PS(PH)
SofS

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HEPATITIS C HISTORICALLY ACQUIRED THROUGH TREATMENT WITH CONTAMINATED BLOOD:
Keeping the clinical and scientific evidence under review, and ensuring the discretionary payments scheme functions as intended

Issue

1. Following SofS's commitment to the House on 10 January 2011, that PS(PH) would meet again with the contaminated blood campaigners, PS(PH) met a representative group of campaigners on 29 June 2011.

2. At the meeting on 29 June, PS(PH) committed to:
   - write to the Prime Minister, to let him know the campaigners' views, and how she intends to provide some assurance to them that the system of financial support works as intended. PS(PH) said she will do this by:
     i. meeting a group of scientific experts to discuss the evidence base for the eligibility criteria for stage 2 payments from the Skipton Fund (which makes payments to people with chronic hepatitis C), and

ii. looking at the operation of the Caxton Foundation, (which will make discretionary payments to people infected with hepatitis C) in late 2012, after it has been operating for a year.

3. PS(PH) has now asked for more detailed advice on how those commitments can best be achieved, and what the potential implications might be.

The need to keep the arrangements under review

4. There is an active group of campaigners who remain dissatisfied with both the scope and scale of the new payments announced in January. The campaigners are engaging MPs, some of whom remain interested in this issue, and there is a possibility that it could develop momentum again, particularly if the Department does not have a clear mechanism to take account of new evidence. Therefore, we recommend that the arrangements that have been put in place are kept under review to ensure they are delivering what was intended by Ministers, and that they remain consistent with new and emerging scientific evidence.

5. A common complaint from campaigners following the announcement on 10 January 2011, is that recurrent payments should be given to individuals with chronic hepatitis C infection, who are suffering serious ill health, but whose condition is not sufficiently severe to qualify for the stage 2 payment, which includes both a second lump sum and recurrent payments. It is not clear how big this sub-set of individuals might be within the group of around 2,600 people in England who have received stage 1 (but not stage 2) payments. A note of the system and level of payments announced by SofS in January 2011 in respect of hepatitis C infection is at **annex A**. There was no change to the existing lump sum payment for stage 1, but Ministers will recall that the lump sum stage 2 payment was increased, and recurrent payments were introduced. In addition, the Caxton Foundation has been established to make discretionary payments for both stage 1 and stage 2 recipients and their families.

The current clinical and scientific advice

6. Decisions regarding the eligibility criteria for Skipton Fund stage 2 payments are a matter for the Department. The approach that has been taken since the Skipton Fund was established in 2004 is that only conditions which are severe are included in stage 2.

7. The members of the original expert group have national and international reputations in their fields and we can have confidence in the robustness of their advice. Their advice, published with the review report in January 2011, did not indicate any reason to move away from the existing differential approach to financial support for those with chronic (stage 1) and severe (stage 2) hepatitis C infection. The latter (progression to cirrhosis, decompensated cirrhosis, or primary liver cancer) will have a substantial impact on life expectancy, and quality of life is substantially reduced and liable to deteriorate over time.

8. The expert group was largely content with the existing definitions of stage 1 and stage 2, but recommended that B-cell non-Hodgkins Lymphoma (a rare life-threatening disease) associated with chronic hepatitis C infection should be added to the criteria for stage 2. The group did acknowledge that there was a wide spectrum of illness associated with stage 1, and that some patients at this stage can experience a significant impact on quality of life. In addition, chronic infection has been associated with a range of extra-hepatic symptoms, including neurocognitive effects that impact on daily life, but many of these are difficult to attribute to hepatitis C infection in an individual. It is for these reasons that we recommended a discretionary needs-based, rather than a fixed, system of financial support for this group.

Advantages of keeping the arrangements under review

9. The advantage of keeping the arrangements under review is that it will help to ensure that they remain consistent with the evidence base, enabling the Department to take a robust line with future campaigning and parliamentary activity. It will also put the Department in a strong position to resist legal challenge (see **Legal advice** at paras 18 and 19 below.).

Disadvantages of keeping the arrangements under review

10. This may highlight a case for making some changes to the existing arrangements from time to time, which could have financial implications.

11. The cost of lump sum and recurrent payments is demand–led and therefore the Skipton Fund must pay whomever meets its eligibility criteria. By contrast, payments from the Caxton Foundation are constrained by the Trustees' charitable judgement, working within a cash allocation from year to year, together with any reserves it might accumulate. DH controls the funding to Caxton for these discretionary payments by only releasing the funds on demand, thus reserves held by the Foundation should therefore be minimised. In addition to this, HMT rules obviously prevent the Department from making any payments in advance of need to strategically top up these reserves for use in future years. We keep this under careful review with DH finance colleagues.

12. There is a possibility that new evidence could emerge in future which might support changes to the existing stage 2 eligibility criteria. There is equally the possibility that new treatments could come on stream that would help limit the progression to stage 2. If, at some future point, ministers agree to amend the stage 2 eligibility criteria as a result of expert advice, the number of people that might be affected is likely to be small. Nevertheless, for every new individual who qualifies for stage 2, costs will increase by £50k one-off to be met in the financial year any change falls, and £13,200 recurrent (uprated annually by CPI).

13. Additional financial costs resulting from any change in eligibility criteria would of course need to be managed against the backdrop of reducing central financial envelopes, further reducing the flexibility to fund other commitments.

Handling

a) Keeping the evidence under review

14. When PS(PH) met with campaigners on 29 June, she agreed to host a meeting of experts to discuss the clinical and scientific evidence, with one or two patients present. We will discuss details

with PS(PH)'s office, including the possible inclusion of one or two additional scientific experts (eg Professor Thomas, an international liver expert and probable Caxton trustee, and a virologist who is not a hepatitis specialist).

15. Looking to the future, we recommend that the Advisory Group on Hepatitis (AGH) should be asked by the Department to keep the evidence base under review on a more regular basis, over a longer time frame, as part of their workplan. CMO is supportive of this approach, which would enable us to use an established mechanism for dealing with new data brought to our attention by patients and others. The AGH would also be well placed to take account of the impact of new treatments for hepatitis C during the chronic stage. Two such treatments are currently within NICE's work programme.

b) Monitoring the new system of discretionary payments

16. The Caxton Foundation has been set up to provide additional discretionary payments to those affected by hepatitis C, based on need. It will not start operating until October 2011, and PS(PH) has asked to meet the Trustees of the Caxton Foundation later this year.

17. Coupled with regular review of the evidence base, we will monitor routine information provided by the Caxton Foundation when it begins to make payments at the end of October 2011, together with reactions from its beneficiaries, and will apprise Ministers of any operational or funding issues for FY12/13 and subsequent years.

18. At this stage, we do not know what will be the level of demand on the Foundation, and the Department will need to assure itself that it is delivering what Ministers intend. As the Caxton Foundation begins to operate, we will gather information on which to make a judgement, and will be in a better position to advise you after it has been operating for a full year. In the interim, if the current financial allocation looks to be insufficient to meet demand in FY 2012/13, we do have some flexibility to address it within the overall system of funding for discretionary payments in respect of contaminated blood, as the Macfarlane Trust (which makes

discretionary payments to those with HIV) currently has a prudent level of reserves. It would be legitimate to make a smaller funding allocation to the Macfarlane Trust in FY12/13, on the understanding that it could run down its reserves (subject to Charity Commission guidelines on appropriate reserves policy). This would free up some resources to divert to the Caxton Foundation. However, there could potentially still be a need for some additional funding for the Caxton Foundation from FY12/13 onwards, and potentially also in future years for the Skipton Fund, should clear evidence emerge that supports wider eligibility for stage 2 payments.

Legal advice

19. The advice of DH Legal Services is that as long as policy is evidence based, the Department has a good case for resisting legal challenge. However, the risk of challenge increases if the arrangements are inconsistent with the scientific evidence base.

20. However, there is in any event a strong case for putting as many resources as possible into the Caxton Foundation, rather than into enhanced Skipton Fund payments, as when matters turn on the individual's circumstances, as in relation to the differential suffering of the Stage 1 people, a discretionary power, such as that which the Caxton Trustees possess, can readily be defended as the best way to get extra resource to those who most need it.

Conclusion

21. Are you content that:
    - The scientific evidence underpinning stage 1 and stage 2 payments via the Skipton Fund be kept under review on an ongoing basis through the Advisory Group on Hepatitis, taking account of the impact of new treatments (para 15).
    - We monitor the operation and funding for the Caxton Foundation to ensure that it is operating as Ministers intended and that funding is adequate; and that any financial pressures that might arise be addressed in FY 2012/13 as far as possible through re-balancing the overall funding allocation for the

Macfarlane Trust and Caxton Foundation (as outlined in para 18).

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ANNEX A

Support available to patients infected with hepatitis C by contaminated NHS supplied blood and blood products, and their families.

The Skipton Fund makes payments to people infected with hepatitis C from contaminated blood and blood products.

It pays in two stages:

- Stage 1 – a one-off lump sum of £20k on diagnosis of chronic hepatitis C infection (i.e infection lasting more than 6 months);

- Stage 2 – a additional; one-of flump sum of £50k, plus annual payments of £13,200 (uprated annually in line with the CPI), for any individual who goes on to develop serious illness as a result, namely cirrhosis, liver cancer, or B-cell non Hodgkins Lymphoma.

The Caxton Foundation will also make additional discretionary payments to individuals infected with hepatitis C and their families, based on need. The Foundation is due to start its work in October 2011, so we cannot say yet what its schedule of payments will be.