CENTRALIZED PURCHASING OPERATOR

Date: ___.___.2026

MINUTES - CONTRACT TYPE - GOODS

ON THE ARGUMENTATION AND APPROVAL OF TECHNICAL SPECIFICATIONS AND QUALIFICATION CRITERIA

Object of the procedure : **"B1 - Purchase of drugs for Anesthesia and Resuscitation systems, Anti-tubercular, Antineoplastic and immunomodulatory drugs, Antiparasitic drugs , Dermatological drugs , Hormonal drugs systemic hormones sexual , Subject contrast for CT, Subject contrast for MRI, Subject contrast Gastrointestinal , Metabolism AND tract solvent , Psychiatry , System cardiovascular ", divided in 117 lots - Agreement Frame with several operators economic (an EO of only THE successful ABOUT each tear)- where THE all CONDiTiONs ARE THE determined - with a term of 24 months".**

Relevant code in the Common Procurement Vocabulary (CPV):

- Products mEDICAL ABOUT disorders gastrointestinal functional -33610000-9
- Products mEDICAL ABOUT disorders gastrointestinal functional -33612000-3
- Products mEDICAL ABOUT SySTEm cardiovascular -33622000-6
- Medicinal products for dermatology-33631000-2
- Agents antineoplastics -33652100-6
- Products mEDICAL ABOUT SySTEm nervous -33661000-1
- Products mEDICAL ABOUT BODIES sensory -33662000-8
- Products mEDICAL ABOUT respiratory system -33670000-7
- Products contrast radiological -33696800-3

Limit fund value : **4,518,179,925 (four) one billion five hundred and eighteen one million one hundred and seventy - nine one thousand nine hundred and twenty five) Lekë excluding VAT , or 47,340,527** (forty-seven million three hundred forty thousand five hundred twenty-seven) euros excluding VAT , with an exchange rate of 95.44 converted according to the official exchange rate of the Bank of Albania dated 26.05.2026.

divided into lots:

No.	system	Tear/ Active Principle	Dosage form	Unit	Total quantity required for 24 months after completion at MK 24	Estimated limit value 24 months IN Lek excluding VAT	Estimated limit value 24 months in Euros
1	system cardiovascular	Lot 1 Torasemide	10 mg/2 ml - 2 ml	Ampoule	32,347	1,050,988	11,012
2	system cardiovascular	Lot 2 Nifedipine	10 mg	tablet	33,663	1,093,856	11,461
3	Dermatological drugs	Lot 3 Betamethasone	0.1% - 15 grams	tube	33,738	1,096,286	11,487
4	Psychiatry	Lot 4 Lorazepam	2.5 mg	tablet	34,704	1,127,772	11,817
5	system cardiovascular	Lot 5 Lercanidipine	10 mg	tablet	37,879	1,231,234	12,901
6	Antineoplastic drugs AND immunomodulator	Lot 6 Mitoxantrone	2 mg/ml -10 ml	bottle	39,475	1,283,237	13,445
7	system cardiovascular	Lot 7 Olmesartan	20 mg	tablet	41,720	1,356,412	14,212
8	system cardiovascular	Lot 8 Nicardipine fl /amp	10 mg-10ml	Fl/Amp	42,311	1,375,666	14,414
9	Psychiatry	Lot 9 Clozapine	100 mg	tablet	45,483	1,479,039	15,497
10	Antineoplastic drugs AND immunomodulator	Lot 10 Dacarbasine	100 mg	bottle	46,223	1,503,156	15,750
11	Contrast material gastrointestinal	Lot 11 Amidotrizoic acid, Meglumine salt + Sodium amidotrizoate	(66 g +10 g)/100 ml	bottle	49,454	1,608,435	16,853
12	Antineoplastic drugs AND immunomodulator	Lot 12 Methotrexate	solution for injection pre - prepared syringe x 10mg/0.4ml	pre - prepared syringe x 10mg/0.4ml	50,003	1,626,339	17,040
13	Antineoplastic drugs AND immunomodulator	Lot 13 Topotecan hydrochloride	4 mg/4 ml	bottle	51,061	1,660,814	17,402
14	Antineoplastic drugs AND immunomodulator	Lot 14 Vinblastine	1mg/ml- 10 ml	Vials / Ampoules	52,633	1,712,011	17,938
15	system cardiovascular	Lot 15 Spironolactone	25 mg	tablet	53,822	1,750,781	18,344
16	Antineoplastic drugs AND immunomodulator	Lot 16 Etoposide	20 mg/ml - 5 ml	bottle	54,810	1,782,959	18,681
17	system cardiovascular	Lot 17 Enalapril	20 mg	tablet	56,079	1,824,331	19,115
18	Psychiatry	Lot 18 Risperidone	2 mg	tablet	56,703	1,844,652	19,328
19	Metabolism AND tract solvent	Lot 19 Atorvastatin	20 mg	tablet	59,105	1,922,913	20,148
20	antituberculosis	Lot 20 PPD Tuberculin	5TU/0.1ml - 2 ml	bottle	61,321	1,995,138	20,905

21	Antineoplastic drugs AND immunomodulator	Lot 21 Methotrexate	solution for injection and infusion x500 mg (10 ml or 20 ml)	Vials / Ampoules	63,140	2,054,413	21,526
22	Psychiatry	Lot 22 Haloperidol	5 mg/1 ml - 1 ml	ampoule	64,355	2,094,005	21,941
23	system cardiovascular	Lot 23 Lanatoside C	0.4 mg/2 ml - 2 ml	ampoule	75,415	2,454,430	25,717
24	Hormonal drugs systemic , hormones sexual	Lot 24 Octreotide	0.05 mg/ml - 1 ml	ampoule	79,572	2,589,881	27,136
25	Dermatological drugs	Lot 25 Silver Sulfadiazine	10 mg/g - 50 g	tube	86,187	2,805,436	29,395
26	Antineoplastic drugs AND immunomodulator	Lot 26 Cytarabine	20 mg/ml - 5 ml	bottle	88,745	2,888,785	30,268
27	Antineoplastic drugs AND immunomodulator	Lot 27 Vincristine	1 mg/ml - 1 ml	Vials / Ampoules	90,851	2,957,428	30,987
28	Dermatological drugs	Lot 28 Fusidic acid + Hydrocortisone	(2% + 1%) - 30 g	tube	97,675	3,179,812	33,317
29	anesthesia reanimation	Lot 29 Dexmedetomidine	100 mcg/1ml-2ml	ampoule	109,155	3,553,900	37,237
30	Hormonal drugs systemic , hormones sexual	Lot 30 Somatostatin	3 mg/ml -1 ml	Vial + Ampoule (diluent)	110,343	3,592,594	37,642
31	system cardiovascular	Lot 31 Porcine Brain derived peptide	215.2 mg/ml - 10 ml	ampoule	112,437	3,660,858	38,358
32	Dermatological drugs	Lot 32 Neomycin sulphate + Bacitracin	(5mg + 500 IU)/1 gr - 30 gr	tube	120,231	3,914,812	41,019
33	Antineoplastic drugs AND immunomodulator	Lot 33 Fluorouracil	50 mg/ml - 20 ml	bottle	127,532	4,152,724	43,511
34	Antiparasitic drugs	Lot 34 Acyclovir	250 mg	bottle	133,926	4,361,112	45,695
35	Metabolism AND tract solvent	Lot 35 Insulin Glargine	100 IU/ml - 3 ml	First syringe prepared	231,684	7,546,720	79,073
36	system cardiovascular	Lot 36 Amiodarone	150 mg/3 ml - 3 ml	ampoule	143,152	4,661,736	48,845
37	system cardiovascular	Lot 37 Dopamine	10 mg/ml - 5 ml	ampoule	143,259	4,665,221	48,881
38	Hormonal drugs systemic , hormones sexual	Lot 38 Misoprostol	200 mcg	tablet vaginal	143,814	4,683,325	49,071
39	anesthesia reanimation	Lot 39 Thiopental sodium	1 gram	bottle	150,177	4,890,677	51,243
40	Antineoplastic drugs AND immunomodulator	Lot 40 Ifosfamide	40 mg/ml - 25 ml	bottle	154,486	5,031,067	52,714
41	Hormonal drugs systemic , hormones sexual	Lot 41 Methylprednisolone	40 mg	Vial / Vial + ampoule (diluent)	154,808	5,041,581	52,825
42	Psychiatry	Lot 42 Olanzapine	10 mg	tablet	157,096	5,116,144	53,606

43	anesthesia reanimation	Lot 43 Remifentanyl	1 mg/ml-4 ml	Fl/Amp	159,075	5,180,639	54,282
44	Antineoplastic drugs AND immunomodulator	Lot 44 Tocilizumab	200mg/10ml	bottle	166,222	5,413,511	56,722
45	Metabolism AND tract solvent	Lot 45 Insulin Glulisine	100 IU/ml - 3 ml	First syringe prepared	169,344	5,515,267	57,788
46	system cardiovascular	Lot 46 Protamine sulphate	50 mg/5 ml	Vials / Ampoules	197,856	6,444,363	67,523
47	Metabolism AND tract solvent	Lot 47 Papaverine hydrochloride	40 mg/1 ml - 1 ml	ampoule	206,199	6,716,250	70,371
48	anesthesia reanimation	Lot 48 Isoflurane	Inhalation vapor , Liquid x 100 ml	bottle	206,686	6,732,107	70,538
49	Metabolism AND tract solvent	Lot 49 Atropine sulphate	1 mg/1 ml - 1 ml	ampoule	209,064	6,809,612	71,350
50	Metabolism AND tract solvent	Lot 50 Insulin Aspart	100 IU/ml - 3 ml	First syringe prepared	215,442	7,017,425	73,527
51	Antineoplastic drugs AND immunomodulator	Lot 51 Epirubicin hydrochloride	2 mg/ml - 25 ml	bottle	227,434	7,408,227	77,622
52	Antineoplastic drugs AND immunomodulator	Lot 52 2-Cladribine	10 mg	Fl/Amp	232,331	7,567,809	79,294
53	system cardiovascular	Lot 53 Glyceryl trinitrate	5 mg/1.5 ml - 1.5 ml	ampoule	260,310	8,479,545	88,847
54	Antineoplastic drugs AND immunomodulator	Lot 54 Originator Trastuzumab	150 mg	bottle	273,612	8,912,998	93,388
55	Antineoplastic drugs AND immunomodulator	Lot 55 Methotrexate	solution for injection x 50mg/ml-0.15 ml	Pre - prepared syringe x 0.15 ml	286,793	9,342,543	97,889
56	system cardiovascular	Lot 56 Dobutamine	250 mg/20 ml - 20 ml	bottle	291,196	9,486,020	99,392
57	Contrast medium for MRI	Lot 57 Gadoteric acid	0.5mmol/ml-10ml	Vials /Ampoules	292,235	9,519,865	99,747
58	Antineoplastic drugs AND immunomodulator	Lot 58 Cyclophosphamide anhydrous	500 mg	bottle	293,520	9,561,748	100,186
59	Antineoplastic drugs AND immunomodulator	Lot 59 Cisplatin	0.5mg/ml - 100 ml	bottle	313,590	10,215,772	107,039
60	Antineoplastic drugs AND immunomodulator	Lot 60 Bleomycin sulphate	Lyophilized powder x 15 mg	bottle	323,685	10,544,714	110,485
61	system cardiovascular	Lot 61 Glyceryl trinitrate	50 mg/50 ml - 50 ml	bottle	330,746	10,774,822	112,896
62	Psychiatry	Lot 62 Haloperidol	2 mg/ml - 10 ml	bottle	348,952	11,368,080	119,112
63	Hormonal drugs systemic , hormones sexual	Lot 63 Methylprednisolone	500 mg	Vial + ampoule (diluent)	351,400	11,447,853	119,948
64	Antineoplastic drugs AND immunomodulator	Lot 64 Rituximab Biosimilar or originator	10 mg/ml-10 ml	bottle	361,945	11,791,490	123,549

65	system cardiovascular	Lot 65 Noradrenaline Tartrate	4mg/4ml	ampoule	365,979	11,922,932	124,926
66	Hormonal drugs systemic , hormones sexual	Lot 66 Progesterone	25 mg/ml - 1ml	ampoule	385,154	12,547,804	131,473
67	system cardiovascular	Lot 67 Adrenaline	1mg/ml - 1ml	ampoule	408,049	13,293,869	139,290
68	Metabolism AND tract solvent	Lot 68 Hyoscine butylbromide	20 mg/1 ml - 1 ml	ampoule	413,617	13,475,311	141,191
69	anesthesia reanimation	Lot 69 Fentanyl	50 mcg/ml - 10ml	ampoule	418,342	13,629,291	142,805
70	Antineoplastic drugs AND immunomodulator	Lot 70 Gemcitabine	200 mg	bottle	419,031	13,651,730	143,040
71	Contrast medium for CT	Lot 71 Iodine x 300mg/ml	100 ml	bottle	427,595	13,930,818	145,964
72	Antineoplastic drugs AND immunomodulator	Lot 72 Cetuximab vials	5mg/ml	Fl/Amp	440,007	14,335,273	150,202
73	Metabolism AND tract solvent	Lot 73 Netupitant+Palonesetron	300mg+0.5mg	tablet	458,028	14,922,522	156,355
74	Metabolism AND tract solvent	Lot 74 Omeprazole	20 mg	capsule	515,561	16,797,321	175,999
75	Contrast medium for MRI	Lot 75 Gadoteric acid (As meglumine salt)	solution for injection 0.5 mmol/ml x 20 ml	vial /ampoule	632,715	20,615,007	216,000
76	Metabolism AND tract solvent	Lot 76 Granisetron amp	1 mg/ml	Fl/Amp	652,089	21,246,323	222,614
77	Metabolism AND tract solvent	Lot 77 Granisetron amp 3mg-3ml	3mg-3ml	Fl/Amp	682,481	22,236,695	232,991
78	Metabolism AND tract solvent	Lot 78 Metoclopramide hydrochloride	10 mg/2 ml - 2 ml	ampoule	699,081	22,777,655	238,659
79	Metabolism AND tract solvent	Lot 79 Calcium gluconate	1 g/10 ml - 10 ml	Vials / Ampoules	779,715	25,405,257	266,191
80	Metabolism AND tract solvent	Lot 80 Ondansetron	8 mg/4 ml - 4 ml	Vials / Ampoules	1,028,925	33,526,183	351,280
81	Antineoplastic drugs AND immunomodulator	Lot 81 Oxaliplatin	5 mg/ml - 20 ml	bottle	1,130,637	36,840,641	386,008
82	Metabolism AND tract solvent	Lot 82 Thiamine hydrochloride (Vitamin B1)	50 mg /1 ml - 1 ml	ampoule	1,252,445	40,809,960	427,598
83	Hormonal drugs systemic , hormones sexual	Lot 83 Oxytocin	10 IU/ml	ampoule	1,256,323	40,936,337	428,922
84	Antineoplastic drugs AND immunomodulator	Lot 84 Irinotecan	20 mg/ml - 5 ml	bottle	1,261,679	41,110,871	430,751
85	Hormonal drugs systemic , hormones sexual	Lot 85 Dexamethasone	4 mg/ml	ampoule	1,276,325	41,588,129	435,752

86	Metabolism AND tract solvent	Lot 86 Pyridoxine hydrochloride (Vitamin B6)	100 mg/2 ml - 2 ml	ampoule	1,316,973	42,912,720	449,630
87	Dermatological drugs	Lot 87 Povidone Iodine	10% - 1000 ml	bottle	1,405,222	45,788,458	479,762
88	Metabolism AND tract solvent	Lot 88 Magnesium sulphate	2.5 g/10 ml - 10 ml	Vials / Ampoules	1,416,002	46,139,771	483,443
89	Antineoplastic drugs AND immunomodulator	Lot 89 Bortezomib	3.5 mg	bottle	1,572,554	51,241,282	536,895
90	Antineoplastic drugs AND immunomodulator	Lot 90 Carboplatin	150 mg/15 ml - 15 ml	bottle	1,592,698	51,897,709	543,773
91	Antineoplastic drugs AND immunomodulator	Lot 91 Filgastrim	300 µg/0.5 ml	First syringe prepared	1,764,807	57,506,154	602,537
92	Antineoplastic drugs AND immunomodulator	Lot 92 Erlotinib	150 mg	tablet	1,773,970	57,804,766	605,666
93	Antineoplastic drugs AND immunomodulator	Lot 93 Docetaxel	20 mg/ml - 4 ml	bottle	2,034,289	66,287,691	694,548
94	Contrast medium for CT	Lot 94 Iodine x 350mg/ml	100 ml	bottle	2,042,430	66,552,999	697,328
95	Antineoplastic drugs AND immunomodulator	Lot 95 Gemcitabine	1 gram	bottle	2,159,661	70,373,178	737,355
96	Contrast medium for CT	Lot 96 Iodine x 350mg/ml 200 ml	200 ml	bottle	2,229,961	72,664,008	761,358
97	system cardiovascular	Lot 97 Furosemide	20 mg/2 ml - 2 ml	ampoule	2,244,086	73,124,302	766,181
98	Metabolism AND tract solvent	Lot 98 Ascorbic acid (Vitamin C)	100 mg/2 ml - 2 ml	ampoule	2,259,126	73,614,420	771,316
99	anesthesia reanimation	Lot 99 Desflurane	100%V/V Inhalation Vapor Liquid X 100% V/V	bottle	2,514,875	81,948,417	858,638
100	Antineoplastic drugs AND immunomodulator	Lot 100 L-Asparaginase	10000 IU	Fl/Amp	2,650,615	86,371,738	904,985
101	Antineoplastic drugs AND immunomodulator	Lot 101 Ocrelizumab	300 mg/10 ml	Fl/Amp	2,824,173	92,027,442	964,244
102	Antineoplastic drugs AND immunomodulator	Lot 102 Goserelin acetate	10.8 mg	First syringe prepared	2,997,184	97,665,290	1,023,316
103	Antineoplastic drugs AND immunomodulator	Lot 103 Crisantaspase	10,000 IU	bottle	3,104,989	101,178,322	1,060,125
104	Antineoplastic drugs AND immunomodulator	Lot 104 Folinic acid	10 mg//ml - 5ml	Vials /Ampoules	3,203,753	104,396,698	1,093,846
105	Contrast medium for CT	Lot 105 Iodine x 370mg/ml	200 ml	bottle	3,257,381	106,144,264	1,112,157

106	anesthesia reanimation	Lot 106 Sevoflurane	100% - 250 ml	bottle	3,828,944	124,769,623	1,307,310
107	Contrast medium for CT	Lot 107 Iodine x 370mg/ml 100 ml	100 ml	bottle	3,878,862	126,396,297	1,324,353
108	Antineoplastic drugs AND immunomodulator	Lot 108 Paclitaxel	100 mg/16.7 ml	bottle	4,216,108	137,386,054	1,439,502
109	Antineoplastic drugs AND immunomodulator	Lot 109 Rituximab Biosimilar or originator	10 mg/ml-50 ml	bottle	5,424,283	176,756,517	1,852,017
110	Hormonal drugs systemic , hormones sexual	Lot 110 Prednisolone	25 mg/2 ml - 2 ml	Ampoule	7,004,217	228,241,367	2,391,464
111	Antineoplastic drugs AND immunomodulator	Lot 111 Avelumab	200mg/10ml	bottle	8,037,889	261,925,381	2,744,398
112	Metabolism AND tract solvent	Lot 112 Omeprazole	40 mg	Vial / Vial + ampoule (diluent)	8,363,963	272,551,056	2,855,732
113	Antineoplastic drugs AND immunomodulator	Lot 113 Doxorubicin	2 mg/ml - 25 ml	bottle	276,817	9,017,454	94,483
114	Antineoplastic drugs AND immunomodulator	Lot 114 Bevacizumab	25 mg/ml - 16 ml	bottle	13,416,660	437,201,913	4,580,909
115	Antineoplastic drugs AND immunomodulator	Lot 115 Trastuzumab Biosimilar or originator	150 mg	bottle	14,647,027	477,295,532	5,001,001
116	Antineoplastic drugs AND immunomodulator	Lot 116 Axitinib 1 mg	1 mg	tablet	112,391	3,659,337	38,342
117	Antineoplastic drugs AND immunomodulator	Lot 117 Axitinib 5mg	5mg	tablet	898,206	29,266,496	306,648

Based on Article 21, point 2, of Law No. 162/2020 "On Public Procurement", as amended, Article 2, point 2/c and Article 78, point 2, of the Council of Ministers No. 285, dated 19.05.2021 "On the approval of the public procurement rules", as amended, the contracting authority/entity, **the Centralized Purchasing Operator** sh.a, has drafted the minutes for the argumentation and approval of the technical specifications and qualification criteria for the above-mentioned procedure, with the following content:

2. SPECIAL QUALIFICATION CRITERIA

1. **The bidder must submit:**

a. *Summary Self-Declaration Form* ***, according to Annex 9;***
b. Bid Security, according to ***Annex 4;***

2. The tenderer must submit:

2.1 Professional capacity of economic operators:

The Bidder must declare that it meets the general eligibility/qualification criteria. These criteria must be met by submitting a written self-declaration of the entity, on the day of bid opening, according to Annex 9 .

2.2 Economic and financial capacity:

1. For him/her proven that operators ECONOMIC HAVE the necessary capacity -ECONOmiC AND FINANCIAL ABOUT THE implemented the contract , you must THE present CONFIRMATION ABOUT lap annual ABOUT years financial (2023, 2024, 2025), where turnover value ABOUT THE AT LEAST A BY years of the period OF THE looking MUST THE BE **not less than 20% of the limit fund/expected value of the lot contracts or the amount of lots for which you bid .** Request ABOUT capacity building FINANCIAL considered fulfilled whether operators ECONOMIC reach turnover value minimum , in THE AT LEAST a year of pERIOD OF THE looking BY authority / entity contractor .

Argument: The above requirement is in Article 77 "Qualification requirements", point 3 of Law No. 162, dated 23.12.2020 "On public procurement", as amended, in which we find it determined that: 3. With regard to the economic and financial situation, contracting authorities or entities may impose requirements that guarantee that economic operators have the necessary economic and financial capacity to perform the contract. For this purpose, contracting authorities or entities may require in particular that economic operators have a certain minimum annual turnover. Also, contracting authorities or entities may require that economic operators provide information in their annual balance sheets showing the ratios between assets and liabilities. The minimum annual turnover required from economic operators cannot exceed twice the estimated value of the contract", Article 43 "Requirements for economic and financial capacities" point 2/a and Article 47 "Open procedure" of the Council of Ministers No. 285, dated 19.05.2021 "On the approval of the rules for public procurement" as amended. The determination of the years required for the submission of the annual turnover certificate is based on point 2 of Article 61 of Law No. 29/2023 "On income tax", as amended, which states that: "The annual tax return is submitted to the tax authority no later than March 31 of the year following the tax year for which the return is submitted". The establishment of this criterion is done with the aim of creating confidence in the Contracting Authority, of the economic and financial capacity of the bidding economic operators, by proving through documents required, that they possess the economic and financial capacity to fulfill the contract as foreseen by the Contracting Authority.

The determination of the required value is argued as follows: The required value of **no less than 20% of the limit fund/expected value of the contracts of the lot or the amount of lots for which the tender is being made** is in accordance with the provisions of Article 43 "Requirements for economic and financial capacities" point 2/a of the Council of Ministers No. 285, dated 19.05.2021 "On the approval of public procurement rules", as amended, which stipulates that:
Point 2. "The minimum annual turnover required of economic operators may not exceed: *a) twice the estimated value of the contract or lot, in procurement procedures above the upper monetary limit* ". In the specific case, the Procurement Unit considered it reasonable that the turnover value for at least one of the years of the required period should be in accordance with the above requirement in order to encourage the participation of economic operators in public

procurement procedures, promote competition between economic operators, and ensure equal and non-discriminatory treatment for all potential economic bidders. Taking into account the definition made in Article 43 "Requirements for economic and financial capacities" point 2/a, the CA cannot exceed twice the estimated value of the lot value in the request for qualification, but in compliance with legal principles and in fulfilling the purposes of the procurement law as cited above, it has the right to request a value lower than twice the estimated value of the contract to meet the minimum annual turnover. This value is requested taking into account the object of the contract, its nature and volume, to serve the contracting authority to recognize the situation and capacities of the economic operator, who must prove that they possess the necessary economic and financial capacities, all in function of the successful implementation of the contract.

2.3 Technical capacity:

1. operator must submit evidence of previous similar supplies carried out during the last 3 (three) years **from the date of publication of the contract notice** , in a value **not less than 20% of the value of the limit fund of the lot or the sum of the limit fund of the lots for which it is bidding .** These previous, similar supplies must be proven with the following documentation :

a. When similar supplies have been made with public entities, the economic operator must submit certificates issued by a public entity for the successful fulfillment of the contract, indicating the value, the deadline for the completion of the contract or tax sales invoices, completed according to the requirements of the legislation in force and declared to the tax authorities, indicating the dates, amounts and quantities of goods supplied .

b. When similar supplies are made to private entities, the economic operator must submit sales tax invoices, completed according to the requirements of the legislation in force and declared to the tax authorities, indicating the dates, amounts and quantities of goods supplied .

Argument : The above requirement is based on Article 77, point 4 of Law No. 162, dated 23.12.2020 "On Public Procurement", as amended, and Article 40, point 4, of the Council of Ministers No. 285, dated 19.05.2021 "On the Approval of Public Procurement Rules", as amended. This criterion requires economic operators to prove that they have the experience necessary to implement the contract, therefore it is required that previous similar supplies be worth no less than 20% of the value of the limit fund of the lot or the sum of the limit fund of the lots for which it is bidding, which is within the threshold value set out in the aforementioned article. The required percentage is considered necessary to prove the reliability and experience of the bidding economic operators, in providing goods similar to the procurement object, for the successful implementation of the contract. Similar experience is considered an essential criterion and therefore economic operators must submit evidence such as references/tax invoices, etc., to prove their performance with both the private and public sectors.

2. Economic operator MUST THE present license THE valid for wholesale THE Barn THE released from the NLC or the NLC .

Argument *:* The above request is determined based on Article 77 of Law No. 162, dated 23.12.2020 "On Public Procurement", as amended, Article 40, point 5, letter a) of Council of Ministers No. 285, dated 19.05.2021 "On the Approval of Public Procurement Rules", as amended, as well as Law No. 105/2014 "On Medicines and Pharmaceutical Services", as amended, Article 28 "Wholesale of Medicines", which provides that the trade of medicines is carried out by licensed entities:

" 1. Wholesale trade of medicines is carried out by the importer, exporter, pharmaceutical distributor, who is a legal or natural person, trader, domestic or foreign, ***equipped with the relevant license for this activity, according to the relevant legislation on licensing.*** *2. The pharmaceutical wholesaler may also wholesale medical devices, according to the definitions made in the relevant legislation on medical devices" and*

Law no. 10081 dated 23.02.2009 (amended) "On licenses, authorizations and permits in the Republic of Albania".

(note - specify the specific legal or sub-legal act and the relevant article, which provides for the licensing of entities, in relation to the relevant supply activity, or in the case of the production of goods subject to procurement, which is related to the subject of the procured contract).

This criterion requires economic operators to prove that they have professional licenses for the production and/or supply of goods, the subject of the contract, issued by the competent state authorities .

3. The economic operator must self-declare the origin of the goods and the manufacturing company/MAH, this should be completed in *Annex 2. Price List of* DST items.

Argument : This criterion is established with the aim of recognizing the origin of the goods and the manufacturing company/trade authorization holder to clearly identify it during its delivery and to ensure that the same offered goods will be delivered to the destination in accordance with Article 40, points 6 and 8, of the Council of Ministers No. 285, dated 19.05.2021 "On the approval of the Public Procurement Rules", as amended.

4. For medicines (on the DST list) authorized for marketing in the Republic of Albania, the following must be submitted :

-document confirming that the offered drug is authorized for marketing in the Republic of Albania, issued by the National Agency for Medicines and Medical Devices,

/or/

-marketing authorization for the drug, issued by the National Agency for Medicines and Medical Devices, within its validity period.

Argument : This criterion is established in accordance with Article 11 of Law No. 105/2014 "On medicines and pharmaceutical services", as amended, where point 1 of this article states:

" *1. Medicinal products placed on the market in the Republic of Albania for human use must be equipped with a marketing authorization from the Agency* ."

5. For drugs (on the DST list) not authorized for sale in the Republic of Albania, the drug being offered must:

a. to have received authorization for marketing and circulation in one of the countries of the European Union, the United States of America, Canada, Turkey, Switzerland, Israel, Japan, Australia, Norway , Iceland and the United Kingdom;

/or/

b. be produced in the Balkan countries, only if it has received authorization for marketing and circulates in its country,

/or/

c. be equipped with a marketing authorization from the European Medicines Agency (EMA), or the Food and Drug Administration (FDA) of the United States of America.

For this, the bidder is required to submit:

- A statement confirming that the drug being offered is licensed for sale and is marketed in one of the above countries (European Union, United States of America, Canada, Turkey, Switzerland, Israel, Japan, Australia, Norway, Iceland and United Kingdom) , or that it has a marketing authorization from the FDA or EMA.

The declaration signed and stamped by the bidder must state: The full name and address of the authorized institution(s) that issued the marketing authorization; Contact details for these institutions (Tel, fax, e-mail, website); Number and date of issue of the marketing authorization (by the authorized institution(s)) of the drug being offered and the validity period of this authorization.

Justification: This criterion is established pursuant to Article 11, point 2, of Law No. 105/2014 "On medicines and pharmaceutical services", as amended, which provides:
"2. In cases of health service needs (for outpatient and/or hospital treatment), for medicines that have no similar alternative, which has a marketing authorization from the Agency, the minister responsible for health authorizes the import of medicines for which a marketing authorization has not been issued by the Agency, according to the rules determined by decision of the Council of Ministers".

Also, in order to guarantee the fulfillment of standards on the safety, quality and efficacy of medicines, even in the case of unauthorized medicines, the same requirements on their origin have been applied, as for medicines authorized for marketing. This, based on Article 12, point 2, of Law No. 105/2014 "On medicines and pharmaceutical services", as amended, which provides:

"2. The Agency shall propose to the Minister responsible for health the granting of marketing authorization for:
a) medicines produced in our country;
b) medicines that have received marketing authorization and are circulating in one of the countries of the European Union, the United States of America, Canada, Turkey, Switzerland, Israel, Japan, Australia, Norway, Iceland and the United Kingdom;
b/1) medicines that have received authorization for local marketing and that circulate in the country, fulfilling the provisions of letter "b" of point 2 of this article.".

c) medicines produced in the Balkan countries, only when they have received marketing authorization and are circulating in their country;
ç) medicines with marketing authorization from the European Medicines Agency (EMA) or the Food and Drug Administration (FDA) of the United States of America."

Based on the declared data, KVO is able to verify them.

6. For the medicines provided for in point 4 of the KVK of the DST, an Authorization (valid for the period 2026 - 2028) is required, issued by the MAH (marketing authorization holder), through which it is confirmed that the bidder is authorized to market his medicines in our country .

7. For the medicines provided for in point 5 of the KVK of the DST, an Authorization (valid for the period 2026 - 2028) is required, issued by the MAH (marketing authorization holder) or the manufacturer, or the authorized distributor, through which it is confirmed that the bidder is authorized to market their medicines in our country .

Note: In the case of authorizations issued by authorized distributors, their (authorized distributors) relationship with the manufacturer/MAH (marketing authorization holder) must be proven with documents.

Justification: Regarding **criteria 6 and 7,** they are set in accordance with Article 77 of Law No. 162, dated 23.12.2020 "On Public Procurement" as amended (technical capacity), as well as point 3 of Article 40 of the Council of Ministers No. 285, dated 19.05.2021 "On the Approval of the Public Procurement Rules", as amended, in order to possess reputation and reliability for the implementation of the contract. The validity period of the authorization is set in accordance with the duration of the MC. These requirements and in particular the connection with the distributor for drugs not authorized for sale in the Republic of Albania, serve the contracting authority to recognize the possibility of the EO for the successful fulfillment of the contract, i.e. the guarantee of the supply of the goods subject to procurement .

All documents must be originals or notarized copies.

Cases of failure to submit a document, or false and inaccurate documents, are considered conditions for disqualification.

II. Justification of technical specifications

Material Specification: According to Annex 1 of the DST

Description of the implementation requirements of the services in relation to them:

- Expiration date : The expiration date on the day of delivery of the goods must be no less than 1/2 of the time between the date of production and the expiration date /or/ no less than 1 year from the date of delivery of the goods.
  In special cases, according to justified needs, for some medicines, it is allowed that the quantities consumed for a period of no more than 3 months, the expiration date be twice the calculated time for consumption.
- Form - dosage, unit and volume for each drug is defined in the DST and is mandatory.
- Packaging: Each package must bear the name of the drug, form - dosage, drug code, percentage and content, date of manufacture and expiration, batch number, and in addition to the drug control stamp applied to the outer packaging/box of their packaging, the drugs must also be stamped with the inscription "HOSPITAL USE - SALE PROHIBITED" .
- EOs that will be parties to the Framework Agreements (FA) of 2026 are obliged to immediately notify the beneficiary CBO/CA, at any time, during the validity period of the FA, in cases where:

- Registration status changes and/or
- The approved price of the drug, subject to these Framework Agreements, changes.

The OQB, on a case-by-case basis, acts in accordance with Article 127 or 128 of the LPP and Article 23 of the RRPP.

Justification: According to the requirement set out in the Order of the Minister of Health No. 287, dated 12.07.2011, Prot. No. 2542, dated 12.07.2011 "On the labelling of medicines used in public health institutions".

Justification: The technical specifications have been established in accordance with the provisions of Article 4, point 38/b and Article 36, of the LPP:
"38/ *b) in the case of public procurement of goods or services, the specification defining the characteristics of the product or service, such as the level of quality, environmental and climate impacts, description of all conditions, including accessibility for persons with disabilities and conformity assessment, level of realization, use of the product, safety or dimensions, including the relevant requirements for the product in relation to the name under which it is sold, terminology, symbols, tests and test methods, packaging, marking and labeling, as well as instructions for use, production processes and methods at each stage of the life cycle of the*

goods and services, as well as conformity assessment procedures" and Article 40, point 2, of the Council of Ministers No. 285, dated 19.05.2021, "On the approval of public procurement rules", *"for the goods to be procured, the contracting authority/entity shall provide technical specifications, which must describe the minimum or entirety of the most important constituent elements, which guarantee the required quality, in accordance with Article 36 of the LPP, and which assesses the goods as acceptable for the required functions."*

Note: Determine the technical specifications for the goods subject to procurement, which must describe the minimum or totality of the most important constituent elements, which guarantee the required quality, and which assess the goods as acceptable for the required functions, in accordance with the provisions of Article 4, point 38/b and Article 36, of the LPP, as well as Article 40, point 2, of the Council of Ministers No. 285, dated 19.05.2021, "On the approval of public procurement rules", ***arguing each functional or performance requirement, and/or each required standard*** *, where each reference must be accompanied by the words "or its equivalent".*

Attention: In the technical specifications, unless justified by the subject matter of the contract, no specific brand name or source or particular process shall be mentioned, characterising the products or services offered by a specific economic operator, nor any trade mark, patent, type or origin or specific production, with the aim of favouring or eliminating certain undertakings or products. Such a thing is permitted only in exceptional cases where there is no sufficient, accurate or intelligible way of describing the subject matter of the contract, according to point 3 of Article 36 of the LPP. Such references shall be accompanied by the words "or equivalent".

The delivery schedule/deadline is set by the beneficiary contracting authority.

ABOUT THE created tender dossier IN procurement system Electronics of the PPA and ABOUT THE busy THE all procedure documentation OF THE PROCUREMENT Procurement Unit authorized person responsible ABOUT procurement .

PROCUREMENT UNIT