Dear Sir/Madam

Please find below comments from the Haemophilia Society on whether the statutory period of deferred funding should be extended.

The Haemophilia Society were very pleased to hear that NICE had recommended Sofosbuvir for a variety of genotypes and circumstances.

We are very concerned to hear that NHS England had requested an extension to the usual 3 month funding period.

We accept the arrangements for people living with hepatitis C are complex, however there does not appear to be sufficient evidence to suggest that NHS England could not, if it chose to do so implement the funding for Sofosbuvir using existing treatment pathways for patients already identified as having hepatitis C.

The evidence provided by NHS England tell us that

- the Task and finish group will be completed by the normal deferred funding period. **This should not be a reason for delay**
- NHS England anticipate a substantial increase in patients seeking active treatment, due to public awareness campaigns. **If NHS England do not start public awareness campaigns until they are fully resourced to deal with new diagnosis and returning patients, this risk could be mitigated allowing current patients access to treatment immediately through their existing treatment pathways, placing a moderate increased burden on NHS staff who currently treat people with hepatitis C, which should be manageable.**
- NHS England wish to test assumptions on the long term cost effectiveness of treatment via a new Network. **This is not within the remit of NHS England as NICE have undertaken an HTA**
- NHS England require a dashboard and national database. **This is a reasonable and positive step, but should not be a reason to delay treatment. Data can be collected from first prescription for retrospective entry into a database. For the bleeding disorder community data could potentially be collected via the National Haemophilia Database to enable accurate collection from day one and later transferred to any specific hepatitis C database.**

NICE state that they should be cautious and sure of its judgement before requiring NHS England to provide services it does not consider it can provide, or provide safely and efficiently. NHS England does not believe it has in place the arrangements it considers necessary to provide Sofosbuvir. **There is nothing to suggest Sofosbuvir cannot be provided safely, so the argument must be on the ground of efficiency, with careful consideration of public campaigns and record keeping it is not unreasonable to expect NHS England to provide an efficient service to enable immediate access to Sofosbuvir for patients already in the treatment pathway and gradually expand services and resources to meet demand as it increases over time.**

You also ask if a decision to extend the deferred funding period until 31 July 2015 could have any adverse impact on people with a particular disability or disabilities. **The Haemophilia Society believes a delay in access to treatment would have a significant adverse impact on the haemophilia and other bleeding disorder patient population who have a diagnosis of hepatitis C. Every patient from this community who has hepatitis C was infected via their NHS treatment between 1970 and 1991 and so have had chronic hepatitis for a minimum of 23 years.** The World Health Organisation states A significant number of those who are chronically infected will develop liver cirrhosis or liver cancer. Of those with chronic HCV infection, the risk of cirrhosis of the liver is 15–30% within 20 years. **In light of this there is a strong possibility that that more people with**

haemophilia and other bleeding disorders will progress from chronic hepatitis to cirrhosis or liver cancer during the delayed funding period. These people will not be eligible for treatment under NHS England interim commissioning policy until their disease has progressed. If treatment were prescribed with no delay they may be prevented from progressing to the advanced stage of hepatitis C.

Additionally we would ask NICE and NHS England to consider that for the haemophilia and bleeding disorder patient population, once a patient has progressed to requiring a liver transplant their requirement for Factor replacement treatment cost would significantly outweigh the costs of treating the wider haemophilia and bleeding disorder hepatitis C infected patient population with Sofosbuvir immediately.

In conclusion The Haemophilia Society do not believe NHS England has provided sufficient evidence to justify an extension of the deferred funding period and that NICE should reject this application.

Kind regards
[redacted] on behalf of the Haemophilia Society

[redacted]

[redacted]
The **Haemophilia** Society
Tel: [redacted] Mob: [redacted]