BRITISH SOCIETY OF GASTROENTEROLOGY

9th December 2014

Dear Sir/Madam,

The British Society of Gastroenterology view is that there is no valid reason to impose further delay on the approval of Sobsobuvir by NICE.

The Societies view is that the rationale put forward by NHS England is flawed and will both deny patients at high need therapy and only defer both clinical activity and cost with an even larger potential impact on clinical teams and budgets when approval is granted.

It is disappointing that NHS England have chosen this route. They have a very engaged clinical community linking via the Clinical Reference Group and a highly active patient group (the Hepatitis C Trust) with which to interact. All of those partners are fully aware of the immediate challenges NHS England faces with affordability of the new drugs for hepatitis C and that the current NICE guideline will rapidly be superseded by all oral therapy for hepatitis C. In this context we would anticipate that only patients with a pressing need for treatment would wish to take up Sofosbuvir, interferon and ribavirin based treatment at this time. This will limit the budget impact and the service implications. Further active dialogue with the clinical and patient communities by NHS England would have confirmed this.

There is also an important principle of the independence of NICE which needs to be taken into account and the view from the British Society of Gastroenterology is that there would need to be very cogent arguments to set a precedent for delay of implementation of NICE judgements, we do not believe this to be the case here.

We set out below the specific areas of concern raised by NHS England and the British Society of gastroenterology response.

As set out in the letter from NICE the deferred funding period is 3 months unless one of the following conditions applies:

a. The health technology cannot be appropriately administered until training is in place;

b. The health technology cannot be appropriately administered until certain health service infrastructure requirements including goods, materials or other facilities are in place;

c. The health technology cannot be appropriately administered until other appropriate health services resources, including staff, are in place;

d. The health technology is not yet available in England.

Our understanding is that NHS England wish to delay implementation on the basis of points b and c above.

NHS England states:

"NHS England has confirmed that the treatment of hepatitis C is a priority and notes that 'the *most recent national estimates suggest that around 160,000 adults are chronically infected with hepatitis C (HCV) in England in 2012. Current numbers of patients treated are estimated at 5,000 per year in England - 3% of those currently infected but this will increase rapidly. The CRG (Clinical Reference Group) Hepatitis C sub group have estimated that 10-15,000 people per year may come forward seeking HCV treatment'.*

NHS England considers that the arrangements for the care of people living with hepatitis C are complex, involving *'many components of care delivery in different health settings. Commissioners involved in the diagnostic and treatment hepatitis C pathway include 'NHS England Specialised services, Health and Justice, Public Health England, Local Authorities and Clinical Commissioning Groups and Primary Care.'* It considers that the availability of sofusbuvir, and the potential for other treatments to follow, will challenge these arrangements and so it wishes to establish a 'task and finish group' to *'bring together those involved in commissioning services involved in the Hepatitis C pathway to clarify responsibilities and to agree a coherent set of priorities'.* It anticipates that this group will complete its work by the end of March 2015 and that the actions which arise from it will be implemented in the 2015/16 financial year."

The British Society of Gastroenterology responds:

There is no controversy at all as to clinical priorities for treating patients with hepatitis C with a broad clinical consensus that those with significant liver disease and those who have failed previous therapy and who fit within the NICE guidance should receive therapy as the initial priority. To delay treatment for these groups is unreasonable and runs the risk of patients developing decompensated cirrhosis and cancer with their associated costs, morbidity and mortality which would be avoided in the very significant proportion who will be cured of their HCV infection with Sofosbuvir based

therapy. The principle of the task and finish group is strongly supported by the British Society of gastroenterology with a clear remit to consider other groups who may be at a lower clinical priority and decide a further roll out of treatment based on affordability and benefit. The short-term availability of non-interferon containing regimens mean that the uptake of sofosbuvir, interferon and ribavirin in other patient groups at lower short term risk of serious liver disease related adverse events will be relatively low.

NHS England states:

> NHS England intends to commission a series of *'Hepatitis C Networks'*, consisting of specialist centres which will each manage a caseload of patients, working in partnership with other providers of care in the NHS and in the justice system. The initiative would provide a centralised resource for patients whose care '*occurs as an adjunct to the delivery of other services including HIV, drug and alcohol, sexual health and prison health services, as well as from within gastroenterology and specialist hepatology services'.* Each centre will have a multi-disciplinary care (MDT) team which *will 'support selection of the optimal treatment regimen for each patient.* NHS England estimates that it will take 9 months to establish these centres, with the process allowing for candidates to build partnerships with NHS, local government and prison health services.

The British Society of Gastroenterology responds:

NHS England has already commissioned hepatitis C networks for the Early Access Programme, MDTs are in place with strong links to the services mentioned by NHS England above. The EAP has shown both that the care delivery via these networks is effective and outcomes are excellent. There is no practical reason why the existing centres cannot broaden their remit and take on assessment of patients in those higher risk groups referred to previously. The British Society of Gastroenterology remains in full support of the further development of hepatitis C treatment networks in the future.

NHS England states:

NHS England also intends to establish a database to 'support development of a national database of treatment and collection of outcomes to inform future treatment and commissioning of clinically effective care. It argues that the slow development of liver diseases means that some patients don't need immediate treatment, on clinical grounds, but that any decision to delay treatment would need to be supported by *'robust surveillance and recall systems which are not yet in place'.* It says that *'a national Dashboard is already being developed for 2015/16 that will provide evidence of the reduction in harm from increased treatment of hepatitis C'* but gives no other

information about how long it might take to fully implement its plans. systems necessary to provide a multi-disciplinary team approach to care.

The British Society of Gastroenterology responds:

Patients have already elected to delay treatment in significant numbers through shared decision making and all treating centres have details and local recall systems to ensure such patients can re-engage when more effective therapy is available. There is no need for a national database to enable this particular immediate function and indeed the prospect of rolling out such a national database to all treating centres is a major undertaking which would seem unlikely to be complete and fully functional in the medium term. A far more realistic approach is to again utilise the existing database used to monitor outcomes of therapy in the EAP, HCV UK. This has been highly successful and would fulfil the immediate need.

NHS England states:

'historic low uptake of both testing and treatment means that providers have stated they would need to increase staff resources particularly specialist pharmacy and nurse specialist support in order to treat the expected increase in demand'.

The British Society of Gastroenterology responds:

We do not agree that the historic rate of testing is low. The Health Protection Agency data show that testing has improved immensely in the past 5 years and now runs consistently at about 10,000 per annum and it is likely that more than 50% of infected people have been identified. Treatment rates were increasing up to the time that new treatments came on the horizon when patients more frequently chose to defer therapy. It is therefore incorrect to suggest treatment rates are low because of lack of capacity in the treatment system. In addition, Sofosbuvir treatment for most patients initially will involve interferon therapy but this is for a 12 week period only. As stated earlier, the numbers of patients who will chose to take therapy is likely to be relatively small. The existing staff currently providing therapy are well used to managing interferon related side effects which are not added to by the use of Sofosbuvir. The average duration of interferon based therapy currently is around 30 weeks across all genotypes. Cutting this to 12 weeks per patient means that automatically the capacity to treat patients with the same medical and nursing infrastructure will increase. This means without any additional infrastructure we could increase treatment numbers to cope with the initial demand, pending the outcome of the task and finish group and further NHS England investment in treatment delivery infrastructure to meet the future demand they refer to.

[redacted]

[redacted], British Society of Gastroenterology