

## INDEPENDENT REVIEW PANEL

**In the matter of:**

**Trident Healthcare Ltd**

**(Applicant)**

**v/s**

**Ministry of Health & Quality of Life**

**(Respondent)**

**(Cause No. 01/15/IRP)**

### **Decision**

#### **A. History of the case**

On the 14 November 2014, the Ministry of Health and Quality of Life ("the Ministry") issued bidding documents for the procurement of Consumables for Cath Lab for Dr. A. G. Jeetoo Hospital. The procurement is through Open National Advertised Bidding and the bidding documents bear Procurement Reference No. MHPQ/MDSP/2014/Q8.

The deadline for the submission of bids was the 17 December 2014. However, the tender exercise has been suspended at the instance of the Independent Review Panel, following the application for review of the procurement proceedings by Trident Healthcare Ltd ("Trident").

The latter had decided to bid for five items namely:

1. Item 22                      Coronary Bare Metal Stent
2. Item 23                      Coronary Stents Chromium Cobalt Alloy
3. Item 24                      Drug Eluting Coronary Stents for use in acute coronary syndromes with ST elevation
4. Item 25                      Drug Eluting Coronary Stents for use in acute coronary syndromes without ST elevation and in stable coronary artery disease (as amended by the Public Body on the 8th December 2014)
5. Item 26                      Drug Eluting Coronary Stents for use in long, tortuous and complex lesions.

The Respondent has, in its bidding document, required items 22, 23, 24, 25 and 26 to be BOTH CE (Conformité Européenne) marked AND US FDA (United States Food and Drug Administration) approved.

Those Items were required to have the following marks and approvals:

1. Item 22 "CE and FDA marked"
2. Item 23 "CE and FDA marked"
3. Item 24 "CE/FDA marked" and have "CE (European Union) mark and be FDA (USA) approved"
4. Item 25 "CE/FDA marked" and have "CE (European Union) mark and be FDA (USA) approved"
5. Item 26 "CE and FDA marked"

Trident has submitted a bid for Items 22, 23, 24, 25 and 26 of the Bidding Documents. However, Trident believes that the procurement proceedings are inherently flawed and that it is likely to suffer loss or injury as a result of a breach of a duty imposed on the Ministry by the Public Procurement Act 2008, the reason being that Trident's products are CE certified but not FDA certified.

## **B. The Challenge**

On 17 December and 22 December 2014, the Applicant challenged the award on the following grounds:

- “1. On 01 December 2014, the Bidder sought clarifications from the Public Body in relation to the issue of “standards. The Public Body responded by way of an Addendum No. 1 dated 08 December 2014. By its response the Public Body confirms that the Public body shall only take the following “standards” into consideration for the hereunder listed items:
  - (f) Item 22 (coronary bare metal stents) should to be “CE and FDA marked”;
  - (g) Item 23 (coronary stents chromium cobalt alloy) should to be “CE and FDA Marked”;
  - (h) Item 24 (drug eluting coronary stents with ST elevation should to be “CE and FDA Marked” and should have “CE (European Union) mark and be FDA (USA) approved”;
  - (i) Item 25 (drug eluting coronary stents without ST elevation) should to be “CE/FDA marked” and should have “CE (European Union) mark and be FDA (USA) approved”; and
  - (j) Item 26 (drug eluting coronary stents) should to be “CE and FDA marked” and should have “CE (European Union) mark and be FDA (USA) approved”.
2. Being dissatisfied, the Bidder hereby challenges the decision taken by the Public Body. The Bidder is of the view that the decision to impose such conditions is unfair, discriminatory, arbitrary, irrational and illegal and has the effect of depriving the Bidder the right to participate in the procurement exercise.
3. Such an arbitrary decision acts as a barrier to the promotion of a competitive procurement environment in Mauritius and deliberately prevents and denies national suppliers, such as the Bidder, competitive access to procurement, on the sole ground of “standard”.
4. The Public Body purely and simply rejects all other products, without giving any consideration whatsoever to evidence of:
  - (i) the technical and functional specifications of other products,
  - (ii) the level of safety and efficacy attained by other products, or
  - (iii) the results of clinical trials/meta analyses published in international journals to support the safety and efficacy of other products,such as the bare metal stents and drug eluding stents marketed by the Bidder.

5. *By so doing, the Public Body is effectively and/or distorting competition in the market for the supply of coronary bare metal stents, coronary stents chromium cobalt alloy and drug eluting coronary stents in Mauritius, contrary to both the Competition Act 2007, and the Public Procurement Act 2006.*
6. *Further, the Public body is, for all intents and purposes, acting in a manner contrary to the principles of natural justice and contrary to the interest of the general public at large.”*

### **C. Grounds for Review**

On 05 January 2015, the Applicant seized the Independent Review Panel for review on the following grounds:

*“Under sections 45(a) and 45(c) of the Public Procurement Act 2006:*

- (1) *On 17 December 2014, being dissatisfied with the clarifications provided by the Public Body by way of an Addendum No. 1 dated 08 December 2014, in relation to the Standards required for Items 22, 23, 24, 25 and 26 of the List of Goods and Delivery Schedule of the Bidding Documents, the Applicant challenged the decision of the Public Body impose conditions for the supply of the aforesaid Items, which it considers to be unfair, discriminatory, arbitrary, irrational and illegal and have the effect of depriving the Applicant from the right to participate in the procurement exercise.  
(ii) *The Public Body failed to resolve the challenge and further failed to issue any written decision in response to the Applicant’s first challenge. In the circumstances, the Applicant’s challenge remained unanswered.**
- (2) *In the absence of any decision from the Public body, the Applicant submitted its tender on the closing date namely, 17 December 2014. Thereafter, in accordance with the provisions of section 43(3)(b) of the Public Procurement Act 2006, the Applicant filed a second challenge on 22 December 2014.  
(2.1) *The Public Body failed to resolve the challenge and further failed to issue any written decision in response to the Applicant’s second challenge. In the circumstances, the Applicant’s challenge remained unanswered.**
- (3) *By restricting the bidding process in such a manner that only a few select suppliers are capable of supplying coronary bare metal stent, coronary stents chromium cobalt alloy and drug eluting coronary*

*stents to the Public Body, the Public Body has, in effect, failed to give due consideration and/or any consideration whatsoever that the products marketed by the Applicant have both international and local recognition, are used in approximately 85 countries worldwide and have been CE certified.*

- (4) The Public Body has failed to give due consideration and/or any consideration to the evidence submitted to it by the Applicant demonstrating:
  - a. the technical and functional specifications of its products;*
  - b. the level of safety and efficacy of its products; or*
  - c. the results of clinical trials/meta analysis published in international journals supporting the safety and efficacy of its products**
- (5) The Public Body has failed to give due consideration and/or any consideration whatsoever to the fact that the procurement proceedings are inherently flawed and have been tailor-made to benefit a minority of tenderers whose products are CE and FDA (USA) marked and/or FDA (USA) approved, to the detriment of the majority of tenderers who market products, such as the ones offered by the Applicant, which meet international standards and quality but which are not FDA (USA) marked and/or FDA (USA) approved.*
- (6) The Public Body has failed to give due consideration and/or consideration whatsoever to the fact that the inclusion of a requirement for an FDA (USA) mark and/or FDA (USA) approval in the Bidding Documents, acts as a barrier to the promotion of a competitive procurement environment in Mauritius, deliberately prevents and denies national suppliers competitive access to procurement on the ground that their products are not US FDA and CE compliant, and thereby restricts and/or harms and/or distorts competition in the market for the supply of coronary bare metal stent, coronary stents chromium cobalt alloy and drug eluting coronary stents in Mauritius, contrary to the Competition Act 2007 and the Public Procurement Act 2006.
  - (6.1) By so doing, the Public Body has acted in an arbitrary, inconsistent and unreasonable manner and the Applicant has reason to believe that it has been exceptionally inserted in the Procurement under reference in order to benefit a few select suppliers of those products.**
- (7) The Public Body has failed to give due consideration and/or any consideration whatsoever to the fact that for more than fifteen years*

*the Public Body has been procuring bare metal stents with only CE certification.*

*(7.1) By so doing, the Public Body has acted in an arbitrary, inconsistent and unreasonable manner.*

- (8) The Public Body has failed to give due consideration and/or any consideration whatsoever to the fact and that on 15 October 2014, the Public Body awarded to the Applicant a contract bearing Award Reference No. MHPDO/MDSP/2014/DO63, for the supply of 920 Meril Life Sciences Pvt. Nexgen™ Cobalt Chromium Coronary Stents with CE certification, for the Trust Fund for Specialised Medical Care, Cardiac Centre, Pamplemousses. On 27 November 2014, the Applicant supplied 462 stents to the Public Body with no adverse report, and remaining 458 stents are to be supplied by the end of April 2015.*

*(8.1) By so doing, the Public Body has acted in an arbitrary, inconsistent and unreasonable manner.*

- (9) By arbitrarily and without justification, imposing standards, the Public Body has failed in its inherent duty to act fairly, to promote the participation of legitimate suppliers in the bidding process and to encourage a competitive procurement environment in accordance with the laws of Mauritius, and as such, has acted in a manner which is discriminatory, unjustified, intended to dissuade prospective suppliers from participating in the bidding exercise, and obstructs the promotion of fair conditions of competition for all suppliers in Mauritius. This amounts to a breach of the Public Body's duties and the Applicant will and/or is likely to suffer loss or injury.*
- (10) By limiting, without any valid justification, the standards to a standard required by the US Food and Drug Administration for all products sold within the borders of the USA and a standard certified by the European Committee for standardisation for products sold or traded within the European Market, the Public Body is acting in an unfair and arbitrary manner, contrary to the principles of natural justice and contrary to the interest of the general public at large.*

#### **D. The Hearing**

Hearings were held on 27 May, 08 June, 02 September, 09 September, 14 September 2015. Written submissions were made on 08 June and 14 September 2015, by Applicant and Respondent respectively.

The Applicant was represented by Mr A. Moollan together with Mrs N. Mamodeally, Counsel whereas the Respondent was represented by Mr S. Boodhoo, Principal State Counsel.

### **E. Issues and Findings**

Essentially, the ground for review raised by the Applicant relates to the Respondent having specified the necessity for the said items to be both CE marked and FDA approved which, the Applicant contends, is unfair, discriminatory, arbitrary, irrational and illegal and has the effect of depriving it of the right to participate in the procurement exercise.

If ever the subject matter of a procurement exercise was a matter of life and death, this would be it. The Panel is acutely aware of the necessity for speed and quality for maximum benefit to the public/patient. The decision of the Panel shall be ultimately governed by these considerations rather than the commercial interests of the Applicant.

At the outset, the Panel wishes to dispose of sporadic contention that the requirement has been tailor-made to favour certain bidders to the prejudice of others. It has been established that at least 3 potential bidders would be qualified as their products are accepted for use in both European countries and the US, and have the respective certifications. In the Panel's view, that would provide sufficient competition to abate any suspicion of favouritism. As to allegations of bias, also made by the Applicant, the latter surely does not imply bias against him, as by his own admission the Respondent has awarded contracts to him in the past. Furthermore, the Panel would see no problem with a bias in favour of quality and maximum guarantee to the patient.

It is also necessary to address the contention of the Respondent that the application for review is premature. It has always been the view of the Panel, expressed in several Decisions that bidders should not wait for an award to protest against specifications they consider faulty. The following provisions of the Public Procurement Act support this view.

#### **S43(1)**

*(1) A bidder who claims to have suffered, or to be likely to suffer, loss or injury due to a breach of a duty imposed on a public body or the Board by this Act may, subject to subsections (2) and (3), challenge the*

*procurement proceedings before the entry into force of the procurement contract. (Underlining is ours)*

**S45(1)**

*(1) An unsatisfied bidder shall be entitled to ask the Review Panel to review the procurement proceedings where -*

*(a) the Chief Executive Officer of the public body does not issue a decision within the time specified in section 43(4);*

*(b) he is not satisfied with the decision; or*

Furthermore, a preliminary objection on the part of the Respondent to the effect that the Applicant's application for review was submitted outside the permissible delay was later waived.

During hearings, the Applicant has stressed the quality of his products, and also stated that he has applied for FDA certification, but the application was still pending. The Counsel for the Applicant also pointed out that the Respondent has not been able to show the advantages, if any, of requiring both CE and FDA certifications.

The Respondent has submitted documentation and arguments tending to show the superiority of FDA certified stents over those having CE certification only, but has been unable to show why BOTH certifications would be an advantage. The requirement for both certifications would eliminate all suppliers of FDA (only) certified equipment.

The Panel understands and supports the stated intention of the Respondent to provide patients of public hospitals with the best inserts, and make available to them the same quality of treatment as is available in private practice. However, he has not been able to show how the specifications under discussion will not lead to this objective. There are other ways of achieving this objective, and the Respondent needs have no qualms about using procurement methods or specifications that will ensure results which will give maximum benefit to the public. In this respect, the averment of the Applicant that:

*“the Ministry has acted in breach of section 50(2)(a) of the Public Procurement Act 2008, which imposes a duty on every public body to-*



*"engage in procurement planning with a view to achieving maximum value for public expenditure and the other objectives of this Act."*

is not supported by the evidence and arguments submitted. Rather, it is the Panel's view that the Respondent has sought at all times to act in the best interests of the public by achieving maximum value for public expenditure in terms of the extent and quality of life of end-user patients.

**F. Decision**

For the above reasons, the Panel finds for the Applicant, and recommends under Section 45(10)(b) of the Public Procurement Act the annulment in part of the tender exercise MHPQ/MDSP/2014/Q8, in regard to items 22 to 26 only, and a re-tender exercise with new specifications with stress on quality of the equipment.

**(R. Laulloo)**  
***Chairperson***

**(R. Rajanah)**  
***Member***

**(R. Ragnuth)**  
***Member***

**Dated 06 October 2015**