



Independent Review Panel

Decision No. 25/16

In the matter of:

Trionex Development Ltd

(Applicant)

v/s

Ministry of Health & Quality of Life

(Respondent)

(Cause No. 31/15/IRP)

Decision

A. History of the case

The present application for review relates to the procurement of suture materials through an Open Advertised Bidding Procedure under CPB Reference No CPB/26/2015 and Procurement Reference No MHPQ/MDIS/2015-2016/Q1. On the 24th September 2015, the Ministry of Health and Quality of Life (hereinafter referred the Respondent) issued an invitation for the bids for the procurement same.

The invitation was for the procurement of 61 types of sutures described at pages 42 to 55 of the bidding documents (Item 1-61).

It is to be noted that according to ITB 12.1(h) of the bidding documents, all tenders will be automatically rejected by the Public Body if the requirements of ITB 12.1(h) are not complied with.

On the 21st Oct 2015, the Respondent issued an Addendum No1 MHPQ/MDIS/2015-2016 Q1 Procurement of suture materials following a request for clarification received from Bidders.

On the 5th November 2015, Tribnex Development Ltd (hereinafter referred as the Applicant) submitted its bids for the procurement reference MHPQ/MDIS/2015-2016 Q1.

The closing date of the submission of the said bids was on the 5th November 2015.

On the 9th November 2015, the Applicant challenged the decision of the Respondent in relation to the standards set out in ITB 12.1 (h). On the 12th November 2015 the Respondent responded to the Applicant's challenge. The former made reference to the aforementioned addendum no 1 and maintained the requirements of ITB 12.1(h) of the bidding documents and on the 18th November 2015 the Applicant applied for review before the Independent Review Panel (IRP).

B. The Challenge

On 06 November 2015, the Applicant challenged the award on the following grounds:

- 1. The Ministry of Health has failed to take into consideration the findings of the Independent Review Panel – Decision No. 11/14 dated 10 July 2014, a previous application lodged before the Independent Review Panel by the Applicant, Trionex Development Ltd, in a similar situation, and based on the same bidding documents whilst launching the Bids*

dated 24 September 2015. The Independent Review Panel recommended “that the criterion laid down under paragraph 12.1(h) be accordingly reviewed”.

2. The Respondent has illegally circumvented the decision of the IRP dated 10 July 2014 by unlawfully adding in the present invitation to bid the following “Bidder offering suture materials of standards other than US FDA or EUROPEAN (CE) should submit certificates issued either by US FDA or EUROPEAN (CE) that the quality of their suture material is of same standard as US FDA or EUROPEAN (CE) respectively” thus excluding Trionex Development Ltd from the possibility of participating in the said bid. The Public Body is acting unfairly towards the Applicant and is biased against it. The fact that the matter has been the subject of review by the Panel and the Panel has found in favour of the Applicant. The present bidding documents is a colourable manner to go behind the findings of the Panel and nullify the award made in the Applicant favour.

3. By inserting Clause ITB 12.1(h)(a)(i) as quoted above(A), the Applicant has reasons to believe that the Respondent has acted in an arbitrary, inconsistent biased and unreasonable manner and has reasons to believe that it has been exceptionally inserted in the procurement under reference in order to benefit a single competitor who is being favoured to the detriment of other suppliers including the Applicant.

(2.1).. It is to be highlighted that not all products bearing US FDA or EUROPEAN (CE) certificated are necessarily of good quality. The Applicant has reasons to believe that unless documentary evidence certifying that products bearing US FDA and EUROPEAN CE have never been defective or not to standard, it cannot consider the products being best quality to the detriment of other similar products already being widely used in the hospitals as is the case for the Applicant’s product, namely Synthecon.

4. “Bidders offering suture materials of standard other than”. By adding such Clause as per (A) above, the Ministry of Health has failed to take into account that US FDA and EUROPEAN CE are direct competitors with South African Bureau Standard (SABS SANS 494-1). It is therefore unrealistic to believe that the Applicant will receive a certificate from SABS competitors as to the standard of quality of sutures SABS SANS 494-1. This is an obvious case of judge and party, bias and is totally unrealistic. In so doing, the Ministry of Health has acted in an arbitrary, inconsistent and unreasonable manner and the

Applicant has reasons to believe that this exercise has been tailor-made to the detriment of bidders who do not provide such certification.

5. *South African Bureau Standard (SABS) has a well-defined standard as per annexed document whereas USFDA has no specifically defined standard.*
6. *The Ministry of Health & Quality of Life has failed to give due consideration to the fact that the inclusion of “a requirement for an US FDA and/or CE approval must be provided in the bidding documents” acts as a barrier to the promotion of a competitive procurement environment in Mauritius and deliberately prevents and denies national suppliers competitive access to procurement on the ground that the products are not US FDA and/or European CE compliant, and thereby restricts and/or harms and/or distorts competition in the market for the supply of suture materials in Mauritius thus acting in breach of the Competition Act 2007 and of the Public Procurement Act 2006.*
7. *In the initial tender issued on the 25 September 2015, a requirement was placed at paragraph ITB 12.1(h) (b) (VII) wherein it was stated, inter alia, that COUNTRY OF ORIGIN, MANUFACTURING DATE AND EXPIRING DATE ARE MANDATORY. Therefore an addendum no 1 dated 21.10.2015 was issued stating that “The Country of Origin and Manufacturing date are not mandatory as per US FDA quality system. As far as shelf life and expiry date are mentioned, it is an acceptable alternative. This shows clearly that this is a tailor-made exercise. Why has the Ministry suddenly accepted that manufacturing date and country of origin is not MANDATORY? Whereas Synthecon sutures has the conditions that the Ministry requires for evaluation purposes i.e. production date, expiry date, lot number, supplier name, description of the product, country of origin. All is printed and embossed on the primary packaging on the suture pouch inside and outside box Synthecon sutures qualify all these criteria.*
8. *The product codes of Ethicon (Johnson & Johnson) and its exact description as per its catalogue for each and every item are the same on the tender documents as per (C) above thus showing another indication that the bid is a tailor-made exercise and is not permitted as per section 7 of the Public Procurement Act. In so doing, the Public Body is effectively distorting competition in the market for the supply of sutures in Mauritius, contrary to both Competition Act 2007 and the Public Procurement Act 2006. It has to be noted that Trionex Development Ltd*

was awarded part of the tender referenced OABMHPQ/MDIS/2012/Q31 for the supply of 54,720 suture materials (Synthecon-Made in South Africa) in May 2013. And supplies were made to the full satisfaction of the Ministry of Health and without any complaint from whomsoever. The standards of the products supplied by Trionex Development Ltd are SABS SANS 494-1 and ISO 9001-2008 was duly approved. Further the said Synthecon sutures are imported from South Africa and sold by Applicant at a very competitive price.

9. *The Public Body failed to give due consideration to the fact that Mauritius is a member State of the Comesa and SADC and that in the circumstances, the Public Body is wrongly and arbitrary precluding the internationally recognised and accepted standards and quality certified by SABS.*
10. *Trionex Development Ltd has supplied Synthecon sutures to hospitals (including the Cardiac Centre ever since 2012 through direct procurement and as at date over 198,000 sutures (16,500 boxes of one dozen) have been supplied to the satisfaction of the users with regards to the quality.*
11. *Synthecon sutures raw materials has CE/US FDA approval, i.e. thread and needles used to manufacture Synthecon sutures.*
12. *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. The Reply to Challenge

On 12 November 2015, the Public Body made the following reply to the challenge:

“We wish to inform you that Addendum No. 1 dated 21 October 2015 is self-explicit and reads as follows:

US FDA and/or EUROPEAN (CE) Certificates should be submitted from the manufacturer for all items. Bidders should submit certified true copies of US FDA and/or EUROPEAN (CE) Certificates.

For bidders who are offering suture materials other than US FDA or EUROPEAN (CE) (i.e. SABS SANS 494-1), they should submit certificates issued either by US FDA or EUROPEAN (CE) that the quality of their suture materials is of same standard as US FDA or EUROPEAN (CE) respectively. Certificates should be certified true copies.”

D. Grounds for Review

On 18 November 2015, the Applicant seized the Independent Review Panel for review on the following grounds:

“Under section 45 of the Public Procurement Act 2006

1. *On the 9th November 2015, pursuant to section 43 of the Public Procurement Act 2006, the Applicant challenged ITB 12.1(h) of the Bidding Documents which pertains to standards and which requires that*

“(i) US FDA and/or EUROPEAN (CE) Certificates should be submitted from the manufacturer for all items.

Bidders should submit certified true copies of US FDA and/or EUROPEAN (CE) Certificates.

Bidders offering suture materials of standards other than US FDA and/or EUROPEAN (CE) should submit certificates issued either by US FDA and/or EUROPEAN (CE) that the quality of their suture materials is of same standard as US FDA and/or EUROPEAN (CE) respectively.

(ii) (...)

Non submission of the above will result in rejection of the bid.”

on the ground that the decision of the Public Body is tailor-made, biased, unfair, unreasonable, discriminatory, arbitrary, irrational and illegal and has the effect of (i) depriving the Applicant of the right to participate in the procurement proceedings because the sutures marketed by the Applicant have been certified by a different certifying body namely the South African Bureau of Standards, (ii) restricting competition and (iii)

preventing SMEs from emerging, and for all the reasons set out in that challenge.

1.1 *The Public Body responded to the Applicant's challenge on the 12th November 2015 and maintained ITB 12.1(h) of the Bidding Documents.*

1.2 *The Applicant is dissatisfied with the decision of the Public Body to maintain ITB 12.1(h) of the Bidding Documents, the moreso that the Applicant successfully contested a previous decision of the Public Body to impose US FDA and/or EUROPEAN (CE) certification for suture material under the last Procurement of Suture Materials (National Bidding) issued on the 25th February 2014 bearing Procurement Reference No: OAB MHPQ/MDIS/2013/Q32 (IRP Decision No. 11/14 dated 10th July 2014). That decision of the IRP has not been the subject of any judicial review proceedings. In that case the Independent Review Panel made the following findings -*

"We have duly considered the evidence on record, and the submissions of Counsel, and have come to the conclusion that the exclusion of sutures carrying SABS SANS 494-1 is not justified.

We are therefore of the opinion that the exclusion of sutures carrying SABS SANS 494-1 will deprive the Applicant from participating in the bidding process.

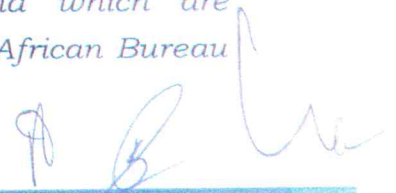
Given the competitive price of sutures carrying SABS SANS 494-1, and given our findings that no evidence has been placed before the Panel to the effect that the materials bearing SABS SANS 494-1 certificate are of poor quality, the Panel recommends that the criterion laid down under para 12.1(h) be accordingly reviewed."

the Public Body is acting in blatant disregard of those findings of the Independent Review Panel and for all intents and purposes-

- [a] *is illegally attempting to circumvent that decision of the Independent Review Panel, and*
- [b] *by requiring bidders offering suture materials of standards other than US FDA or EUROPEAN (CE) to submit certificates issued by US FDA or EUROPEAN (CE) certifying that the quality of their suture materials is of the same standard as US FDA or EUROPEAN (CE), is a colourable device to go behind that decision of Independent Review Panel.*
2. *By restricting the bidding process in such a manner that only US FDA and/or EUROPEAN (CE) certified sutures will be accepted and that sutures of other standards will only be accepted if supported by a certificate from either US FDA or EUROPEAN (CE) which confirms that those sutures are of the same quality as US FDA and/or EUROPEAN (CE) certified sutures, the Public Body is acting in an arbitrary, unfair and unreasonable manner because it is not the objective of either the US FDA or the EUROPEAN (CE) certifying body to compare one standard to another or attest that a product would have the same quality as one which has been certified by it.*
3. *By restricting the bidding process in such a manner that only US FDA and/or EUROPEAN (CE) certified sutures will be accepted and that sutures of other standards will only be accepted if supported by a certificate from either US FDA or EUROPEAN (CE) which confirms that those sutures are of the same quality as US FDA and/or EUROPEAN (CE) certified sutures, the Public Body is acting in a manner, which is contrary to the principles laid down in Directive No. 11 of 2012, issued pursuant to section 7 of the Public Procurement Act 2006 by the Procurement Policy Office.*
4. *By restricting the bidding process in such a manner that only US FDA and/or EUROPEAN (CE) certified sutures will be accepted and that sutures of other standards will only be accepted if supported by a certificate from either US FDA or EUROPEAN (CE), which confirms that those sutures are of the same quality as US FDA and/or EUROPEAN (CE)*

certified sutures, the Public Body is acting in a manner, which is contrary to the principles of the SADC Treaty 1992, the SADC Protocol on Trade 1996 and the COMESA.

5. *By restricting the bidding process in such a manner that only US FDA and/or EUROPEAN (CE) certified sutures will be accepted and that sutures of other standards will only be accepted if supported by a certificate from either US FDA or EUROPEAN (CE), which confirms that those sutures are of the same quality as US FDA and/or EUROPEAN (CE) certified sutures, the Public Body is acting in a manner, which is contrary to the fundamental principles of the Charter of the Indian Ocean Rim Association to which both Mauritius and South Africa are member States.*
6. *The Public Body fails to give due consideration and/or any consideration whatsoever to the fact that in May 2013, prior to that decision of the Independent Review Panel dated the 10th July 2014, the same Public Body awarded to the Applicant part of the tender referenced OAB MHPQ/MDIS/2012/Q31 for the supply of suture materials and the Applicant supplied the Public Body with around 4560 boxes of Synthecon sutures to its satisfaction. The Applicant supplied a further 3000 boxes of the same sutures to the same Public Body through direct procurement in the same year and again with no adverse report.*
7. *The Public Body fails to give due consideration and/or any consideration whatsoever to the fact that since that decision of the Independent Review Panel dated the 10th July 2014, the Applicant has supplied more than 9800 boxes of Synthecon sutures to the Public Body by way of some 85 Informal Quotations, without any adverse report and that as such the decision of the Public Body to now impose a requirement for US FDA or EUROPEAN (CE) standard, is inconsistent with the Public Body's track record for the procurement of sutures.*
8. *The Public Body fails to give due consideration and/or any consideration whatsoever to the fact that Synthecon sutures, and which are manufactured in South Africa, are certified by the South African Bureau*



of Standards, have been attributed the South African National Standard SANS 494-1: 2008, and have also been certified as ISO 90001 compliant.

9. *The Public Body fails to give due consideration and/or any consideration whatsoever to the Applicant's representation that-*
 - 9.1 *the SABS certified Synthecon sutures, which are marketed by the Applicant in Mauritius, are used extensively both in Mauritius and worldwide, and*
 - 9.2 *the South African Bureau of Standards (SABS) certification is recognised and accepted both internationally and locally.*
10. *The Public Body fails to give due consideration and/or any consideration whatsoever to the fact that the procurement proceedings for Procurement Reference No: OAB MHPQ/MDIS/2015-2016/Q1, are inherently flawed and have been tailor-made to benefit a minority of tenderers who are able to satisfy the US FDA and/or EUROPEAN (CE) certification, to the detriment of bidders who import products from countries such as South Africa, which have their own standards and quality certification and which meet the norms of international standards and quality.*
11. *By restricting the bidding process in such a manner that only a few select suppliers are capable of supplying suture materials to the Public Body, the Public Body is, by its conduct, favouring certain suppliers over others without reason and/or justification.*
12. *The Public Body fails to give due consideration and/or any consideration whatsoever to the-*
 - a. *technical and functional specifications of Synthecon sutures;*
 - b. *level of safety of Synthecon sutures; and/or*
 - c. *cost of Synthecon sutures, which are approximately 50% cheaper than their counterparts.*

13. *The Public Body fails to give due consideration and/or any consideration whatsoever to the fact that the inclusion of a requirement for US FDA and/or EUROPEAN (CE) Certificates, acts as a barrier to the promotion of a competitive procurement environment in Mauritius, deliberately prevents and denies suppliers and especially small and medium enterprises such as the Applicant, competitive access to procurement on the ground that their products are not US FDA and/or EUROPEAN (CE) compliant, and thereby restricts and/or harms and/or distorts competition in the market for the supply of sutures in Mauritius, contrary to the principles of the Competition Act 2007 and the Public Procurement Act 2006.*
- 13.1 *By so doing, the Public Body is acting 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 sutures.*
14. *By arbitrarily and without justification, imposing US FDA and/or EUROPEAN (CE) standards, the Public Body is failing 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 drive out 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.*
15. *By limiting, without any valid reason and/or justification, the standards to a standard which is normally required by the US Food and Drug Administration for all products sold within the borders of the USA and/or a standard which normally is certified by the European Committee for Standardisation for products sold or traded within the European Market, the Public Body is acting in a biased, unfair, unreasonable, discriminatory, arbitrary, irrational and illegal manner, contrary to the principles of natural justice and contrary to the interest of the general public at large."*
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E. Reply of the Respondent

1. Any Public Body is perfectly entitled to formulate its procurement requirements in terms of international and national standards in line with Directive 11 (issued by the Procurement Office of the Ministry of Finance and Economic Development pursuant to section 7 of the Public Procurement Act).

Para (b)(ii) of the said Directive reads as follows:

(B) Descriptions and definitions of the procurement requirements:-

(ii) May be formulated in terms of international and national standards so as to maximize competition and avoid creating unnecessary obstacles to participation by bidders in the procurement proceedings, while ensuring that applicable national and international standards and the requisite quality levels are met.

2. The implications of any such formulation as is permissible under para (b)(ii) above is then clearly set out at para (d) of the said Directive and which reads as follows:-

(a) Where a public body makes use of the option of referring to standards or common technical specifications it cannot reject a bid on the grounds that the goods and services proposed for do not comply with a required standard or common technical specification where the bidder can show in its bid by whatever appropriate means that the solutions the bidder proposes satisfy in an equivalent manner the requirement defined by the technical specifications in the bidding documents. An appropriate means is constituted by a technical dossier of the manufacturer or a test report of a bid which is a third party.

3. It is clear from a reading of para (d) of the Directive no 11 that a bid cannot be rejected on the grounds of non-compliance with a required standard subject to the bidder showing that the solutions proposed satisfy in an equivalent manner the requisite standard. The present application is therefore misconceived in as much as the onus is on the bidder to show compliance with the requisite standards.

4. The state of local healthcare system renders the formulation of its own certification and control standards with respect to the products under consideration highly impractical such that the only logical and sensible option is to rely on foreign national or international standards. In the context of the present bid, considering the intended purpose and utility of the products under consideration, the requirement as formulated would clearly give adequate assurances of both safety and effectiveness.

F. The Hearing

Hearings were held on 07, 14 and 17 December 2015.

The Applicant was represented by Mr A. Moollan together with Mrs N. Mamode Ally, Counsel and Mr O. Bahemia, Attorney whereas the Respondent was represented by Mr S. Boodhoo, Principal State Counsel.

E. Findings

The Panel have duly considered the evidence on record and the submissions of Counsel.

The Panel took note that the Respondent is relying mostly on Directive 11 that is they wanted to make sure that the National and International standards and requisite quality levels are met.

However the Panel observed that in May 2013, Applicant has supplied to the Respondent with around 4560 boxes of Synthecon sutures to its satisfaction. The Applicant supplied a further 3000 boxes of the same sutures to the Respondent through direct procurement in the same year and again with no adverse report. Furthermore the Panel observed that the Applicant has supplied more than 9800 boxes of Synthecon sutures to the Public Body by way of some 85 informal Quotation, without any adverse report.

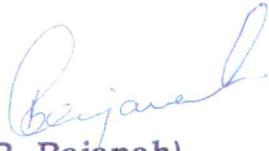
The question that the Panel is bound to ask at this juncture is that if those sutures supplied by the Applicant to the Respondent are not to the quality and standard of the US FDA and/or European (CE), why the Respondent purchased those sutures of the South African Bureau Standard in first place. The Panel note with great concern that no evidence has been placed on records before the Panel to the effect that the materials bearing SABS 494-1 certificate are of poor quality.

Conclusively the Panel observed that the exclusion of sutures carrying SABS 494-1 certificate is not justified and the exclusion of the said sutures will certainly deprive the Applicant from participating in the bidding process. Thus the Panel recommends that the criterion laid down under Para 12.1 (h) be accordingly reviewed.

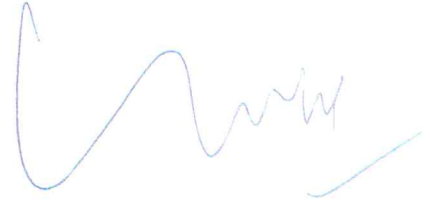
Same Decision applies in the case of Trionex Development Ltd v/s Ministry of Health & Quality of Life (CN 30/15/IRP).



(A. Kallee)
Vice-Chairperson



(R. Rajanah)
Member



(V. Mulloo)
Member

Dated 27 September 2016



