

1 Introduction

As part of the implementation of the World Bank (Bank) Procurement Framework (launched on 1 July 2016), the Bank committed to establishing an **Industry Engagement Program** (IEP) to improve procurement outcomes in targeted sectors. In FY17, two sectors have been targeted; Large Medical Diagnostic Equipment and High Voltage, Direct Current (HVDC) electricity transmission.

The IEP has been designed to work closely with industry sector experts (both client and supply side) to identify and address recurring procurement problems in Bank financed projects to achieve improved procurement and development outcomes.

Program objectives are to:

- Motivate the right companies to bid;
- Speed up procurements;
- Improve readiness for project implementation;
- Reduce complaints;
- Reduce costs of bidding (clients and suppliers);
- Achieve Value for Money (VfM) to deliver better outcomes and results;
- Bring greater transparency to the bidding process.

The Large Medical Diagnostic Equipment industry actively participated in the consultations on the Bank's new Procurement Framework providing written comment on proposed changes to the Bank's Procurement Regulations for Borrowers. This included identification of specific procurement issues and initial proposed solutions relating to Large Medical Diagnostic Equipment.

2 Large Medical Diagnostic Equipment Industry Engagement Workshops.

As part of the Bank's IEP for Large Medical Diagnostic Equipment, a workshop with industry experts was held on June 1, 2017, in Paris. The workshop was the second face-to-face engagement with industry, this time with Europe based manufacturers and industry experts.

The objectives of the workshop were to:

1. Provide attendees with a clear understanding of the IEP;
2. Obtain input on procurement issues in the sector;
3. Obtain input on proposed solutions, including input on how the sector could assist the Bank and clients in implementing proposed solutions;
4. Identify emerging trends and innovation that may influence a procurement approach;
5. Understand how clients and industry operate in the sector.

The primary focus of the workshop was to discuss procurement issues and proposed solutions previously raised by industry and Bank staff, and achieve a common understanding.

3 Large Medical Diagnostic Equipment Procurement Identified Issues and Proposed Solutions

A high level set of issues and proposed solutions have been identified based on prior engagement with industry. One objective of the workshop was to move towards a more granular understanding to develop more effective and precise solutions.

The issues broadly fall into three distinct themes, which map to the procurement process outlined below:

- **Theme 1 - *Identification of Procurement Opportunities and early-Market Engagement***
 - Procurement opportunities need to be publicly available in advance;
 - Procurements need to be better planned to suit the circumstances of the project;
 - Fair and transparent early market engagement with industry needs to be put in place.
- **Theme 2 - *Approach to Market and Contract Award***
 - Specifications need to be better defined and not biased;
 - Contract award decisions need to focus less on price;
 - Borrower and Bank technical expertise needs to be bolstered to support improved evaluation of proposals;
 - Complaints handling, management and escalation needs to be improved.
- **Theme 3 - *Capacity and Capability Building***
 - Allocation of risk between parties needs to be more realistic and equitable;
 - Lengthy negotiations on contractual terms and conditions need to be avoided;
 - Client capacity needs to be strengthened for procuring Large Medical Diagnostic Equipment.

Annex 1 provides more detail on procurement issues and proposed solutions identified during engagement prior to the workshop.

4 Workshop Format

The workshop opened with remarks from the Bank's IEP Program Lead Procurement Specialist providing background and context on the IEP. The identified sector issues and proposed solutions were outlined along with a high-level program timeline.

The workshop was structured in three different plenary sessions to discuss sector specific issues and solutions based on the three procurement themes. Each session was facilitated by a Bank representative.

- **Theme 1 - *Identification of Procurement Opportunities and early-Market Engagement***
- **Theme 2 – *Approach to Market and Contract Award***
- **Theme 3 – *Capacity and Capability Building***

Annex 1 provides a list of all workshop attendees.

5 Plenary Session Discussions

A summary of the session discussions are detailed below:

Theme 1 – Identification of Procurement Opportunities and Early-Market Engagement

1. **Industry does not have input during Project design phase, or earlier.** Currently, industry is not engaged until bidding opportunities are advertised. At this point specifications are already defined. Industry should be engaged at a much earlier stage, to help define what equipment is best suited based on actual clinical needs. As it stands, equipment could be procured that is not the best solution to the needs of patients.
2. **Information on Projects and Procurement is too vague.** Granular information on procurement opportunities appears at a late stage of project preparation. Project Plans that are published are inconsistent and in some cases not detailed enough. Overall project needs are not defined well enough in published project-related documents.

Theme 1 – Suggested Outcomes

- Earlier and more regular engagement with industry, and more interaction across the whole procurement process.
- Industry involvement at an earlier stage of project preparation to enable discussions and input on specifications, requirements and request for proposals prior to issue for the formal Request for Proposals.
- Use of more interactive procurement approaches such as competitive dialogue, when appropriate at tender stage.
- Clinical need identification prior to finalizing the procurement approach and approaching the market.
- The understanding of the Borrowers' environment specific to disease priorities and strategies.
- Publication of procurement opportunities and information in a consistent format, in particular procurement plans.
- Use of external technical experts (i.e. trade associations or a panel of approved experts) to define the clinical needs of a project at the earliest possible stage in the project cycle.
- Consultants' expertise should span therapeutic areas and technology platforms, intersecting in 'Care pathways' as relevant to the borrowing states' disease burden. It needs to be defined when and how this interaction shall take place. This process must be aligned to the procurement process and consultations should take place well ahead of upcoming tenders.
- Establish an independent evaluation panel as a filter for specifications and to support bid and proposal evaluation. Several issues like biased specifications or an unusual configuration of lot's may be identified early which may avoid complaints later on.

Theme 2 – Approach to Market and Contract Award

1. **Technical specifications are too detailed.** Specifications are too detailed, which leads to accusations of bias. Specifications should be based on outcomes, and allow for private sector to propose solutions, rather than comply with detailed specifications.
2. **Equipment in many cases are procured in mixed lots.** In many cases equipment is grouped in lots which are not consistent, i.e. a supplier bids knowing that some of the goods will have to

be sourced from third parties. This makes the process inefficient, as the right supplier may not be willing to bid, as they cannot supply every item in the lot.

3. **Timelines for tenders are too tight.** Six weeks is currently the standard; this should be extended to 2 to 3 months. Complaints are sometimes submitted by suppliers just to slow the process down. This issue would also be eased if there were earlier engagement with industry.

Theme 2 – Suggested Outcomes:

- Use an independent panel of experts approved by all manufacturers to help develop and review specifications.
- Industry and trade associations / bodies should be sent draft specifications and request for proposal documents to provide independent and non-attributable feedback on the draft documents.
- Compile a list of “approved” consultants that are independent for technical expertise when issuing technical specifications and to support bid or proposal evaluation.
- Use performance based outcomes/specifications to help ensure wider competition and encourage innovative solutions to meet the clinical needs.
- Framework agreements should be utilized to reduce bidding costs and speed up procurements.
- Request for proposals / specifications / requirements should be used that stipulates the requisite level of service to be delivered providing freedom for suppliers to propose the optimum service level to maximize outcomes such as utilization of equipment and patient throughput.
- Patient and operator safety (i.e. dosage levels) should be a primary requirement set out in all specifications.
- The use of refurbished equipment should be considered more often and bidding / proposal documents should explicitly state if refurbished equipment is an option for the contract.
- Prequalified lists of suppliers (a standing list) should be put in place to improve efficiency and effectiveness of the procurement process, to reduce the bidding overhead for suppliers as well making prequalification a less resource intensive activity for Borrowers.
- Tender specifications in the MedTech segment should focus stronger on Patient Safety. Such as:
 - Concepts for reduction of dose in X-Ray technology (especially Computed Tomography)
 - Concepts to reduce use of contrast media
 - Image Quality at given input factors as a criterion to evaluate quality of a device rather than technical parameters

Theme 3 – Capacity and Capability Building

1. **Government officials and World Bank expertise in medical technology is low.** This sector is highly dynamic, with fast moving technology. Implementing agencies and Bank staff do not have the knowledge on the latest innovations within the med-tech industry.
2. **Difficulty retaining capacity in implementing agencies.** It is difficult for government agencies to retain high capacity personnel. Adequate training programs and guidance needs to be put in place to mitigate this.

- 3. Terms and conditions are unclear.** Clarification of terms and conditions after contract award delay contract signature. An industry standard set of terms and conditions, such as with civil works (FIDIC), should be established to mitigate this.

Theme 3 – Suggested Outcomes:

- Evaluate the opportunity of establishing an industry standard set of contract terms and conditions agreed by all manufacturers through direct engagement with manufacturers and trade associations / bodies.
- Standardization on requirements such as manufacturer warranties, spare parts support and service levels should be considered to help ensure a more equitable and realistic balance of risk is established.
- Industry are able to offer consultancy services that help identify equipment based on clinical needs and should be engaged earlier in the project cycle to perform this activity to augment Borrowers capability.
- Framework agreements should be established to mitigate lengthy negotiations over contractual terms and conditions.
- Engagement should take place early with the private sector to ensure the correct technology is being procured based on clinical needs.
- Industry should be given the opportunity to provide support to capability building support to Borrowers and Bank staff.
- Consideration of clinicians and technicians training requirements should be considered as an ongoing requirement (as part of the contract) to help mitigate turnover of key staff and ongoing efficient operation of the equipment
- Contract award notices should include more information such as products offered and subcontractor information

The Bank will continue to engage with the Large Medical Diagnostic Equipment Sector as part of our engagement plan during 2017. Outcomes of all workshops will be posted on the Industry Engagement Program website.

6 Priority of issues/solutions (based on individual participant feedback)

- Early and interactive engagement with industry.
- Unbiased specifications based on actual clinical needs.
- Establish an independent evaluation panel as a filter for specifications and to support bid and proposal evaluation.
- Total cost of ownership should be used when evaluating bids, with a particular focus on linking equipment evaluation and performance.
- Equipment should be specified on basis on actual clinical needs.
- Prequalify suppliers should be prequalified and pre-approved list of suppliers should be established.
- There should be a focus on building government/implementing agency capacity and capability through the provision of training and ongoing support, which could be provided by the industry.

- Standard contractual terms and conditions should be established for the sector.

Annex 1 - List of Workshop Attendees

| Representation | Organization | Attendee name |
|--------------------------|---|--|
| Non-Profit | ECRI | 1. Philip Hodsman |
| Trade Association | DITTA | 2. Nicole Denjoy |
| Supplier | General Electric | 3. Sophie Perceval 4. Veronique Soltani |
| Supplier | Siemens | 5. Michael Klug 6. Gino Fiore |
| Supplier | Varian Medical Systems | 7. Fernando Martín |
| Supplier | Toshiba | 8. Lo Wuite |
| Supplier | Esaote S.P. A | 9. Bakhos Fares |
| Council of Europe | CEB | 10. Kitty Villani |
| World Bank | Standards, Procurement, and Financial Management (OPSPF) | 11. Christopher Browne 12. John Williams 13. Barnaby Wiles 14. Simon Mckinley |