Ministry for Health

Request for Participation (Negotiated) for the Supply of Curative Treatment of Hepatitis C

Clarifications No. 1 – dated 13/10/2017

Questions submitted by Economic Operators

Question 1: Can a guarantee be provided that the submitted and awarded price of the negotiated tender for the curative treatment of Hepatitis C treatment will not be made visible and be held within strict confidentiality by CPSU.

Answer 1: We confirm that the unit price will not be disclosed and this will be maintained strictly confidential.

Question 2: Can you kindly clarify whether renal patients with HCV will be part of the eradication plan and what the estimated percentage of this patient cohort is.

Answer 2: Yes renal patients with HCV will be part of the eradication plan and the estimated number of patient in this cohort will be in the region of 5%.

Question 3: Published dossier fails to mention and address situations where, for various reasons, treatment may be discontinued half way or alternatively patients drop out. How does the department intend to compensate for product used for treatments ceased prematurely?

Answer 3: We have had no similar situation for the first cohort that has been treated and we will not make any payments unless the treatment is proved to be successful.

Question 4: Award Criteria state that the Clinical Consultants will indicate the curative treatment for the patients. Can the department please indicate which treatment protocols/guidelines will be followed to determine indicated treatment?

Answer 4: The protocols / guidelines being followed by the Department are in line with the European Association for the Study of the Liver (EASL) and Infectious Disease Society of America (IDSA) / American Association for the Study of the Liver (AASL).
**Question 5:** Payment  

a. Condition states “will only be effected after recommended test is undertaken and results show…..” Please confirm that these tests will be performed and funded by your department.  

b. “…….. a negative HCV vital load at 24 weeks.” When is the 24 week clock started? At treatment commencement? At end of treatment? At SVR12? At SVR24?  

c. Special Conditions - Article 26.3 states that payment is made within 60 days from acceptance (certified cure?). Does this mean that payment will be effected after 60 days beyond 24 weeks mentioned in 3b above?  

**Answer 5:**  

a. Yes the tests will be funded by the Department as long as the results confirm that the patient has been cured. Alternatively, if the patient result show to the contrary, than all costs related to these tests will be borne by the economic operator providing this service.  

b. At 24 weeks after the end of the treatment.  

c. Payment will be carried out within 30 days from when the patient is certified as being cured from this condition.  

**Question 6:** Transparency  

a. How can the successful economical operator have visibility of where and how supplied product is being used?  

In similar scenarios internationally, the hospital / clinic delivering the treatment would issue periodic (monthly) reports with details of patients’ number, infection genotype and subtype, date of treatment commencement, prescribed treatment duration, SVR(NN) results.  

b. Does the department intend to disclose a similar individual patient progress and status along the treatment with respective awarded contractor/s?  

**Answer 6:**  

a. The department will provide details of patients’ number, infection genotype and subtype, date of treatment commencement, prescribed treatment duration, sustained viral response results.  

b. Yes but in a codified structure so as not to expose/disclose the identity of the clients in line with the Data Protection Act.  

The above clarifications are constituted to form an integral part of the original published procurement documentation. Other sections in the original procurement document which are not effected by this clarification will remain unchanged.