SPEAKING NOTE

As I announced at the end of last month, I am very pleased to bring good news to this Committee about our proposed scheme. The UK government has agreed that the Executive does have the necessary powers under the Scotland Act to establish our proposed scheme. And, as you will know, the Department of Health has stated that it too will establish a scheme.

This means we can now get on with the detailed business of setting up our scheme. We still need to make sure that the people who receive these payments do not lose social security benefits – but now that other parts of the UK are adopting a similar approach I am hopeful that this can be resolved without difficulty. There may be other advantages to this new situation and we will certainly be exploring these.

I realise the Committee is concerned that matters are taking so long. I share that concern and am very hopeful that all these discussions can be brought to a satisfactory conclusion and the people affected in this way will be able to receive the payments we have proposed – and gain full benefit from them.

SOCIAL SECURITY

Q: What exactly is the latest situation on the social security issue?

A: There has been a lot of discussion at official level about the way payments could potentially be treated for benefit purpose, but this could not be brought to a conclusion until the devolved power issue had been resolved. Now that has been settled I am hopeful that it won't be a problem for our scheme.

However the social security issue can't be finally agreed until the key details of the schemes here and in the rest of the UK have been finalised.

Q: If social security regulations need changing how long is that going to take?

A: That is a matter for DWP. However, I understand that the relevant social security legislation is routinely reviewed and amended twice yearly. Our working assumption is that any amendments to cover our scheme could come into effect next April.

Q: Will you press Andrew Smith to make arrangements earlier than this?

A: We will confirm the need for legislation and the timetable once the scheme has been finalised.

This won't, of course, prevent the scheme paying out to claimants who would be unaffected by social security benefit loss. It also won't prevent the scheme from processing applications in advance of the date when social security legislation is amended – so the actual payments can be made without delay after that date.

PAYMENT DATE

Q: So when exactly is this scheme going to be up and running?

A: People who satisfy the eligibility requirements for the scheme as of today will qualify for payments. But at this stage I can't tell you exactly when we will be in a position to make those payments.

The first step is to finalise details of the scheme and how it will be administered. Our preferred method of making these payments will be through a charitable Trust. That was the method adopted for HIV infection via the Macfarlane and Eileen Trusts – and I believe it is the right thing to do in terms of ensuring claims are processed in an transparent, objective and independent fashion.

That Trust will need to be established, the detailed rules for its operation worked out and agreed and charitable status obtained. That will all take a little time. But I hope it should be possible for the Trust to be operational early in the new year. We will make a high profile announcement at that time advertising the scheme and making it quite clear what people need to do to apply.

Q: So what happens if someone dies between that date and the time the Trust is able to make the payment?

A: In those circumstances I think that, provided the Trust was confident the application was sound, then the payment would be made to the dependants. I realise that might appear inconsistent with our policy of not paying the dependants of people who died before eligibility was set for the scheme – and I suppose we could be hard nosed about it and reject payments to these dependants too – but I think the pragmatic thing to do is just live with that inconsistency.

Q: Won't you need to enact Scottish legislation to give you the necessary powers to make these payments?

A: I am assured that existing legal powers are sufficient to establish this scheme – so legal powers won't be a limiting factor in terms of getting the payments to the people who need them.

SCHEME PARAMETERS

Q: Will you stick to the proposals you have previously announced – even if the details of the English scheme prove to be different?

A: I don't envisage any major departure from the basic awards I have previously announced.

Q: But you don't intend to pay the dependants of people who died before the establishment of the Trust?

A: No – I have made that quite clear in previous statements. I have great sympathy for those dependants, but I have to consider the effects of the financial outlay on this scheme on our ability to provide treatment for other patients. For that reason our scheme focuses on those who are currently suffering.

I know that excluding payments to dependants may seem heartless but the implications for the Health Department budget are very large. If 580 people come forward in the first three years then the cost to that budget is likely to be over £15m – that is as much as I can afford to divert away from other patient care. Those payments in the first three years would almost certainly cover all the haemophiliacs still alive and also some people infected via blood transfusions.

We know that isn't the end of the story – we expect that another 580 people infected via transfusion will come forward in due course. And if we were to pay out in respect of people who have died then we are potentially looking at 4000 claimants and a bill of over £100m.

Q: Do you intend using the Macfarlane Trust to administer this scheme?

A: That sort of detail has yet to be decided. Using Macfarlane is just one possibility under consideration.

SCHEME PARAMETERS (cont'd)

Q: And is it going to be a requirement for eligibility that applicants have been registered with SCIEH?

A: No – definitely not. When I mentioned SCIEH at the time of my announcement in January it was purely in the context using the current SCIEH figure to estimate outgoings from the scheme over the next three years.

The basic requirement for people to be eligible will just be that they have contracted Hepatitis C as a result of having received blood or blood products from the NHS in Scotland before they were made 'Hepatitis C safe' – and that they have not cleared it spontaneously.

People in those circumstances will receive £25,000. People who have progressed to a more serious stage of the illness (and we are still considering the best way to define that) will receive a further £25,000.

Q: So you don't intend increasing the payments in line with those being offered in the Republic of Ireland (Variously quoted as £100k, £200k, £300k)?

A: I was quite open with you when about this in January. I made it clear that the amounts we are able to pay are dictated by other demands on the Health budget. The Health budget simply cannot cope with awards greater than the ones I have already announced.

People are always quoting the Irish scheme but it is not at all comparable to the situation in Scotland. The payment made in the Republic followed on from a judicial inquiry which concluded that the contamination of the Irish blood supply should have been avoided, and was due to wrongful practices on the part of the Irish Blood Transfusion Service Board.

Those wrongful practices started when a blood from a patient with jaundice was used to manufacture blood products, and a catalogue of poor management following on from this meant that the entire Irish blood supply was jeopardised. (continued)

SCHEME PARAMETERS (cont'd)
Republic of Ireland Q (cont'd)

The size of the awards made in the Republic have to be viewed in that context – where clearly the Transfusion Service could have been held to be negligent. And, much as you would expect in a scheme that is effectively making out of court settlements, there is no fixed tariff of awards. Every case is considered on its merits – so it is really very misleading to quote an average of £X00k as though it was a standard award.

In contrast we do not acknowledge here in Scotland that there was any wrongful practice or negligence on the part of the Scottish National Blood Transfusion Service.

Q: Will you still be using cirrhosis as the trigger for the 2nd payment?

A: We will be taking a fresh look at that to see whether we can use a better medical trigger. I know there are genuine concerns about using cirrhosis as the trigger and in particular about risks associated with liver biopsies – especially for haemophiliacs. This is a complex medical area and I shall be guided by the experts in this field.

Q: Do you intend making payments to people who have cleared the virus under treatment or who have had liver transplants?

A: These are all details, albeit important details that still have to be worked out. At this stage we have an open mind on this.

Q: What about payments to people who have been infected as a result of the virus being transmitted from someone themselves infected by NHS blood?

A: Same answer as above.

SCHEME PARAMETERS (cont'd)

Q: I would have thought you have had plenty of time to think through all these details – it is hard to avoid the conclusion that you have been sitting on your hands hoping you would be saved from doing anything by a legislative impasse on devolved powers.

A: I am not saying that we have not had initial thoughts on all of these issues, but we need to develop these now to a stage where they can be robustly incorporated into a scheme constitution. We will do that quickly – but until we have done so it would be counterproductive to make them public.

Q: Do you intend to consult with patient organisations on the detail of the scheme?

A: We already have a good idea of the views of patient organisations from their involvement with the Expert Group report. We shall certainly seek the views of patient organisations when we come to consider the administrative mechanisms to be used to implement the scheme.

Q: Do you envisage a cut off date after which the Trust will cease to exist and no further payments will be made?

A: Obviously the Trust won't go on forever' but we haven't made any decision on a cut off date at this stage.

UK SCHEME

Q: Is the fact that England is also establishing a scheme affecting what we do up here Scotland?

A: The Department is working in close collaboration with officials in England, Wales and Northern Ireland. I think it is in everyone's interests for schemes across Great Britain to be operating on a common basis if that is possible.

Q: Does that mean the details of the Scottish scheme will be dictated by England – with consequent delay?

A: There will be no deviation from the key scheme parameters that I have already announced – except possibly on the medical trigger. We will share our thinking on other details with the other administrations and also hope to learn from their deliberations – in the interests of achieving a robust workable scheme here in Scotland. However, we won't allow these discussions to unreasonably delay implementation in Scotland.

Q: Are we looking at the possibility of a UK scheme?

A: I wouldn't rule that out as a possibility. It may have some attractions – but it could equally turn out that separate, similar schemes might be the best way forward.

PUBLIC ENQUIRY

Q: You will have seen the recent press articles revealing that government officials knew back in the mid 1970s the dangers of Hepatitis C in blood – yet did nothing about it. Won't you now institute a public enquiry?

A: I don't want to comment in detail on these allegations. I know they refer to a specific document and I have yet to see it personally. But I think it is important not to jump to conclusions without stopping to consider the bigger picture.

I am certain that there will have been worries amongst health professionals at the time – but there will have also been worries about the consequences of not treating haemophiliacs and about not having enough blood to provide essential blood transfusions. There was no specific test for the virus and the alternative of using surrogate tests had only a 40% reliability at best – with many false positives.

As regards a public enquiry, I am not convinced that there are any lessons to be learnt that have not already been learnt. Nowadays risk management and the precautionary principle are key issues for the Health service. And we are committed to better communication between clinicians and patients – especially on risk.

BACKGROUND NOTES

UK dimensions

In Northern Ireland, Angela Smith, Minister with responsibility for Health, Social Services and Public Safety, has announced her intention to establish a financial assistance scheme.

In Wales, Health Minister Jane Hutt has made a more guarded statement that "the Welsh Assembly Government will be looking closely into the implementation of a financial assistance scheme".

Social security

In the absence of secondary legislation, general social security rules would apply. These are complex and would severely restrict the circumstances under which someone could receive and use an award without losing means tested benefits.

DWP officials do not envisage any problem with amending social security legislation now that other UK administrations have signed up to having a scheme.

Andrew Smith was fully consulted on social security aspects before the DoH announcement. The lead DWP official has input to the wording of the above speaking note [NB this has altered from previous drafts of this document].

Income Tax

Needs to be explored in greater detail, but doesn't appear as though there will be any problem.

Charitable Trust

DoH favour asking Macfarlane to take on this role (as Macfarlane did with the Eileen Trust). This would still require establishment of a new charitable Trust. Membership of Macfarlane/Eileen panels are based on HIV infection – different membership would need to be recruited for a Trust dealing with HCV infection. We have previously approached Macfarlane and they had indicated they were prepared to administer such a scheme.

Scottish legislation

OSSE are exploring whether the Executive can make these payments using statutory powers (ie the NHS Scotland 1978 Act), common law powers or whether it will be necessary to raise primary legislation in Scotland to enable Health Department funds to be used in this way – but payments can almost certainly be made under the authority of the Budget Act as an interim measure.

There are also a number of detailed issues associated with administration of the scheme that will need to be resolved before the scheme can start to operate i.e., eligibility criteria, evidence, payments to people co-infected with HIV, payments to people who have received money from litigation etc (as outlined in 6/8 submission).

Medical Trigger

What we want to investigate is the feasibility of using non-invasive tests to establish "serious liver inflammation" as the medical trigger instead of cirrhosis – but we don't want to make any definite commitment at this stage beyond that given in the speaking note.

The main disadvantages of using cirrhosis are a) it would allow the additional payment to some people who have cirrhosis but are not suffering particularly as a result – whilst not allowing it to others who are experiencing serious suffering; b)

people are likely to pester their clinicians for liver biopsies to prove they have cirrhosis so they can claim the extra payment – clinicians would be putting them at unnecessary risk if they agreed.

Previous discussion at HCCC on liver biopsies was centred around the fact that our scheme failed to recognise 'chronic Hepatitis C' sufferers as a separate category of eligible claimant (as it had been in the Expert Group recommendations). HCCC members had refuted suggestions that liver biopsies would be necessary to identify people in that category. We had argued that most people who had cirrhosis would have already had a biopsy (to determine their treatment regime) so using cirrhosis as a trigger wouldn't involve any specific requirement to have a new biopsy. This argument ignores the likelihood of people requesting biopsies (as above).

Whilst our medical advice is that alternative non-invasive tests of liver function could be used as a measure of serious liver inflammation, this runs counter to draft (confidential) NICE guidance that argues that such tests are not yet reliable enough to be used to determine treatment regimes. We really need DoH to sort this out before we can go any further down the route of considering an alternative medical trigger.

Scheme criteria

'HCV safe' – **in Scotland** this means:

- Factor VIII blood clotting factor was made 'HCV safe' (by heat treatment) in April 1987;
- Factor IX blood clotting factor was made 'HCV safe' (by heat treatment) in October 1985; OR
- Other blood products (including blood transfusion and tissue transfer) were made 'HCV safe' heat treatment by the introduction of screening of blood donations in September 1991

'

Financial basis for awards

Philip Dolan questions the validity of our estimate of 4000 people originally infected and 1165 still alive – he believes these to be over-estimates. He has previously quoted David Goldberg of SCIEH as saying that the statistics (prepared by a DoH statistician) was suspect. I have checked this out with Goldberg – he says that some of the assumptions made in developing the statistics are questionable, but was not prepared to say whether better assumptions would yield larger or smaller numbers.

Estimate previously approved by Ministers was based on the assumption that the 568 individuals reported by laboratories to SCIEH as of 31/12/01 as having 'HCV from blood' would claim swiftly i.e. within the next 3 years. The 568 were assumed not to contain any individual who had cleared the virus spontaneously. This means that 25% of them would be eligible for the higher award. This gave an estimated expenditure of **£15m over the next 3 years** – and would include payments to all the haemophiliacs still alive.

[NB the 568 figure comprised 225 individuals allegedly infected via blood transfusion and 343 individuals infected by blood clotting factor. This latter group is likely to comprise all the haemophiliacs who have been infected.]

The number reported to SCIEH has increased to 584 according to more recent SCIEH figures (June 2002). This increase is almost entirely made up of newly identified blood transfusion cases. However, we understand from SCIEH that 16% of the 584 are now dead – which leaves 491 still potentially eligible for payments under

the scheme. SCIEH also advise that 6.9% of those still alive are co-infected with HIV and it is proposed that this group does not receive the basic payment of £20k. On the basis of these assumptions a revised estimate for payments to the 'SCIEH group is **£12.2m over the next 3 years**.

Beyond this there will be other blood transfusion 'victims' – some of whom may not yet know they are infected. Out of the 4000 people believed to have been infected in Scotland, 1165 are thought to be still alive. This means that, in addition to the 'SCIEH group', a further 581 individuals might be eligible. Taking account of co-infection, payments to this additional group of 581 could account for **a further £16.3m**. These payments could be spread over the next 20 years, but likely that the bulk will occur **in the next 10 years**. Possible that some of these could die of other causes before reaching the stage where they claim.

The total possible outlay deriving from these revised estimates is £28.5m – which compares with DoH's estimate of £212.5m for the equivalent group of patients.

Payments in the Republic of Ireland

The payments in the Republic are linked to incidents involving the contamination of the Anti-D supply as detailed below (Anti-D is a manufactured blood product obtained from women at the end of the their pregnancy). People who had received the contaminated Anti-D then went on to donate blood – thus potentially contaminating the whole blood supply.

Extract from the report of the 'Tribunal of Enquiry into the Blood Transfusion Service Board':

- *The primary cause of the infection of Anti-D with Hepatitis C was the use of blood or plasma from Patient X (in 1976), a person undergoing therapeutic plasma exchange treatment who developed jaundice and hepatitis*
- *The use of this plasma was clearly in breach of BTSB's own standards for donor selection…..*
- *BTSB failed properly to react to reports made to them that recipients of the Anti-D made from the plasma of Patient X, had suffered jaundice or Hepatitis C.*
- *BTSB failed to properly investigate the possible existence of complaints by other recipients of Anti-D which were suspected of being contaminated.*
- *BTSB failed to recall the contaminated batches which had been issued and to prevent issue of any further batches made from plasma obtained from patient X.*
- *BTSB acted unethically in obtaining and using plasma from her without her consent*
- *A further cause of infection of Anti-D with Hepatitis C was the use of plasma from Donor Y (in 1989) who was undergoing a course of therapeutic plasma exchange and whose plasma was subsequently used, notwithstanding that it had been tested for Hepatitis C, and in four separate tests proved positive*

*The main reasons why these **wrongful acts** were committed……..*

The Irish Hepatitis C Compensation Tribunal made 114 awards during the last recorded year. These ranged in size from £7,869 to £762,827. The largest award made so far is £1.6m.

The total expenditure since amounts to £291.4m in respect of 1406 awards (an average of £208k).

Public Enquiry

The Committee itself rejected a public enquiry in its own Hepatitis C report in October 2001. It said *"we would be unwilling to advocate any new enquiry on this issue. In practice this would presumably involve hearing evidence as to memories or conversations between practitioners and patients 15 or more years ago and then attempting to adjudicate on whether clinicians negligently failed to give adequate advice on risk assessment. Clearly there would be practical difficulties involved in any enquiry along these lines. A more fundamental objection is that such an investigation would again perpetuate the link between fault-finding and examining the case for providing practical assistance for Hepatitis C sufferers"*

In practice there would be little mileage in holding an enquiry here in Scotland because most of the documentation that would need to be reviewed relates to bodies based in England. Possible that calls for an enquiry in Scotland are an attempt to gain a UK enquiry by the back door.

Media allegations of a cover up

The existence of a further hepatitis virus was proposed in the mid seventies after it was shown that there were cases of post-transfusion hepatitis not caused by either of the hepatitis A or hepatitis B viruses. The illness was called "post transfusion non-A, non-B hepatitis". At the time it was not perceived to be serious by all clinicians. There was much debate in the medical press and between individuals as to whether non-A non-B hepatitis was a serious issue or not. Some 20 years later, and with the knowledge that hepatitis C may take 15 – 30 years to manifest itself in causing liver disease, it is not surprising that these discrepancies of opinion were present. This divergence of opinion continued until a large study was published in 1895 which showed clear progression over 6 years from various types of mild liver disease to cirrhosis. After that Non-A Non-B hepatitis was viewed as a potentially serious condition.

The actual Hepatitis C virus causing this condition was only identified in 1989 following major advances in molecular biological techniques. Blood plasma collected from individual donors goes into large pools (20,000 to 60,000 units) for the manufacture of blood products. This meant that, because of the prevalence of hepatitis C in the donor population, all haemophiliacs using blood products were inadvertently infected with hepatitis C before effective heat treatment was introduced in the mid 1980s. People receiving blood transfusions and other manufactured blood products also risked having the virus transmitted to them during the treatment.

A specific screening test was not developed until 1990/91 and was used to screen blood donors from September 1991. Prior to that the only tests available were the anti-HBc and ALT tests. These were surrogate tests – they did not detect a virus but the fact that the liver functions were abnormal. This abnormality could be due to

other reasons than viral infections. The two tests used together would only have eliminated 40% of infected donations and would have generated a significant number of false positives (with adverse repercussions for the blood supply available to transfusion services). A few countries introduced these tests but most did not. Mr Justice Burton (in his notes in the event that his High Court ruling was appealed) took the view that surrogates tests should have been introduced – but we and DoH would strongly contest that view.

The article quotes a report entitled "Haemophilia Centre Directors Hepatitis Working Party for Year 1980/81". Haemophilia Directors maintain that the general information included within this report was widely available at the time in published scientific medical journals and was known to relevant patient societies including the Haemophilia Society and its Scottish Branch.

The report indicated that Haemophilia Directors were gathering data on which blood clotting factors were related to non-A non-B hepatitis (as detected by surrogate tests). At that time, Scotland was not self – sufficient in blood clotting factors and there would have been no option but to import product from abroad (mostly from the US). These imported products were better than having no products available in the sense of quality of life for haemophiliacs and also the fact that patients could die of bleeding complications in the absence of sufficient concentrate being available. Patients claim they were not made aware of the risks connected with this treatment and there is probably truth in that.

All the imported products would have been licensed by the forerunner of the Medicines Control Agency, and it would have been reasonable for Haemophilia Directors to accept that as some indication of safety. The evidence to cast doubt on that (as quoted in the media articles) was available to the medical fraternity and it then remained a decision for individual clinicians as to which product was used for particular patients. There was no central direction as to which product to use although some products were available free to NHS Trusts via the DHSS central contract – and that included Hemofil (a product quoted as having a high incidence of non A non B hepatitis).

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