Witness Name: Donna McInnes

Statement Number: WITN5737001

Exhibits: None

Dated: 22 December 2021

INFECTED BLOOD INQUIRY

WITNESS STATEMENT OF DONNA MCINNES

I, DONNA MCINNES, Deputy Head of EU & International Policy, Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf, London will say as follows:

1. I prepared a draft of this statement in November 2018. In May 2021 I was asked by the Inquiry to finalise and sign this statement. In doing so, I am reliant on the work done back in November 2018. I have not worked for the Department of Health and Social Care ('the Department') since January 2020 and moved from the role this statement addresses in August 2018. I am currently Deputy Head of EU and International Policy at the Medical and Healthcare products Regulatory Authority. This statement should be read in that context – as whilst it is dated [December 2021], it was initially drafted several years ago. I can only comment on the position as it was before November 2018 on the basis of the documents that were made available to me in late 2018.

2. I worked in a number of roles within the Department from September 2015 until January 2020. In addition to a wide range of other responsibilities, in my previous role as Head of Infected Blood Scheme Reform (from approximately January 2017 to August 2018). I was responsible for policy on the blood payment schemes. I have prepared this statement from my knowledge. Wherever I have relied on information outside my own personal knowledge, I have explained or provided the source of that information.

Setting up of the trusts

3. Since 1988, successive governments have voluntarily provided support for people infected and affected by HIV, and more recently for those infected and affected by HCV, through treatment with NHS supplied blood or blood products. When I prepared a draft of this statement in November 2018, over £450 million had been paid out to infected persons and their family members.

4. Support developed incrementally in response to lobbying and litigation in relation to HIV. It was provided via five schemes:

   i. I understand that the Macfarlane Trust was established first, in 1988. It was designed to help haemophiliacs infected with HIV (and their families). Support from this Trust was increased after an out-of-court settlement in 1991.

   ii. I understand that the Eileen Trust was created in 1993 in order to support non-haemophiliacs with HIV (and their families). The Eileen Trust was established in response to initial moves towards litigation by a group of affected non-haemophiliac patients.

   iii. In 2004, the Skipton Fund was established to provide financial support to those who had contracted HCV and their families, paralleling reforms developing in Scotland. The Skipton Fund provided two levels of lump sum payment, dependent on the person's condition, based on advice from experts. It did not cover those who developed HCV and subsequently cleared the virus from their bodies without treatment within 6 months. It provided a lower level of support to all those who contracted chronic HCV ("stage 1"), and a higher level to those who developed serious, cirrhotic liver disease or its sequelae proven to be caused by HCV' ("stage 2").

   iv. Following the 2009 Archer Report (the result of a non-statutory independent inquiry) in early 2010, the Government set up MFET Ltd to provide annual payments to those with HIV and introduced annual payments for those with stage 2 HCV through the Skipton Fund.

   v. In 2011, the Government established the Caxton Fund in order to provide additional, discretionary support to those with HCV. This followed an internal "Review of the support available to individuals infected with Hepatitis C and/or HIV by NHS supplied blood transfusions or blood products and their dependants".

5. As a result of the above developments, by 2016, the following support was provided via all the various funds cumulatively:

Beneficiaries with stage 1 HCV	One-off lump sum payments of £20,000 Discretionary individual grant payments Free prescriptions and counselling Winter payment for all those receiving discretionary funding
Further support provided to stage 2 HCV	An additional one-off lump sum payment of £50,000 Annual payments of £14,749, uprated with the CPI Access to discretionary benefits as above
Beneficiaries with HIV*	One-off lump sum payments of £20,000 Additional one-off lump sum payments from £21,500 to £60,500 reflecting an out-of-court settlement from 1991 Annual payments of £14,749 uprated with CPI Discretionary individual grant payments Regular means-tested top-up payments for those below a certain household income threshold Free prescriptions and counselling Winter payment available to those receiving discretionary funding
Dependants of those with HIV	Fixed rate support to dependent children, assessed annually (including those who have lost a parent) Discretionary individual grant payments Regular means-tested top-up payments to widows/widowers with low income families Winter payments available to those receiving discretionary funding

Dependants of those with HCV	Discretionary individual grant payments Means-tested top-up payments for those below a certain household income threshold Winter payment for all those receiving discretionary funding

*beneficiaries who are co-infected with HIV and HCV (stage 1 or stage 2) are entitled to receive both the HIV and relevant HCV payments.

6. In summary, the previous schemes provided some support for all beneficiaries. All infected individuals received the same initial lump sum of £20,000. The key differences in support before the 2016/17 scheme reforms were that those with stage 2 HCV and those with HIV also received annual payments of £14,749 (uprated with CPI), whereas those with stage 1 HCV received no annual payments. Further, those with HCV received a second lump sum of £50,000 when and if they progressed to Stage 2. Beneficiaries with HIV will also have received an initial lump sum of between £21,000 to £60,500, depending on their circumstances, following on from the 1991 litigation settlement.. In addition, the discretionary schemes were available to all beneficiaries.

Reviews, consultations and reforms

7. Below, I try to draw out how the policy behind the scheme reforms in 2016/17 was developed by reference to the key issues, I first explain our ultimate aim at the time. I then explain the substantive development of the policy by reference to making the schemes simpler, respecting historic expectations, managing financial constraints, reflecting the differences between the infections and limiting the extent to which beneficiaries would be subjected to assessment. I then address directly why we felt that the scheme would achieve our ultimate aim in a fair and effective way. Finally, I have included a table showing a summarised chronology of the policy development process.

The ultimate aim

8. There was a basic problem. We had a group of people whom the Government wanted to continue to support: those who had contracted HIV and/or HCV from contaminated NHS blood and blood products and those affected by this. However, the support that we were providing was not as effective or fair as we wanted it to be because:

a) Support was complicated to understand and access, because beneficiaries had to deal with multiple schemes with different rules and processes.
b) Support was not targeted fairly and effectively at those who needed it most. In particular, some people with stage 1 HCV needed more support than they were receiving.

9. As we tried to solve this problem, we were working within the following parameters:

a) People had become used to receiving a particular level of support, and some were reliant on that support. Ministers, and particularly the Prime Minister, from mid-2015 gave a firm steer that people should not be worse off under the new schemes. We referred to this as the idea that there should be "no losers" as we developed system reform.
b) All of Government was working under severe financial constraints. We would not have an unlimited budget with which to design an ideal scheme. The new scheme had to be affordable.
c) We had always known that there were some important differences between the infections, but the impact and the understanding of these changed over time. We needed to make sure that the new scheme addressed, as best we could, the different situations of people with these different infections and the latest, emerging medical evidence.
d) As the policy process developed (and particularly post-consultation), it became clear that there were profound and widespread concerns about any scheme that subjected all or large numbers of beneficiaries to extensive or invasive assessment of their means and needs. We were told that this would be intrusive and stressful for beneficiaries. It would also be expensive and complicated to administer. Therefore, whatever scheme we designed would need to target support as broadly and fairly as best we could, while at the same time, limiting the number of people who had to go through new assessment processes.

10. In that context, the challenge was to design a scheme that was as fair and effective as we could make it, while respecting historic expectations of people supported by the schemes, remaining affordable, addressing the different situations of people with these different infections, responding to medical advances and involving limited assessment of beneficiaries.

Consultation

11. A consultation document on “Infected blood: reform of financial and other support” was published in January 2016 and the public consultation ran from 21 January to 15 April 2016. The proposal was as follows:
    a) The current five schemes would be replaced with one scheme operated by a single body to assist eligible people who were infected in England. This was intended to be simple and accessible.
    b) The new scheme would have to meet the requirements of the Equality Act 2010 so that everyone was treated on an equitable basis in light of the health impact they have suffered.
    c) The bereaved would have the option of either a lump sum or continuing access to discretionary funding.
    d) Eligibility for the reformed scheme would be as it was for the current schemes. The only change being that new HCV applicants would receive an individual assessment to determine impact of infection and level of payment.
    e) Unlike the current schemes, all infected individuals would receive an annual payment.
    f) Individual assessments would be introduced for those with stage 1 HCV and for all new entrants to the scheme to determine the amount of the new annual payment. The rationale for assessing those at stage 1 then in receipt of no annual payments reflected the evidence concerning the variable impact of the infection on quality of life.
    g) The exact format was to be determined following responses to the principle as set out in the consultation. Assessments could potentially be paper-based, at least in the first instance, with some overarching clinical or expert governance. The aim at that time was to make the process simple and easy to understand for beneficiaries. The consultation indicated that the highest payment band would be equivalent to the annual payments received by those with HIV and HCV stage 2.
    h) Newly bereaved partners/spouses would be provided with a final payment equivalent to one further annual payment at the level their partner was receiving at the time of their death. Views were sought on the future arrangements for those already bereaved, and whether that should be through a one-off lump sum or through continuation of a means tested discretionary element, or a choice of either.
    i) Consideration would be given, depending on the views of consultees, to offering some early access to new HCV treatment for those for whom the treatments were clinically appropriate on the basis of a treatment assessment and who were unlikely

to receive it in the near future on the NHS. This idea had been rejected as a use of the first additional £25m, but was being reconsidered in light of the further additional funding.

12. The consultation document acknowledged that any proposal would be subject to affordability: the level of annual payments would be determined by reference to the numbers of individuals expected to fall within each band.

Responses to the 2016 consultation

13. The Government response to the 2016 consultation is at WITN3953052. 1,557 responses to the consultation were received. The majority of all respondents (58%) had HCV, 6% had HIV and 20% were immediate family members or carers of an infected individual. 1350 respondents were registered with one of the payment schemes.

14. The content of the responses can be summarised as follows:
    a) Most (66%) of respondents preferred one scheme over five schemes.
    b) In response to the proposal of a new annual payment with individual assessments to determine the amount, 52% of respondent beneficiaries indicated that they did not want to have individual health assessments. The most common reason given for this was that respondents felt that they should not have to prove that they were ill to receive an annual payment. Only 4% of respondents were supportive of introducing individual assessments.
    c) 72% thought that the reformed scheme should retain the lump sum of £20k when an infected individual joins the scheme. Of those that commented, the main themes were that everyone should get this lump sum not just the infected new joiners and that the £20k sum was too little and should be increased.
    d) 53% of those that responded thought that the reformed scheme should maintain the difference between those with HIV and HCV by retaining the lump sum payment of £50k provided for those who develop cirrhosis because of HCV infection. . 20% of those who answered the question thought that the reformed scheme should not differentiate between those with HCV and HIV and remove the lump sum of £50K for progression to HCV stage 2.
    e) In relation to payments for the newly bereaved, 70% of respondents wanted a choice between one final year of payment, or continued access to discretionary support.

f) For the existing bereaved, 69% wanted a choice between a final lump sum or continued access to discretionary support. In addition, around 10% said that they wanted both a lump sum and access to discretionary support, with 27% wanting a more generous offer or support akin to that being provided to the bereaved by the Scottish Government.

g) 70% of respondents (and 47% of those infected with HCV) thought that access to treatment should be provided under the reformed scheme, whilst 22% of respondents who answered this question thought not. 38% said that treatment should be provided by the NHS, with many commenting that providing treatment through this scheme amounted to making beneficiaries pay for their treatment.

h) 80% of respondents considered that discretionary payments should be available for travel and subsistence relating to ill health. 26% said that discretionary payments should cover more than just travel and subsistence costs. 20% of respondents said that discretionary support should not be provided at all, on the basis that annual payments should be enough that discretionary support is not needed, or that a large lump sum should be provided instead.

i) 5% said that discretionary payments should be made on the basis of financial need.

j) 5% said that applying for grants felt 'like begging' and should be more easily accessible.

k) Many respondents considered that the type of cost they would like the discretionary scheme to cover included winter fuel payments, home care, prescriptions and respite.

l) The link between annual payments and CPI was important to respondents, especially for younger beneficiaries.

m) Many were concerned that reforms to the discretionary aspect of the scheme would impact negatively on their financial situation.

n) In relation to particular groups of people, especially those with protected characteristics, the most common concerns were:

- That those who were disabled as a result of their infection might receive less under proposed reforms than they did at the time of the consultation;
- that since many disabled people already had to go through various forms of assessment for government support, subjecting them to further assessment was not fair;
- that older beneficiaries were more reliant on discretionary support, such as winter fuel payments, than younger beneficiaries;

- that, as the majority of the bereaved were women, they were disproportionately affected by reforms to provide support for the bereaved;
- that the 'working poor' were least likely to benefit from a discretionary scheme based on an income threshold; and
- that support for carers needed to be recognised.

Making the schemes simple

15. From 2014 onwards, all the options under consideration were aiming to create a new, single structure to replace the complex overlapping schemes, and to enable those who were infected to receive an annual payment of some kind. Before, only those with stage 2 HCV and HIV had received annual payments. This would extend annual payments to around 2,400 additional people in the English scheme; that is, those with stage 1 HCV.

Managing within the financial constraints

16. Throughout the policy development period, we were keenly aware of the financial constraints on our work. Ministers and officials worked hard to increase the budget available for the scheme, but it remained limited.

17. Up until 2014, the intention was to maintain the annual budget for the schemes at its existing levels of £25m annually. These financial constraints meant that we would have real difficulties in respecting historic expectations of those receiving support under the schemes, while also extending support for those who needed it.

18. On 25 March 2015, the Prime Minister announced that a one-off extra £25m would be provided in England.

19. In December 2015, a further £25m per year was secured through the Spending Review ("SR") for the period to 2020/2021 (a further £100m in total). This more than doubled the available funding and allowed greater scope for the development of options. It was more money than any Government had ever previously provided to support this group. However, it still left us with significant financial constraints in meeting the aims of reform.

Addressing the different situations of people suffering from the infections

20. As explained above, the previous schemes provided annual payments to those suffering from HIV and stage 2 HCV, but not those with stage 1 HCV. There were also additional lump sum payments for those with HCV who progressed to stage 2. We needed to

consider whether these differences in support still addressed the different situations of beneficiaries with these different conditions.

21. In summary, our understanding at the time of the material differences between the impacts of the two infections was that:

    a) Of the three groups, those with stage 2 HCV faced a significant reduction in their life expectancy. Those with HIV also faced some reduction in life expectancy. Those with stage 1 HCV did not face any significant reduction in life expectancy unless and until they progressed to stage 2 HCV, a risk that is was reduced in light of new treatment.

    b) HCV could be completely cured, whereas HIV and the conditions arising from cirrhotic (stage 2) HCV could not be cured or fully reversed. New treatments were at least 95% effective in curing the HCV virus. Individuals with stage 1 HCV could expect to have no enduring symptoms of their condition after cure.

    c) Those infected with HIV suffered from more serious stigma than those with HCV, which had a significant adverse impact on their wellbeing. Those with HCV may also suffer from stigma, but not to the same profound degree. This meant that even if someone with HIV was symptom-free, they were likely to suffer significant negative impacts on their lives, due to stigma.

    d) Some of those with stage 1 HCV - who had not yet been cured - could suffer from symptoms that had a significant adverse impact on their ability to carry out day-to-day activities. Examples included, depression and fatigue. Those with stage 1 may well suffer from such symptoms that are more serious than those who are living with HIV. However, there were also people with stage 1 who were symptom-free or virtually symptom-free.

Respecting historic expectations

22. We gave much thought to the situation of those who had become accustomed to receiving a certain level of support.

23. On the one hand, we faced limitations on the budget, and we wanted to target support to those who needed it most. We knew that the symptoms and prognosis for HIV infection were much improved than when the original schemes were introduced.

24. On the other hand, we also knew that many individuals had received and relied on this support for a long time. It was undesirable for their situation to worsen as a result of the reforms.

25. Weighing up these factors, we considered some options whose effects might have included a reduction in support levels for some beneficiaries until mid-2015. At that point, Ministers - and particularly the Prime Minister - made it clear that the reforms must have "no losers", meaning that no-one should be worse off. From that point onwards, we only considered options for annual payments that maintained at least the existing levels of support for all beneficiaries.

26. This approach was strongly supported by those who responded to our consultation in 2016. Overall, the most common concern raised in response to the consultation was around individuals being financially worse off as a result of the reforms.

Limiting the extent to which beneficiaries were subjected to assessment

27. When the policy process began, our idea was that the level of annual payments would be scaled according to the impact of the infection on each beneficiary's health. This would be based on an assessment of each individual's condition. This was intended to be the fairest and most targeted way to get support to those who needed it most.

28. However, in late 2015, Ministers confirmed to officials that they would not be reducing annual payments to any beneficiaries, it was therefore agreed there would be no point in subjecting those who already received annual payments (those with HIV and stage 2 HCV) to individual assessment. We would meet their historic expectations regardless.

29. The question was how we should decide who among those with stage 1 HCV should also be given higher levels of support. Given the budgetary constraints, we calculated that we could not provide higher levels of support to everyone with stage 1 HCV while respecting the historic expectations of those with HIV and stage 2 HCV. Further, the clinical evidence suggested that increasing support for everyone with stage 1 HCV was not necessary in principle: the evidence was emerging that the vast majority of this group would soon be cured by the newly available treatments. This was a very significant difference between them and those with HIV and stage 2 HCV. Further, they did not have to face the comparable stigma affecting those with HIV. However, expert advice

was that some members of this group suffered from a significant adverse impact of the infection on their lives, which would continue unless and until they were cured by the new treatments.

30. When we published the policy consultation in January 2016, we proposed that individual assessments would be introduced for all those with stage 1 HCV in order to determine the amount of their new annual payment. This was intended to ensure that those with stage 1 HCV who needed increased support as a result of the impact of their HCV infection received it.

31. However, we did not receive good feedback on this proposal. Only 4% of respondents to the consultation were supportive of introducing individual assessments. More than half indicated that they did not want to have individual health assessments. Our expert reference group advised that in light of the variability and often subjective assessment of symptoms, it would be difficult to deliver a fair and meaningful assessment using objective evidence-based criteria without a face-to-face assessment. This group was made up of independent clinical experts, individuals with third sector experience, and scheme/beneficiary representatives. A face-to-face assessment was considered to be intrusive, expensive and complicated to administer. It would also be more burdensome for those who were elderly and/or disabled.

32. Therefore, following the consultation, the policy evolved so that all those with stage 1 HCV would receive new annual payments of £4,500 in 2018/19 (The payments were £3,500 from 2016/17). However, if individuals believed that they needed a higher level of support, they would be able to choose to be assessed. The assessment would determine whether they should receive the increased level of annual support given to those with HIV and stage 2 HCV. We originally referred to this as the "Special Appeals Mechanism", but it was renamed the "Special Category Mechanism" ('SCM') by the time of the further consultation in early 2017.

33. By late 2016 we decided to consult further on the details of the SCM. This was particularly important given the concerns raised that it would be difficult to devise a fair and objective assessment process.

How the 2016 scheme achieved our ultimate aim in a fair and effective way

34. In July 2016, we announced our policy, designed to achieve our ultimate goal, in light of the parameters that I have described above.

35. The five schemes would be replaced by one unified scheme relating to people who were infected in England.

36. All stage 1 HCV beneficiaries would continue to receive a £20,000 lump sum when joining the scheme. Those who progressed to stage 2 HCV would continue to receive a £50,000 additional lump sum. This would reflect the reduction in their life expectancy as opposed to the other beneficiaries.

37. Our policy on annual payments was that all beneficiaries would now automatically receive some annual payments. These would be CPI-linked and include a winter fuel payment:

    a) £3,500 for those with HCV stage 1, in years one and two. This rose to £4,500 in 2018/2019.
    b) £15,500 for those with HIV or HCV stage 2, in years one and two (increase from £14,749 pa). This rose to £18,500 in 2018/2019.
    c) £18,500 for those co-infected with HIV and stage 1 HCV in years one and two. This rose to £22,500 in 2018/2019.
    d) £30,500 for those co-infected with HIV and HCV stage 2. This rose to £36,500 in 2018/2019.

38. Those with HCV stage 1 who felt that they were suffering from a substantial adverse impact from their infection could choose to apply to the SCM to receive the increased annual payments given to those with HIV and stage 2 HCV. This was introduced from 2017/2018, and my recollection is that the first payments being made in March 2018.

39. There would also be a continuation of a discretionary element into the new scheme for all infected and bereaved family members, as well as 'softer' support, such as debt and benefits advice, with an increased budget in 2018/2019. Regardless of the type of infection all beneficiaries would continue to be able to apply for non-fixed discretionary payments. There would be a one-off payment to bereaved spouses or partners of

£10,000 from 2016/2017. This would apply to those already bereaved and the newly bereaved.

40. We felt that this policy was objectively justified because:
    a) All infected individuals would receive the initial lump sum. There was a clear justification for those with stage 2 HCV receiving the further lump sum due to the significant reduction in their life expectancy.
    b) All beneficiaries would now have access to an annual payment.
    c) All beneficiaries would have equal access to non-fixed discretionary payments.
    d) Our judgement was that it was unfair to depart from the historic expectations of those used to receiving the higher level of payments.
    e) The clinical evidence supported our judgement that there was a principled justification for not giving all those with stage 1 HCV the same higher payments. They had a better than 95% chance of being completely cured imminently and without any significant side effects, when the other beneficiaries could not be cured. They also did not face the same stigma as those with HIV, which caused many with HIV to suffer significant adverse impacts even if they were symptom-free.
    f) We could not afford to give all beneficiaries the higher level of annual payment, historically given to those with HIV and stage 2 HCV.
    g) However, there was no doubt that some people with stage 1 HCV were facing significant hardships as a result of their infection. We wanted them to be able to access increased support.
    h) We did not want to force anyone to undergo an assessment unnecessarily or against their will or consent.

41. Balancing these concerns, we considered that the policy that we designed was a fair and effective way to achieve our ultimate aim.

42. This decision on new annual payments was implemented from July 2016, with the new annual payments being made from December 2016. The only part of the scheme as announced at that time that was delayed was the introduction of the Special Appeals Mechanism which was later renamed the SCM (by the time the consultation was published in 2017).

Chronology of policy development to the best of my knowledge

Date	**Policy process**
2011-	Beneficiaries and organisations continued to lobby Ministers and MPs.
July 2012	Public Health Minister, Ann Milton, commissioned advice from the Independent Expert Advisory Group on Hepatitis on whether any new scientific evidence regarding HCV had emerged since 2010, with a view to informing decisions on financial support.
July 2013	Independent Expert Advisory Group on Hepatitis reported.
September 2013	Officials made a recommendation to the Minister to enhance discretionary funding with some measures to provide new regular, lower level, payments to those least well-served by the existing schemes.
October 2013	New Public Health Minister (Jane Ellison) was appointed. She decided that she would prefer to consider a wider range of options and review the position strategically in light of the Penrose Report, which was then expected to be concluded in March 2014. Officials began developing a new programme of work accordingly.
Late 2013-2014	Officials were advised by experts that new treatments for HCV did not carry the unpleasant side effects of the old treatments, and emerging empirical evidence at that time was suggesting that the new drugs gave cure rates approaching 80%.
2014	Internal consideration began of the cost estimates of the various options.
May 2014	In May 2014, Ministers agreed to officials' proposals to rationalise the current five schemes into one, and to work further on: possible lump sum options; a proposal for individual health assessments; and the impact of new non-interferon based, simpler and effective treatments coming on stream.
June 2014	The Prime Minister asked officials to see what might be done if a one-off extra £25m was allocated to support beneficiaries in England. Officials advised that this would only go a limited way to securing meaningful reform. Consideration was given to using this money to broaden access to the new cures for HCV. By 2015, this was ultimately rejected as an unnecessary use of scarce funds, which should be spent on support, while the NHS funded treatment.

June 2014	A view was emerging amongst officials and Ministers that enhanced support for the HCV stage 1 group should be a priority, based on the health impact of infection on an individual.
August-September 2014	Consultation paper prepared. Draft proposals included offering new payments to HCV stage 1 beneficiaries. Draft proposals focused on the Minister's then preferred option of offering beneficiaries a choice between continuing annual payments or a lump sum for exiting the scheme.
January 2015	Report published University College London's Institute of Education, commissioned by the Government. This was a systematic review of evidence on the impact of living with chronic HCV prior to the development of serious liver disease.
January 2015	Letter before claim from Leigh Day highlighted equalities issues between those with HCV and HIV.
25 March 2015	Penrose Report did not apportion blame or identify any government liability for the events that had occurred pre-devolution in Scotland, and did not make any recommendations in relation to support or compensation.
25 March 2015	The Prime Minister announced the additional one-off £25m, and issued a statement of regret.
May 2015	Officials worked on ensuring options paid due regard to the Public Sector Equalities Duty (PSED).
October 2015	Advice sought from counsel on scheme reform and equalities issues.
October 2015	Meeting held with beneficiaries to gather views on options for reform.
November 2015	Officials recommended to Ministers a system based on assessment of all individual beneficiaries to place them within a system of tiered annual payments. Ministers gave their clear view that there should be "no losers" from the scheme reform.
December 2015	A further £25m per year was secured for the period of the Spending Review. The consultation document was updated to reflect the wider options available with this additional funding, taking account of the Ministerial steer on "no losers".
February 2016	The Department established an expert reference group to support policy development, including independent clinical experts, individuals with third sector experience, and scheme/beneficiary representatives, who would act as a testing ground for policy thinking.

January 2016	Consultation document, impact assessment and equality impact assessment were published.
15 April 2016	Consultation closed.
July 2016	Revised impact assessment and equality impact assessment were published.
13 July 2016	The Prime Minister announced response to consultation and plans for reform. New scheme began to be implemented.
December 2016	New annual payments implemented.

Further development of the scheme reforms following 2016 consultation response

43. Having introduced the above policy, we then had to design a fair and effective assessment procedure. This developed the previously proposed special appeals mechanism that came to be known as the SCM.

44. It should be noted that other details of the scheme were developed at the same time. This included adding certain health conditions to the definition of stage 2 HCV and developments in the policy relating to the non-fixed discretionary elements of the scheme.

45. The NHS Business Service Authority ("NHSBSA") undertook a review of non-fixed discretionary payments and published details of the same, and it is my recollection that the reformed discretionary scheme started in April 2018.

46. Development of the SCM was the responsibility of others within the team so while I was aware of progress and occasionally stepped in to meetings, the majority of the information below is not based on my direct involvement with the SCM. When I drafted this statement in 2018, I would have been relying on emails and files which I had access to in DHSC.

Setting the test for passing the SCM

47. The key question for the Department when designing the SCM was what the test should be for gaining access to the higher level of payments. The intention was to provide extra support to those who needed the higher payments due to the impact of their condition.

48. It was not easy to define the test in a way that would achieve this goal. The reference group flagged up potential difficulties, such as how to balance the subjective nature of

an individual's experience of living with HCV with an objective assessment of the impact of that infection. In seeking to address this problem, the policy team considered, with the reference group, potential proxy measures of impact such as viral load or whether an applicant might be receiving treatment. The policy team determined that these would not be effective proxies. The policy team also looked at how DWP assessed "disability", and existing measures that were used to assess an individual's assessment of their health such as the SF36 questionnaire. The policy team rejected these because they were lengthy processes not tailored to assessing the needs of this specific group and therefore did not meet the aims.

49. The policy team also considered the test for when a person is disabled for the purposes of the Equality Act 2010. The view was that importing the test in section 6 of that Act wholesale would not be effective. My understanding was that applying the "progressive condition" aspects of that definition would mean that many people with stage 1 HCV would be likely to pass the SCM, despite having had only fairly minor symptoms; and perhaps now being totally asymptomatic. This would not have helped with achieving the aim of channelling the higher payments to those who really needed them. It also seemed unnecessary in principle, since, if their condition did "progress" to being more serious, then they would be able to gain access to higher payments anyway, either via the SCM or by developing stage 2 conditions.

50. Therefore, the policy team needed to design a test that focused on symptoms and the impact of those symptoms on beneficiaries' everyday lives. It was decided that the wording of the primary test for disability in the Equality Act 2010 would be useful, even though the rest of the provisions defining disability were not.

51. Throughout this process, the policy team sought advice on what proportion of the stage 1 cohort might qualify. In discussions at the reference group meetings and in conversations with other experts, it was clear that there was a range of opinion. However, the final consensus was that, based on the SCM test as developed, a significantly increased proportion of stage 1 HCV beneficiaries could be eligible for higher annual payments, perhaps in the region of 50 to 70%.

52. The policy team were concerned about the impact of this high proportion of successful applicants on our budget, in light of the fixed budget for the new unified scheme. The policy team identified this concern in the consultation. However, in the end, the policy

team felt that this was the fairest test in the circumstances. The policy team modelled the impact of different proportions of beneficiaries passing the SCM. If the high proportion who passed was to lead to problems with the affordability of the scheme in future. The policy team bore in mind that they could then consider adjusting the discretionary payments system.

Designing the assessment process for passing the SCM

53. From the outset, the intention was to ensure that the process would be as simple and user-friendly as possible for applicants, their physicians/nurses and the new scheme administrator, whilst also producing fair and consistent results.

54. In order to capture adequately the extent of impact of infection, it was decided that the SCM should require evidence from applicants of the impact of their HCV infection, with supporting evidence from clinicians that the applicant's HCV was having a substantial and long-term adverse effect on the applicant's ability to carry out his/ her daily activities.

55. To this end, the policy team designed a paper-based application process. The medical evidence to support the application would be provided by a hospital consultant or viral hepatitis nurse, as they would be likely to have a detailed understanding of the individual's condition. In some cases, a GP could be best placed to provide this evidence, such as where the individual had not been in regular contact with a consultant or hepatitis nurse. The scheme would reimburse any reasonable costs incurred in obtaining medical evidence.

56. The application form was designed to provide alternative routes for a beneficiary to show that they passed the threshold. One section asked the applicant's hospital doctor to identify any specified, clearly identifiable medical conditions that would automatically qualify the patient for higher payments (provided the doctor confirmed substantial and long term adverse impact). If that was not applicable, a separate section asked the applicant to state how HCV infection may otherwise be impacting on their daily life, due to mental health or fatigue issues, and the duration of that impact, with supporting evidence from their clinician. Regardless of which of those sections were completed, there was a section to be signed by the patient's medical practitioner confirming that the applicant's infection was having a substantial and long-term adverse impact on his/ her ability to carry out daily activities. The policy team also proposed an expert appeals process for those who were dissatisfied with the outcome of their application.

57. Around February 2017, it was decided that the NHSBSA would be the administrator for the reformed scheme and they that they would introduce and operate the SCM. The thinking behind making the NHSBSA the administrator was that, as an established organisation, they were already experienced in providing various financial and other services to the public and to the NHS and would be well-placed to run a scheme of this nature. It also meant the Government could avoid the costly and lengthy process of external procurement of the service.

58. The expectation was that straightforward applications - for example, where an applicant had one of the conditions listed on the form - would be decided without the NHSBSA needing to take external advice. However, in cases where the evidence was less clear-cut, B, the NHS BSA would take advice from an appropriate expert or experts, such as psychiatrists, consultant hepatologists or social workers. They would be NHS employees or similar, and would be consulted as and when required. Previous schemes were already assisted by a number of HCV and HIV experts, who decided on applications (albeit it had not been confirmed at the time of the consultation that exactly the same individuals would perform that role in the new scheme).

59. If the NHSBSA rejected an application, the applicant would have a right to appeal to an independent appeals panel. The panel would consist of medical experts including haematologists and legal experts.

60. Applications for the SCM opened on 1 November 2017.

Chronology of policy development following the 2016 consultation response

Date	**Policy process**
August 2016	Department looked at number of stage 1 beneficiaries seeking support from the Caxton Foundation, as an indicator of unmet need.
22 August 2016	Discussion with reference group on the design of the SCM, focusing on how individuals were impacted by the HCV infection at stage 1.
24 August 2016	Letter before claim from Leigh Day.
16 November 2016 to January 2017	Ongoing discussion with reference group, including seeking advice from officials at DWP who advised on disability-related benefits, as well as other experts outside of the reference group.

15 February 2017	Draft impact assessment and equality impact assessment sent to the Minister for consideration.
March 2017	Consultation, impact assessment and equality impact assessment published.
17 April 2017	Consultation closed.
June 2017 onwards	Department of Health engagement with NHSBSA to support the roll out of the SCM.
28 September 2017	Consultation response published with revised equality impact assessment and impact assessment.

Expert evidence

61. In order to make the best use of evidence and apply it in a meaningful way for the benefit of those affected, the Department established a reference group to support policy development in respect of SCM planning. The reference group comprised an informal mix of independent clinical experts, individuals with third sector experience, and scheme/beneficiary representatives, who would act as a testing ground for policy thinking. The group would support the internal Department governance arrangements for the reform programme. Such an approach is not unusual in policy-making. The idea is that the views of various stakeholders can be taken into account flexibly along the way to help inform and/or test policy.

62. From discussions with the reference group and based on the available clinical evidence, we identified the following key facts about HIV and HCV, which were important to us when shaping the policy:

   a) Symptoms of HCV infection could vary from mild to moderate to severe. They could be non-specific and fluctuate, with no clear or consistent trajectory of disease.
   b) Not all those with HCV were equally affected, and there was also no direct or consistent comparison with HIV infection.
   c) In light of the variability and often subjective assessment of symptoms, it would be difficult to deliver a fair and meaningful assessment using objective evidence-based criteria, especially without a face-to-face assessment.

63. Advice from clinical experts within the reference group indicated that it should also be possible to refine the definition of stage 2 HCV by expanding the list of potential conditions that may, in certain circumstances, be directly linked to HCV, such as:

d) Type 2 or 3 cryoglobulinaemia, if accompanied by:
   i. Membranoproliferative glomerulonephritis;
   ii. Vasculitis with major arterial complications; and/or
   iii. Peripheral neuropathy.

e) Any other complication of HCV where the treating consultant considered that:
   i. the health impairment was as great as for the list above;
   ii. the health impairment was causally related to HCV infection;
   iii. the condition was objectively verifiable by clinical means; and/or
   iv. the condition was long-term and permanent.

64. This advice was used to guide policy development relating to the assessment of the impact of HCV infection.

Impact assessment

65. The Government published an Equality Impact Assessment ("EQIA") and Impact Assessment ("IA") alongside the consultation on scheme reform in January 2016. In 2014/2015 officials had considered how the proposals for the new scheme fitted with the Government's obligations under the Equality Act 2010.

66. In developing the January 2016 consultation, the Department initially proposed to tailor the scheme so that the levels of annual payment were based on the impact on an individual's health.

67. In preparing the EQIA and in order to take account of protected characteristics, the Department relied on "soft" evidence such as anecdotal evidence from scheme beneficiaries, personal narratives from MPs writing on behalf of their constituents, and insight into the experience of individuals who worked with those with HIV or HCV infection. This was particularly the case in respect of the way in which the reforms might impact on those beneficiaries who had a disability. The assumption was that the highest

annual payments for those with HCV would correspond to those suffering the greatest impact on their health.

68. The January 2016 IA was drawn up by the Department's analysts and economic advisers, in discussion with the policy team. Health Ministers continued to consider the impact of the proposals as they developed.

69. The Department published a revised EQIA and IA with the consultation response of July 2016. In revising the EQIA, the Department took account of the responses to the consultation, the diversity information provided by the scheme beneficiaries who responded and on-going correspondence and parliamentary questions, and it sought the views of the reference group. As set out in the revised EQIA, the Department at all times remained aware of its Equality Act obligations, and in particular of scheme beneficiaries who might be disabled.

70. The revised EQIA acknowledged that one of the biggest sources of criticism of the current schemes was the difference in levels of payments between infected individuals who were disabled and in receipt of annual payments, and those who may be disabled and who would only receive annual payments based on an individual health assessment. As discussed below, the decision was therefore made to provide new annual payments to all those infected with stage 1 HCV, without the need for individual assessments.

71. The consultation responses, combined with the expert evidence, prompted us to reflect carefully on our initial proposals, especially in relation to individual assessments and the annual payments for those infected.

Are the policies, quantum of payments, methods of administration entirely devolved?

72. In respect of the scheme of support and financial assistance in place after the reforms, which are still administered through each of the devolved administrations, the policies, quantum of payments and methods of administration were also entirely devolved. Accordingly, the DHSC had no influence over or involvement in the administration of the current scheme of support in Wales, Northern Ireland or Scotland.

Is funding entirely devolved, or has HM Government allocated any additional funding to the devolved administrations for the funding of these devolved schemes?

73. The DHSC made payments to the devolved administrations for HIV as per normal funding rules. The DHSC was required to match the HIV payment made to infected individuals and specific family members in England, for those infected in the devolved administrations. The total amount of funding that was transferred to each country, was calculated based upon the number of people infected with HIV that reside there. It was entirely a matter for the devolved administrations as to whether or not they wanted to increase the funding of the devolved schemes. Hepatitis C payments were accounted for under devolution.

Is there any mechanism of oversight or comparison to monitor the consistency of policy and awards made across the devolved administrations?

74. As explained above, the schemes are entirely devolved. In the circumstances, the DHSC did not have any oversight over their administration or a mechanism by which it sought to monitor the consistency of policy and awards made across the devolved administrations. There were, however, monthly conferences between junior officials from the DHSC and the devolved administrations during which any issues with the schemes or proposed changes could be discussed. Senior officials were not party to these conferences.

A list of individuals within the DOH whose role it is to liaise with, oversee or communicate with each of the current schemes in the devolved administrations.

75. The DHSC did not liaise with, oversee or communicate with the schemes themselves; only with counterparts in policy teams across the devolved administrations.

76. The information in the statement is accurate based on the documentation I had available at the time of drafting and on my recollection.

I believe that the facts stated in this witness statement are true and confirm I am duly authorised to make this statement on behalf of the DHSC.

Signed: GRO-C

Dated: 22/12/2021

Full name: Donna McInnes

Position: Deputy Head of EU & International Policy, Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf, London.