ANNEX B

# HEPATITIS C

## Treatment

### Interferon

1. Interferon alpha (IFNα) is the only extensively studied agent shown to be effective, but results are disappointing. It has generally been used in patients with HCV with chronic active hepatitis in an attempt to prevent progressive liver disease. In approximately 50% of patients with chronic hepatitis C treated with IFNα, serum aminotransferase values are normal and HCV RNA is undetectable by the end of therapy. This response usually occurs before twelve weeks. Relapse rates are high, with perhaps 50% of those responding relapsing within the first year of stopping treatment and a small number relapsing during the second or third years. Only 20-25% of patients currently being treated for hepatitis C have a sustained response to IFNα. Different trials have used different doses of IFNα which has to be given by subcutaneous injection three times a week for six months. The effectiveness of higher doses of IFNα or an extended period of treatment are currently being evaluated, as is the use of IFNα in combination with other antiviral agents.

### Cost implications

2. Roche have recently received a product licence for the use of IFNα in chronic hepatitis C. Their prescribing information recommends induction with 6 million IU three times weekly for three months followed by maintenance with 3 million IU three times a week in responders (normalised ALT). The cost of 3 million IU of IFNα is given as £16.96 which would put the cost for an individual patient using the proposed regime for six months of £1,984.23. This could be reduced to around £1652.60 overall if treatment on non-responders was terminated after three months. With present results, the cost-benefit ratio is high as 4-5 patients have to be treated to obtain one sustained response. There are no long term follow up studies. There is no information on the benefits of early treatment, although it may be advocated by some, and could be an area for research.

## Improving access to (testing and) treatment

3. Since any lookback study for hepatitis C among transfusion recipients and subsequent referral for treatment is likely to raise expectation that similar treatment will be offered to those infected by other means, the question of improving access for screening and treatment is essentially one of resources. This would require purchasers to assess the implications for their own populations and then ascribe the testing and treatment of hepatitis C the appropriate level of

priority. It is possible that priority levels might not rate equally among different purchasers resulting in an unequal approach to treatment etc. There is the danger that there might be calls for 'ring-fenced' monies for hepatitis C as there were for HIV/AIDS. There is also the question as to whether the current specialist units could cope adequately with increased referrals. Haemophiliacs are another group who are asking for increased provision of services.

Research

4. Possible areas of research could be:-

i) Seroprevalence study - this would probably need to be fairly large and could be expensive. The British Liver Trust have sought funding for this from ASPU. A study might be cheaper if commissioned from the PHLS and if it were possible to access any existing sera banks. PHLS are currently developing methods for economic detection of anti-HCV in serum by 'serum pooling' strategies, research funded by DH.

ii) Use of interferon - trials with IFNα in chronic hepatitis C have mostly been on patients with more severe liver damage (usually with chronic active hepatitis); there have been no controlled trials in the so-called 'asymptomatic carriers' or on those with lesser liver damage. I am not aware of any clear indications for the use of IFNα and the Roche prescribing information for its use in "chronic hepatitis C" leaves this wide open.

iii) there could be more research into genotypes and their relation to disease progression and the response or not to interferon

iv) a follow-up evaluation of asymptomatic carriers with apparently mild disease

v) more basic science into possible measures of infectivity in individual patients, of understanding the mechanism of viral persistence in those who have acquired hepatitis C and of the mechanisms of hepatitis C virus induced liver damage.

vi) no vaccine against hepatitis C is likely for several years; the recent court ruling in favour of Chiron may cause some investigators to withdraw from this field.