Q1. We would like to have a further clarification meeting, could you please add in the Timetable?

A1. We agree to grant a final clarification meeting for Tuesday 12th December 2017 at 9am at Mater Dei Hospital.

Q2. With reference to our question 29 and your reply: "*We cannot give any guarantee on the uptake of the system at Healthcare sites other than MDH. However as per tender conditions, the concessionaire would be paid for the services rendered in other Healthcare sites for the production of single doses based on the model of savings being adopted. It is thus being made clear that for evaluation purposes, the savings model has to be done using the MDH project.*" Please confirm that the implementation plan will be accepted with general reference to "Other Healthcare Sites" and that the actual implementation plan will be defined in execution stage.

A2. Yes

Q3. In the Software Model some variables are indicated to be used as normalization factors. The cited normalization factors (number of bed days in the specific ward, number of discharges from the particular ward, the severity of patients treated within the ward, number of procedures carried out within the ward, number of users of the particular medicine item) are suitable for evaluation of savings in the inpatient ward or in theatres and similar places. Could you please indicate what kind of normalization factors are proposed for evaluation of savings in health centres and outpatient clinics?

A3. The normalisation factors being proposed for evolution of savings in health centres and outpatients clinics, shall include but might not be limited to Number of patients in outpatient clinic, type of treatments, Number of examinations, type in laboratories and exams services, Number of patients treated in health centre units and complexity of the treatments, Number and complexity of surgical procedures in theatres, Number of patients and complexity of treatments in Healthcare centres.

Q4. With reference to the software model could you please confirm that the normalization factors will include also:

a. n. of patients in outpatient clinic and type of treatments;

b. n. of examinations and type in laboratories and exams services(eg: radiological exams, Histological samples analyzed, Blood exams, …);

c. n. of patients treated in day care units and complexity of the treatments;

d. n. and complexity of surgical procedures in theatres;

e. n. of patients and complexity of treatments in Healthcare centers.

A4. Yes amongst possibly others which shall be mutually agree to between the Contracting Authority and the awarded candidate.

Q5. With reference to our previous question 2 and your reply: "*(...) Kindly use CPSU and MDH personnel to sice the solution.*" Please confirm that in case of adoption of the complete proposed management model by a Healthcare Site (e.g.: MCH) will be possible to have the Pharmacy store personnel and Consumables Store Personnel seconded.

A5. Only the salaries of the seconded personnel, for the direct cost of operation and supply chain management of the systems being installed by the concessionaire, will need to be covered from these charges. These salaries will have to be paid from the charges collected by the concessionaire only once there is enough savings to make up for the salaries of these employees.

Reference is also being made to the following extract from the BAFO document;

Concessionaire shall, as from the Commercial Operations Date, be responsible for supply chain / inventory management from the time of placing the order with the relevant supplier to the point of delivery of the items to the relevant Health Care Sites. Delivery to Mater Dei Hospital shall include delivery of Medical Products to the Pharmacy Robot, smart cabinets, 2-bin

systems. Delivery to the other Health Care Site shall be of pre-packaged Medical Products (via the single dose repackaging system referred to in Section 2.5.1 below), and if requested by the Contracting Authority, into the 2-bin systems installed in the relevant Health Care Sites. Title to and ownership of all Medical Products shall at all times remain with the Contracting Authority.

It is thus being re-stated that the cost of all this operation has to come out of the charges. However should it be expected that the concessionaire operates ALL of stores, including supplies to pharmacies, then the Client would second the personnel required to do this work to the concessionaire whilst still continuing to pay their salaries and the concessionaire would be able to charge the Contracting Authority an additional management fee. However this would be outside the scope of this agreement and will have to be mutually agreed upon between both parties.

Q6. In order to evaluate the logistic effort of the project, please kindly confirm that in case of no other healthcare sites, except MDH, will be included in the project, the distribution related activities will be anyway in charge of the Concessionaire (according to the implementation plan).

In case of negative answer, please indicate how the Contracting authority aim to manage the SG site, ensuring the contemporaneous logistic activities operated following two different logistic model and staff (Concessionaire model for MDH and actual logistic model for other Healthcare sites).

A6. Agreed and the Contracting Authority will make arrangements to run both operations separately and distinct.

Q7. Regarding our question 30 and your related answer: "*The client's safety and quality requirements are the legal, regulatory and other Quality Improvement (QI) frameworks set by MDH Pharmacy's Quality Assurance framework (QA). It also includes world-class standards such as for example compliance to International Accreditation schemes.*"

We kindly ask you to provide the accessible reference to the documents you are referring to in order to be conformant to what is required. Please enclose the principle quality and safety guidelines set by MDH Pharmacy's Quality Assurance framework.

A7. MDH Pharmacy's Quality Assurance is developed upon the requirements of local legislation (Pharmacy related and adjunct) together with the transposition of Directive 2001/83/EC and other applicable directives. As with all quality systems, it evolves and adjusts to the technological situations and realities that pertain to the current *modus operandi*, so as expected it is a fluid, evolving approach.

Policies and operational documents are risk analysed in line with the principles mentioned above. Other directives that may apply include (but are not limited to) transpositions of; Directive 95/46/EC – Data protection, as are applicable parts of directive 2003/94/EC when it comes to activities involving GMP.

Currently, as a Pharmacy we hold a licence, and are consequently inspected by the Malta Medicines Authority. This means that the Quality System and its evolution is at the end also approved by the Local Licensing Authority. Current document used in inspection is PIC/S PE 010-4, together with local legislation schemes.

Furthermore, where we mention International Accreditation Schemes we are referring to International Hospital Accreditation Standards.

It is pertinent to note that the awarded candidate will be responsible to abide to GMP and GDP EU practises.

Q8. Consignment of products to POYC will start anyway from SG store? Will this be managed by Concessionaire or CPSU Staff?

A8. Yes and managed by the Concessionaire

Q9 . With reference to the document issued today (Answer 6): we kindly ask to consider the payment of calculated savings on annual basis when they are realised (also in the first and second year).

A9. Not possible as the concession agreement commences after the first 24 months and runs through for 15 years.

Q10. With reference to the document issued today (Answer 4): regarding the payroll of the seconded staff kindly confirm that payment of any salaries from the concessionaire will be reimbursed by the Contracting Authority as they will be a ceasing government cost.

A10. Please refer to this clarification under A5.

Q11. With reference to the document issued today (Answer 2): the amended Annex 4 Financial Form does not exclude POYC indeed considering the annex F quantities are:

a. total pharma 272.520.553 -

b. total POYC 236.318.992 =

c. total in the scope of the concession 36.201.561

Could you please amend the Financial Form accordingly?

A11. Yes correct on avreage since these figures were drawn up from the customer demand which may vary in accordance to clinical needs and requirements. Moreover the financial form will remain unchanged as per last revised, since this is for evaluation purposes only.