From: [redacted] [redacted] [redacted]
Sent: 22 June 2015 17:26
To: Meindert Boysen
Cc: [redacted]
Subject: Access to all oral therapies for patients with HCV.

Dear Meindert,

NICE HCV Assessment of all oral antiviral therapy for chronic HCV infection

We are writing as the clinical and patient representatives on the NHSE Hepatitis C Clinical Advisory Group (CAG). The HCV CAG is a formal subgroup of the Infectious Diseases Clinical Reference Group (CRG), with representation from the Hepato-Bilary CRG, which was constituted to advise NHS England on the commissioning of treatment for patients with hepatitis C infection. We have been active in this role since September 2013, and we are obviously aware of the ongoing discussion about future commissioning of all oral antiviral agents for hepatitis C infection. Our experience with the commissioning process to date may be helpful to the NICE committee in reaching a decision on patient access to these valuable new therapeutic options.

In December 2013 the Chair and Vice chair of the CAG met representatives from NHSE to outline the issues regarding the efficacy and costs of the new all oral drugs. It was understood by all those present that the drugs had extraordinary potency with minimal side effects, and it was anticipated that they would be both popular and expensive. After discussion we agreed that patients with advanced, decompensated cirrhosis should be prioritised for treatment and we developed a policy that offered treatment to patients with decompensated cirrhosis through an early access scheme. NHSE agreed to fund sofosbuvir for such patients and the pharmaceutical companies (Gilead and BMS) provided NS5A inhibitors free of charge. Patients *in extremis* were offered therapy in April 2014 and 17 designated treatment centres were then established and became operational in June 2014 when patients with decompensated cirrhosis were offered antiviral therapy. We agreed with NHSE that with the imposition of strict clinically-determined criteria no more than 500 patients would be treated before the licensing of the NS5A inhibitors, and at the time of licensing of these drugs just over 500 patients had been registered for therapy. This demonstrated the ability of the treatment networks to prioritise and control the flow of patients to match the budget set by NHSE. Data from the early access scheme was collected centrally and in August 2014 NHSE agreed to extend the scheme to treat a further 500 patients and, at the time of writing, the scheme remains operational for patients with decompensated cirrhosis and a total of just over 1000 patients have received antiviral therapy.

NHSE and the HCV CAG understand that patients with HCV induced cirrhosis are at high risk of developing decompensation and liver cancer (approximately 5% per year develop one of these complications) and accept the clinical evidence that oral antiviral therapy can reduce the incidence of these adverse events. In discussion with NHSE the CAG agreed that such patients should be prioritised for therapy and it was initially agreed that such patients should be able to start antiviral therapy in January 2015. At a meeting with the NHSE Clinical director for Specialised Commissioning in December 2014 members of the CAG were informed that therapy for patients with cirrhosis would commence in April 2015. An

announcement in parliament reiterated the April start date but this was subsequently changed to a start in 'the first half of the year'. During the NICE review of Pegylated interferon, ribavirin and sofosbuvir NHSE asked NICE to extend the implementation period from 90 to 180 days and informed NICE that therapy for patients at high risk would be available by April 2015. NICE commented that 'NHS England is making a considerable effort to ensure that patients for whom a delay in access to sofosbuvir represents a serious medical risk will have access to it under the existing and planned interim commissioning policies'. In April 2015 the HCV CAG were informed that to conform to NHSE requirements the cirrhosis program could not start until May, and in May we were informed of a further delay. The program to treat patients with HCV cirrhosis was formally announced on 10 June 2015, some 18 months after the original discussion with NHSE, 6 months after the initial proposed start date and 2 months after the start date provided to NICE. It is likely that a number of patients will come to significant harm, including in some cases the development of liver cancer, as a result of the delay in treatment from January to June 2015. We believe, therefore, that it is important for NICE to be cautious in placing undue reliance on assurances from NHSE regarding timetables for delivery of care. Our experience is that, even for patients at high risk of imminent complications from their infection, NHSE – for whatever reason – may not be able to deliver therapy in a timely fashion. Deviations from published timetables cause very considerable difficulties to doctors planning services and patients suffer marked anxiety and, in some cases, choose alternative, suboptimal, therapies to avoid the trauma of continued waiting. NICE will be aware that less effective, more expensive therapies for patients with mild HCV infection (pegylated interferon, ribavirin and sofosbuvir) must be provided in August 2015 and whilst patients may be willing to defer therapy for a NICE mandated (and thereby guaranteed) alternative it is probable that many patients will insist upon the more expensive, less efficacious therapy if they perceive that NHSE controls the delivery timetable.

NHSE have agreed to establish a nationwide chain of HCV networks with operational delivery networks that will supervise access to therapy from hospitals and other health care providers in each area. These 'administrative regions' will ensure that all patients with chronic HCV are discussed with knowledgeable clinicians through an MDT system, and that the most clinically and cost effective therapies can therefore be prescribed. Access to therapies can be prioritised effectively so that NHS resources can be deployed in the most appropriate manner, as dictated by local clinical conditions. At the time of writing the commissioning process for the network centres has commenced, and the networks are scheduled to become operational in August 2015.

The issues about the use, deliverability, and affordability of oral antiviral therapy for hepatitis C infection are complex, and England is not alone in struggling with them. In other European countries where unrestricted access has been approved we are not aware of any examples of massive over prescribing leading to unmanageable budget deficits. The HCV CAG will continue to work with NHS England to try to balance clinical demand with the huge potential cost. NICE clearly has a vital role in providing independent authoritative guidance on new therapies, and we look forward to hearing the NICE opinion on future access to these extraordinary drugs.

Yours sincerely,

[redacted], [redacted] [redacted], [redacted] [redacted], Charles Gore, [redacted] [redacted], [redacted] [redacted]