purchasers will need to take into account the fact that Alpha Interferon is now available to treat Hepatitis C in their purchasing plans and to discuss this with local providers.

8. The advice of the Chief Medical Officer in his letter of 3 April was that all anti-CV positive patients found as a result of the transfusion lookback should be referred for further assessment to a specialist with an interest in the condition. The management of these patients requires the use of appropriate treatment regimes and the expertise to decide on the optimum duration of therapy. It is for the specialists working with their Health Authority, as purchaser, to address the issue of costs, based on their funding priorities.

9. Clinical need determines the scope and level of the provision of treatment, but it is an issue that health authorities will need to look at in the light of their own local circumstances. Also DH officials will remain in touch with the Haemophilia Society, the British Liver Trust, patients and professionals on questions relating to treatment of, counselling for and management of the disease.

3. RESEARCH

Society's recommendation (summary)

Further research, particularly on combination therapies.

Line to take

The NHS Standing Group on Health Technology has identified the evaluation of the use of alpha interferon in the treatment of hepatitis C virus infection as a top priority for research. This is being actively taken forward by the Medical Research Council. A Trial Development Group has met with researchers to help them in the design of a clinical trial of alpha interferon and ribavirin in patients with chronic hepatitis C. It is intended that patients with haemophilia will be invited to enter the trial (cf. Recommendation for Action by the Haemophilia Society contained in the Haemophilia and Hepatitis C Research Report - para 5.1.4).

Work is also being taken forward to try to establish a national registry of transfusion acquired hepatitis C infection of a known date of acquisition.

Research proposals will soon be sought on establishing the prevalence, transmission routes and natural history of hepatitis C infection. A one-off budget of £1m has been made available by the Department's Research & Development Division.

The Medical Research Council is funding a three year study to investigate the course and complications of hepatitis C virus-induced liver disease in a group of infected haemophilia patients. The study is being conducted in Edinburgh and is scheduled to finish in May 1996.

Background : Haemophilia and Hepatitis C Research Report

Research Recommendations

- Research on the support needs of partners of people living with hepatitis C (5.2.3 of recommendations)

  This recommendation is addressed to Haemophilia Society, not Government.: [The Department's Policy Research Programme and the NHS R & D programme have both taken forward research into the area of carers generally. The Central Research and Development Committee (CRDC) agreed in December 1995 that work on an Advisory Group on Consumer Involvement in the NHS R & D Programme be taken forward.]

- Research in the role of complementary medicine/therapy (6.1.10 of report).

  This recommendation is directed in the report to Haemophilia Centre Directors, although it seems more appropriate to DH. The Department's Policy Research Programme is funding a programme of research on complementary therapists. The first project within the programme is a national survey of access to complementary health care via general practice, it is just completing.

4. PUBLIC EDUCATION

Society's recommendation

A public education programme about Hepatitis C

Lines to take

The Department of Health and the Advisory Group on Hepatitis are keeping the area under regular review. Leaflets produced by the Health Education Authority and Department of Health guidance on the prevention of blood borne diseases will be updated to include specific mention of hepatitis C.

Information and publicity are often best provided by voluntary organisations like the British Liver Trust whose efforts the Department of Health has supported through the Section 64 scheme (section 5 of briefing refers).

Background

1. The Haemophilia Society, the British Liver Trust and others have referred to public ignorance of and prejudice about hepatitis C, and have called for a widespread public information campaign.

2. The Department will continue to consider, in the light of competing priorities, whether there is a case for direct publicity from central funds, but also believes that the best conduit for publicity may be those organisations that represent the patients and the risk groups. The Department will give help and encouragement to those groups where this is seen to be necessary.

3. The main organisation representing people suffering from liver disease (including hepatitis C) is the British Liver Trust (BLT). DH officials have met BLT on a number of occasions and are happy about BLT's abilities. Accordingly BLT has received core funding under the Section 64 scheme as well as a project grant under that scheme for their "Hepalert" public awareness and information campaign. In this year's Section 64 awards BLT will receive a further grant towards the provision of a Hepatitis C Co-ordinator whose job will be to research information and disseminate it to the public as well as providing direct support to Hepatitis C patients.

Hepatitis C - Prevention

(i) Hepatitis C can be spread by the same means as other bloodborne viruses, although the risks of mother to baby and sexual transmission of the virus are considered much lower than for hepatitis B and HIV.

(ii) Hepatitis C appears to be intermediate in its infectivity between hepatitis B (which is more infectious) and HIV (which is less infectious). In health care settings, adherence to well established barrier precautions to prevent contact with blood or other potentially infectious body fluids will protect health care workers from all bloodborne viruses including hepatitis C. Reusable equipment should be decontaminated appropriately, and disposable sharps disposed of safely. Proper observance of all these long established health and safety measures prevent spread of hepatitis C and other BBVs.

(iii) Hepatitis C is also known to be spread by drug users who share injecting equipment. HIV and hepatitis B are also spread in this way, and health promotion messages stressing that injecting equipment should not be shared are long established.

(iv) Hepatitis C, like HIV, does not appear to be spread by any normal social or domestic contact, provided there is no opportunity for blood to blood contact, such as sharing of toothbrushes or razors.

(v) The blood supply is protected as all donations are now screened for hepatitis C (though there is a very small residual risk from donors who have been too recently infected for infection to show up);.

(vi) Advice given on the prevention of spread of HIV and hepatitis B would also enable those at risk to protect themselves from hepatitis C.

28/02/96

5. FUNDING FOR WORK BY HAEMOPHILIA SOCIETY

Society's recommendation

Funding for the Haemophilia Society in delivering information, advice and support. The letter to Ministers mentions the fact that the project grant must end in 1998.

Line to take

The Haemophilia Society is receiving grants totalling £126,900 from the Department in the current financial year. These will rise to £155,000 in 1996-97 - an increase of over 22%. We have advised the Society that while the project grant must be brought to an end, they can put in a bid thereafter for increased core grant funding to cover ongoing work on hepatitis C. We will certainly try to look sympathetically at any such bid, without being able to guarantee at this stage that such a bid will be met (in full). *

Background and argument

The Haemophilia Society had Section 64 grants for 1995/96 totalling £126,900 :

* core grant £35,000 (for work with those with HIV)

* project grant £ 91,937 (Hepatitis ABC Support project, to provide information and support for the approximately 3,000 haemophiliacs infected with HepC. The research work leading to the present report was funded from this)

The society has recently been notified that its grants for 1996/97 will be :

* £38,000 core grant
* £117,000 continued project grant (cut from the £129,000 requested) because of general financial restrictions.

We have also warned the society that their project grant must be wound up as 3 years plus one years extension only are allowed under the scheme. We have however suggested that any ongoing work on Hepatitis might be included instead in their bid for core funding (without committing us to accepting this).

The report makes a number of recommendations to the Society which would increase its activity in the field of Hepatitis C, and presumably therefore its costs. The Society should bear those cost implications in mind when deciding what measures to adopt. It is also important, as the report recommends, that the society liaises with others working in a similar field and does not undertake work better done by others.

* We are aware that PS(C) is keen to see tapering of core grants, but he acknowledges that there are a number of organisations that genuinely need need the continuation of DH grant in order to survive. We have assumed that, in current circumstances, PS(H) would not want the message to out to the Society that they should be expecting their core grant to reduce.

28/02/96

British Liver Trust

The British Liver Trust also receives a Section 64 grant from the Department. This includes grant specifically to deal with the additional workload of advising patients infected with the virus.

28/02/96

6. FUNDING FOR RECOMBINANT PRODUCTS (AND VAT)

Society's recommendation

Funding to ensure that plasma-based products are replaced by recombinant products.

Line to take

The safety of blood products depends on a number of factors which taken together reduce as far as possible the risk of viral transmission. These include screening of donors, plasma pool testing and the ability of the manufacturing process to remove and inactivate viruses. Recombinant Factor VIII is significantly more expensive than Factor VIII derived from human plasma, and clinicians need to be convinced that the extra costs involved have demonstrable benefits.

Background

The Society's letter to Ministers say that while heat treatment destroys known viruses such as hepatitis C and HIV they wish to avoid the risk of transmission of as yet unknown viruses, particularly as the haemophiliac community has already been hit by two infections. However, the recombinant Factor VIII which is currently available uses albumin, which is a blood product, as a carrier, so the risk of infection cannot be completely ruled out. Albumin involves a viral inactivation step. Any unknown virus resistant to current procedures for viral inactivation in plasma derived Factor VIII might also be resistant to Albumin viral inactivation.

VAT ON RECOMBINANT PRODUCTS

Line to take

This is a matter for Customs and Excise [If pressed : The question of whether VAT is payable on Factor VIII and other products turns on whether they are derived from human blood. My Department has provided technical advice to Customs and Excise on that issue. While recombinant products do contain human albumin which is derived from human blood, it is not the active ingredient of the product, but is used only as the stabiliser/carrier for the active ingredient (which is not itself derived from human blood).]

It is for clinicians to decide what products are used in the light of available resources and the needs of individual patients. Factor VIII derived from human plasma is used for the majority of patients and is exempt from VAT.

Background

Lobbying for the removal of VAT on recombinant products is included in the recommendations in the report (para 5.1) but is not mentioned in the press release or the letter to Ministers. This may be because the Customs lead is recognised. It is understood from Customs that recombinant products are subject to VAT in most EU countries.

28/02/96