Please find the following submission which is both included in the body text of this email and attached as a separate Word.docx document.

Submission from [redacted], on behalf of HIV i-Base

Thank you for the opportunity to comment on the request by Public Health England (PHE) or an extended time for the sofosfuvir approval process.

We would like to express concern for any further delay and would therefore register an objection to allowing this extension.

1) There has already been sufficient time for PHE to prepare for use of sofosbuvir.

The timeline both development of new drugs and the approval process itself has been not only well publicised but keenly followed by patients, doctors, nursing staff and presumably other NHS departments. The i-Base submission for sofosbuvir approval highlighted the urgent need by people living with hepatitis C and especially for those coinfected with both HIV and HCV. Further delays to this essential new medicine are not acceptable.

2) There is no logical way that patients who already have a clearly unmet need will be helped by a further delay in access, even when PHE suggest that continued use may be possible.

The level of need for sofosbuvir, detailed in earlier submissions, is not only acknowledged by PHE but is recognised as being one that will be taken up immediately. The solution to a pressing demand for a new medicine cannot be helped by further delay in access.

3) We are concerned that a simpler treatment is being blocked based on an unjustified fear of a "potential challenge". NHS England appear to be overcomplicating the issues related to similar treatment in order to avoid providing better treatment.

Health care support needed to prescribe sofosbuvir is significantly more simple than current treatment. It will require less intensive support and care than previous treatment. The treatment period is shorter and the treatment itself has far fewer side effects and other complications.

We believe that PHE are over-stating and over complicating the need for staff training. Our experience is that clinics, certainly for people with HIV/HCV coinfection, are already well-prepared to provide wider access and that this approval process is in fact the rate-limiting step.

4) Availability of additional new medicines should also not be a reason to delay

access to current new options.

If, and when, new drugs become available, the situation may or may not be different based on cost and price. This will continue to be a moving target for several years. It is not reasonable to force patient to continue with suboptimal treatment options because of hoped for future medicines. European treatment guidelines already recognise DAA combinations as the standard of care.

5) Patients should not be made to wait further while NHS England develop new services. If NHS England are falling behind in their timeline for planning, this should not be an excuse to change the standard regulatory timeline for drug approval.

6) Broader access to effective treatment is not dependent on establishing a new network for aftercare. The data supporting the effectiveness clearly argue against this suggestion.

An end date of August 2015 is completely unacceptable. PHE and NICE should be ashamed to be suggesting this.

In summary, we are concerned at further extension to the predetermined timeline for the decision on approval.

[redacted] [redacted]
HIV i-Base