PROCUREMENT REVIEW PANEL, appointed by the President Pursuant to the article 105 as well article 106 of the Law on Public Procurement of the Republic of Kosova no.04/L-042, amended and supplemented by Law No. 04/L-237, amended and supplemented Law no.05/L-068, amended and supplemented Law no.05/L-092, composed of: Mr. Blerim Dina – President, Mr. Nuhi Paçarizi – referent, Mr. Goran Milenković - member, deciding on the complaint lodged by the EO "Medical Group"Sh.p.k. - Prishtinë, against the cancellation notice, regarding with the procurement activity with title: "Supply with medicines from the Essential List for the needs of HUCSK "LOT 2", with procurement no: 00220-20-980-1-1-1, initiated by the Contracting authority/ University Clinical Hospital Service of Kosova/UHCSK/, on the 08.07.2020 has issued this:

DECISION

I. REFUSED, as ungrounded the complaint of the Economic operator: "Medical Group"Sh.p.k. – Prishtinë, regarding with the procurement activity with title: "Supply with medicines from the Essential List for the needs of HUCSK "LOT 2", with procurement no: 00220-20-980-1-1-1, initiated by the Contracting authority/ University Clinical Hospital Service of Kosova/UHCSK/.

II. CERTIFIED the cancellation notice, regarding with the procurement activity with title: "Supply with medicines from the Essential List for the needs of HUCSK "LOT 2", with procurement no: 00220-20-980-1-1-1, initiated by the Contracting authority/ University Clinical Hospital Service of Kosova/UHCSK/.

III. Contracting authority within 10 days must inform in written the Review panel for all actions taken regarding with this procurement activity and other parties in the procedure.

IV. Non-compliance with this decision obliges the Review Panel conform with the legal provisions of article 131 of the Law for Public Procurement of Kosova No.04 / L-042, amended and supplemented by Law No. 04/L-237, Law no.05/L-068, Law no.05/L-092, to take action against the Contracting Authority.

V. Since the complaint of the complaining economic operator is refused as ungrounded, it is confiscated the insurance fee of the complaint and will pass to the budget of the Republic of Kosova.

REASONING

Complaining economic operator “Medical Group sh.p.k.- Prishtina”, as a dissatisfied party has filed a complaint in the PRB, on the 28.05.2020 with procurement no. 345/20, against the notification for cancellation of the procurement activity with title: “Supply of medicines from the Essential List for the needs of HUCSK” LOT 2 with procurement no. : 00220-20-980-1-1-1, initiated by the contracting authority (CA) - University Clinical Hospital Service of Kosova (HUCSK).

• Contracting authority has acted in contradiction with article 7 and 59 of the Law on Public Procurement of the Republic of Kosova

Procurement Review Body, conform article 113 and 114 of the LPP on the 08.06.2020, has authorized the review / technical expert of the procurement to review the validity of all claims of the complaining party.

Review expert / technician in the report dated: 15.06.2020, regarding the complaining claim of the complaining EO explains as follows.

Answer to Claim no. l
Regarding the complaining claim that EO is responsible according to the Essential List of okra to which the tender dossier refers is unfounded because EO has not met the requirement 9.1 & 9.2 of DT regarding the technical and professional capacity where he has not proved AM issued by PAKPM in doses as required in annex 1 of DT where the pharmaceutical product Enoxaparin 20mg /0.2ml; 40mg / 0.4ml; 60mg / 0.6ml and 80mg / 0.8ml is requested while the complaining EO has offered the product DALTAPARIN SODIUM 5000IU / 0.2ml although with the claim that the essential list has provided for the use of symbols, ie the square sign which means the use of products of the same group with the same effect allowing the possibility to apply the alternatives specified in LE but HUCSK has requested the pharmaceutical product ENOXOPARIN and not the alternative DALTEPARIN which was offered by the complaining EO, this product which was not a request of the tender dossier. Based on the above data, we consider that the complaining claim is unfounded.

Answer to Claim no.2
Regarding the complaining claim that the bid of the EO is responsible because the PRB has decided in the same case that the bids with 5000IU are fully responsible does not stand because the PRB in the two preliminary decisions PSH. No. 209-2019 dated 01.07.2019, and PSH.nr 662-664-2019 dated 02.12.2019 has reviewed the same complaining claims of the same economic operator for the same product and the same have been rejected as ungrounded because neither the dose nor the volume has matched and according to the list even the generic name does not match the essential cloud according to the request of the contracting authority HUCSK. Based on the above data, we consider that the complaining claim is unfounded.

Opinion of the review expert / technician
Based on the above clarifications, review expert / technician proposes to the review panel that the complaint of the complaining EO “Medical Group” Sh.pk to be rejected as ungrounded while the decision of the CA for cancellation of this procurement activity-Lot 2, of remains in force.

On the 22.06.2020 are notified the parties regarding the report of the review expert respectively the procurement technical.

Contracting authority, on the 18.06.2020 through memo, has notified the PRB as follows:
Dear

Referring also to the Essential Drug List, for the pharmaceutical product Dalteparin (and Nadroparin), * alternatives are limited to nadroparin and dalteparin 2500IU / 0.2ml; 7500IU / 0.3ml; 10000IU / ml; 12500IU / ml / 0.5ml; 15000IU / 0,6ml; as can be seen the alternative of 5000 IU is not in LE. We would also like to inform you that the clinics as research units have not planned (requested) Daltepari and Nadropar in any of the mentioned alternatives according to the respective doses.

As an illustration, to further argue, clinics have not planned for these two alternatives either:
Ox enoxaparin *, 120 mg / 0.8 mL; Injection: pre-filled ampoule or syringe
□ enoxaparin *, 150 mg / 1 mL. Injection: ampoule or pre-filled syringe.
Consequently, for these two enoxaparin product alternatives, we have not proceeded at all.

We proceed based on the planning of the research units and in the present case, the clinics have planned for several alternatives of the pharmaceutical product: □ enoxaparin *
With respect
Mr.Sc.Selami Krasniqi

Economic Operator, on the 25.06.2020 notifies the PRB via email as follows:
Dear,

We confirm the acceptance of the expert report and in accordance with Article 115 of Law no. 04 / L-042 on Public Procurement of the Republic of Kosovo, as amended and supplemented, we express our response to the expertise.

Medical Group LLC does not agree with the findings of the expertise, and considers it clearly illegal.

Given that the findings of the expertise and the Contracting Authority are completely illegal in the Report with the Essential List of Drugs approved in 2019, which in the main parts aimed to avoid abuses in tenders according to the model we are facing. For this reason, we have requested a written interpretation from the Commission that approved the Essential List and from the Ministry of Health, who have promised a prompt response.

In this regard, we respectfully ask you to wait for the Decision of the Commission of 43 officials who have approved the Essential List of Medicines, and the Ministry of Health which has approved the list.

The decision in this case according to the illegal recommendation of the review expert is a dangerous illegal precedent with the approved Essential List and will cost the Kosovo budget millions of euro more expensive prices.

With respect,

MEDICALGROUP

Skender Kutllovci, MD MSc. / CEO

The hearing session was held on: 08.07.2020 without the presence of the parties conform article 24.1 of the Regulation of the PRB, where the case files were reviewed by checking and analyzing the documentation for the procurement procedure which consists of: authorization of initiation of the procurement activity, contract notice, minutes on the opening of the bids, decision on the establishment of the bid evaluation commission, bid evaluation report, notification for cancellation of the procurement activity, complaint of the economic operator, report of the review expert / technical and all memos of the parties to the proceedings.

Regarding the claim of the complaining EO “Medical Group” Sh.pk - Prishtina that contracting authority has violated article 59 of the LPP. The decision to eliminate the bid of “Medical Group” Sh.pk - Prishtina as irresponsible is completely contrary to public procurement legislation and the decision on the essential list of drugs. In this case, we are dealing with violation of the articles of the LPP, as in the following article 59 - evaluation, comparison and examination of the tenders - the offer of the EO “Medical Group” Sh.pk - Prishtina, is fully responsible and in accordance with the requirements of the tender dossier and the essential list specifically addresses the issue of products and doses according to international units IU, this due to previous abuses with this topic. Complaining EO continues to claim that in this regard, the offer of Medical Group "LLC is fully responsible and that through this complaint argue and prove that A) The essential list of drugs to which the tender dossier refers addresses that" Medical Group "Sh .pk - Prishtina, is responsible and that B) PRB has decided for the same cases that the offer with 5000 IU are completely responsible.

A) The essential list of medicines to which the tender dossier refers addresses that "Medical Group" Sh.pk - Prishtina is responsible.

CA through decision of the 26.05.2020, rejects as ungrounded the request for reconsideration of the complaining EO “Medical Group” Sh.p.k with the reasoning that the EO in question has not offered with any of the forms required in the tender dossier. More specifically, Annex 1 of the mandatory technical specifications (LOT 2) requires the product Enoxaparin *, injects ampoules or pre-filled syringes with different doses according to the new essential list (20mg /0.2mL; 40mg / mL; 60 mg / 0.6mL; 80 mg / 0.8 mL). Whereas, according to CA “Medical Group” Sh.p.k has not offered in any of the above forms but has offered with the product Delta Parin Sodium 5000 IU (anti-Xa) /0.2ml.

Complaining EO adds that initially through the new essential list approved by the Ministry of Health the new decision for the essential list no. 43/2019, provides for the use of symbols within the LE which means allowing the use of products of the same group with the same effect.

Enoxaparin product is published in LE decision on LE page 50, point 10.2 Drugs that affect coagulation and in the tender dossier page 17 Annex 1 mandatory technical specifications with the square symbol before the product. The use of the square symbol is an essential element of the WHO List on the principles of which the LE has been

compiled in the Republic of Kosovo, and in all products where the list with the square symbol is used, “the supply can be made from any product within that pharmaceutical category ”(See Essential List of the Republic of Kosovo, page 10, paragraph 3, and WHO Essential List).
For the product envisaged by Lot 4, a square sign was used, allowing the possibility to apply the alternatives specified in the LE published by the MoH page 50 point 10.2 where the alternatives are placed which the box makes responsive with its own doses of applicable based on product characteristics and applicable IU international units. Consequently, according to the decision of the essential list, the offer of Enoxaparin 400 IU, is the equivalent alternative allowed based on LE for the product Deltepari 5000 IU, with which EO "Medical Group" Sh.pk has offered in this tender, a product which is produced by the company Pfizer and has AM for the Kosovo market. So, effectively we are dealing with the same product expressed for concentration mg / ml, while the other form of the product is expressed through International IU units.
Consequently all products that possess Marketing Authorization and which are within the Square List with equivalent doses are liable.
Review panel conform review / technical expert evaluates that the complaining claim that EO is responsible according to the essential list of drugs, to which the tender dossier refers is ungrounded because EO has not fulfilled the requirement 9.1 & 9.2 of the dossier. technical and professional capacity where there is no evidence of AM issued by KMA in doses as required in Annex 1 of the tender dossier, where the pharmaceutical product Enoxaparin 20mg /0.2ml; 40mg / 0.4ml; 60mg / 0.6ml and 80mg / 0.8ml, while the complaining EO has offered the product DALTAPARIN SODIUM 5000IU / 0.2ml although with the claim that the essential list has foreseen the use of symbols respectively the square sign which means the use of products of the same group with the same effect allowing the possibility that apply the alternatives specified in the essential list. However, HUCSK has requested the pharmaceutical product ENOXOPARIN and not the alternative DALTEPARIN which has been provided by the complaining EO, products which was not a request of the tender dossier. Therefore, this complaint is unfounded.

Regarding the claim of the complaining EO “Medical Group” Sh.pk - Prishtina that B) The bid of the EO “Medical Group” Sh.pk is responsible because the PRB has decided in the same case that the bids with 5000 IU are fully responsible . CA claims that the elimination of EO “Medical Group” Sh.pk was obtained based on two identical cases where the product LOË MOLECULAR WEIGHT HEPARIN was requested which in the new essential list is named Enoxaparin, which cases have been handled by the PRB and In both cases the review panel of the PRB has confirmed the decisions of the CA. This claim is completely unfounded because the Decision of the PRB PSH-136/17, where for the same product with the same dose the PRB has decided that the offer with 5000 IU is fully responsible. Regarding these illegal practices, the PRB Decision PSH-136/17, specifies and clarifies that all products which offer within concentrations of 2000 IU-6000 IU are fully responsible. So the products which offer with 2000 IU (international unit) 2500 IU (international unit), 3000 IU (international unit), 5000 IU (international unit) or 6000 IU (international unit) are all responsible for tender purposes. Further, the PRB has reasoned that in the case between 40mg / ml is the same as 4000 IU (international units). But, it was exactly this illegal change of the PRB practice in two cases after the first decision that damaged the budget of the Republic of Kosovo with over 1 million euros for the Ministry of Health to improve the essential list to prevent such abuses. New essential list approved by the MoH, new decision on the essential list no. 43/2019 is legally binding for both the HUCSK and the PRB, and this list specifically

provides that the offer of "Medical Group" Sh.p.k. it is legal. In addition, the decision of the contracting authority for elimination is contrary to the professional principles set out in the essential list and the symbols which are part of this list. Therefore, in the following we will present the facts which one by one will prove that the offer of EO "Medical Group" Sh.pk is fair and responsible. Facts about LE and the box:
The square box symbol (□) is intended to indicate similar clinical performance within a pharmacological class. In cases where there are square boxes the supply can be made with any product within that pharmacological category in accordance with the procedures provided for this purpose. (this is the text described in the LE approved by the decision of the MoH) decision of dt. 20.09.2019, p. 16.
2. Since in the LE revised by the MoH as reference they have taken the model of the WHO list where it is described that the product listed as the first is taken as an example of the class for which it has the best evidence for effectiveness and safety or in some In some cases, the first drug that obtains marketing authorization is listed, and in other cases, licensed substances that may be safer or more effective are obtained. When there are no changes in terms of efficacy and safety data the listed drug should be the one that is generally available at the lowest price, based on international drug pricing information sources.
3. In the section of the essential list where all the comments from the addressing of all companies for inclusion in the LE of certain products are listed, it is very clearly described that the group of LMËH is accepted by the commission for revision of the essential list "increasing the doses of Dalteparine product "page 139 LE which you find attached to this explanation from the document Essential List 2019 final.
4. Low molecular weight heparins in LE are classified under the general ATC code B01AB DO means as combinations of unfractionated heparin and not as specific substances such as Enoxaparin, Dalteparin or Nadroparin. Based on this feature during the tender all agents of this class have proven to be equivalent in terms of therapeutic effect and health institutions around the world use them mutually. Therapeutic equivalence is proven only on the basis of efficacy and safety reviews as well as in accordance with WHO guidelines and clinical guidelines.
5. Regarding the clinical performance of these 3 similar products (certainly with more benefits of Dalteparine substance as in pharmacokinetics and pharmacodynamics) for all those who are interested in learning the name of the product that it is exactly Dalteparin and not Dalta parine as we wrote in the decision. All information can be found in the links below: https: /www.ncbi.nlm.nih.gov/pmc/articles/PMC4720650/ https: /www.ncbi.nlm.nih.gov/pubmed/11827560 https: /journals.lww.com / ajpmr / Abstract / 2001/12000 / Dalteparin vs Enoxaparin as Prophylaxis for .4.aspx Consequently the offer of EO "Medical Group" Sh.pk with the product FRAGMIN 5000 IU (anti-Xa) /0.2ml, for Lot 2 is responsible because it is within the international units (IU) and inside the box of the essential list of drugs. Therefore, allowing the elimination of EO "Medical Group" Sh.pk and canceling this activity at this stage would be discriminatory in relation to companies that have submitted responsive bids and the manufacturer Pfizer and as such also illegal as there is no no objective of elimination and cancellation. Review panel conform review / technical expert evaluates that the complaining claim that the bid of the EO is responsible because the PRB has decided in the same case that the bids with 5000IU are completely responsible does not stand because the PRB in the two preliminary decisions PSH. No. 209- 2019 dated 01.07.2019, and PSH.nr 662-664-2019 dated 02.12.2019 has reviewed the same complaining claims of the same economic operator for the same product and the same were rejected as unfounded because it did not match neither the dose nor the volume and according to the new essential list does not

match either the generic name at the request of the Contracting Authority-HUCSK. Therefore, this complaint is unfounded. Review panel considering the progress of this procurement activity, and the explanations of the review / technical expert and based on the case file, concludes that the cancellation of the procurement activity in question has been done in accordance with article 62 of the LPP, because contracting authorities should consider the offer of an economic operator as liable only if it complies with all the requirements set out in the contract notice and in the tender dossier.

Review panel conform article 117 of the LPP, and based on the evidence presented above decided as in the provision of this decision.

Legal advice:
Aggrieved party can not appeal against this decision,
but it can file charges for damage compensation
within 30 days, after the receipt of this decision
with the lawsuit In the Basic Court In Prishtina
at the Department for Administrative Affairs.

President of the Review Panel

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Mr. Blerim DINA

Decision to be submitted to:
1x1 CA – University Clinical Hospital Service of Kosova/UHCSK
1x1 EO – Medical Group"Sh.p.k. - Prishtinë,
1x1 Archive of the PRB
1x1 For publication on the website of the PRB.