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Kate Moore
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From [redacted]

4 September 2014

Dear Ms Moore

Re: Sofosbuvir for treating chronic hepatitis C [ID654] – ACD2

The Royal College of Physicians (RCP) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing over 30,000 Fellows and Members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare.

The RCP is grateful for the opportunity to respond to the above ACD2. Overall, our experts are far more supportive of the new version. They feel that there has been considerable reappraisal and that the recommendations are in the main clear and reasonable; addressing a significant unmet need. However, we would like to make the following points:

- The wording in a number of the conclusions that 'sofosbuvir is recommended as an option for…' allows for considerable clinical variation in the actual treatment used for specific patient groups. It is essential that treatment decisions are made by clinicians experienced in the management of hepatitis C (preferably working as a team through MDT meetings) to ensure that the most appropriate and cost effective treatments are used.

- This is particularly the case for interferon-free regimens (ie sofosbuvir plus ribavirin), which may be seen as a safer and easier option (and may be preferred by many patients). There is concern that inexperienced clinicians, who may not consider using interferon because of adverse effects and monitoring requirements, might choose to start treating patients with sofosbuvir/ribavirin. The current criterion for using interferon free treatment ('ineligibility or intolerance') is vague, and open to misinterpretation or misuse which could pose a risk to some patients. It should therefore be clarified within the guidance. This regimen should clearly be seen as a second line therapy, for patients who are truly unable to take interferon.

- Genotype 2 is not mentioned at all in the summary of treatment recommendation for sofosbuvir/interferon. Our experts appreciate that evidence is limited in this group, but for completeness there should be some statement as to whether or not NICE recommends this treatment as an option in g2.

- While it is appreciated that the number of patients studied with genotypes 4, 5, and 6 is small, there is more evidence for genotype 4 than the other two, and they should not necessarily be lumped together. There is a real unmet need for treatment for patients with g4 who have not responded to currently available therapies, and we would welcome a reappraisal of the evidence specifically in this group (although our experts recognise that the evidence submitted may not be adequate for the minimum requirements of NICE).

- Genotype 4 accounts for up to 30% of the UK HIV/HCV co-infected population (UK CHIC study - unpublished data) and represent a significant unmet need in terms of liver disease burden and risk of progression. Our experts would therefore urge reconsideration of allowing Sofosbuvir treatment for the IFN-eligible G4 sub-group with advanced fibrosis.

- In para 4.19 it is stated that generic (Teva) ribavirin is licensed for use with pegylated interferon alpha 2b. The licence (and recommendation from EMA/MHRA) states that Teva ribavirin is for use with interferon alpha 2b (not pegylated). While our understanding is that bioequivalence studies support the use of this generic preparation, it is important (given that NICE is basing its cost efficacy calculations on the use of the Teva drug) to confirm that NICE recommends the use of generic ribavirin with all types of interferon, and with sofosbuvir.

Yours sincerely

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