Query	Action	Response
1. We would like you to provide us with the layout in DWG of all the areas where we are expected to install the technologies.	Committee	Not available. However, candidates have been given details on the situation at each entity during the site visits.
2. Annex 1, Page 42, Paragraph 1.1, Point 4: Does this mean that all the personalized therapies should be identified with a label containing human readable data (patient name, ward, etc)?	Committee	Yes
3. Annex 1, Page 42, Paragraph 1.2: Could you please clarify the terms `ward automation` and `pharmacy stock automation`.	Committee	The automated process indicates the closed loop system from receipt of item to administration of item to patient, always safeguarding stock management principles. Pharmacy automation refers to the part where an item is received, repackaged and sent to ward according to prescription system. Ward automation refers to the part of the automation related to the ward top-ups, cabinet top-ups and patient administration according to prescription module. In either case stock management and reconciliation of stock is necessary.
4. Annex 14 - Could you please clarify the contents of this annex?	Committee	Annex 14 denotes the forecasted consumption for pharmaceuticals, medical materials and surgical devices on the first 6-month period for 2017 extrapolated till end of year together with quantities and total values per entity.
5. Could you please clarify the following: – on the front cover of the document the mandatory bid bond is Euro 500,000 whilst in Annex 6 – Bid Bond Form – the bid bond is Euro 50,000? To date we have provided Consultancy throughout the tendering process, submitted full business plans and Financials and been charged for any visits of the Tendering Committee to learn and understand the technology that exists. Considering the cost incurred by all parties to date leading up to the creation and submission of the Bid we ask that the Bid Bond is reduced drastically and therefore have the €50,000 as the accepted value.	Committee	No
6. Page 8 – Paragraph 2.5.5 and 2.5.6 – The Contracting Authority shall have the right to request the Concessionaire to install 2–bins and smart cabinets in the other health care sites. This makes it very difficult for us to quote since the number of installations can vary drastically. Would we be able to quote for the equipment required as per the previous tender and quote a price per installation for both 2-bin and smart cabinets for the other health care sites.	Committee	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.
7. Do all the hospital units share the same HIS system?	Committee	YES
8. Do all the units share the same accounting software?	Committee	YES
9. Does each hospital unit have its own data centre?	Committee	NO
10. Does the client ensure Server infra-structure or shall the vendor consider it?	Committee	Vendor must provide any servers and related licences.
11. Does the client provide database and server licencing infra-structure?	Committee	Vendor must provide any servers and related licences.
12. Are the units all network connected? What is the quality of the connection?	Committee	The major entities are network connected and the rest will be connected before this project is in place. The quality of the connection is stable and will need to be tested prior the project operational implementation.
13. How many primary care centres exist?	Committee	Eight with possible expansions and/or centralisations.
14. Are these also network connected?	Committee	YES
15. Are the patient records shared between healthcare units and centralized?	Committee	YES
16. Are the Patient Records connected between Primary care and hospital units?	Committee	Yes

17. Do all hospitals have Wi-Fi installations? Which protocol? What is the coverage in clinical areas?	Committee	All hospitals have Wi-Fi installations, some are of a corporate nature, others for public use. Multiple protocols are in use, coverage is dependent on the specific hospital and clinical area, limited clinical use as of today pertinent to corporate use of such connectivity. (Annex D and E)
18. Do all the hospital units share the same product master data for products?	Committee	Yes
19. Do all the hospital units share the same product master data for products?	Committee	Yes
20. Are all the purchases centralised today?	Committee	Yes
21. Are all the purchases centralised today?	Committee	Yes
22. In the tender, when mentioning CPOE there is also mention of "treatments". Please clarify regarding the medication prescription?	Committee	"Treatments" include all dosage forms in-various forms of topical, enteral and parenteral. Important treatment modalities administered at our hospital, and hence which the CPOE system is expected to be able to handle via close loop; include Parenteral Nutrition and Cytotoxic Chemotherapy protocols, as are other centrally prepared aseptic preparations (prepared by Pharmacy MDH) – e.g. antibiotics and other injectables.
23. Page 6 – 2.4.4 – in relation to stock outs – if the supplier would have not delivered the goods in time, would the concessionaire be penalized for this?	Committee	NO as long as the ordering cycles have been respected.
24. Page 7 – 2.4.6 – What happens with deliveries of short dated stock? Would the concessionaire have to accept this stock if in a low stock situation? Who would be responsible for any expired stock?	Committee	Yes as long as the ordering cycles have been respected. In cases where CPSU purchases stock with short expiry, than this would need to be collected back in order for CPSU to get credit, where applicable.
25. Page 7 – 2.5.1 – since a robot will not be installed in the other health care sites and a 2 bin system will be installed at a later stage – how will the concessionaire charge for unit doses delivered to these sites?	Committee	Prior to any charging mechanism there needs to be the installation of the two bin system.
26. In long-term contracts of such duration, proviso should be made for inflation and Cost of Living Adjustments (COLA), more so especially in the case of employees seconded by Government. Any changes to prices are made by reference to changes in the retail price index published by the NSO. Changes in prices are effected at annual intervals. Please indicate where in the document is reference to such adjustments and clarify.	Committee	Please refer to draft contract.
27. Expired Stock The tender document states that the Concessionaire is responsible for expired stocks. On the other hand, the Concessionaire is expected to retain sufficient levels of stocks to avoid stock outs. In the interval, however, changes in a number of factors beyond the control of the Concessionaire may lead to an overstock of some medications and consumables, such as changes in prescribing practices, change in protocol regarding drug handling and administration thereof, acceptance of short dated stock due to low stock levels etc. How does the Government propose to control such issues and compensate the Concessionaire?	Committee	These risks fall within the scope of service of the Concessionaire to manage.
28. Stock controls - The Concessionaire is being requested to carry out inspection, quality control and testing upon receipt of goods from suppliers. The Concessionaire will never be in a position to test that goods received are in line with tender since the Concessionaire is not involved in any part of the procurement process, and this process falls outside its remit.	Committee	It is the remit of the Concessionaire to release products in line with the contracts as setup by CPSU.

29. Financial Offer Form - Annex 4 of the Concession Document refers to quantities for Unit Dose, Smart Control Cabinets and Two-Bin System. These quantities, in no way, tally with any information supplied by the Contracting Authority during the various stage of the tender. Please support the quantities that are now being proposed.	Committee	For evaluation purpose kindly note that there was an arithmetical error in the number of the materials: Thereby we confirm that medicines are 250M; Specials are 5M and Materials are 100 M.
30. Software model - The document refer to a software model that will be developed by the Contracting Authority. Savings linked packages can be notoriously complex and for these packages to provide meaningful results, not only a significant amount of data will be required, but would above all need to be analysed and interpreted. To date we have been provided with total volumes only and this data fails to capture any trends. Additionally for experts to be able to interpret the data and to establish a benchmark position for the quantification of the potential savings, one year of daily and volume consumption practices may be insufficient. Please clarify how the software model will be drawn up and provide the basis of its operation. Please also clarify the source of this software. Has this software been used in project saving calculations of a similar nature? If so kindly provide us with a reference of such projects in order for us to be able to qualify the validity of such software. Please also clarify	Committee	Please refer to the Savings Guidence note.
31. Charges per Medical Product administered - The Concession Document states that if the patient is to be administered 1g of a medical product but two 500-mg of the said Medical Products are administered, this will be deemed to be an administration of a unit dose (not two unit-doses). In this regards, the Concessionaire has no control over the types and doses of medical products being either prescribed or administered. Moreover, irrespective of the dosage being administered, each unit of medical product would still have been individually prepared in terms of machine time and packing. Please clarify how this process will be monitored and managed to compensate the Concessionaire.	Committee	It is the responsibility of the Concessionaire to ascertain that the software collates such doses in order to reduce the amount of unit doses.
32. Pre Financing arrangements - Article 2.12.3 states that as from the twenty fifth month from the Effective Date, until the Commercial Operations Date, the Concessionaire shall be entitled to any Charges and their related Share of Savings (calculated on the basis of the Net Savings and not the Residual Net Savings). Does this mean that the Concessionaire will not be allowed to invoice the Contracting Authority for any dispensations/top-ups effected during the first twenty-four months even though roll out may have already started? If this is so, what is the reason for requesting a €1.5 million Performance Guarantee simultaneously with the signature of the Concession Contract?	Committee	Charging can only commence after the first 24 months, however the Performance Guarantee must be in place by the signature of the concession agreement.

33. Additional Services – Article 27 of the Main Agreement to the Proposed Contractual Framework - This states that the Concessionaire shall be required to undertake the Additional Services without any compensation other than the Charges and Share of Savings. In view that this would consist of different installations and roll-out periods how will the Contracting Authority compensate the Concessionaire for the set up costs? How long will it be before the Concessionaire can start invoicing the Contracting Authority? At what stage would the data of current usages would be available for Concessionaire to assess equipment required?	Committee	The compensation for the setup must be included as part of the charging model, i.e. included in the charges and the share of savings. The concessionaire may start invoicing the contracting authority after 24 months from the commencement date and any charge will only be paid if sufficient savings are generated following the first 24 months. The Concessionaire together with the Contracting Authority have to collect this data within the first 24 months or before the start up of the charging mechanism in the particular unit, whichever is the latest.
34. Extension required - Page 15 – Paragraph - 3.3 The scope of the project has changed completely to one of a National Project proposal. Our business plans and basis of our submissions to date do not reflect the new scope. Time is required to recalculate all based on the new scope of the project. We would need to receive the new data so that in turn we can analyse, verify and clarify it. The Software should need to be verified. All of this would require time as well as, possible a further round of clarifications. For this reason it would only be feasible to decide upon and to prepare the BAFO by the end of February 2018.	Committee	Kindly be guided by previous clarification reply
35. Page 5 – Paragraph 2.3.2 - The Commercial Operation Date is stated as being 3 years after the effective date which is the time that was originally stated as the time required for a full rollout of the system. We would like to propose that this model is changed so that one is able to charge as soon as there is an effective measurable activity of dispensing. This could be phased in as one roles out the ward by ward thus allowing the charging to occur on a ward by ward basis until such time as the complete hospital is being serviced	Committee	The concessionaire may start invoicing the contracting authority after 24 months from the commencement date and any charge will only be paid if sufficient savings are generated following the first 24 months.
36. Page 6 – Paragraph 2.4.3 - 'Provided that the Contracting authority reserves the right to order stock against the said supply contracts if deemed necessary to ensure security of supply' on what criteria will this be implemented? How will this be managed and agreed upon?	Committee	The Contracting Authority will retain the right to place orders against its own contracts according to stock management principles without impinging on the operations of the concessionaire unless there is any default on the same concessionaire to maintain an adequate stock level.
37. Page 6 – Paragraph 2.4.4 - ' Risks and cost related to stock management shall be borne by the Concessionaire …….including stock outs, excess stocks and expired stock ' once an agreed upon stock management process in place we cannot accept to bear the risk and costs related to stock outs, excess stock and expired stock where Procurement and Demand is driven by Government. We ask that this clause is removed.	Committee	The concessionaire is required to bear the risk and responsibility for the full supply chain. However the responsibility for setting up the master contractual agreement rests on the Contracting Authority, to meet the demand levels indicated by the Concessionaire at least Six (6) months prior to the expiry of the contract value.
38. As mentioned in question 36 above we cannot be responsible for the cost of expired stock including the management (destruction costs) thereof.	Committee	The Concessionaire will be responsible for any expiry and related costs of replenishment and destruction thereof, should this result as lack of appropriate supply chain management from their part.

39. Page 7 – Paragraph - 2.5.1 'No Charges will be paid for unit dosing……' we have from the initial phase of this project presented a case whereby, in order to reduce the risk element of the project, as well as to provide a reasonable basis for investment risk both to the Investors, the Suppliers as well as to the Banks in order to procure financing, then there must be a charge element for the services which we would be providing. This charge, at the worst must cover the costs for the investment in Equipment, Human Resources and Time. What is being provided is not just an investment in Technology and Equipment resulting to a savings to government but an investment into the Automation and Upgrading of the Government's Supply chain and Logistics. We are being asked to take over, upgrade, Automate and Guaranty a service which would revolutionize the Heath Care system in Malta. The result would be a Health Care system consisting of Fully Automated E Prescribing, Full Accountability, A massive reduction in presc	Committee	No charge will be accepted before the first 24 months and this may only be paid through the generated savings after the same period. Refer to savings guidance
40. Page 7-8 – Paragraph 2.5.4-2.5.6. The entire scope of the project has changed. The business plans submitted therefore need to be re calculated to reflect the new scope of the project. The Costings and Results compensation will need to be revisited and new proposals submitted. In addition to this the installation of equipment will only be according to the submitted proposals and only in exchange for a guaranteed time frame for achieving a Commercial Operations.	Committee	NO the scope of the project has remained the same and the Contracting Authority has taken initiative to reduce certain risks that were presented by both candidates. These elements were resulting in increase of costs such as and not limited to the value of the supplies and manpower, since these will be under the responsibility of the Client for the first 36 months.
41. Page 8 – Paragraph - 2.5.7 The Government must guarantee full cooperation of the Contracting Authorities ICT System or PAS System. How will the Contracting Authority handle the co-ordination of the various departmental interactions?	Committee	The Contracting Authority commits for such co-ordination process.
42. Page 9 – Paragraph - 2.5.10 The Government must by fully responsible and accountable for the Cooperation of its staff. We cannot afford delays due to lack of adherence of staff to training schedules thus resulting in delays to the rollout of the service. How does the Contracting Authority propose to handle its employees in this regard? We ask for a guarantee by the Contracting Authority of staff cooperation in learning curve, or an exemption of any delays in this respect.	Committee	The Contracting Authority has already started briefing its workforce in order to get the staff in line with this process.
43. Page 10 – Paragraph - 2.10.3 The Concessionaire cannot accept this proposal. The software model must be tried and tested and prove beyond any doubt to be able to provide the necessary results prior to any investments made. It needs to be approved prior to BAFO otherwise it is impossible for us to move forward not knowing that we have a model that works.	Committee	The software model is based on an international method used widely in such model.
44. Page 11 – Paragraph - 2.11 Charges: I refer to question 37. Whilst we agree in the principal of the way we are charged, we cannot agree in the way we are paid. We submit once again that an element of payment separate from the savings model is proposed in exchange for the services provided. The savings model is then used for both parties to enjoy the profits and the real savings.	Committee	This is not acceptable as it goes against the concession model as introduced at the onset of this process.

45. Page 12 – Paragraph - 2.12 Share of Savings; The Concessionaire is not to be held responsible for expired goods as the model will ensure FIFO as well as full automation.	Committee	The concessionaire is responsible for any expiries that are being generated out of their own supply chain process. It is also pertinent to note that the client uses FEFO (First Expiry First Out) method.
46. Page 14 – Paragraph - 3.1.3 this statement is of course unacceptable. Our business plan, investment decisions and return on investment expectation is based on the validity of the data submitted. This must therefore be confirmed to be accurate. If the case proves otherwise, the Concessionaire must be compensated accordingly. A formula must be agreed upon ahead of the commencement of the project. Please clarify?	Committee	Kindly refer to clarification meeting minutes and to the attached savings formula. The formula is used worldwide for such projects. The data given is also realistic and it has been defined as per clarification meeting. The main objective of piloting the formula is to safeguard the concessionaire too. The fact that the formula can be normalised with the input of the preferred bidder should place reassurance on the involved stakeholders.
47. Page 14 – Paragraph - 3.1.4 We propose to remove this statement.	Committee	We respect your position however as per clarifications responses these statements cannot be removed
48. Page 15 – Paragraph - 3.1.5 This statement is impossible and unpractical and we propose it is removed.	Committee	We respect your position however as per clarifications responses these statements cannot be removed
49. Page 15 – Paragraph - 3.2.5 We propose to remove this statement.	Committee	We respect your position however as per clarifications responses these statements cannot be removed
50. Page 19 – Paragraph - 4.3.5 ii. If for some reason which is valid the composition changes then we submit that an option is given to change partners during the period of the Concession Contract.	Committee	In terms of the concession documents changes in the identity or composition of the candidate is not permitted throughout this competitive procedure.
51. Page 19 – Paragraph - 8.4.3 The financing of this project is already high. We ask that the performance guarantee to be reduced drastically from Euro 1,500,000 to Euro 500,000 and valid for 18 years.	Committee	This was already negotiated and this is the least we could go as per usual legal and contractual obligations
52. Page 37 – Paragraph 10.2 – Point: 31(a) The cost to submit a complaint is extremely low in relation to the value of the tender. We ask that this value is raised drastically.	Committee	As per Public Procurement regulations set out when this process was initiated the maximum value is 58K Euro and thus cannot be altered.
53. Page 59 - Annex 4 – Financial Offer Form – Point 9. Capping. We cannot understand the basis behind the capping calculation nor do we feel it reflects a fair value. We ask that any form of capping is removed and that the principals of Competition allow us to offer what we feel is a fair charge based on the investment required.	Committee	The capping was undertaken from research and from what bidders submitted in their dossiers basing facts on the actual data from January till June 2017 extrapolated to 12 months. Thereby the capping is deemed as fair and reasonable. Once you make use of the attached savings model you will be able to understand better.
54. **Data** - In view of concerns raised during the first meeting, we require updates consumption data, by facility and by ward. In order to understand the dynamic changes of consumption patterns which are relevant to calculate the savings model (which is now being proposed as the main source of revenue), three years of consumption is required.	Committee	As per clarification meeting minutes we did check if we can extract 3 years consumption but unfortunately since we changed the IT system we are no longer in a position to do so. However, since the PQQ we submitted 3 extracts of data which bidders can refer to.
55. **New sites data** - Several new sites have been added to the scope of the project. For each site we need the following detailed information: Detail description of wards / consumption points including location, no of beds, employees , average stay per patient detailed list of product and consumables dispensed per ward / consumption point Detailed information per site of storage / distribution facilities Detailed information on current storage areas per consumption point	Committee	The sites were made available during the site visit for any measurements required. Annex C includes relevant details.

56. Page 5 – Paragraph - 2.3.1 - if during the implementation phase, we are obliged to start dispensing to the sections which are operational then we should be in a position to charge as well, considering that the fixed costs will remain. Who will decide on which unit / active ingredient or pack will a product be dispensed in? This is relevant since the charging model is based on e-prescription dispense and does not take into consideration the what is purchased or is on stock	Committee	As per clarification meeting the concessionaire is obliged dispensing after 36 months during which the implementation phase would have been completed. The Contracting authority will be deciding on explicit data basing facts on what was learnt during the competitive dialogue and through evidenced-based research. However, there is always an element of constructive dialogue to come up to the best solution with the Concessionaire. In the competitive dialogue both bidders were directed regarding what will be used depending on the item's use, value and nature.
57. Page 7 – Paragraph - 2.4.6 - Procedures on accepting goods has become the onus of the Conc	Committee	Procurement will remain the remit of CPSU. However, the concessionaire will be accessing specifications to be able to tackle quality issues. This will be surely the concessionaire's remit.
58. Page 7 – Paragraph - 2.5.4 - Final list of Heath care sites is required. Consumption in all mentioned sites needs to be guaranteed if e-prescription implementation needs to be guaranteed	Committee	To reclarify for Health Care sites the item needs to be processed in single doses however regarding e-prescription etc these will be tackled with each entity at later stages. In fact the model to be used should refer to CPSU and MDH. The Health Care sites are defined as per data in BAFO and in clarification meeting minutes.
59. Page 7 – Paragraph - 2.5.2 - If the complete system (i.e. two bin and smart cabinet systems) is not implemented in the health care sites after the e-prescription is installed. How will the charging model and savings advantage be calculated and materialised effectively?	Committee	There needs to be a 2-bin system in place to be able to initiate the charging and savings model.
60. Page 8 – Paragraph - 2.5.7 - Should there be any technical issues related to third party software functioning or integration and required usage thereof, how will the risk and responsibility be managed via-a-vis the concessionaire?	Committee	Any technical issues related to third party software not related to this project will be tackled centrally by the department as per usual practice.
61. Page 14 – Paragraph - 2.14.4 - The annual salary package of the proposed government employees for secondment is indicated as varying between Euro 15,000 and 20,000. Is this indication the total package of such employees or are there any other benefits, allowances or increments which need to be factored in.	Committee	It is the average salary per employee including allowances or increments.
62. Page 14 – Paragraph - 3.1.3 - It has already been expressed in several instances that the consumption data being provided is not complete and in many instances, in our opinion, does not reflect the actual consumption patterns. This data is essential in calculating the correct equipment, HR compliment and operations required to execute such an operation. Since the complete investment, operations and risk assumption is being passed on to the Concessionaire without reasonable safeguards nor limitations, it is important that the contractor defines such data or shares the risk, especially in view of the non - performance fines included in the tender should the Concessionaire not be in a position to deliver the set targets or KPIs due to the erroneous data being provided.	Committee	Refer to Annex F that denotes the customer demand as set-up by the entities
63. Page 43 – Paragraph 1.2 - Point (g) - Please clarify details on chemo and non-chemo modules required for intravenous compounding software.	Committee	No specific details exist however this was discussed during the competitive dialogue. It is pertinent to note that a mixture that is compounded will have the raw materials and then a final product. This needs to be captured by the system

64. Page 44 – Paragraph 3.1 – Point (d) - Inflation is being taken in consideration for the price of products but not for price of services being given. Please clarify.	Committee	Confirmed
65. Page 52 - The tenderer is being asked to submit full scale drawings of the solution. In order to submit such information we must receive full scale AutoCad drawings of all related sites.	Committee	Kindly submit this basing facts on CPSU and MDH as the model. In fact AutoCad drawings had been submitted during the dialogue.
66. Page 57 – Please provide an updated realistic consumption figures with details of which medicaments and products are included. Ex POYC, discharge medicaments, by ward/ consumption centre. When this information is received the whole equipment bill of quantity and HR procedures need to be calculated and hence the necessary extensions time is required from time of receipt of information.	Committee	Refer to Annex F that denotes the customer demand as set-up by the entities
67. What happens if the testing is not successful due to third party equipment, software or structure? Government clause 7.3/ 7.4 /7.5. and 9.2.3 state that there will be no government liability for any delay consequences. Clause 10.2 states that fines due to third party delays are 'recoverable ' and hence would still have to be paid up front.	Committee	Any delays attributable to third parties will make them liable.