Republika e Kosovës
Republika Kosova – Republic of Kosovo
ORGANI SHQYRTUES I PROKURIMIT
TELO ZA RAZMATRANJE NABAVKE
PROCUREMENT REVIEW BODY

Psh. No.975/23

The Review Panel, appointed by the President of PRB, based on Article 105, 106, and 117 of the Law on Public Procurement of the Republic of Kosova (Law no. 04/L-042, supplemented and amended by Law 04/L -237, Law 05/L-068, supplemented and Law 05/L-092) as well as article 29 and 31 of the PRB Work Regulations 01/2020 amended with dt. 09. 08. 2023 composed of Vedat Poterqoi - President, deciding according to the complaint of the Economic Operator (EO) N.SH.T "NeraMed", against the Decision to award a contract or a competition for the design of SHSKUK - Hospital Service University Clinic of Kosova in the capacity of the Contracting Authority (CA) regarding the procurement activity "Supply of Medicines from the Essential List for the Needs of SHSKUK (110)" with procurement number 00220-23-9623-1-1-1, on the 27/12/2023 has issued this:

DECISION

1. The complaint of EO N.SH.T "NeraMed" under no. 2023/0975, dated 04/12/2023, whereas the decision of the CA SHSKUK - Kosova University Clinical Hospital Service regarding the procurement activity "Supply of Medicines from the Essential List for the Needs of SHSKUK (110)" with procurement number 00220-23-9623-1-1-1 for LOT 13 is cancelled, while the procurement activity is returned to Revaluation.

2. Within a period of 10 days, the CA must inform the PRB about all the actions undertaken in relation to this procurement activity, otherwise, the PRB has the right to take measures against the CA for non-compliance with the decision as provided by the provisions of the article 131 of the LPP.

3. The funds deposited in the name of the tariff tax for submitting the complain't to the account of the Economic Operator S.SH.T "NeraMed" are returned. The complaining EO is obliged to comply with Article 31 point 6 of the Rules of Procedure of the PRB, within a period of sixty (60) days to make a request for the return of the insurance of the complaint, otherwise the deposit will be confiscated, and these funds will go to the Budget of the Republic of Kosova.

REASONING

- *Procedural facts and circumstances -*

MUNICIPALITY OF GJAKOVA, in the capacity of the contracting authority on the 25.08.2023, has published the Contract Notice related to the procurement activity entitled: “Road traffic equipment and signaling” with procurement number 632-23-9062-1-1- 1. While on 01.11.2023 he published B58 Notice on the decision of the Contracting Authority.

The contracting authority has implemented an open procedure, the type of contract is supply and the estimated value of the contract is 240,000.00 €.

On the 06.11.2023, the complaining EO made a request for reconsideration of the aforementioned decision of the CA, while on the 07.11.2023 the MUNICIPALITY OF GJAKOVA rejected as unfounded the request for reconsideration of the Economic Operator.

-On the stage of preliminary review-

The Review Panel has concluded that the complaint contains all the elements defined through Article 111 of the LPP and as such was submitted within the legal term in accordance with Article 109 paragraph 1 of the LPP after the preliminary procedure for resolving disputes in the sense of Article 108/A of the LPP, from the economic operator who is an interested party according to article 4 paragraph 1 sub-paragraph 26 of the LPP. In this way, the Review Panel has concluded that it is competent to review this complaint according to Article 105 of the LPP and there is no procedural obstacle to proceed with reviewing the complaint in a meritorious manner.

Findings of the CA regarding the request for reconsideration of EO "NeraMed"

Answer from the Contracting Authority regarding complaints 1, 2, 3 and 4: Regarding the claims of the Economic Operator that the matter has been returned to Reevaluation and the CA has sent a standard letter for abnormally low tenders where it has received the letter from the EO recommended with breakdown detail of the price offered, Regarding the claim for variation of the product, here we have nothing to do with a variation of the product, but with the commercial change of the name of the manufacturer or holder of AM where it is documented in the offer of the recommended EO. As long as a product has a valid MA from the KPA, then that product can circulate freely in the Kosovo Market and in the presented documents of the Recommended EO it can be seen that the EO has presented a valid MA. Conclusion: Based on the above reasons, the Contracting Authority rejects this request for reconsideration as unfounded. For us, all Economic Operators are important and equal. Against this decision, the unsatisfied party can submit a complaint to the PRB.

The claims of the complaining economic operator EO "NeraMed" are presented as follows:

• Claim set forth (I), the Complainant claims that: "Initially, on 09/11/2023 we as EO submitted a request for reconsideration to CA - ShSKUK where the same request was approved as well-founded and the matter was returned to re-evaluation, but despite this fact, CA - ShSKUK again recommends for awarding the contract the irresponsible economic operator in terms of the

financial offer and in terms of the requirements of technical, professional capacity and professional suitability. EO "Neramed" Sh.P.K. again on 22/11/2023 submits a request for reconsideration, but now CA - ShSKUK rejects our request and leaves in force the decision - the proposal for awarding the contract despite the fact that our company has presented concrete evidence through which it is proven that the EO proposed for award of the contract in lot 13 of the procurement procedure entitled "Supply of Medicines from the Essential List for the Needs of the National Health Service of Ukraine (110) - Lot 13 - Solution for injection 250mcg/5ml, there are also qualifying requirements" is irresponsible. CA - ShSKUK according to the decision - rejection of the request dated 24/11/2023 has violated paragraph 8, point 8.4 of article 108A of the LPP, respectively it has not addressed any of our complaints. 8. The contracting authority will reject a request for reconsideration when: 8.4 The contracting authority has reviewed its decision in terms of what is requested by the complainant.

• The second claim (II), the Complainant claims that: initially on 06.11.2023, the CA published form B58 - Notice on the decision of the CA, where for lot 13- "Solution for injection 250mcg/5ml", it recommended for awarding of the contract to EO "Agro Med", which presented irresponsible offers. Complainant EO "Neramed" shpk, dated 09.11.2023, has submitted a request for reconsideration, where we as a company have presented facts and evidence where it has been proven that the EO which the CA has recommended for contract award in lot 13, is without accountability. Initially, the CA - ShSKUK approved our request as based on the matter and returned it for re-evaluation, surprisingly on 18.11.2023, again recommending it for award to the same EO, ignoring our complaints and trying to conclude contracts with the EO, which you can't even import products. In the tender dossier in point 4.1, it is determined that the Variants are NOT authorized and the CA cannot conclude a contract with a product variant or a manufacturer variant.

• The third claim (III), the Complainant claims that: the Contracting Authority - SHSKUK, in the requirements of technical and professional capacity in point 9.1 & 9.2 position 1, requested: Claim 1. Authorization from the manufacturer to participate in this tender or from the authorized representative from the manufacturers. In case of authorization by the representative-dealer, the authorization of the dealer by the manufacturer is also required. As documentary evidence - evidence is defined: Evidence 1. Authorization from the manufacturer to participate in this tender or from the representative authorized by the manufacturer - with the procurement number of this procedure (with data on the manufacturer, address, phone number, email, website, etc. , for possibility of verification). In the case of authorization from the dealer-representative, the authorization of the dealer from the manufacturer is also required", while in point 2, Authorization for Marketing in Kosovo is requested from AKPPM. The economic operator, which the CA - SHSKUK, is trying to recommend for the award of the contract "Agro Med" shpk, again despite the fact that the matter has been reassessed, has offered the product of the manufacturer "Haver Trakya medicine san. Vetic" on one side and on the other side for the product "Solution for injection 250mcg/5ml, the same EO has presented the "Marketing Authorization in the name of "MS Pharma Ilac ve Ticaret Anonim Sirketi", product registered on 09.12.2019, of documented by KKPPM as holder of MA with manufacturer "MEFAR Ilac

Sanayii A.S Turkey". This issue is undeniable, but surprisingly the CA tries to manipulate it. Proof: Letter of Authorization, financial offer and AM.

• The fourth claim (IV), the Complainant claims that: the Economic Operator, recommended for the award of the contract in lot 13, in the offer presented a letter from the Turkish Business Registry dated 28.11.2022, where the subject was changed from "MS Pharma Ilac ve Ticaret Anonim Sirketi", in "Haver Trakya drug san. Vetic", while AM has not been changed as required by the legal provisions in force. With the law no. 04/L -190, for medicinal products and devices in article 3, point 1. 44 and 1.45 it is determined that: 1.44 Marketing authorization holder - a legal person who has received marketing authorization for the medicinal product. 1.45. The representative of the marketing authorization holder - a legal person, usually known as a local representative, appointed by the marketing authorization holder to represent it in the Republic of Kosova; So the legal entity which has given authorization to the economic operator recommended for awarding the contract in lot 13, "Haver Trakya medicine san. Vetic", for the product "Solution for injection 250mcg/5ml", is not the holder of the Marketing Authorization nor the manufacturer, but the holder of the AM is "MS Pharma Ilac ve Ticaret Anonim Sirketi" with manufacturer "MEFAR Ilac Sanayii A.S Turkey". and as such does not meet the qualifying requirements defined in point 1 and 2, of the technical and professional capacity defined in the tender file. Administrative instruction no. 01/2015 - Marketing Authorization for Medicinal Products article 6, Submission of Application for Marketing Authorization paragraph 5 defines: "The applicant is obliged to inform KKPPM immediately about any change of residence address, location of the manufacturer, production process or other changes related to the marketing authorization application, which is under review. After the marketing authorization is issued, information must be provided by the marketing authorization holder".

For this matter, the CA - SHSKUK is well aware that the Variant of the Marketing Authorization form and the Manufacturer's Variant of the product cannot be offered, also the CA is aware that changes in the product, changes in the manufacturer must be reported in the Ministry of Health of the Republic of Kosovo, namely in the Agency for Medical Products and Equipment in such a way that the AM is changed, while the EO recommended for awarding the contract in lot 13 has not done such a thing, therefore the offer of the same it is irresponsible. And despite the above clarifications, CA-SHSKUK has been obliged to request additional information from the Agency responsible for registration of medicinal products and for the issuance of Import Licenses - AKPPM, such a thing has not been done by CA-SHSKUK, apparently deliberately.

• The fifth claim (V), the Complainant claims that: The other issue which shows the irresponsibility of the offer, is the low value offered by the EO recommended in lot 13 for this product where a value of €4.58 per unit was offered, while CA - SHSKUK, as the estimated value for this product, has determined the total of €75,000.00, or €15, price per unit. AK - SHSKUK, according to the re-evaluation process, abused legal provisions, abused and insulted our company. The reference price determined by you as the CA is €15, the complaining EO has offered the price but €4.58 and the CA treats it as a normal price, a product which cannot be imported legally and with persistence CA, the Procurement Office endangers public health . CA, during the re-evaluation of the offers, it was necessary to apply the provisions of Article 41

"Tenders not normally reduced", paragraph 41.3 where it is defined: 41.3 The contracting authorities will ask the economic operators to explain the price offered for responsible tenders, when all the following conditions are met: i. the price offered is more than 30% lower than the average price of responsible tenders; ii. the price offered is more than 10% lower than the price or costs of the second lowest tender; iii. at least 3 (three) tenders have been submitted. The EO recommended for awarding the contract cannot under any circumstances be qualified as a responsible EO, even at the initial threshold it would have to be eliminated since the price of the same EO is more than 30% lower than the average price of responsible tenders. AK SHSKUK, the bid evaluation commission did not apply the provisions of Article 61 of the LPP, nor did it apply the provisions of Article 41 of the RRPP. According to the decision dated 24/11/2023, CA - ShSKUK mentions that it has received the letter from the EO recommended with a detailed reduction of the offered price, but there is no letter and no communication related to this issue in the E-Procurement platform. The provisions of the LPP and other rules oblige the CA that all communications be made through the e-procurement platform.

- *Administration and evaluation of evidence* -

In order to fully verify the factual situation, the review panel administered as evidence the expert's report, the opinions of the parties related to the expert's report, the submissions and documents of the complainant, the letters and documents of the contracting authority, the relevant documents related to the procurement activity as and all the evidence that has been proposed by the procedural parties.

Relying on article 111 paragraph 5 related to articles 113 and 114 of the LPP, the Review Panel dated 05/12/2023 has authorized the review expert to conduct the initial review of the file and claims according to complaint no. 975/23, while on 15/12/2023 the report of the review expert was submitted with no. 2023/0975 with the following recommendations: "Based on the above-mentioned clarifications, the review expert proposes to the review panel that the complaint of the complaining EO be approved as grounded, the contract award notice be canceled and recommends that the matter be returned for re-evaluation".

Regarding the claims of EO "NeraMed", the review expert through report no. 2023/0975 assessed as follows:

• First finding (I): The review expert assesses that the return to re-evaluation according to Article 40.2 of RRPP 001/2022 A decision to re-evaluate the selection of bidders or the award of the contract does not mean a change in the initial result. During the revaluation procedure, the CA clarified the claim for abnormally low prices by means of the standard letter for abnormally low information dated 13.11.2023, but that clarification was not reflected in the report of the revaluation commission dated 16.11. 2023. During the justification of the abnormally low price, the EO recommended for the contract had also sent a request for confidentiality, which included the explanation given for the breakdown of the price as a business secret. As for the request for reconsideration dated 24.11.2023 and the claim that the CA has not addressed any of the claims of the complaining EO, the review expert assesses that the CA with the decision of 24.11.2023 has rejected as unfounded all the claims of the complaining EO . Despite the fact that the

reviewing expert estimates that not all concrete claims have been addressed, a general answer has been given. Therefore, the reviewing expert assesses that the CA has acted in accordance with Article 60 of the ROGPP in relation to Article 63.1.1 a) as well as Article 63.2 of the RRPP 001/2022 and that the claim in this point is not founded. The expertise's report has been duly accepted by all procedural parties. CA declares that it does not agree with the recommendations of the review expert's report, while EO has declared that it agrees with the review expert's report.

• Second finding (II): Regarding the claim of the complaining EO, which is related to the request 9.1 & 9.2 for the technical and professional capacity, the reviewing expert clarifies that according to the tender file, the following was requested: Request 1. Authorization from the manufacturer to participate in this tender or by the manufacturer's authorized representative. In case of authorization by the representative-dealer, the authorization of the dealer by the manufacturer is also required. Evidence 1. Authorization from the manufacturer to participate in this tender or from the representative authorized by the manufacturer - with the procurement number of this procedure (with data on the manufacturer, address, phone number, email, website, etc., for the possibility of verification). In case of authorization by the representative-dealer, the authorization of the dealer by the manufacturer is also required. The EO recommended for the contract with offer has submitted the manufacturer's authorization issued by "Haver Trakya sanayi Vetic" for the product PALONEX 250 MCG 5 ML IV SOLUTION FOR INJECTION (palonosetron hydrochloride). In the offer, the EO recommended for the contract has offered the Marketing Authorization Certificate with no. MA No: MA-5953/09/12/2019 in the name of: MS Pharma Ilac Sanayi ve Ticaret Anonim Sirketi for the product with the trade name PALONEX with INN: Palonosetron HCI* (Equivalent to 0.050 mg/ml Palonosetron) in which the manufacturer is declared: MEFAR Ilaç Sanayii A.S., Turkey. It is worth noting that the trade name "MS Pharma Ilaç San. ve Tic. A.S" at the request of the applicant with no. E-62820468-000-952720 was duly changed in the commercial register to "Haver Trakya Ilaç San. ve Tic. A.S" from the Ministry of Health of the Republic of Turkey.

• Third finding (III): Regarding the claim of the complaining EO regarding the change of the trade name and the data of the EO in the Marketing Authorization, the review expert estimates that answers have been given to claims 3 and 4 and therefore will not be reviewed here.

• Fourth finding (IV): Regarding the claim of the complaining EO, which is about abnormally low prices, the reviewing expert explains that the same has been elaborated in the answer no. 1 of the claim, but which adds that the CA in accordance with Article 41.3 and 41.6 of RRPP 001/2022 has dealt with the offer of the EO recommended for the contract and for which he received a response from the EO recommended for the contract on 15.11.2023. The CA has handled the clarification in accordance with Article 41.3 of RRPP 001/2022 and consequently received an answer. Based on Article 41.10 of RRPP 001/2022 41.10 After the Contracting Authority receives the written explanation from the Economic Operator, the Contracting Authority must either: a. If the clarification is sufficient, treat the tender the same as other tenders; b. If the clarification is not enough, reject the tender and, in accordance with Article 61 of the LPP, notify the KRPP, using the standard form approved by the KRPP, "Notice of rejection of the tender not normally reduced", within two days from the date of the decision.

Therefore, based on the administered documents, the review expert assesses that the complaining claim at this point is not grounded.

The expertise's report has been duly accepted by all procedural parties. The CA declares that it does not agree with the recommendations of the review expert's report, while the EO has not declared regarding the opinion and findings given in the review expert's report.

The review panel has assessed that the conditions have been met to decide on this case without a hearing in the sense of Article 24 paragraph 1 of the Rules of Procedure of the PRB, taking into account that the claims of the parties and their submissions, the evidence as well as the expert's report reviewers provide sufficient data to decide on the merits of the case.

- Findings of the Review Panel -

The review panel independently and objectively, conscientiously and professionally evaluated all the evidence of the case. From the clarifications given above, it is concluded that the review expert handled the claims of the complaining economic operator "NeraMed" in a professional and objective manner. The argumentation in the expertise report is quite detailed, comprehensible and fully based on the relevant documents that refer to the procurement activity. The given findings can be confirmed through the tender file and other documents.

The review panel after the administration and assessment of the evidence, the complete ascertainment of the factual situation, relying on the LPP as applicable material law, after reviewing the complaining claims, taking into account all the documents of the case and the recommendations of the review expert, has found that the Economic Operator's complaint must be approved as grounded. However, it should be noted that the expert's report is not binding on the Review Panel and that each such report is evaluated and/or analyzed in the general context of the case documents, asserted facts and other possible evidence, taking into account the nature of the violations. event, the course, nature and purpose of the procurement activity. Therefore, the fact that in which cases and for what, the Panel supports or not, any report and/or any of the recommendations, belongs to his/her independent and professional judgment, just as these responsibilities are addressed in the sense of article 98, 99 related to article 105 of the LPP.

-Conclusion-

According to the complaint claims and the answers given by the contracting authority after examining the request for reconsideration, it can be seen that the CA during the examination of this procurement procedure did not act as provided for in Article 59 of the LPP.

The Review Panel has decided in accordance with the legal powers in the sense of Article 104 paragraph 1 in relation to Article 103, Article 105 and Article 117 of the LPP for the implementation of the procurement review procedure in a fast, fair, non-discriminatory manner, in order to legal and effective resolution of the case. Therefore, the Review Panel based its findings on the relevant provisions of the LPP, which foresee and regulate such situations, which may appear during a procurement activity.

For point I of the decision, it was decided based on article 117 of the LPP in relation to article 29 and paragraph 31 of the Rules of Procedure of the PRB.

For point II of the decision, it was decided based on article 131 of the LPP in relation to article 29 paragraph 3 of the PRB Work Regulations.

For point III of the decision, it was decided based on article 31 paragraph 4 and paragraph 6 of the PRB's Work Regulations related to article 118 of the LPP.

From what was said above, it was decided as in the provision of this decision.

President of the Review Panel

Mr.Vedat Poterqoi

Legal advice:
An appeal is not allowed against this decision,
but the dissatisfied party can appeal to the Commercial Court,
within 30 days from the date of acceptance of this decision.

Decision to be submitted to:

1x1 CA – **SHSKUK - UNIVERSITY CLINICAL HOSPITAL SERVICE OF KOSOVA;**
1x1 EO – **"N.SH.T "NERAMED";**
1x1 Archive of the PRB;
1x1 For publication on the website of the PRB.