P.SH 397/22
409/22

REVIEW PANEL, appointed by the President Pursuant to the article 105 as well article 106, and 117 of the Law on Public Procurement of the Republic of Kosova no.04/L-042, amended and supplemented by Law No. 04/L-237, Law no.05/L-068, and Law no.05/L-092, composed of: Mrs. Kimete Gashi – President, Mrs. Nita Bejjta- referent, Mr.Vedat Poterqoi –member, Mrs. Vjosa Gradinaj Mexhuani - member and Mr. Agon Ramadani - member, deciding on the complaint lodged by the Economic operator: "Pharma Lider LLC" Prishtina and economic operator "Meditech" ShPK Prishtina, regarding with the procurement activity: "Supply of Insulin analogues from the Essential List" Lot 1 and 3", with procurement no: 206- 20-8397-1-1-1,initiated by the Contracting authority- Ministry of Health, on the 11 of October 2022 has issued this:

DECISION

1. **Approved**, as grounded the complaint of the Economic operator: "Pharma Lider LLC" Prishtina, submitted to the Procurement Review Body on August 26, 2022, protocol number 397/2022, regarding with the procurement activity: "Supply of Insulin analogues from the Essential List" Lot 1 and 3", with procurement no: 206- 20-8397-1-1-1,initiated by the Contracting authority- Ministry of Health.

2. Refused as not allowed for reviewing the complaint of the Economic operator: "Meditech" ShPK Prishtina, submitted to the Procurement Review Body on August 29, 2022, protocol number 409/22, regarding with the procurement activity: "Supply of Insulin analogues from the Essential List" Lot 1 and 3", with procurement no: 206- 20-8397-1-1-1,initiated by the Contracting authority- Ministry of Health.

3.**Cancelled**, the Decision dated 12.08.2022 for the cancellation of the procurement activity so that this procurement activity is returned to Re-evaluation and the Ministry of Health, in the capacity of the Contracting Authority, is obliged to re-evaluate the offers, in relation to the activity "Supply of Insulin analogues from the Essential List" Lot 1 and 3", with procurement no: 206- 20-8397-1-1-1.

4. Within 10 days, the CA must inform the PRB Review Panel in writing about all the actions taken in relation to this procurement activity, specified by number and date as in the preliminary paragraphs of the provision of this decision.

5. Non-compliance with the decision, obliges the Review Panel as provided by the provisions of Article 131 of the Law for Public Procurement of Kosova No.04 / L-042, Law No. 04/L-237, Law no.05/L-068, and Law no.05/L-092, to take action against the Contracting authority.

6. The return of the deposited amount is allowed in the case of submitting a complaint for EO "Pharma Lider LLC" and for EO "Meditech", in accordance with article 31 point 6 of the PRB Work Regulations, while the cited EO has the right to of sixty (60) days to make

a request for the return of the complaint insurance, otherwise the deposit will be confiscated and the funds will go to the Budget of the Republic of Kosova.

8. A monetary fine is imposed on the Contracting Authority in the amount of 5,000.00 €, due to non-compliance with the Decision of the PRB dated 25.03.2021, in accordance with Article 131, of the Law on Public Procurement in the Republic of Kosova.

9. 9. The procedure for the revocation of the procurement certificate is initiated against the responsible procurement officer of the CA, due to violations of the provision of Article 25, paragraph 8, of the LPP.

REASONING

- *Procedural facts and circumstances*

On the 12.12.2020, the Ministry of Health, in the capacity of the Contracting Authority, published the Notice for the contract, related to the procurement activity described (number, date and name) as in the introduction of this Decision, while the public opening of the offers was done on the 05.01.2021.

On the 22.02.2021, CA (with data as above) published its Decision, according to which:
- "Pharma Leader" LLC is the recommended EO for the contract for Lot I with the offer value of 1,097,467.36 E and Lot III, with the offer value of 4,109,006.12 E. Whereas,
- "Meditech" EO recommended for contract for Lot II, with the value of the offer 913,315.00 E

On the 26.02.2021, EO "Meditech" submitted a Request for reviewing, which was approved by the Decision of the CA dated 01.03.2021, while the procurement activity has been returned to reviewing.

On the 05.03.2021, the CA made a Decision, according to which:
EO "Meditech" has also been recommended for Lot I at a price of €1,114,726.72

And Lot III, priced at 4,456,908.24 €.
According to this Decision, it is implied that, EO "Meditech" is now the only EO recommended for 3/3 of this procurement activity.

On the 10.03.2021, EO "Pharma Leader" LLC submitted a request for reviewing, which was rejected as ungrounded by the Decision of the CA dated 12.03.2021. Against this Decision, EO in this case submitted a complaint to the PRB on the 15.03.2021.

On the 25.03.2021, PRB took a Decision (No. 240/21) according to which the Contract award Notice for Lots I and III was canceled, while the procurement activity was returned to Revaluation.

On the 27.04.2021, (published on the 28.04.2021) deciding on the re-evaluation procedure, the CA made a Decision according to which it recommended for contract EO "Meditech".

On the 30.04.2021, EO “Pharma Leader” LLC submitted a request for reviewing, which was rejected by the CA with the Decision dated 06.05.2021.

On the 11.05.2021, against the aforementioned Decision of the CA, EO “Pharma Leader” LLC filed a complaint at the PRB.

Deciding on the Complaint, the PRB had engaged the review expert to, according to his authorizations, provided by article 113 and 114 of the LPP, make a preliminary evaluation of the complaint’s file and claims. In this, according to the expert's preliminary assessment, the complaining claims of EO “Pharma Leader” LLC are considered grounded. However, the complaint’s procedure in this particular case was not closed with a final administrative act (decision), since the mandate of the PRB Board (in its preliminary composition) had expired in terms of Article 100 of the Law on Public Procurement in the Republic of Kosova.

On the 23.06.2022, the Assembly of Kosova has appointed the Board of this Institution, and the same on the 12.07.2022, PRB has taken Decision No. 397/21, according to which the EO's complaint (together with a number of others) was rejected as not allowed for reviewing.

On the 12.08.2022, CA (with data as above) published the Notice on the Decision to cancel the procurement activity, against which on the 16.08.2022, “Pharma Leader” submitted a request for reviewing. Likewise, EO “Meditech” on the 17.08.2022 submitted a request for reviewing. Both Requests cited above were rejected by the CA with the Decision dated 02.09.2022 as ungrounded, while the Decision to cancel the procurement activity remained in force.

Against the above-cited Decision of the CA. EO “Pharma Leader” submitted a Complaint to the PRB on 26.08.2022 (Protocol 397), while on the 29.08.2022 EO “Meditech” also filed a Complaint (Protocol No. 409/22).

- *Evaluation and administration of evidence* –

PRB considers that EO Complaints have been exercised in accordance with Article 109.1 of the LPP, according to which against any decision taken by the contracting authority, any interested party has the right to submit a complaint to the PRB. Since the EO has applied for reviewing, it means that its actions refer to Article 108/A at the same time, since according to paragraph 1 of Article 109, it is provided that, quoted: “The complaint must be submitted only after conducting a preliminary resolution procedure of the dispute in accordance with Article 108/A of this law”. Therefore, the PRB considers that the Complaint fulfills the prerequisites in terms of the provisions now cited in relation to Article 111, and the same falls under its powers in terms of Article 105, of the LPP.

Based on the actions taken as above, PRB has engaged the procurement review expert in accordance with Article 111, paragraph 5, of the LPP, with the duty that the same in the sense of Article 113 and 114 of the cited Law, do the initial review of the file and complaining claims regarding the procurement activity described above. In this regard, the review expert submitted the evaluation report on the 15.09.2022, with the following recommendations:

- Approve EO's complaints as grounded;
- To cancel the CA Notice dated 12.08.2002 for the cancellation of the procurement activity;
- The case is returned for re-evaluation;

- *Public session with parties*

The Review Panel analyzed all the documents of this case, including all the acts and/or actions of the parties, as described above (procedural facts and circumstances) and convened the main review session on the 03.10.2022, with the aim of a fair evaluation of the case. The statements of the parties, the administered evidence and the expert's explanations are recorded in the minutes of this session, which in this case, for the needs of this decision, are presented (briefly) as follows:

1. Complaining statements of EO "Pharma Leader"
EO "Pharma Leader" has stated that it stands by the complaint and the complaining claims, demanding that the Decision dated 25.03.2021, No. 240-21, of PRB to remain in force, the reasoning that

1.1. The CA's attempt to cancel Lot 1 and 3 is contradictory to the evaluation of the offers by the first evaluation commission of this CA, dated 08.02.2021 and the Notice on the decision dated 22.02.2021, which are confirmed by the Decision of PRB with No. 240-21, dated 25.03.2021, according to which it was established that EO "Pharma Leader" presented a responsive offer in accordance with the requirements of the TDS and with the cheapest price for 400,000.00 €.

1.2. Taking advantage of the institutional vacuum (PSH means: Absence of the PRB Board), CA has ignored the Decision of PRB, cited above and, among other things, has signed an agreement with UNOPS for the Supply of Analogue Insulins, instructing the same to exclude the application of UA No. 02/2014, in order to eliminate competition in favor of an EO. And as a result, medicinal products in some tendering processes are purchased at more expensive prices than from local companies. After pressure from the public opinion, the CA did not extend the contract with UNOPS, but nevertheless on 23.03.2022, it announced the notice for a new tender, under procurement number 206-22-221 l-l-l-l, for the same procurement purpose, excluded from the conditions again the application of UA 02/2014. In this case, CA acted in the contrary to the cited Decision of PRB and applied direct purchase with negotiation, at higher prices than EO "Pharma Leader".
1.3. The request for reviewing of EO "Meditech" was submitted outside the legal deadline provided by paragraph 3, related to paragraphs 8. and 8.1, of article 108/A, of the LPP. Contrary to the cited provisions, CA has accepted the request as timely, acting contrary to the cited provisions of the LPP and the Guidelines of the PPRC.

1.4. Also acting in the contrary to the clarifications of the Kosova Agency for Medical Products and Equipment (AKPPM), the CA has used an Opinion of an incompetent person, causing confusion in the interpretation of the Law on Medical Products and Equipment, which the officials of CA use it as a pretext to avoid UA 2/2014 and to escape responsibility for their actions, with which they have damaged the budget of CA with 400,000.00 €, since for many the offer of EO "Pharma Leader" is cheaper.

1.5. Furthermore, EO “Pharma Leader” has emphasized that PRB with Decision No. 200/19, dated 11.06.2019, had left in force the decision of CA-MH despite the fact that the product had not been registered with a Marketing Authorization, while UA 02/2014, had not been part of the qualification requirements in the TDS. From this aspect, CA is in contradictory because:
i. Regarding the case cited above, CA has requested explanations from KKPPM according to which the product in question is registered in the EU market and that it can be used in the Kosova market;
ii. However, in this case, CA has not considered the explanation of KKPPM according to which: Fumigation with insulin analogues is allowed according to UA 2/2014, as evidenced in the Tender File “Marketing Authorization, with the required specification of the product. In case there is no parallel registered in Kosova, UA 02-2014 applies". In this case, the aforementioned tends to interpret the TDS File in a one-sided manner.

1.6. Regarding the claims of EO Meditech, that according to the law in force and the practice of CA, not having a Marketing Authorization does not allow a certain EO to be rewarded with contracts in a procurement activity" EO “Pharma Leader” declares that this Operator there are two contracts related to SHSKUK for similar products that are used for the treatment of the same disease (but with different ATC Codes) as follows: (a) One product has Marketing Authorization; while (b) The other product worth about 2 million € imports based on UA 02/2014.

1.7. In addition to the above statements, EO “Pharma Leader” has asked the PRB to compel the CA to cancel or revoke the now attacked decision, taken during the procurement activity, including the illegal conditions, to impose fines for continuous violations of the LPP and to I request the revocation of the certificates for the responsible officials of CA, on the grounds that PRB Decisions are binding.

2. Complaining statements of EO “Meditech Sh.P.K”
2.1. EO “Meditech Sh.P.K” has stated that the request of EO Pharma Leader L.L.C. to sell unregistered medicaments in Kosova is a threat to life and public health and addressed in relation to this responsibility to the PRB under the assertion that, quoted: "What you decide as a panel in this case, has an impact on the 3628 medicaments whose producers have respected the laws of Kosova, the safety of the products and have registered them with the Agency of Medicinal Products of Kosova.

2.2 Meditech Sh.P.K has stated that the Marketing Authorization is actually considered as a passport of the product, since it determines the quality control, its origin, the chain of storage and care from the manufacturer to the patient, and maintenance on the effects of the drug, reports on side effects and the like. Through the Marketing Authorization, the responsibility is also determined, and the quality of the products is ensured. So, Marketing Authorization has the European Union, America, and there is no country in the world that we are aware of that allows circulation of drugs without Marketing Authorization. The Government of Kosova has changed the Administrative Instruction in force so that it has accelerated the registration process for Marketing Authorization.

2.2. Law No. 04/L-190 on Medicinal Products and Devices, amended and supplemented by Law No. 08/L-047, in its Article 16, paragraph 1, expressly states that: “The medicinal product may be placed in the Republic of Kosova only after receiving Marketing Authorization from KKPPM”. The only case when a product can be imported without a

Marketing Authorization is when the import is for personal needs as expressly defined in Article 12 of the cited Law. However, in this particular case, since the insulins are imported for the needs of the CA, a public institution, it follows that article 16, mentioned above, applies to insulin. Also, since the product that is the object of this procurement activity is already registered, it is illegal to allow the import of an identical but unregistered product. If this panel decides to approve Pharma Leader's request, then we must tell the other 3628 drugs, do not respect the safety requirements in Kosova and remove the registrations.

2.3. CA, on the 04.04.2022, held a consultative meeting and came to the conclusion that "the supply of insulin requires a Marketing Authorization, because the Law prevails over the UA, due to the importance of the products, the responsibility of the holder of the marketing authorization in case that you run into trouble with a product". In spite of the above, in this particular case, the review expert has ignored the main evidence for this case: the institutional position between the KKPPM and the CA (Ministry of Health) - mentioned above.

2.4. A very important issue that we must take into account in this procurement activity is the fact that the issue of Marketing Authorization has been judged a total of 3 times: 1 time before the PRB and 2 times before the United Nations Agencies. In the PRB it was not decided in a meritorious way, but it was returned for re-evaluation as a partially based Complaint to verify the statements of the KPAPM. This is in a dubious process, within 9 days, with no session being held at all, nor were the legal deadlines for comments in the expertise respected.

2.5. The expert emphasized that EO Meditech submitted the Request for Reviewing outside the legal deadline. This despite the fact that the CA made a Decision on the 12.08.2022, while the EO in question submitted a Request for Reviewing on the 17.08.2022. So, it turns out that the Expert calculated the day of acceptance of the decision as "day 1". In this particular case, the Expert took such an assessment in the contrary to the practice created by him, but also to the legal acts in force. Thus, among others, in the cases PSH 371/18, PSH 273/19, 295/19, and PSH 281/22, the same Expert has concluded that the date of notification, namely the date of acceptance of the decision/notification, is "the day 0". The aforementioned provision clarifies the fact that the date 12.08.2022 is considered as day 0, and that the deadline runs from tomorrow - that is, from the date 13.08.2022. From 13.08.2022 to 17.08.2022, meanwhile, there are a total of 5 days. Consequently, it appears that EO Meditech submitted the Request for Reviewing within the deadline, more precisely on the 5th day.

2.6. Through the Decision dated 25.07.2022, PRB clarified that the complaint of EO Pharma Leader L.L.C. it is inadmissible. Such a thing gives the CA only two options: (a) to sign the contract with EO Meditech Sh.P.K.; or (b) cancel the entire procurement activity in question. Given that the legal conditions have not been met to cancel the procurement activity in its entirety, it turns out that the only real solution is for CA to sign the contract with EO Meditech.

2.7. In the event that you, as a review panel, allow the importation and placement of products without a Marketing Authorization. Also, this would tell the 3628 drugs registered by all other manufacturers that it is not necessary to register such products and they should be removed from Kosova.

3. Affirmations of the Contracting Authority
3.1. After the decision of PRB No. 397/21 dated 25.07.2022, the Ministry of Health canceled the procurement activity according to the Decision dated 12.08.2022 and announced the new procurement activity No. 206-22-9901-1-1-1 for the same products, considering that the cancellation of the PA by the MH was in harmony with the decisions of PRB No. 397/21 dated 25.07.2022. Explaining the reasons for the cancellation and announcement of the new procurement activity, the CA explained, among other things:

a. the opening of offers for this activity was done on the 05.01.2021, a long time has passed since the time of tendering, circumstances have changed, there is a change in market prices;
b. The cancellation of the PA is also necessary from an administrative point of view - there are defects in the Tender dossier, explaining the following:
c. The description of the prices as part of the TDS is not drawn up correctly, the quantity is described incorrectly: indicative quantity for 12 months, deviation allowed +/- 30%.
d. While in DT in Section II. The Tender Data Sheet (TDS) is specified that: “This public commission contract has a duration of 24 months and is effective from the date on which it enters into force" i.e. we have changes within the documents of the same activity,
e. Both bidders have bid according to the price description for 12 months and no one from the EO has asked clarifying questions to correct this error.
p. Also in TDS article 2.6 - Estimated value, it is specified in total 7,024,056.00 € (estimated value of three Lots for 24 months), it is not described separately for each Lot.
g. These defects in the Price Description and the Value provided in the TD cannot be corrected at this stage, but we consider that they are a very big reason for the cancellation of this activity, based on Article 62 of the LPP.

3.2. DT's request was: 2. Registration of the drug is required - authorization for marketing from KKPPM, with the required specification of the product. In the event that there are no parallels registered in Kosova, UA 02/2014 For the simplification of procedures for the registration and import of medicinal products that do not have parallels registered in the Republic of Kosovo shall apply. This criterion has been formulated as a standard for all drug activities in the Essential List and has not given alternatives “this or that”, but with the exception of this case, it has been understood that each is required as primary AM, if there is no AM, the possibility is given with UA 02/2014.

3.3. After the dilemmas presented by the complaint claims during this activity, a Legal Opinion was given according to which the criterion of the tender file is in principle in function of the implementation of Law No. 04/L-190 on Medical Products and Devices, where the registration of products with Marketing Authorization in the Republic of Kosova.

Declaring the following that, the decision of the PRB on this matter has a direct impact on the security of the insulin supply system for over 15,000 diabetics who receive insulin for free from the state, whose life becomes difficult in their absence (as happened last year past) and proposing to the Panel to support the Decision of the CA for the cancellation of this activity, as a fair decision that protects the public interest, life and health of the patient and to take into account article 104.4 of the LPP, according to which: In undertaking the measures set forth in this Part IX, the PRB must (iii) take as a basis the

possible consequences of the actions or measures in all interests that may be harmed, including the public interest.

EO “Pharma Leader”, contradicting the assertions of EO “Meditech Sh.P.K” stated that:
(1) EO “Meditech Sh.P.K” has 2 active contracts for 2 products from the same pharmaceutical group:
a) a product that helps the organization to produce electricity is registered; courses,
b) the other product is unregistered and imported according to UA 02/2014 for one year;
c) The same product from another company has been imported over two years according to UA 02/2014;
Therefore (according to EO ‘Pharma Leader”) i.e. that, according to EO “Meditech Sh.P.K”, marketing authorization is foreseen or not for a product, depending on its commercial interest. Explaining further that: In EU countries, products are registered in the European Agency because I cannot circulate a product as unregistered, whereas our product is registered in more than 190 countries in EM. Therefore, the marketing authorization does not cover the quality of the product, but the fact of its registration.

EO “Meditech Sh.P.K”: The law on medicinal products is clear and that point 9.1 and 9.2 TDS is applied only when there is no offer with marketing authorization. When a product is registered with a marketing authorization, parallel import is not applied. Emphasizing that, I am scandalized by the expert's attitude, because it is not acceptable to quote a paragraph by email and not to take a common institutional position, why did 3628 products come and companies like Pfaizer, Astrazeneka, Roshe with registered products in Kosovo, because import without parallel is not applicable.

- *The opinion of the review expert*

(a) EO “Pharrna Leader” has met the qualifying criteria according to 69 of the LPP, since the tender dossier provided, quoted: “Registration of the drug is required - authorization for marketing by KKPPM, with the required specification of the product. In case of not has parallels registered in Kosova, applies UA 02/2014, For the simplification of procedures for the registration and import of medicinal products that do not have parallels registered in the Republic of Kosova”. Regarding this KKPPM, explained, citing: “The products of offered by EO “Pharma Leader” have no parallels and as such can be subject to UA No. 02/2014 For simplification of procedures for registration and import of medical products since they are not parallel products”.

(b) The Request for Reviewing of EO “Meditech Sh.P.K” submitted to CA on the 17.08.2022, was out of time and the same was reviewed in violation of Article 108/A of the LPP and Article 4 of the Regulation on submission of requests for reviewing or complaints to the PRB, because:
- The notification for the decision to cancel the procurement activity was published on the 12.08.2022; While,
- The request for reviewing of EO “Meditech” was submitted on the 17.08.2022.

(b) The Request for Reviewing of EO "Meditech Sh.P.K” submitted to CA on the 17.08.2022, was out of time and the same was reviewed in violation of Article 108/A of the LPP and Article 4 of the Regulation on submission of requests for reviewing or complaints to the PRB, because:

- The notification for the decision to cancel the procurement activity was published on the 12.08.2022; While,
- The request for reviewing of EO “Meditech” was submitted on the 17.08.2022.

(c) The review expert assesses that, in the event of the cancellation of the procurement activity, none of the conditions foreseen with the deposits of Article 62 of the LPP have been met. CA has emphasized that there are price changes in the market and has compared the prices offered by EO “Meditech” with the prices of other contracts, which are not known under what conditions or circumstances those contracts were concluded. According to the review expert, the CA cannot take as a pretext for canceling the procurement activity the price changes in the market as long as participating EOs have expressed interest in a procurement activity and stand by the offers whose prices are within the planned budget.

(d) Therefore, with the Decision dated 25.03.2021, PRB had requested that the procurement activity be re-evaluated because the CA had not respected the qualifying criteria according to the Decision dated 05.03.2022, while the evaluation of the offers was not done in accordance with Article 59 of LPP. However, the CA with the decision dated 28.04.2021 has again recommended EO “Meditech” whose offer is higher in the amount of 400,000.00 €. The fact that the CA has not respected the decision of PRB No. 240/21, is considered a violation of Article 105 of the LPP.

(e) However, the Decision of PRB dated 12.07.2022, No. 397/21, (according to the expert) does not prejudice the result as claimed by EO “Meditech Sh.P.K” because with the cited decision PRB has only confirmed that the deadline has passed regular for reviewing complaints. Regardless of this, not taking as a basis the criteria defined for qualification and the criteria defined for evaluation during the re-evaluation means that the CA has violated the basic principles of LPP such as competition, transparency and equal treatment since the non-implementation of these principles means favoritism-discrimination of one party in relation to the other party.

Briefly based on the above, the expert has recommended that the CA should cancel the notification dated 12.08.2022 for the cancellation of the procurement activity and re-evaluate the offers in accordance with the criteria defined for qualification and the criteria defined for evaluation, in accordance with The decision of 25.03.2021.

- *Findings of the Review Panel –*

After reviewing and administering the documents of this case one by one, analyzing the acts and/or actions taken by the PRB, CA, EO, reviewing the complaints, statements of the parties in the main review session and recommendations to the review expert, the Review Panel considers that:

The flow of the procurement activity in this particular case is characterized a priori by the acts and actions of the CA, which in relation to the intended purpose of this procurement, from the point of view of this Panel, were not implemented with increased care and in a professional manner as required in meaning of article 1, of the LPP (consolidated version), according to which this law aims to promote the creation of a professional, ethical institutional culture, following the principle of the most efficient use, with

economic cost, transparent and right of public funds and resources by strictly adhering to the procedures and essential conditions of this law. In addition, the Panel considers that in the integral context of this Law, each CA (of which instance) enjoys full autonomy in the procurement process, in relation to the identification of public interest needs and budget planning. On the other hand, in the context of some assertions from the documents available in this matter, the responsible messages should be addressed to the PRB, which also in the integral sense of this Law, exercises the powers, a priori from the moment when the procurement activity turns into a contested issue. However, in the context of the documents of this matter, the PRB, guided by ethical and professional principles, has tried to preserve the institutional integrity of the CA and legal stability in the implementation of this procurement, at least in two concrete cases as follows:

1. With the Decision dated 25.03.2021, the PRB has requested that the CA reevaluate the procurement activity in terms of the circumstances explained in this decision (without the need to repeat them). In this case, it is inconclusive that the CA did not act in harmony with the cited Decision, which in the sense of the legislation means the administrative act of a competent body, with binding effects for all parties since it originates from the mandatory norms of the LPP and the powers of PRB, from its quality as a second-level state administration body. The panel considers (without any prejudice) that the consideration of the cited Decision would effectively avoid any dilemma, in relation to the aforementioned criteria, for the reason of fumigation with the specific medicine, according to the facts and circumstances described as in the introduction of this decision, unnecessarily took on a dramatic character.

2. Meanwhile, with the Decision dated 12.07.2022, PRB has taken Decision No. 397/21, has left the management of this procurement activity to the full discretion of the CA-MH (due to the absence of the Board in a considerable time frame), but of course without denying the Decision cited above this body.

Therefore, based briefly on the two facts cited above, this Panel considers that the cancellation of the tender by the CA with the Decision dated 12.08.2022, was done in violation of the provisions of the LPP, at least for the principle fact that while the Decisions of PRB do in the jurisdiction of the LPP, the same in the context of Article 1, of this Law are included and mean, quoted: "...conditions and rules that will be applied, procedures that will be followed, rights that will be respected and obligations that will be fulfilled..." On the other hand, based on the documents of this Case, PRB notes that Administrative Instruction No. 2/2014 constitutes a key issue throughout the course of this procurement, related to the fact that when and/or in which circumstances, the same applies. From this point of view, the Panel thinks that the CA has not released the relevant information about this CA to the public opinion to an appropriate degree, in order to avoid possible dilemmas related to this, since it has professional capacity at least starting from the mission of the CA and since the Administrative Instruction in this case dates from 2014, while the procurement activity was initiated with the Contract Notice on 12.12.2020. i.e. 6 years after the adoption of the UA and almost 2 years from now retroactively.

In this case, regardless of the opinion of the parties, the Panel thinks that the interpretation and/or evaluation of the provisions of the by-laws, in relation to the relevant laws of a CA, does not fall under the jurisdiction of PRB. The existence of this

AI constitutes for this Panel a factual issue, the norms of which have a cogent character and it is a well-known fact that as long as it is in force, it is considered part of the relevant legislation, the harmonization and/or validity of the norms of which is not found within the jurisdiction of LPP and PRB.

The content of this UA is characterized by provisions of a specific nature, dedicated precisely to the specific procurement activity, in which case its terms, notions and/or definitions are dedicated precisely for fumigation purposes and as such are placed in the tender file. However, its name, for every subject of interest, offers orders that a priori this AI means the simplification of the supply procedures (not the complication). Therefore, the Panel considers that an ambiguity (ambiguity) has been unnecessarily created, which has objectively influenced the entire procurement process. Looking at the papers of this case, the Panel notes that (within the CA) two opinions dominate, from which two parallel actions for the same activity have been created. Between these two opinions, the Panel trusts the Kosova Agency for Medicinal Products and Devices (AKPPM), a competent entity within the CA, has explained that, quoted (correspondence within the CA dated 02.03.2021 and 02.05.2021):
■ You are allowed to import the product with ATC Code A10AB04 and A10AD04, based on UA 2/2014, since the last level of the ATC code changes with the products that are registered"
■ "If the ATC Code of this product at the last level of its code changes with the medicinal product that has AM, you are allowed to import it in Kosovo, according to UA 2/2014"

However, the panel took into consideration a Legal Opinion, drafted for the needs of CA, which comments on the harmony or not, of the provisions of this CA in relation to the Law on medical devices and products. The panel thinks that, even if it were to start from the assumption that this opinion contains a professional lecture, it still remains an opinion, and it remains at the CA's discretion that the CA in the specific case leave it in force, revoke it or initiate the procedure for assessing the legality of his. The panel considers that, apparently, the cited Opinion has created effects on the CA for the cancellation of the tender, despite the fact that it is emphasized that "this opinion represents personal conviction according to research and legal analysis and does not necessarily present the position of the MH or DL". The panel considers that, in institutional practice, such opinions have the character of confession or advice, but do not create effects on institutional actions. However, the actions of each institution are actions of an administrative nature and end with an administrative act, which is based on the norms of a legislative nature (not on opinions). Despite the fact that such opinions may originate from different (international) organizations, the sovereignty of a country (in the name of which each department exercises part of the state powers) is exercised on the basis of laws. Therefore, the Panel considers that:

■ The opinion in this case does not prevail over the mandatory norms of UD No. 2/2014;

The use of the Opinion to create, modify or change technical specifications in a Tender dossier, from the opposite aspect of what is provided for by an AI, turns the procurement activity into an illegal administrative action (with the character of absolute nullity);

Therefore, in the opinion of this Panel, avoiding the application of this UA means avoiding from the UA, and this results in the fact that the TD is created with pre-determined technical specifications. Due to the nature of this issue, this CA approach

preemptively eliminates other EOs, without the need for bid's evaluation. If this procurement approach were to be accepted for the Panel, then the PRB's approach would qualify as an action in contrary to Article 7 of the LPP, according to which: "The contracting authority shall not execute any aspect of the procurement activity in a manner that reduces or eliminates competition between economic operators or that discriminates to the detriment or benefit of one or more economic operators" without citing a series of other provisions which, in the integral context of the LPP, sanction competition and the principles of the liberal market.

From the facts and circumstances described above, from the statements of the parties and from the documents of this case, according to this Panel, they objectively present: The same procurement activity, for the same CA, for the same purpose and the same product; with one tender file, but with two conflicting solutions and two parallel procurement systems:

First: On the 22.02.2021, the CA published the Decision according to which:
- "Pharma Leader" LLC is the recommended EO for the contract for Lot I with the bid value of 1,097,467.36 E and Lot III, with the bid value of 4,109,006.12 E. Whereas,
- "Meditech" EO recommended for contract for Lot II, with the value of the offer 913,315.00 E

Second: On the 05.03.2021, for the same procurement activity, with the same criteria in the Tender dossier, the CA has recommended for contract (including the other two lots):
- EO "Meditech Sh.P.K"
While EO "Pharma Leader" LLC has been eliminated, for the following reasons:

- Registration of the drug is required - authorization for branding by KKPPM, with the required product specification. In the event that there are no parallels registered in Kosovo, UA 2/2014 applies for the simplification of procedures for the registration and import of medicinal products that do not have parallels registered in the Republic of Kosova.

From the documents of this case, it is established that, continuously, a series of actions have been taken by the parties (OE "Pharma Leader" LLC) and the CA, until the date 27.04.2021, when the CA communicated the results of this procurement. In this aspect, the Panel considers that the CA did not consider the Decision of the PRB dated 25.03.2021, according to which the PRB requested that the CA re-evaluate the procurement activity for the reasons cited. This approach of the CA, in the opinion of this Panel, contradicts:

- With Article 105 (Competencies of PRB) related to Article 131 of the LPP.
- With Article 51 of the LPP, according to which, the CA must emphasize in the contract notice and define all the selection criteria in the tender file. And again from the point of view of this Panel, it means that while the same formal criteria have been published, CA has practically applied other selection criteria (in relation to DT) making the procurement process incompatible with the published formal conditions of this procurement activity. The panel considers that the announcement of the tender and the cancellation of the same, for the reasons highlighted in the now attacked Decision of the CA, contradicts the institutional goals as provided by Article 9 of the LPP.

The Review Panel considers that the CA has acted contrary to the provision of Article 62, specifically violating paragraphs 2.1 and 2.2, and from this aspect, the findings of the procurement review expert and his recommendations, the Panel took as a basis and considers that there is no violation of Article 7 of the LPP (as explained above) and there is no basis for the tendering process to benefit according to Article 62. paragraph 1, subsection 1.1. of the LPP, because in article 62 of the LPP it is stated, among other things, that CAs can end that procurement activity which will not result in the award of the contract for one of the reasons:

- All tenders contain prices that exceed the budget of the contracting authority - which did not happen;
- Due to objective events and reasons that are beyond the control of CA and cannot be predicted at the time of initiation of the procurement - which did not happen either;
- The CA cannot take price changes in the market as a pretext for canceling the procurement activity, as long as the EO has expressed interest in a procurement activity and stands behind the offers whose prices are within the planned budget;
- The decision of PRBO dated 12.07.2022, No. 397/21, does not prejudice the outcome of the tender and does not override the provision of Article 62 of the LPP and at the same time does not constitute a basis for canceling the procurement activity because the conditions of provided for in points 2.1 and 2.2, of paragraph 2, of article 62 of the LPP.

- Not taking as a basis the criteria defined for qualification and the criteria defined for evaluation during the re-evaluation, means that the CA has violated the basic principles of LPP such as economy and efficiency, competition, transparency and equal treatment since the non-implementation of these principles means favoritism-discrimination of one party in relation to the other party acting contrary to paragraph 1, article 6, of the LPP;

Regarding the Complaint of EO Meditech Sh.P.K. The panel took into consideration the findings of the review expert according to which the request for reconsideration of the EO in the present case was exercised outside the legal deadline and the same was reviewed by the CA in violation of point 3.3, paragraph 3, of article 108/A of the LPP, related to point c. of Article 4, of the "Rules for submission of requests for reconsideration to the Contracting Authorities, submission of complaints to the PRB and the value of the fees for complaints". Therefore, regarding the complaint of EO Meditech Sh.P.K. This panel decided as in point 2, of the operative part of this Decision. The Review Panel carefully analyzes all the legal provisions of the legislation in force regarding the calculation of deadlines in order to avoid all potential dilemmas in relation to the complaining statements of the applicant in this particular case. However, this Panel considers that the PRB must strictly implement the law in force on public procurement (consolidated version), from which the mandate of this body originates. From this point of view, the Panel considers that regardless of different opinions, no matter how contradictory or well-founded, this Panel is bound by the provision of Article 108/A of the LPP, which in paragraph 3 point 3.3 applies to the issue in the present case, because it is referred to in express way the CA's decision for annulment. In its citation, this paragraph says quoted "Whenever the request for reconsideration is related to the decision to cancel the procurement process within five (5) days from the day when the procurement activity was officially canceled through the cancellation notice". This means that the time limit in relation to the Meditech request begins effectively from the day the decision is officially annulled. Without specifying and/or explaining any other action of the body or the parties, therefore, according to this provision, the deadline runs from the

day it was officially decided. The panel expresses its opinion that this provision obliges without any alternative. In this sense, the Panel considers that the request of the applicant Meditech should be treated as having been submitted after the expiration of the deadline as specified in point c, of paragraph 4.1 of the regulation cited above, which is compatible with paragraph 3.3 of article 108/A of the LPP . Since in this particular case the decision of the CA was published on the same day, this means that the CA has fulfilled the obligation in terms of paragraph 4.2 of article 4 of the regulation. in the calculation of the deadline in this case, the day of the notification is counted as a day within the predetermined deadline, not as the "zero" day.

The panel also decided:
- That a monetary fine be imposed on the Contracting Authority in the amount of 5,000.00 €, due to non-compliance with the Decision of the PRB dated 25.03.2021, in accordance with Article 131, of the Law on Public Procurement in the Republic of Kosova;
- To initiate the procedure for revoking the procurement certificate against the responsible procurement officer of the CA, due to violations of the provisions of Article 25, paragraph 8, of the LPP;
To allow the return of the insurance fee for the complaint for EO "Pharma Lider" ShPK, and for EO "Meditech" ShPK according to article 31, paragraph 6 of the Rules of Procedure of PRB, No. 1/20, dated 03.03.2020;

- *Conclusion* –

PRB always starts from the fact that every CA (at every level) enjoys complete independence in the exercise of powers and the determination of needs in harmony with budget capacity. However, the Review Panel considers that undertaking actions to initiate the procurement and then canceling the same and applying double criteria, contradicts the notions, principles and basic institutes of the LPP. Therefore, starting from the above and carefully managing all the evidence attached to the documents of this case, the Review Panel has decided as in the provision of this decision, convinced that it has applied the appropriate solution in accordance with the legislation in force and the nature of the case in the case concretely.

Based on the powers of the PRB provided by Article 105, in relation to Article 106 of the LPP, the Review Panel implemented, among others, Article 103 of the cited Law according to which all interested parties will have equal access to the review procedures of procurement and legal remedies and that no decision of the PRBO will be taken or made in a way that discriminates in favor or to the detriment of a participant in the procedure or of another person or enterprise.

Based on the above, the Review Panel decided as per the provisions of this decision, in accordance with Article 117 of the LPP.

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 Commercial Court
at the Department for Administrative Affairs.

President of the Review Panel

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Mrs. Kimete Gashi

Decision to be submitted to:
1x1 CA – MH;
1x1 EO – "Pharma Leader";
1x1 EO- "Meditech Sh.P.K";
1x1 Archive of the PRB;
1x1 For publication on the website of the PRB.